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Contents

Original Papers

Reviews

Impact of the Cardio-Meds Mobile App on Heart Failure Knowledge and Medication Adherence: Pilot Randomized Controlled Trial

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Abstract

Background: Heart failure (HF) is a prevalent chronic condition for which optimal management depends not only on guideline-directed medical therapy but also on patients' understanding of their disease, recognition of warning signs, and sustained medication adherence, which remains challenging in routine care. Mobile health interventions may support therapeutic education and self-management; however, many available apps lack validated content and local relevance. Cardio-Meds is a mobile app developed at Geneva University Hospitals to support HF self-management through structured educational content, interactive quizzes, medication lists with reminders, and tools for monitoring weight and vital signs.

Objective: This study aims to evaluate the impact of a 30-day Cardio-Meds intervention on HF knowledge and medication adherence in patients with HF with reduced or mildly reduced ejection fraction.

Methods: We conducted a single-center, pilot randomized controlled trial in patients followed at the outpatient HF clinic or enrolled in cardiac rehabilitation at Geneva University Hospitals in 2024. Eligible participants had HF with a left ventricular ejection fraction less than 50%, were receiving HF-specific pharmacotherapy, speak French, and owned a smartphone. Participants were recruited by phone and randomized to Cardio-Meds use for 30 days, a self-guided intervention with a single standardized technical support call. Outcomes were self-assessed using standardized questionnaires: HF knowledge and self-management using the Dutch Heart Failure Knowledge Scale (DHFKS; score range 0 - 15); medication adherence using the Basel Assessment of Adherence to Immunosuppressive Medication Scale, covering initiation, implementation, and persistence; and usability in the intervention group using the System Usability Scale (score range 0 - 100). Between-group differences in DHFKS scores were analyzed using analysis of covariance adjusted for baseline values.

Results: A total of 49 participants were included (25 intervention, 24 control); 78% (n=38) were male, and the mean age was 62 (SD 11.4) years. In the intervention group, median app usage was 123 (IQR 74 - 273) minutes, with a median of 43 (IQR 19 - 85) logins. Mean baseline DHFKS scores were similar between groups (intervention 11.1, SD 2.4 vs control 10.5, SD 2.9). At 30 days, mean scores increased significantly in the intervention group (12.4, SD 2.4; mean change +1.3; P<.001) and remained stable in the control group (10.4, SD 3; mean change –0.1; P=.82), with a significant adjusted between-group difference of +1.3 points (P<.001). No significant between-group differences were observed for medication adherence. Usability was high, with a mean score of 84.3 (SD 15), and 64% (16/25) of intervention participants reported that they would continue using the app.

Conclusions: In a stable ambulatory HF population, the Cardio-Meds intervention demonstrated short-term improvement in HF knowledge, while no effect was observed on medication adherence within the 30-day follow-up period. The app showed high usability and acceptability. Larger multicenter studies with longer follow-up are needed to assess clinical impact.

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KEYWORDS

heart failure; mHealth; medication adherence; patient education; digital health intervention; randomized controlled trial; mobile health

Introduction

Heart failure (HF) is a chronic disease affecting more than 64 million people worldwide [1], including approximately 200,000 in Switzerland [2]. Its prevalence is increasing due to aging populations and improved survival. Despite advances in therapy, HF remains a leading cause of morbidity, mortality, and health care utilization. In the European Society of Cardiology-HF Long-Term Registry, 1-year all-cause mortality after hospitalization for acute HF was 23.6%, with a combined incidence of death or HF-related readmission reaching 36% [3]. Readmissions contribute significantly to the clinical and economic burden of HF. In Europe and North America, HF accounts for 1% to 2% of total health care expenditures, largely due to hospitalizations [4,5]. Effective outpatient strategies are therefore crucial. Guideline-directed therapy for patients with reduced or mildly reduced ejection fraction (HFrEF and HFmrEF) includes 4 foundational drug classes: angiotensin receptor–neprilysin inhibitors, angiotensin receptor blockers or angiotensin-converting enzyme inhibitors, beta-blockers, mineralocorticoid receptor antagonists, and sodium-glucose cotransporter 2 inhibitors [6]. These treatments clearly improve outcomes but require a high level of adherence, which remains challenging in patients with multiple comorbidities.

Therapeutic education and structured follow-up are therefore central to improving adherence and clinical outcomes in patients with HF. Cardiac rehabilitation programs, recommended by both European and American guidelines (class I, level A), reduce readmissions and improve quality of life [7]. Broader evidence also supports educational interventions in improving self-care behaviors and adherence [8-10]. A meta-analysis by Van Spall et al [8] demonstrated reduced readmissions with nurse-led follow-up and therapeutic education, while Ruppar et al [10] found lower mortality with adherence-focused interventions. However, scalability and patient engagement remain challenges. Mobile health (mHealth) technologies offer accessible, personalized, and cost-effective support. Self-management apps provide education, monitoring, and behavioral reinforcement outside clinical settings. The 2021 European Society of Cardiology guidelines recommend self-management strategies to reduce HF-related hospitalizations and mortality [11,12].

Recent randomized controlled trials (RCTs) have evaluated multicomponent mHealth interventions integrating mobile apps and connected devices, reporting improvements in self-care behaviors and symptom outcomes in HF populations. Kitsiou et al [13] tested the iCardia4HF program in a phase 1 RCT of combined consumer apps and feedback messages, demonstrating feasibility and preliminary efficacy on self-care measures. Moreover, the SMART-HF study employed a smartphone app with remote monitoring and feedback, showing symptomatic benefits and supporting the role of digital strategies in HF management [14]. Systematic reviews of recent RCTs also highlight the potential of digital health interventions to affect clinical outcomes and self-care, though evidence remains heterogeneous [15].

However, current HF apps often lack validated content and integration into national health care systems. Dunn Lopez et al [16] found that most apps were difficult to understand, poorly referenced, and lacked personalized feedback. Apps such as WOW ME 2000mg, WebMD, and My Cardiac Coach provide generic tools but do not account for local medications or structures [17-19]. Usability, health literacy, and personalization remain key success factors for mobile apps [20,21].

This RCT evaluates the impact of Cardio-Meds, an mHealth app developed by the Cardiology Department at Geneva University Hospitals (HUG) [22], on HF knowledge and therapeutic adherence in patients with HFrEF or HFmrEF. The study aims to determine whether a mobile intervention can enhance disease understanding and support adherence in a real-world outpatient setting.

Methods

Study Design

This single-center, prospective, pilot RCT was conducted at HUG. Participants were randomly assigned to either the intervention group (using the Cardio-Meds app) or the control group (usual care). A total of 50 participants were planned for inclusion, with 25 participants per group. The primary objective was to assess whether Cardio-Meds improves knowledge and self-management of HF compared with usual care. Secondary and exploratory objectives were to evaluate its impact on medication adherence and user satisfaction. The study was designed as an exploratory evaluation of short-term effects on HF knowledge, feasibility, and usability rather than as a definitive efficacy trial for medication adherence.

Ethical Considerations

The study was submitted to the local ethics committee (Commission cantonale d'éthique de la recherche, Geneva, Switzerland; ID 2023 - 01337) for review. The Commission cantonale d'éthique de la recherche reviewed the submission (ID 2023 - 01337) and determined that formal approval was not required given the low-risk, educational nature of the study and the absence of clinical or safety end points. All participants provided written informed consent prior to participation. Participant privacy and confidentiality were maintained. Study data were securely stored at Geneva University Hospitals and analyzed in pseudonymized form. Participants did not receive any financial compensation for participation.

This exploratory, single-center RCT was not prospectively registered in a public trial registry. At the time of study initiation, prospective registration was not requested for this type of low-risk educational intervention. All study outcomes, analyses, and end points were predefined before data collection and are reported consistently, with no outcome switching. Future

larger-scale or multicenter randomized trials evaluating Cardio-Meds will be prospectively registered in accordance with international recommendations.

Description of the Intervention (Cardio-Meds App)

Cardio-Meds is a research version of a mHealth app developed at HUG through collaboration between cardiology, pharmacy, the medical directorate, and IT departments. A recent usability study rated it good to excellent, supporting its feasibility in the HF population [23]. The app was designed with and for patients to help individuals with HF manage their condition through educational resources, self-monitoring, and adherence support.

Key features include the following:

- Educational content and daily quizzes on HF, its treatment, and lifestyle. The content is organized into 4 chapters (my condition, warning signs, my medication, and lifestyle, Figure 1). Quizzes provide immediate feedback and brief explanations (Figure 2).
- Tools to track weight, blood pressure, and heart rate, enabling early detection of decompensation. Graphs can be generated and used during consultations (Figure 3).
- A treatment plan, easily accessible on the user's phone, allows patients to enter their medication regimen (Figure 4). Medications can be added by scanning the barcode, enabling the app to identify the drug via access to the Swiss medication database. The user can then specify the dosage and timing for each medication intake (Figure 5).
- Intake confirmation and optional reminders to support adherence (Figures 3, 4, and 6).

Figure 1. Educational information section of the Cardio-Meds mobile app for heart failure self-management. Screenshots show the structured educational content available in the Cardio-Meds app, organized into thematic modules (disease understanding, warning signs, medications, and lifestyle). The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024.

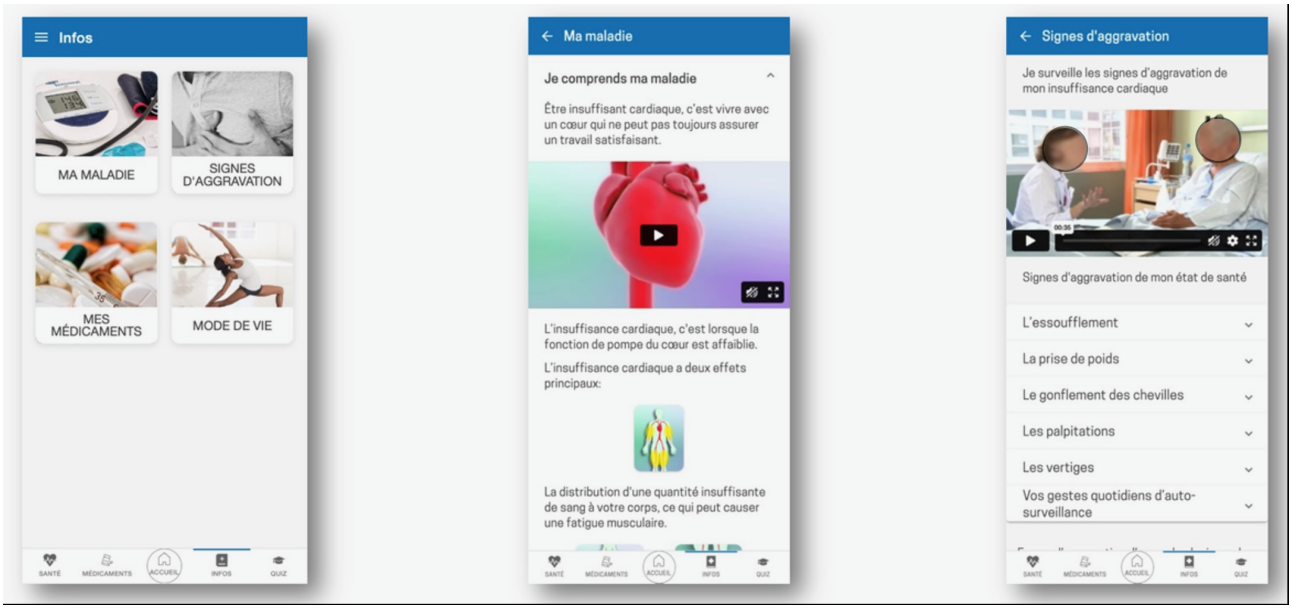


Figure 2. Interactive quiz module of the Cardio-Meds mobile app for heart failure self-management. Screenshots depict the quiz interface of Cardio-Meds, including multiple-choice questions and immediate feedback with brief educational explanations. The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024.

Figure 3. Home screen and health monitoring section of the Cardio-Meds mobile app**.** Screenshots illustrate the home interface and the health monitoring module of Cardio-Meds app. Shown features include daily medication overview, intake confirmation, and graphical tracking of self-reported weight, blood pressure, and heart rate. The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024. All data displayed in the app screenshots are fictitious and were entered solely for illustrative purposes.

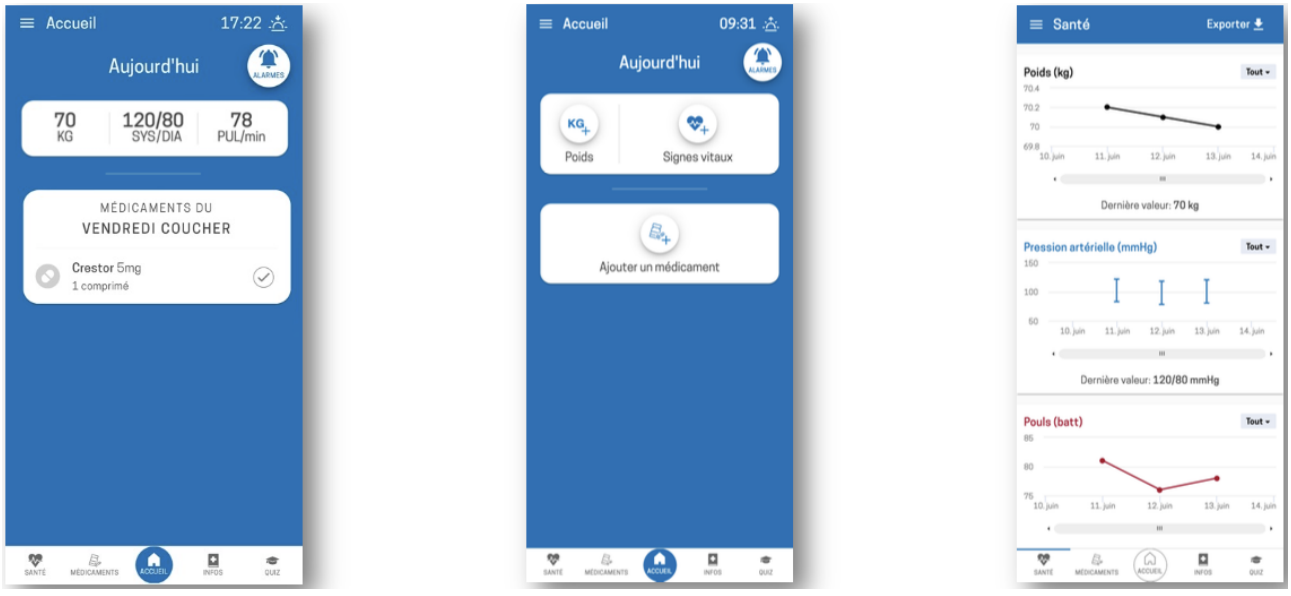


Figure 4. Medication management section of the Cardio-Meds mobile app (treatment list, intake confirmation, and history). Screenshots illustrate the medication section of Cardio-Meds, including the individualized treatment list, daily intake confirmation, and medication history. The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024. All data displayed in the app screenshots are fictitious and were entered solely for illustrative purposes.

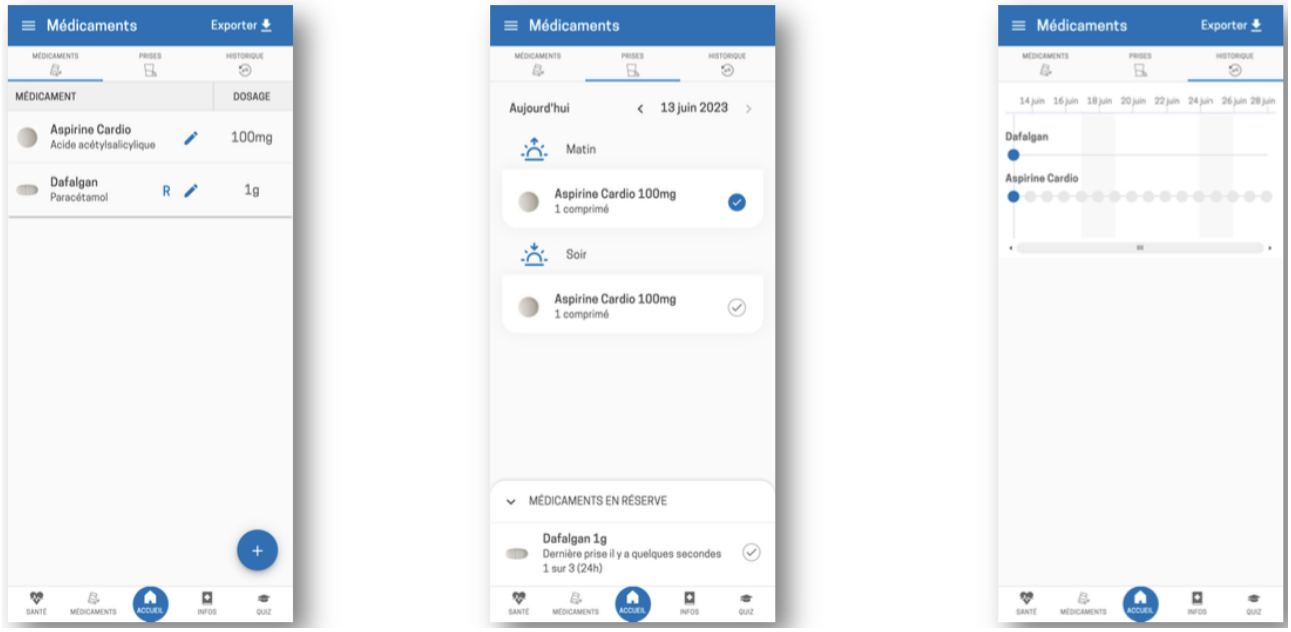


Figure 5. Procedure for entering a medication into the Cardio-Meds mobile app. Screenshots show the step-by-step process for adding a medication in Cardio-Meds, including barcode scanning linked to the Swiss medication database, dosage specification, and intake scheduling. The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024.

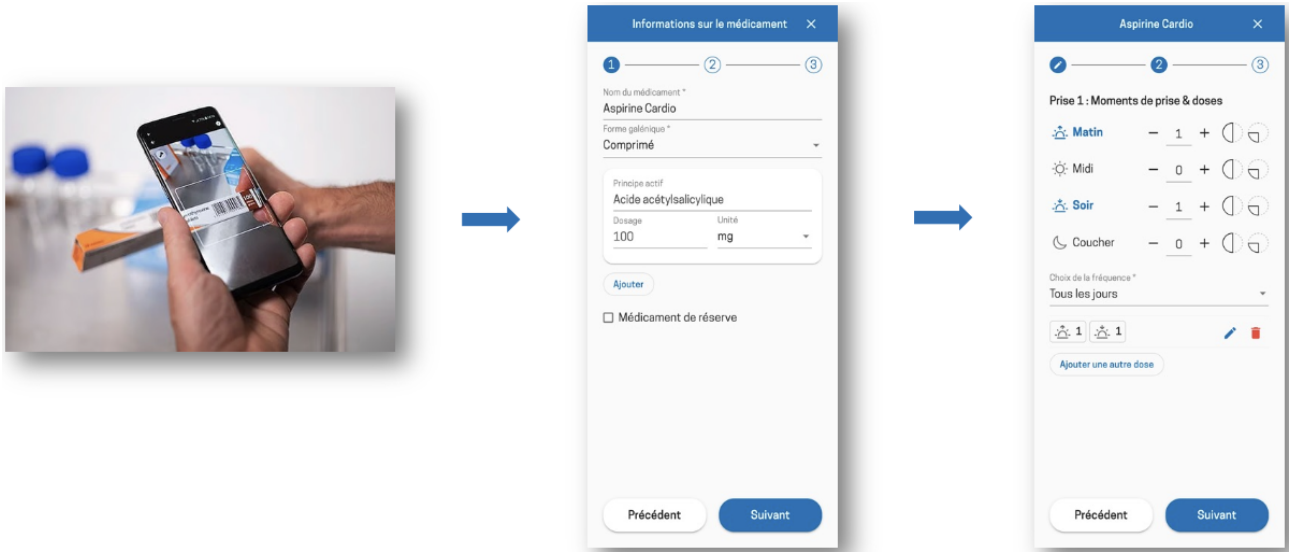
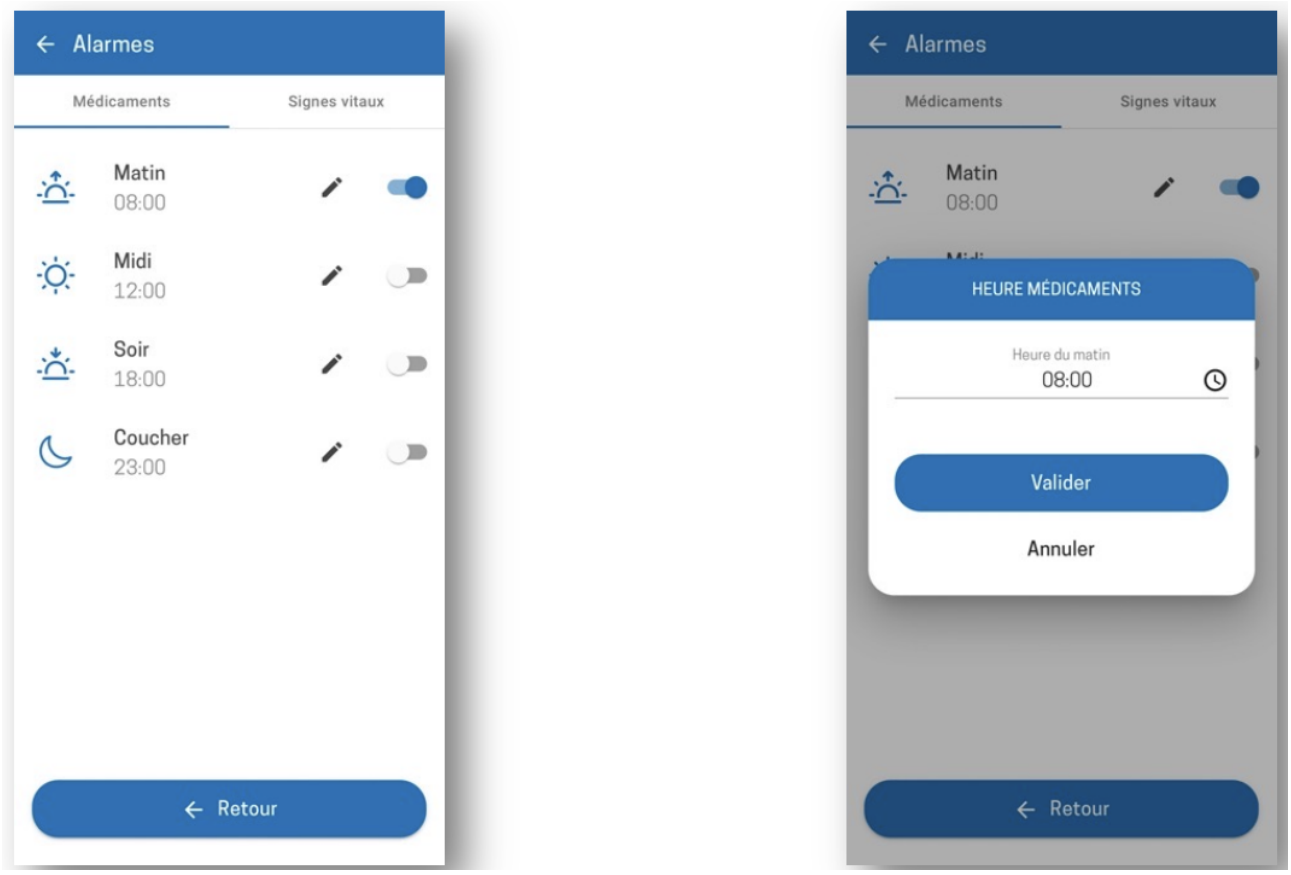


Figure 6. Procedure for setting medication reminder alarms in the Cardio-Meds mobile app. Screenshots illustrate the configuration of medication reminder alarms, including timing and activation of notifications. These reminders are optional. The app was evaluated in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult outpatients with heart failure during a 30-day intervention period in 2024.



The Cardio-Meds app enables patients to manage health data, access structured learning, and share information with health care providers. It was designed to ensure ease of use and fulfill legal and best practice requirements for data protection and confidentiality.

Study Population and Recruitment

Participants were recruited from the HF clinic and cardiac rehabilitation programs at HUG from March to November 2024. Two cardiologists and 2 specialized HF nurses preidentified eligible participants, who were contacted by a medical student who explained the study and verified smartphone ownership. Participation was voluntary, with the option to withdraw at any time without affecting medical care.

Participants were eligible for inclusion if they met the following criteria:

- Aged 18 years or older
- Diagnosed with HF with reduced (≤40%, or HFrEF) or mildly reduced (41% - 49% or HFmrEF) left ventricular ejection fraction
- Currently receiving HF-specific medications
- No cognitive impairment and fully capable of decision-making
- Capability to read, understand, and communicate in French
- Ownership of a smartphone

Participants were excluded if they met any of the following conditions:

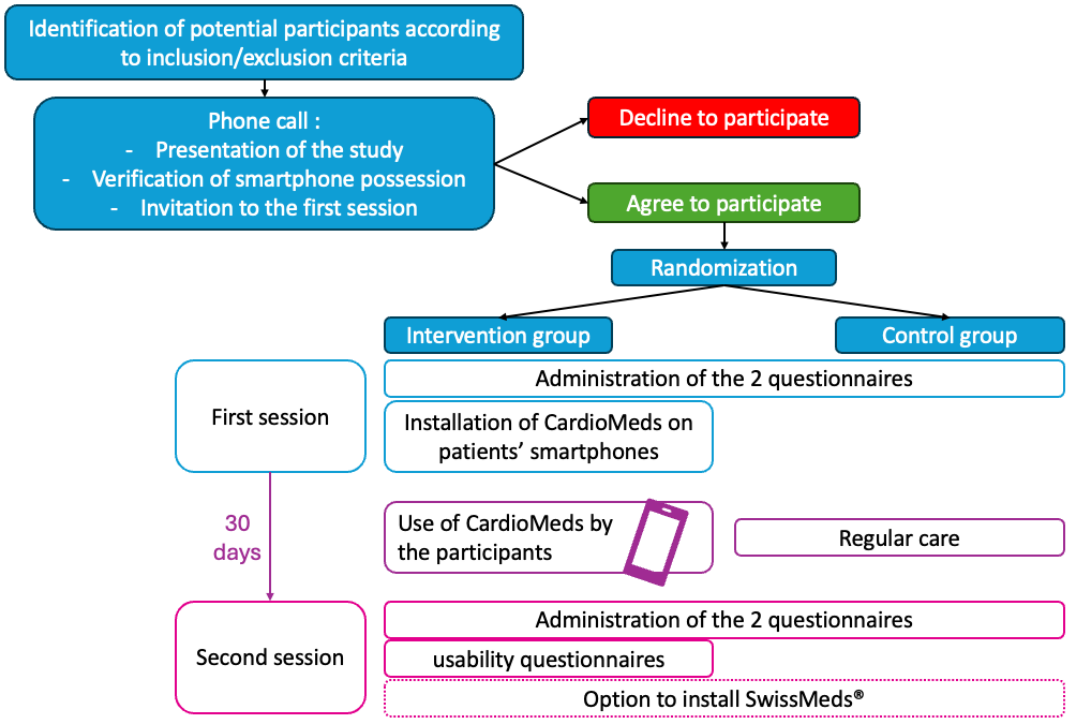
- Inability or unwillingness to comply with study procedures
- Status as an asylum seeker, individuals experiencing homelessness, or detainees

Study Procedures

After providing oral consent and before the first session, participants were randomized using a computer-generated random allocation sequence with a 1:1 ratio between the intervention and control groups, without stratification or blocking. The allocation sequence was generated by a member of the research team not involved in participant recruitment or outcome assessment. Randomization was conducted prior to the first study session for logistical reasons related to group-based study organization. Participants were enrolled by study investigators, and baseline questionnaires were administered before any information regarding group allocation was disclosed (Figure 7). Neither participants nor study personnel responsible for distributing and collecting the questionnaires were aware of group assignment at the time of baseline data collection. Group allocation was revealed only after completion of baseline assessments, at which point participants in the intervention group received instructions for app installation. Given the nature of the digital intervention, blinding of participants and study staff after allocation was not feasible. Outcome assessment relied on self-administered

questionnaires, and data analysis was conducted on deidentified datasets by analysts not involved in intervention delivery.

Figure 7. Flowchart of the study design and procedures of a pilot randomized controlled trial evaluating the Cardio-Meds mobile app. The figure outlines participant recruitment, randomization, intervention, and follow-up procedures in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) between March and November 2024. Adult patients with heart failure were randomized to either a 30-day Cardio-Meds intervention plus usual care or to usual care alone. Heart failure knowledge and medication adherence were assessed at baseline and at 30 days using the Dutch Heart Failure Knowledge Scale (DHFKS) and the Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS).



During session 1, after written informed consent, participants completed 2 baseline assessments:

- The Dutch Heart Failure Knowledge Scale (DHFKS) assessing HF-related knowledge and self-management
- The Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS) evaluating medication adherence

Intervention group participants installed the Cardio-Meds app on their smartphones with guidance on usage and for medication entry. A brief standardized mid-study support call was conducted solely to identify and resolve potential technical issues related to app installation or functionality. No medical advice, educational reinforcement, or adherence-related counseling was provided during this call. After 30 days, all participants returned for a second session, completing the DHFKS and BAASIS again. Intervention participants also completed a usability questionnaire and had the possibility to give nondirected feedback on the app. At the end of the study, both groups could install SwissMeds, the publicly released version of the app, soon to include modules for other chronic conditions.

Most participants attended group sessions (5 - 12 participants) held in March, May, and November 2024. Remaining participants were seen individually during the week following each of these sessions.

The following anonymized usage data were collected from the app:

- Total time spent on the app
- Number of logins
- Time spent on the information section
- Number of weight, blood pressure, and heart rate entries over the 30-day follow-up period
- Percentage of correct answers to the quizzes

Clinical and personal data were collected from the electronic medical record at HUG, anonymized, and securely stored on HUG servers for 10 years in compliance with institutional policy.

Outcome Measures

Primary Outcome

HF knowledge and self-management were assessed using the DHFKS, a validated 15-item questionnaire covering general knowledge, dietary recommendations, sodium and fluid restrictions, and recognition of alarm symptoms. This tool was selected for its validity and sensitivity in evaluating the effect of therapeutic education in patients with HF. The questionnaire was translated into French using neural machine translation (DeepL) and reviewed for clinical accuracy and clarity by an experienced HF specialist (PM). No formal forward-backward translation or psychometric validation of the French version was performed, and the scale was therefore used as an exploratory measure to assess within-group changes in knowledge rather than as a fully validated French-language instrument. Scores range from 0 to 15, with higher scores indicating better knowledge. Based on pragmatic and clinical

considerations, an absolute improvement of 2 points on the DHFKS was prespecified as a meaningful change for sample size estimation. This threshold was used as an assumption for planning purposes rather than as a validated minimal clinically important difference (Multimedia Appendix 1).

Secondary Outcome

Medication adherence was assessed using the BAASIS, a structured self-report questionnaire originally validated in transplant populations. In the absence of an HF-specific validated adherence questionnaire at the time of study design, the BAASIS was used as an exploratory tool to capture core adherence behaviors (initiation, implementation, and persistence) relevant to chronic disease management. BAASIS covers three dimensions of adherence behavior:

- Initiation (starting newly prescribed medications during the reference period)
- Implementation (missed doses, wrong dosage, or timing)
- Persistence (discontinuation without medical advice)

Responses are binary (“yes”/“no”), with frequency details for selected items. For the “Initiation” domain, analyses were restricted to participants who had a newly prescribed medication during the respective reference period, as specified by the BAASIS instrument; therefore, denominators vary across time points and do not reflect missing data or participant exclusion. A validated French version was used (Multimedia Appendix 2).

Exploratory Outcome

Usability of the app was evaluated in the intervention group using the System Usability Scale (SUS), a 10-item questionnaire with responses on a 5-point Likert scale. The final score ranges from 0 to 100, with higher scores reflecting better usability (Multimedia Appendix 3).

Statistical Analysis

Descriptive statistics were used to summarize baseline characteristics and outcomes. Continuous variables are presented as mean (SD) and were compared between groups using Student *t* test when appropriate. Categorical variables are presented as frequencies and percentages and were compared using chi-square or Fisher exact tests, depending on expected cell counts.

The primary outcome, change in HF knowledge, was analyzed using an ANCOVA, with the postintervention DHFKS score as the dependent variable, study group as the independent variable, and baseline DHFKS score as a covariate. No post hoc adjustment was performed for other baseline variables, given the limited sample size and exploratory nature of this pilot study.

Analysis Population

All outcome analyses were conducted according to randomized group assignment. Primary and secondary outcome analyses included all participants who completed both baseline and follow-up assessments (completers-only analysis). Participants with missing follow-up data were not included in the corresponding outcome analyses. No participants were excluded post randomization due to intervention-related reasons; analyses were restricted to participants with available baseline and follow-up data for the corresponding outcomes. Secondary outcomes related to medication adherence, assessed using the BAASIS questionnaire (initiation, implementation, and persistence domains), were analyzed descriptively and compared between groups using chi-square or Fisher exact tests, as appropriate. Usability outcomes measured by the SUS and app usage metrics were analyzed descriptively.

The sample size was estimated to inform feasibility rather than to power a definitive efficacy trial. Based on a mean control group DHFKS score of 10.9 (SD 2.3), an anticipated absolute between-group difference of 2 points, a power of 80%, and a 2-sided significance level (α) of .05, an initial sample size of approximately 40 - 45 participants was estimated. Allowing for an anticipated dropout rate of 25% to 30%, a target sample size of 50 participants (25 per group) was considered feasible and appropriate for this pilot exploratory RCT. The study was powered for the primary knowledge outcome only and was not designed to detect differences in secondary outcomes such as medication adherence, particularly in a population with high baseline adherence.

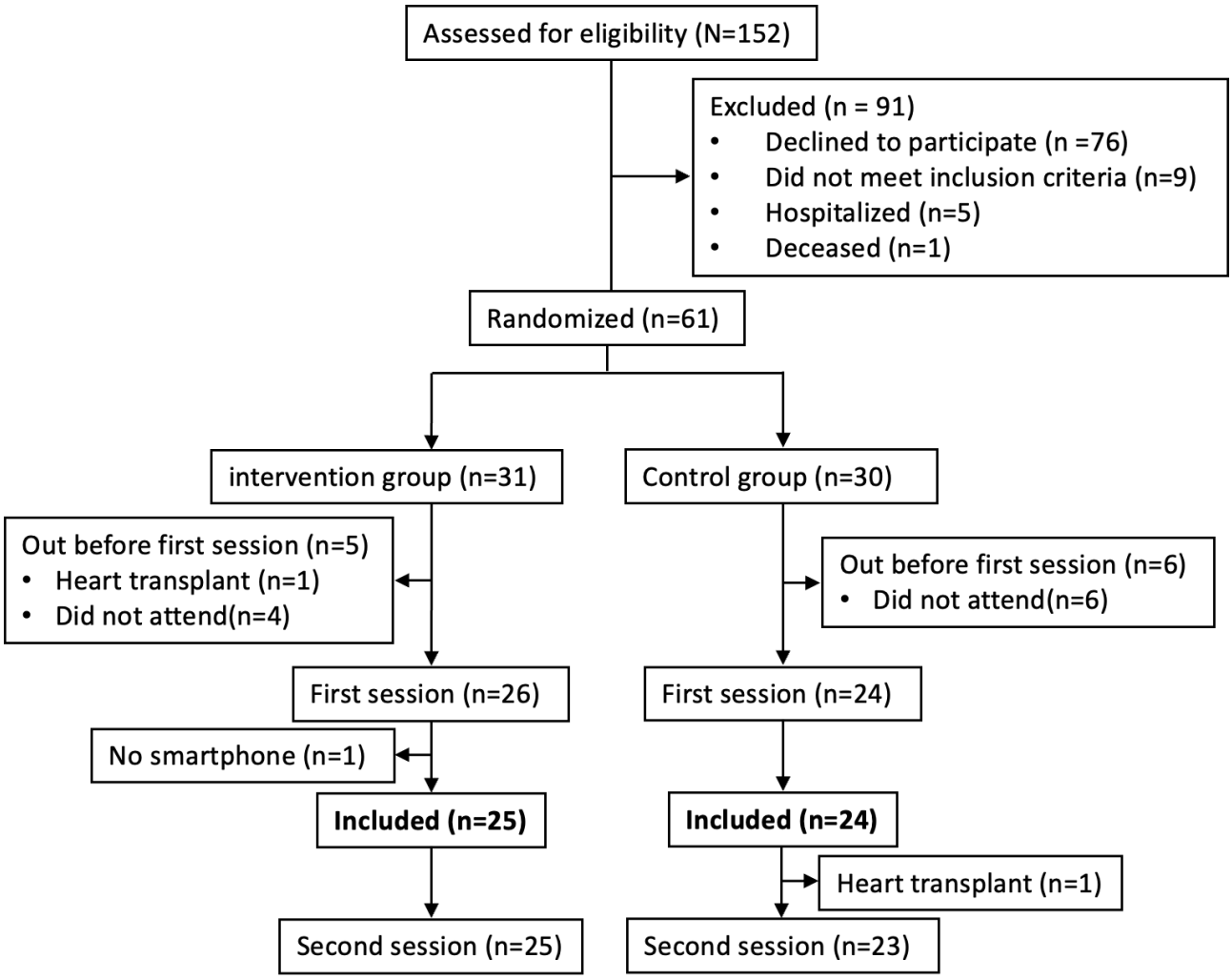
All analyses were performed using R software (version 4.4.2; R Foundation for Statistical Computing). Statistical significance was defined as a 2-sided $P<.05$.

Results

Participants Characteristics

A total of 152 patients with stable HFrEF or HFmrEF followed in the outpatient clinic or undergoing rehabilitation at HUG were preselected by nurses (Figure 8). After the initial phone contact, 61 patients met the eligibility criteria and agreed to participate, while 91 were excluded: 76 declined participation, 9 did not meet the inclusion criteria, 5 were hospitalized, and 1 had died. Among the 61 participants, 31 were randomly assigned to the intervention group and 30 to the control group. Before the first session, 11 participants dropped out: 10 did not attend the scheduled session, and 1 participant in the intervention group underwent heart transplantation. Ultimately, 50 participants attended the first session, and 49 were included, as 1 participant did not own a smartphone. During follow-up, 1 participant in the control group underwent heart transplantation and was therefore unable to attend the second session, and 2 participants did not complete the BAASIS questionnaire at follow-up.

Figure 8. Flowchart of patient recruitment, randomization, and follow-up. The flow diagram shows screening, inclusion, randomization, and follow-up of adult outpatients with heart failure recruited at Geneva University Hospitals (Geneva, Switzerland) between March and November 2024 for a pilot randomized controlled trial of the Cardio-Meds mobile app.



This pilot study included a total of 49 adult participants with HF, of whom 78% (38/49) were male, with a mean age of 62 (SD 11.4) years. Most participants were French- or Italian-speaking and demonstrated a good level of comprehension of French. Both ischemic and nonischemic etiologies of HF were represented, with a mean left ventricular ejection fraction of 37.2% (SD 12). Participants were generally polymorbid, with common comorbidities including diabetes, hypertension, and atherosclerotic cardiovascular disease. All participants were receiving guideline-directed medical therapy, including angiotensin-converting enzyme inhibitor/angiotensin receptor blocker/angiotensin receptor–neprilysin inhibitors, beta-blockers, mineralocorticoid receptor antagonists, and sodium-glucose cotransporter-2 inhibitors. The average number of daily medications and intakes was high (more than 8 medications per day), reflecting the complexity of treatment in this population. Overall, the cohort was representative of a typical population of individuals with HF managed in an outpatient and rehabilitation setting (Table 1).

Table . Baseline characteristics of participants included in a pilot randomized controlled trial of a mobile health intervention for heart failure (N=49).[a]

Characteristic	Intervention group (n=25)[b]	Control group (n=24)[b]	*P* value[c]
Gender, n (%)			.67
Female	5 (20)	6 (25)	
Male	20 (80)	18 (75)	
Mean age (y), mean (SD)	59.2 (10.3)	65.2 (11.9)	.06
HF[d] etiology, n (%)			.98
Ischemic	10 (40)	9 (37.5)	
Arrhythmic	4 (16)	5 (20.8)	
Valvular	3 (12)	2 (8.3)	
Toxic	6 (24)	3 (12.5)	
Genetic	6 (24%)	5 (20.8)	
Hypertensive	5 (20)	4 (16.7)	
Infiltrative	3 (12)	3 (12.5)	
Idiopathic	4 (16)	3 (12.5)	
Other	1 (4)	0 (0)	
Time since diagnosis (mo), mean (SD)	55 (85.6)	66.3 (87.6)	.65
HF medication, n (%)			>.99
ACE[e]/ARB[f]/ARNI[g]	23 (92)	22 (91.7)	
BB[h]	21 (84)	21 (87.5)	
MRA[i]	16 (64)	17 (70.8)	
SGLT2[j]	23 (92)	21 (87.5)	
Loop diuretic	13 (52)	13 (54.2)	
Number of medications, mean (SD)	8.5 (3.6)	8.9 (3.1)	.65
Daily intakes, mean (SD)	9.6 (3.8)	10 (4.3)	.76
Comorbidities, n (%)			.13
AF[k]	8 (32)	8 (33.3)	
COPD[l]	0 (0)	1 (4.2)	
PAD[m]/Stroke	8 (32)	2 (8.3)	
Diabetes	3 (12)	8 (33.3)	
Hypertension	13 (52)	10 (41.7)	
LVEF[n], mean (SD)	38 (12)	37 (12)	.69
NYHA[o], mean (SD)	1.8 (0.9)	1.8 (1.1)	.75
Employment status, n (%)			.56
Full-time	13 (52)	8 (33.3)	
Part-time	3 (12)	3 (12.5)	
Unemployed or disability benefits	2 (8)	2 (8.3)	
Retired	7 (28)	11 (45.8)	
Ethnicity, n (%)			.64
Caucasian	22 (88)	20 (83.3)	
African	3 (12)	4 (16.7)	

Characteristic	Intervention group (n=25)[b]	Control group (n=24)[b]	*P* value[c]
Level of French comprehension and expression, n (%)			.61
Excellent	19 (76)	19 (79.2)	
Good	5 (20)	5 (20.8)	
Average	1 (4)	0 (0)	
Mother tongue, n (%)			.25
French	12 (48)	16 (66.7)	
German	0 (0)	1 (4.2)	
Italian	2 (8)	3 (12.5)	
English	1 (4)	0 (0)	
Other	10 (40)	4 (16.7)	

[a]Baseline demographic, clinical, and treatment characteristics of adult outpatients with heart failure with reduced or mildly reduced ejection fraction enrolled at Geneva University Hospitals (Geneva, Switzerland) between March and November 2024, stratified by randomized group (Cardio-Meds intervention vs usual care).

[b]Baseline characteristics are reported for participants who attended the first study session and completed baseline assessments.

[c]Baseline group comparisons are presented for descriptive purposes only and should not be interpreted as formal tests of randomization balance.

[d]HF: heart failure.

[e]ACE: angiotensin-converting enzyme.

[f]ARB: angiotensin II receptor blocker.

[g]ARNI: angiotensin receptor–neprilysin inhibitor.

[h]BB: beta-blocker.

[i]MRA: mineralocorticoid receptor antagonist.

[j]SGLT2: sodium-glucose cotransporter 2.

[k]AF: atrial fibrillation.

[l]COPD: chronic obstructive pulmonary disease.

[m]PAD: peripheral artery disease.

[n]LVEF: left ventricular ejection fraction.

[o]NYHA: New York Heart Association.

App Usage in Test Group

During the 30-day follow-up period, participants in the intervention group used the app for a mean total duration of 177.4 (SD 130.4) minutes, with a mean of 48.6 (SD 36.2) logins. App usage was highly variable across participants. Total usage time had a median of 123 (IQR 74 - 273) minutes, and the number of logins had a median of 43 (IQR 19 - 85), indicating a skewed distribution with a subset of highly active users. The mean time spent per login was 5.3 (SD 3.6) minutes. Participants spent a mean of 7.9 (SD 9.9) minutes on the information section. Weight was recorded a mean of 5.9 (SD 9.6) times, blood pressure and heart rate were entered a mean of 6.8 (SD 10.3) times, corresponding to an average of approximately 1 entry every 4 to 5 days. Among participants who accessed the quiz feature, a mean of 16.4 (SD 17.6) questions were answered, with a mean of 12.5 (SD 13.9) correct answers, corresponding to a mean accuracy rate of 0.7 (SD 0.3) (Multimedia Appendix 4).

HF Knowledge and Self-Management (Primary Outcome)

The DHFKS questionnaire was administered at both study sessions. At baseline (session 1), the mean score was 11.1 (SD 2.4) in the intervention group and 10.5 (SD 2.9) in the control group. In the primary analysis using ANCOVA adjusted for baseline DHFKS score, the intervention group had significantly higher follow-up knowledge scores than the control group, with an adjusted mean between-group difference of +1.3 points (95% CI 0.40 - 2.20; $P<.001$). For descriptive purposes, within-group analyses showed that DHFKS scores remained stable in the control group (10.5 [SD 2.9] at baseline vs 10.4 [SD 3] at follow-up; $P=.82$), whereas the intervention group demonstrated a statistically significant increase (11.1 [SD 2.4] to 12.4 [SD 2.4]; $P<.001$) (Figure 9)(Table 2). Although the improvement in the intervention group was statistically significant (+1.3 points), it did not reach the prespecified +2-point threshold used for sample size estimation. No significant association was observed between app usage metrics (including total usage time and number of logins) and change in DHFKS score .

Figure 9. Heart failure knowledge scores before and after a 30-day mobile health intervention. Boxplots show Dutch Heart Failure Knowledge Scale (DHFKS) scores at baseline and after 30 days in the intervention group (Cardio-Meds plus usual care) and the control group (usual care alone). The data are derived from a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) in adult patients with heart failure between March and November 2024.

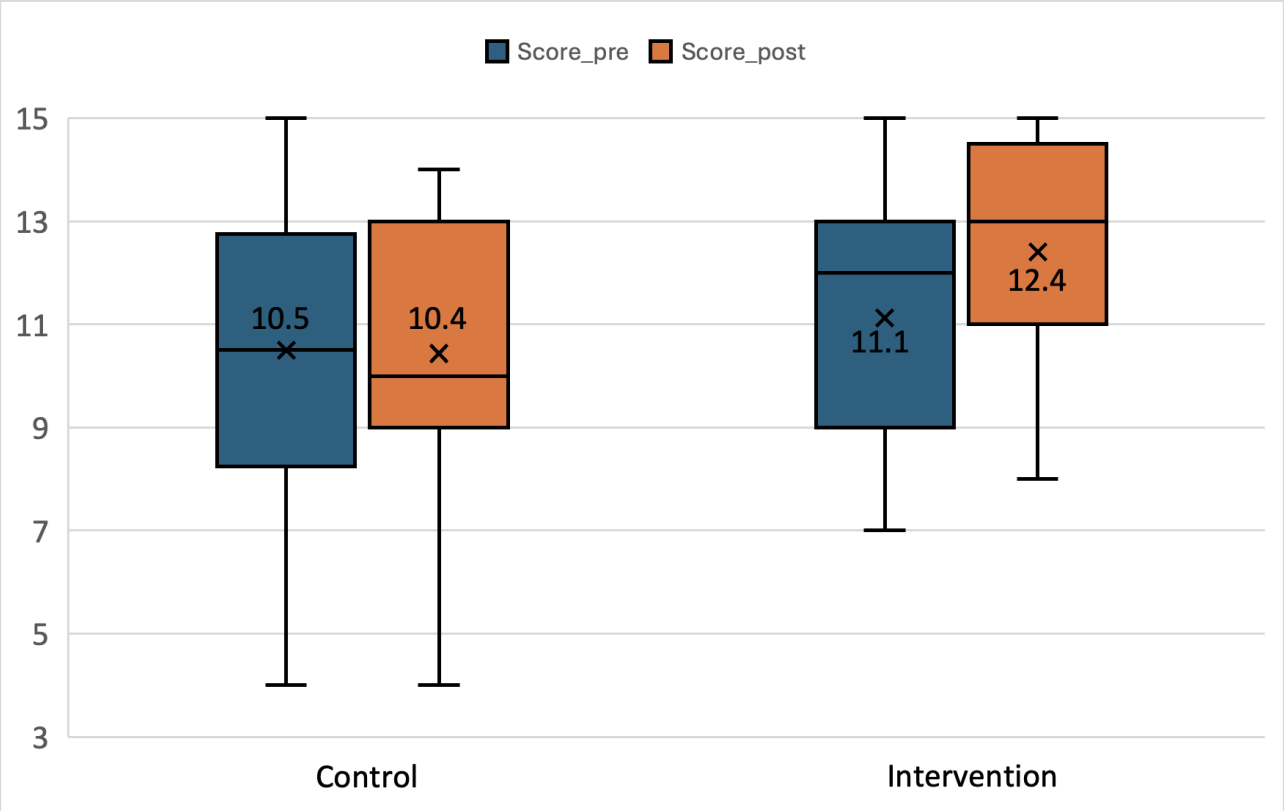


Table . Heart failure knowledge before and after a 30-day intervention using the Cardio-Meds mobile app.[a]

Group	Preintervention, mean (SD)	Postintervention, mean (SD)	Mean change	*P* value
Control	10.5 (2.9)	10.4 (3)	–0.1	.82[b]
Intervention	11.1 (2.4)	12.4 (2.4)	1.3	<.001[b]
Adjusted between-group difference (ANCOVA[c])	—[d]	—[d]	1.3 (95% CI 0.40-2.20)	<.001[e]

[a]Dutch Heart Failure Knowledge Scale scores at baseline and after 30 days are shown for intervention and control groups in a single-center pilot randomized controlled trial conducted at Geneva University Hospitals (Geneva, Switzerland) among adult patients with heart failure in 2024. Within-group changes and adjusted between-group differences are reported.

[b]Paired *t* test (within-group).

[c]ANCOVA: analysis of covariance.

[d]Not applicable.

[e]ANCOVA adjusted for baseline DHFKS score.

Medication Adherence (Secondary Outcome) With BAASIS

For the initiation domain, analyses were restricted to participants with newly prescribed medications during the reference period, resulting in very small sample sizes (control group: n=5 at follow-up; intervention group: n=7). The intervention group maintained a score of 100% at both time points, while the control group showed a decrease from 100% at baseline to 80% at 1 month. The between-group comparison was not statistically significant (*P*=.38); however, this result should be interpreted cautiously given the very limited sample size and lack of statistical power for this specific domain. As per the BAASIS instrument structure, denominators for the "Initiation" domain vary across assessment time points depending on whether participants had newly prescribed medications during the reference period. For the implementation domain, the intervention group showed a decrease from 64% at baseline to 52% at 1 month. In contrast, the control group showed a slight increase, from 46% to 48%, likely due to missing responses from three participants at follow-up. The between-group difference was not statistically significant (*P*=.61). For the

persistence domain, the intervention group decreased slightly from 100% to 96% after the intervention, while the control group remained relatively stable, from 96% to 95% (Table 3). These small variations correspond to 1 participant in each group: in the control group, 1 answered "yes" at both time points; in the intervention group, 1 answered "yes" only at the second session. The between-group comparison showed no statistically significant difference (P=.76).

Table . Medication adherence outcomes assessed with the BAASIS questionnaire before and after a 30-day follow-up period.[a]

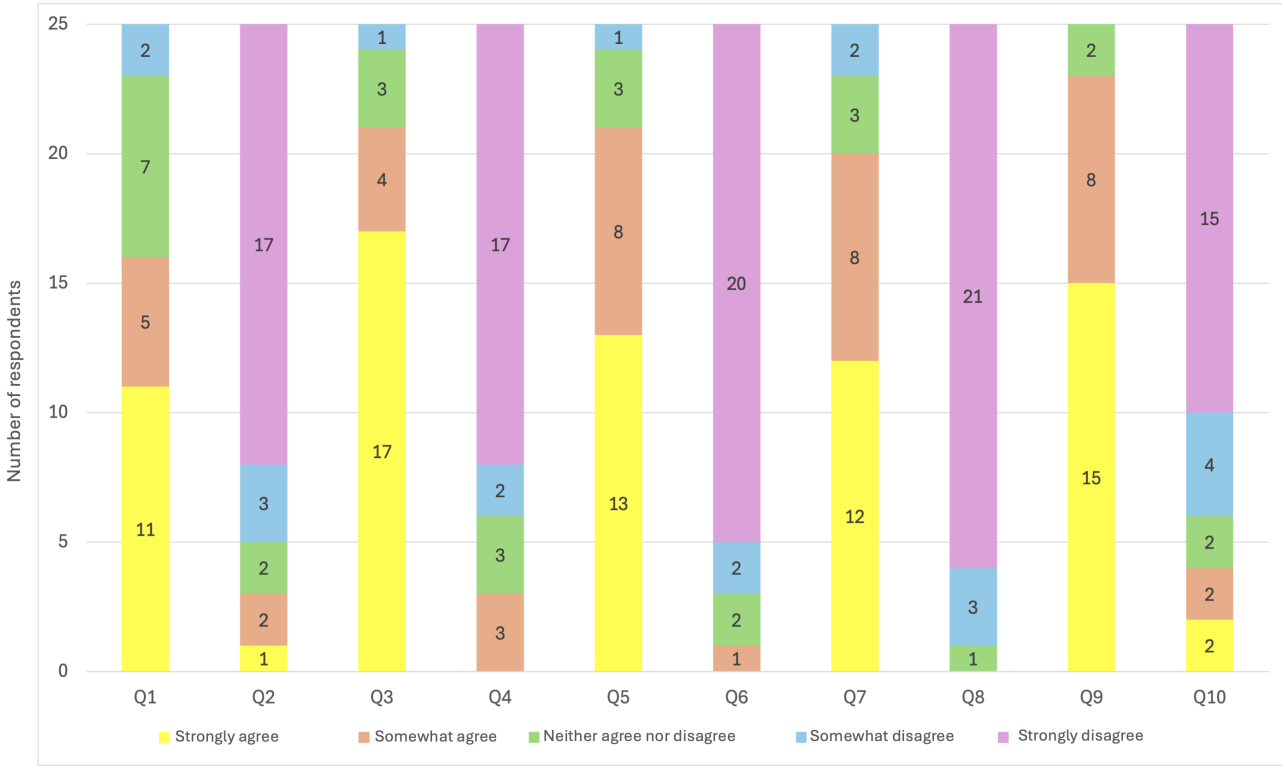
Domain and group	Preintervention, n/N (%)	Postintervention, n/N (%)	*P* value
Initiation			.38
Control	4/4 (100)	4/5 (80)	
Intervention	14/14 (100)	7/7 (100)	
Implementation			.61
Control	11/24 (46)	10/21 (48)	
Intervention	16/25 (64)	13/25 (52)	
Persistence			.76
Control	23/24 (96)	20/21 (95)	
Intervention	25/25 (100)	24/25 (96)	

[a]Initiation, implementation, and persistence domains of the Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS) at baseline and 30 days in intervention and control groups. Data derived from a pilot randomized controlled trial evaluating a mobile health intervention in adult outpatients with heart failure conducted at Geneva University Hospitals (Geneva, Switzerland) between March and November 2024. Initiation denominators reflect only participants with newly prescribed medications during the reference period, according to BAASIS specifications.

Usability of the App (Exploratory Outcome)

The usability of the app was assessed using the SUS, a standardized questionnaire designed to evaluate user experience and ease of use. The mean SUS score in the intervention group was 84.3 (SD 15) (Multimedia Appendix 5), indicating excellent usability, as it falls within the 90th percentile of usability scores [24]. Notably, 64% (16/25) of participants indicated they would continue using the app (Figure 10). However, beyond the predefined usage metrics collected (eg, total time, logins, section time, and entries), no additional backend analytics were available to characterize navigation pathways or feature-level sequences. Future studies should include backend analytics to better understand interaction dynamics with the app. Across all SUS items, most of the responses reflected positive user experience and good perceived usability of the Cardio-Meds app (Figure 10).

Figure 10. System Usability Scale (SUS) item responses for the Cardio-Meds mobile app. Likert-style plots display responses to the 10 items of the SUS completed after 30 days of app use by participants randomized to the intervention group in a pilot randomized controlled trial. The study was conducted at Geneva University Hospitals (Geneva, Switzerland) between March and November 2024 among adult outpatients with heart failure.



Participant Feedback

Participants could provide comments at the end of the questionnaires. Overall, the app was seen as well-designed and pleasant to use, with 1 participant describing it as a "companion that sets the rhythm of his day." Users appreciated features such as the motivational message "Everything is fine today," medication images for easy identification, and the reminder function. Quizzes and educational content were well received. Reported difficulties included deleting medications after input errors, handling missed doses, and grouping medications, often due to unfamiliarity with the app's functions. Suggestions included improving text contrast, syncing reminders with smartwatches, managing time zones, integrating with health platforms, storing prescriptions, and adding tracking for weight and blood pressure. Some participants also requested video content and information on disease progression. These comments will inform future app development.

Discussion

Principal Findings

In this pilot RCT conducted in a stable ambulatory HF population, a 30-day intervention using the Cardio-Meds mobile app was associated with a statistically significant short-term improvement in HF knowledge and self-management compared with usual care. After adjustment for baseline knowledge, the intervention group demonstrated a statistically significant between-group improvement of 1.3 points in the DHFKS score compared with the control group. The magnitude of improvement, while statistically significant, was smaller than the prespecified effect size and should therefore be interpreted as an exploratory signal rather than a clinically definitive change. In contrast, no significant differences were observed between groups in self-reported medication adherence across the BAASIS domains; small numerical variations should be interpreted cautiously in light of the pilot design and reliance on self-reported measures. The app demonstrated high usability and acceptability, with excellent SUS scores and a majority of participants reporting willingness to continue using the app. Taken together, these findings should be interpreted as short-term, exploratory results primarily informing feasibility, usability, and educational impact rather than durable behavioral change.

Comparison With Prior Work

Previous digital health interventions for HF have reported mixed but generally encouraging effects on self-care behaviors and symptom outcomes. For example, Yoon et al [14] found that a smartphone-based intervention with remote feedback improved HF symptom burden over follow-up, and Kitsiou et al [13] showed that multiapp interventions may enhance self-care engagement. Systematic evidence also supports the value of digital health tools in HF management, reinforcing the need for continued innovation and larger, long-term studies [15]. In this context, the improvement in HF knowledge observed in our study is consistent with prior evidence showing that digital interventions can enhance patient understanding and engagement. A recent systematic review by Mouselimis et al [25] reported that mHealth tools frequently improve disease knowledge and engagement, although effects on clinical outcomes and adherence remain heterogeneous. Fernández-Gutiérrez et al [20] emphasized the importance of validated, patient-centered educational content in HF apps, an

aspect directly addressed in Cardio-Meds through guideline-based information and interactive quizzes. Similarly, Choi et al [26] demonstrated that an HF-specific mobile app improved functional and echocardiographic parameters, although such clinical endpoints were not assessed in the present study. Unlike the findings of Ruppar et al [10], who reported improvements in medication adherence following adherence-focused interventions, we did not observe a significant adherence effect. This discrepancy may partly be explained by the characteristics of the study population. Baseline adherence was high in the persistence domain, with nearly all participants reporting continued use of prescribed medications, reflecting a stable ambulatory population with established treatment routines. In contrast, baseline adherence in the implementation domain was suboptimal in both groups, indicating difficulties related to day-to-day medication-taking behavior rather than treatment discontinuation. Despite this, no significant improvement in implementation adherence was observed after the 30-day intervention, possibly due to the short follow-up period, reliance on self-reported measures, and the exploratory nature of the study. Usability and acceptability are critical determinants of digital intervention success, and Cardio-Meds performed well in this regard, with a mean SUS score of 84, consistent with excellent usability [24] and comparable to other successful HF apps.

Limitations

Several limitations should be acknowledged. First, this pilot study was powered exclusively for the primary outcome of HF knowledge. Consequently, it was underpowered to detect differences in secondary outcomes such as medication adherence, particularly in a stable ambulatory population with high baseline adherence. Adherence findings should therefore be interpreted as exploratory and hypothesis-generating rather than confirmatory.

Second, the short follow-up period limited assessment of longer-term knowledge retention, sustained behavioral change, and clinical outcomes. Short-term improvements may partly reflect transient or “honeymoon” effects, and longer follow-up will be required to evaluate the durability of effects on self-management and adherence.

Third, medication adherence was assessed using self-reported measures, which are inherently subject to recall and social desirability bias. Although validated instruments were used, future studies would benefit from incorporating objective adherence measures such as pharmacy refill data or electronic monitoring. In this context, the small, non-significant decrease in implementation adherence observed in the intervention group may reflect increased awareness of medication-taking behavior and more accurate self-reporting following exposure to the intervention and repeated questioning, rather than a true deterioration in adherence.

Fourth, the single-center design and inclusion of a stable, chronically treated outpatient population may limit generalizability, particularly to recently hospitalized or higher-risk patients.

Fifth, HF knowledge was assessed using a French translation of the DHFKS that did not undergo formal linguistic or psychometric validation. While the items are factual and clinically straightforward and the original scale was developed in a population comparable to the Swiss context, this limits the interpretation of absolute score values and the strength of conclusions regarding knowledge gains. In addition, the absence of a validated minimal clinically important difference for the DHFKS constrains assessment of the clinical relevance of the observed improvement. Accordingly, knowledge findings should be considered exploratory.

Sixth, app engagement showed marked heterogeneity, with a small number of highly active users and overall limited use of specific features such as physiological self-monitoring. This skewed distribution limits the interpretation of average usage statistics and precluded meaningful dose-response analyses. Consistent with this, no clear association was observed between engagement metrics and improvement in knowledge scores. Although a testing effect from repeated questionnaire administration may have contributed to knowledge gains, this would be expected to affect both groups similarly, and the absence of improvement in the control group suggests that testing alone is unlikely to explain the observed between-group difference.

Finally, the intervention group received a brief mid-study technical support call that was not mirrored in the control group. Although this contact was limited to troubleshooting and did not include educational or behavioral guidance, an attention-related or Hawthorne effect cannot be fully excluded. In addition, baseline imbalances were observed between groups, with the intervention group being younger and including more non-native French speakers. Such differences may occur by chance in small pilot studies and could have influenced engagement, as age may proxy digital literacy. Given the limited sample size, post hoc adjustment was not performed, and these factors should be considered potential confounders.

Future Directions

Future research should evaluate Cardio-Meds in larger, multicenter randomized trials with longer follow-up and inclusion of clinical endpoints such as hospitalization, emergency visits, or quality of life. Studying the intervention in the early post-discharge period, when patients are particularly vulnerable and educational needs are high, may be especially informative. Further development could also include adaptation to different literacy levels and languages to enhance accessibility and equity of care.

Conclusions

In this pilot RCT, use of the Cardio-Meds mobile app was associated with a statistically significant but modest short-term improvement in HF knowledge compared with usual care, without measurable changes in self-reported medication adherence. The app demonstrated high usability and acceptability in a stable ambulatory HF population. These findings should be interpreted as exploratory and hypothesis-generating and support further evaluation of

Cardio-Meds in larger studies with longer follow-up and clinically relevant outcomes.

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The authors confirm that all data reported in this manuscript are original, were collected at Geneva University Hospitals, and were analyzed by the study team. Generative artificial intelligence (ChatGPT; OpenAI) was used solely to assist with language editing and drafting of selected sections of the manuscript and response-to-reviewers documents under full author supervision. In addition, DeepL was used to support translation of study materials, as described in the Methods. Neither tool was used for data collection, statistical analyses, outcome assessment, or generation of results. All content was critically reviewed, verified, and approved by the authors, who take full responsibility for the accuracy, integrity, and scientific content of the work.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to institutional data protection policies and the inclusion of sensitive health-related information. Deidentified data may be made available from the corresponding author upon reasonable request and subject to approval by Geneva University Hospitals, in accordance with applicable regulations.

Authors' Contributions

Conceptualization: PM, FE, KB, EM
Data curation: VB, HH
Formal analysis: VB, PM
Investigation: VB, ET, LS, GG, AS-P, SP, LG
Methodology: PM, FE, KB, EM
Project administration: PM
Software: FE, HH
Supervision: PM
Writing – original draft: VB, PM
Writing – review & editing: All authors

Conflicts of Interest

None declared.

Multimedia Appendix 1
Dutch Heart Failure Knowledge Scale questionnaire translated in French with DeepL.
[DOCX File, 17 KB - cardio_v10i1e83022_app1.docx]

Multimedia Appendix 2
Basel Assessment of Adherence to Immunosuppressive Medications Scale (BAASIS) in French.
[DOCX File, 27 KB - cardio_v10i1e83022_app2.docx]

Multimedia Appendix 3
Usability questionnaire.
[DOCX File, 285 KB - cardio_v10i1e83022_app3.docx]

Multimedia Appendix 4
Usage of the app in the intervention group during the 30 days follow-up.
[DOCX File, 19 KB - cardio_v10i1e83022_app4.docx]

Multimedia Appendix 5
System Usability Scale (SUS) questionnaire responses.
[DOCX File, 19 KB - cardio_v10i1e83022_app5.docx]

Checklist 1
CONSORT checklist.
[PDF File, 465 KB - cardio_v10i1e83022_app6.pdf]

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Abbreviations

BAASIS: Basel Assessment of Adherence to Immunosuppressive Medication Scale
DHFKS: Dutch Heart Failure Knowledge Scale
HF: heart failure
HFmrEF: heart failure with mildly reduced ejection fraction
HFrEF: heart failure with reduced ejection fraction
HUG: Geneva University Hospitals
mHealth: mobile health
RCT: randomized controlled trial
SUS: System Usability Scale

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Short-Term Arrhythmia Prediction Using AI Based on Daily Data From Implantable Devices: Multicenter Prospective Observational Study

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Abstract

Background: Predictive medicine relies on algorithms to determine clinical treatments tailored to each patient's individual characteristics. Predictive models based on artificial intelligence have shown promise in identifying atrial fibrillation episodes; however, they rarely focus on short-term dynamic prediction.

Objective: This study aimed to evaluate the use of an artificial intelligence model and remote monitoring data extracted from pacemaker devices to predict the onset or worsening of arrhythmias in the short term.

Methods: This was a multicenter prospective observational study in which data from 314 patients were analyzed. A total of 65,243 data sequences were collected, of which 55,532 (85.1%) were used to train the algorithm. This model used 31-day records to predict whether the number of arrhythmic episodes would increase, decrease, or remain the same in the following 14 days.

Results: The sensitivity and specificity of the generated predictions were calculated from 9711 prediction-observation pairs. The global sensitivity was 66.4% (95% CI 64.3%-68.3%), and specificity was 77.4% (95% CI 76.4%-78.4%). For patients with baseline arrhythmia, sensitivity was 76.8% (95% CI 74.6%-78.8%), and specificity was 39.6% (95% CI 35.8%-43.5%). The prediction for patients with no baseline arrhythmia showed a sensitivity of 39% (95% CI 35.1%-43%) and a specificity of 81% (95% CI 80.0%-81.9%). The analysis for the patient subgroup without history of atrial fibrillation (232/314, 73.9%) yielded a 69% sensitivity (95% CI 66.5%-71.5%) and an 80% specificity (95% CI 79.3%-81.3%).

Conclusions: This model was capable of predicting short-term increases or decreases in arrhythmic episodes with reasonable sensitivity and specificity using data collected through remote monitoring of implantable devices. The model's performance is expected to improve progressively as more data samples become available, including demographic data and clinical records.

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KEYWORDS

artificial intelligence; AI; atrial fibrillation; AF; machine learning; telemedicine; pacemaker; arrhythmia prediction; predictive medicine

Introduction

In recent years, the use of artificial intelligence (AI) for the diagnosis, prognosis, and evaluation of risk factors and the response to treatment of different pathologies has shown significant advancements. This has had a positive impact on health care systems, improving the efficiency of medical handling and reducing the number of adverse events [1,2].

Cardiac electrophysiology has emerged as one of the fastest-growing subspecialties within cardiology over the last few decades [3,4], which is evidenced by numerous technological advancements aimed at detecting, predicting, and managing cardiac arrhythmias [5,6]. Among those, the prediction of cardiac arrhythmias is especially relevant for patients with atrial fibrillation (AF), who are 5 times more likely to experience thromboembolic events than patients without AF [7].

AI training of information systems based on enormous data quantities from clinical reports and complementary tests from millions of patients not only enables episode prediction in patients diagnosed with AF but also allows for the diagnosis of asymptomatic patients, allowing for early intervention and reducing the number of clinical events [8]. However, cardiac implantable devices can also be leveraged to train AI models for the detection of cardiac arrhythmias. They are particularly well suited for machine learning (ML)–based arrhythmia prediction because they provide continuous, high-fidelity rhythm monitoring over long periods, enabling precise quantification of atrial arrhythmia burden and enhancing diagnostic remote monitoring workflow and device-based therapies [9], with the additional advantage of being already implanted on the patient.

Although several authors have published many AI- and ML-based models for AF prediction in different contexts with good results [10-12], these models were primarily trained and evaluated for predictions over extended periods (often up to 1 year), which provided them with a great amount of input data. However, algorithms supporting short-term, dynamic AF prediction in patients with implantable cardiac devices are scarce. Short-term arrhythmia prediction is uniquely challenging because it requires anticipating nonlinear state transitions driven by heterogeneous and rapidly evolving physiological signals. While long-term prediction is valuable for estimating the risk of AF development in the general population—supporting primary prevention and population-level care planning—dynamic short-term prediction may be particularly impactful in patients who have already been diagnosed with AF. In this context, continuously collected data from implantable cardiac devices enable high-resolution, longitudinal assessment of cardiac rhythm, creating an opportunity for near-term forecasting of AF burden progression. Such device-based prediction could support timely optimization of medical therapy, generation of real-time alerts, and prevention of downstream adverse outcomes. Moreover, in patients with newly diagnosed AF, device-derived dynamic prediction may facilitate closer disease monitoring, guide medication escalation, and enable proactive risk factor modification [10,13].

For that reason, this study aimed to evaluate the use of AI on data extracted from remote pacemaker monitoring for short-term prediction of the onset or increase of AF episodes. Our hypothesis was that data obtained from remote pacemakers could be used to train AI models to predict the onset of atrial arrhythmias with a relatively high sensitivity and specificity without the need for additional datasets.

Methods

Study Design

IA Pacing is a multicenter prospective observational study that started in May 2022 and is ongoing as of January 2026 across 12 centers in Spain. All participating centers used implantable cardiac pacing devices from the same manufacturer (Boston Scientific) with no variation in the telemetry or remote monitoring platform, which was uniformly provided by the vendor. Remote monitoring procedures consisted of daily monitoring.

Ethical Considerations

All procedures performed in this study were conducted in compliance with relevant laws and institutional guidelines and were approved by the ethics committees of the participating centers, including the Comité Ético de Investigación Clínica del Área de Zamora (approved May 25, 2023), Comité Ético de la Investigación Médica of Hospital Universitario 12 de Octubre, Comité Ético de Investigación Clínica de Badajoz (updated November 30, 2021; protocol code: IA-Pacing), Comité Ético de la Investigación Clínica of Hospital Universitario Clínico San Carlos, Comité Ético de la Investigación con Medicamentos of Hospital Universitario Infanta Leonor, Hospital Lozano Blesa (under the protocol approved by the Comité Ético de la Investigación con Medicamentos of Hospital Universitario Puerta de Hierro), Clínica Quirón La Luz and Quirón Pozuelo (both contingent upon favorable review by the Comité Ético de la Investigación con Medicamentos of Hospital Universitario Puerta de Hierro), and Comité Ético de Investigación Médica del Área de Salud de Salamanca (approved March 30, 2022).

Written informed consent was obtained from all participants before enrollment in the study. Participants were informed about the objectives and procedures of the study and their right to withdraw at any time without consequences for their medical care. All procedures performed in this study were conducted in accordance with the ethical principles of the Declaration of Helsinki and complied with applicable European and Spanish regulations governing biomedical research and personal data protection, including the General Data Protection Regulation (Regulation [EU] 2016/679), Ley 14/2007 de Investigación

Biomédica, and Ley Orgánica 3/2018 de Protección de Datos Personales y garantía de los derechos digitales.

To protect participant privacy and confidentiality, all data were pseudonymized before analysis. Identifiable information was stored separately from the research dataset in secure institutional systems with restricted access, and only authorized members of the research team were allowed to access the data. Data handling and storage complied with institutional data protection policies and applicable European and Spanish data protection regulations.

Participants did not receive financial compensation for their participation in the study. Inclusion criteria for the study and complete patient recruitment by hospital can be found in Multimedia Appendix 1.

Baseline Characteristics of the Population

Medical records were used to assess patients' baseline characteristics, including demographic data, cardiovascular risk factors, history of arrhythmias, details of the implanted device, procedural data, and pharmacological treatment.

Prediction of Arrhythmia Onset Using AI

To calculate arrhythmia predictions, we used data generated through remote monitoring of patients' pacemakers, which included the following variables:

- General variables—activity level, respiratory rate, and maximum and mean heart rate
- AF-related variables—total number of arrhythmia episodes per day, total duration of those arrhythmias, atrial tachycardia response (mean and maximum ventricular rate during rapid ventricular response events), and apnea-hypopnea index
- Heart failure–related variables—percentage of left ventricular pacing and SD of the average NN intervals every 5 minutes

When considering arrhythmia episodes per day, we took into account only those arrhythmias that were of the "supraventricular tachycardia" or "atrial fibrillation" type as categorized by the device, with no time limit restrictions.

The algorithm divided the data into sequences of 45 days. The first 31 days were used for the algorithm to analyze and predict what would happen in the following 14 days. This time was selected after various tests with different times of training and prediction, with no major changes among them. Furthermore, based on medical criteria, a 14-day predictive time window was considered sufficient to allow for patient scheduling and timely intervention if required. Therefore, after observing the telemetry data for 31 days, a prediction was generated for the following 14 days. The appearance or absence of arrhythmias was divided into 4 categories as follows:

- Increase—the patient already had arrhythmias during the 31 days of observation, and the average number of arrhythmias during the 14 days of prediction increased.
- Decrease—the patient already had arrhythmias during the 31 days of observation, but the average number of arrhythmias during the 14 days of prediction decreased.
- Remains at 0—the patient did not have arrhythmias during the 31 days of observation, and the average number of arrhythmias during the 14 days of prediction remained at 0.
- Goes from 0 to something—the patient did not have arrhythmias during the 31 days of observation, but some arrhythmias occurred during the 14 days of prediction.

Subsequently, to simplify the analysis, the previous 4 categories were regrouped into 2:

- Increased—the average number of arrhythmias during the day increased (categories 1 and 4).
- Maintained or decreased—the average number of arrhythmias during the day was maintained or decreased (categories 2 and 3).

Detailed information about these categories is provided in Multimedia Appendix 2. Similarly, information about data preprocessing and final data volume is provided in Multimedia Appendix 3. Finally, the creation of the predictive model using AI, along with its parameters, its training, and its final results over the *test* data, is detailed in Multimedia Appendix 4.

Furthermore, to generate explanations in the model, a specialized tool called Shapley additive explanations (SHAP) was used, which leverages game theory–based results to identify the variables that had the greatest importance in making each prediction. In Multimedia Appendix 5, the average results for the predictions of each class can be observed, where some clinically relevant variables stand out, such as the presence of apneas or the SD of the average NN intervals. Alongside SHAP, the entropy of the classification was used as a measure of uncertainty to obtain confidence estimations for each prediction, as explained in Multimedia Appendix 6. These tools combined reduce the opacity of AI models, increasing trust in them as a tool for clinical decision-making.

Web Application Development

On the basis of the AI-generated predictions of arrhythmias for the following 14 days and the explanations based on SHAP and confidence estimation, a web application was developed to allow medical personnel to monitor each patient.

Statistical Analysis

Categorical variables are presented as frequencies and percentages, whereas quantitative variables are expressed as means and SDs. The sensitivity and specificity of the arrhythmia prediction were calculated from a 2 × 2 contingency table considering prediction and reality during the follow-up period. Sensitivity and specificity were calculated from 9711 prediction-observation pairs. Statistical analyses were performed using SPSS (version 17.0; IBM Corp).

Results

Data from 314 patients enrolled in the IA Pacing study between May 2022 and May 2024 were analyzed. A total of 65,243 data sequences from implantable devices were collected, of which 55,532 (85.1%) were used to train the algorithm, and the remaining 9711 (14.9%) were used to analyze the sensitivity and specificity of the generated predictions.

Baseline Characteristics of the Population

Table 1 shows the clinical characteristics of the participating patients. A total of 61.3% (192/313) of the patients were male, and the mean age was 77 (SD 9.2) years. The most common indication for pacemaker implantation was atrioventricular block, whereas the predominant pacing site was the right ventricular apex. In total, 81.9% (158/193) of the patients had at least one cardiovascular hospitalization in the year before enrollment.

Table . Baseline characteristics of the patients (N=314). Variables are reported as n/N to account for missing data.

Baseline characteristics	Values
Sex (male), n/N (%)	192/313 (61.3)
Age (y), mean (SD)	77 (9.2)
Pacemaker indication among patients, n/N (%)	
AV[a] block	240/313 (76.7)
Sinus bradycardia	24/313 (7.7)
Other indications	49/313 (15.7)
Pacing type among patients, n/N (%)	
Right ventricular apex	259/310 (83.5)
Left branch	51/310 (16.5)
Type of device used by patients, n/N (%)	
Dual-chamber pacemaker	302/314 (96.2)
Tricameral pacemaker with resynchronizer	12/314 (3.8)
Pacemaker models used by patients, n/N (%)	
Boston Scientific PROPONENT MRI L211	101/314 (32.2)
Boston Scientific ACCOLADE MRI L311	67/314 (21.3)
Boston Scientific PROPONENT EL MRI L231	15/314 (4.8)
Boston Scientific ACCOLADE EL MRI L331	119/314 (37.9)
Boston Scientific VISIONIST X4 CRT-P U225	3/314 (1)
Boston Scientific VISIONIST X4 CRT-P U228	9/314 (2.9)
Patients with CV[b] hospitalizations in the last y, n/N (%)	
0	35/193 (18.1)
1	132/193 (68.4)
>2	26/193 (13.5)
CV risk factors among patients, n (%)	
Arterial hypertension	236/308 (76.6)
Diabetes mellitus	118/296 (39.9)
Dyslipidemia	202/302 (66.9)
Obesity	54/273 (19.8)
Current smoking	22/286 (7.7)
Current alcoholism	14/275 (5.1)
CV history among patients, n/N (%)	
NYHA[c] I	101/187 (54)
Ischemic cardiopathies	52/277 (18.8)
Valvulopathies	77/284 (27.1)
Myocardiopathies	34/279 (12.2)
TIA[d] or stroke	36/277 (13)
Peripheral vascular disease	21/269 (7.8)
AF[e] stroke risk score (CHA_2DS_2-VASc), mean (SD)	3.5 (1.5)
Arrhythmia history among patients, n/N (%)	
AF	42/275 (15.3)
Ventricular arrhythmia	5/313 (1.6)

Baseline characteristics	Values
Other comorbidities among patients, n/N (%)	
COPD[f]	24/273 (8.8)
Asthma	17/270 (6.3)
Pharmacological treatment among patients, n (%)	
Antiaggregants	124/314 (39.5)
Anticoagulants	57/314 (18.2)
ACE[g] inhibitors, ARBs[h], or ARNIs[i]	178/314 (56.7)
β-blockers	79/314 (25.2)
Loop diuretics	66/314 (21.1)

[a]AV: atrioventricular.

[b]CV: cardiovascular.

[c]NYHA: New York Heart Association.

[d]TIA: transient ischemic attack.

[e]AF: atrial fibrillation.

[f]COPD: chronic obstructive pulmonary disease.

[g]ACE: angiotensin-converting enzyme.

[h]ARB: angiotensin II receptor blockers.

[i]ARNI: angiotensin receptor-neprilysin inhibitor.

Regarding cardiovascular risk factors, most patients had hypertension (236/308, 76.6%) and dyslipidemia (202/302, 66.9%), whereas the prevalence of diabetes mellitus was 39.9% (118/296). The mean CHA_2DS_2-VASc score was 3.5 (SD 1.5). A history of AF was present in 15.3% (42/274) of the patients.

Prediction of Arrhythmia Onset Using AI

The sensitivity of the AI-based predictive model was 66.4% for the full sample (1456 true positive cases; 1696 false positive cases; 95% CI 64.3% - 68.3%), whereas specificity was 77.4% (95% CI 76.4% - 78.4%), corresponding to 738 false negative cases and 5821 true negative cases.

Next, we grouped the patients based on whether they had presented arrhythmias during the initial 31-day period used by the algorithm to generate predictions. Two groups were defined: patients with arrhythmias during the baseline period (those classified in the “increase” or “decrease” categories) and patients without arrhythmias during the baseline period (those in the “remains at 0” or “goes from 0 to something” categories).

On the basis of the contingency tables generated, we obtained a sensitivity of 76.8% (95% CI 74.6% - 78.8%) and specificity of 39.6% (95% CI 35.8% - 43.5%) in patients with arrhythmias during the baseline period (1219 true positive cases, 393 false positive cases, 258 true negative cases, and 368 false negative cases) and a sensitivity of 39% (95% CI 35.1% - 43%) and specificity of 81% (95% CI 80% - 81.9%) in patients without arrhythmias during that period (237 true positive cases, 1303 false positive cases, 370 false negative cases, and 5563 true negative cases).

In addition, using data sequences from patients with no history of AF (232/314, 73.9%; 7259 data points), we calculated the model’s sensitivity and specificity for arrhythmia prediction considering both supraventricular tachycardia and AF as the presence of arrhythmia. These were 69% (95% CI 66.5% - 71.5%) and 80% (95% CI 79.3% - 81.3%), respectively.

The raw values from the contingency table for each group can be found in Table 2.

Table . Arrhythmic episode prediction and ground truth for both patient groups.

AI[a] arrhythmia prediction	Follow-up ground truth		Sensitivity (%)	Specificity (%)
	Increased	Maintained or decreased		
Total patients, n			66.4	77.4
Increased	1456	1696		
Maintained or decreased	738	5821		
Patients with arrhythmia in the last 31 days, n			76.8	39.6
Increased	1219	393		
Maintained or decreased	368	258		
Patients without arrhythmia in the last 31 days, n			39.0	81.2
Increased	237	1303		
Maintained or decreased	370	5563		
Patients with no AF[b] history (n=232), n			69.1	80.3
Increased	951	1157		
Maintained or decreased	426	4725		

[a]AI: artificial intelligence.

[b]AF: atrial fibrillation.

Web Application Development

The web application interface can be observed in Figure 1 and Figure 2 and presents the prediction along with its confidence score (expressed as a percentage), aiding clinical decision-making. The main view of the web platform shows the list of patients with their predictions and estimated confidence along with a summary of the patients' results and search filters to aid physicians (the number of patients is higher as predictions can be made on patients with 31-45 days of measurement instead of just the >45 days used to validate the AI model). Details of a patient with their prediction, estimated confidence, most important variables for decision-making based on SHAP (pie chart), and variable evolution can also be observed on the web platform.

Figure 1. Main view of the web platform showing the list of patients with their predictions and estimated confidence along with a summary of the patients' results and search filters to aid physicians (the number of patients is higher as predictions can be made on patients with 31-45 days of measurement instead of just the >45 days used to validate the artificial intelligence model).

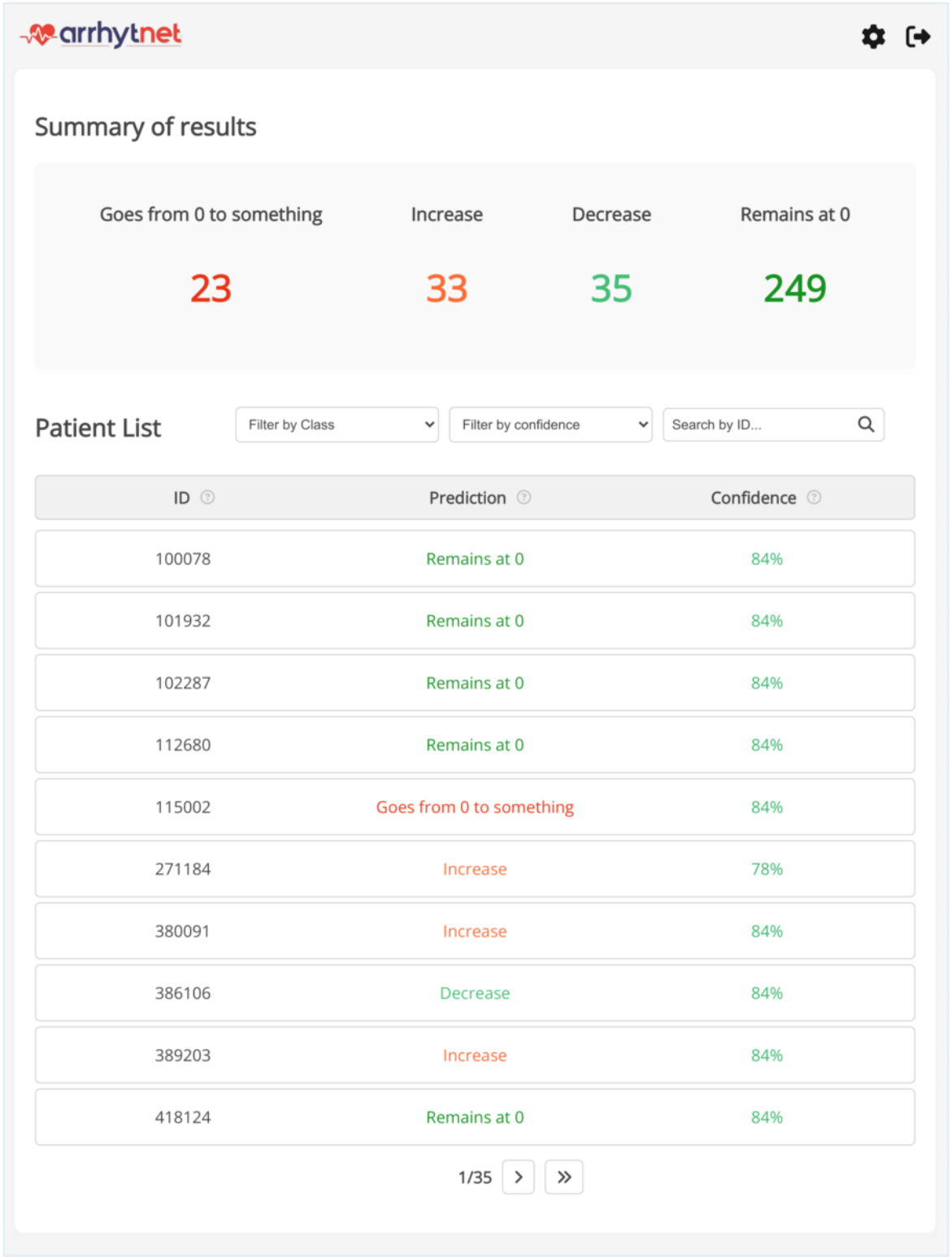
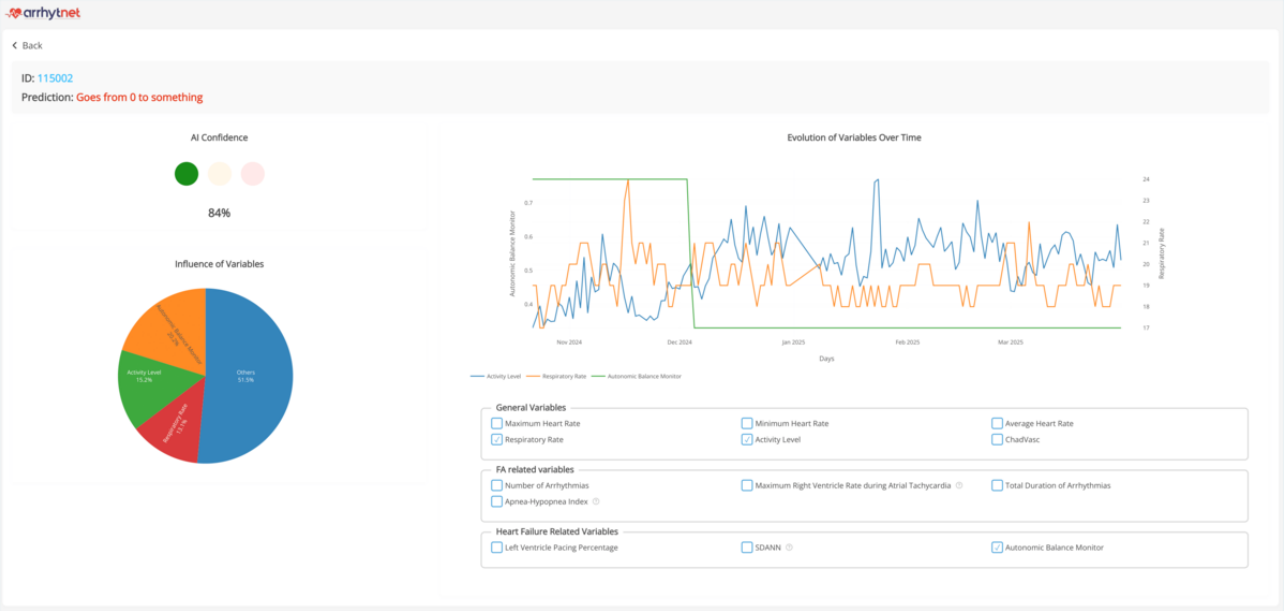


Figure 2. Details of a patient with their prediction, estimated confidence, most important variables for decision-making based on Shapley additive explanations (pie chart), and variable evolution.



Discussion

AI implementation is transforming health care in cardiology, especially in the context of heart rhythm–related disorders. We developed an initial algorithm with information obtained from the remote monitoring of pacemakers that predicted atrial arrhythmia onset within the 14 days following the 31-day monitoring period with a 66.4% sensitivity and 77.4% specificity. This study is, to the best of our knowledge, the first to use data exclusively from remote pacemaker monitoring to dynamically predict arrhythmia onset in patients with atrial arrhythmia in the short term.

Given how important arrhythmia detection is for the identification of patients at risk of having a stroke or systemic embolism, AI algorithms have lately been used for detection, prediction, and treatment tailoring of patients with AF [8]. Focusing on AF episode prediction, several authors have achieved significant advancements in developing AF-predicting algorithms in varying periods from initial measured data. Kao et al [14] developed a model able to predict new arrhythmic episodes in the span of a year with a 98.7% specificity using a database of clinical data gathered for 3 years from older patients with no electrocardiographic data. Similarly, Tiwari et al [15] predicted 6-month AF onset with 75% sensitivity and 85% specificity by developing a model using 200 clinical features from more than 2 million clinical records. Another algorithm worth mentioning developed from clinical records is the one from the Future Innovations in Novel Detection of Atrial Fibrillation study by Nadarajah et al [16] that predicted AF onset within 6 months with a sensitivity and specificity of 78.1% and 73.1%, respectively. Clinical data have also been used to train ML models to detect risk factors for developing AF in asymptomatic patients, as described by Hill et al [10]. Another author used data from 100,000 electrocardiograms (ECGs) taken from 40,000 patients in a mean of 2 years of follow-up to predict the time before a new arrhythmic episode, obtaining similar results to medical record–based predictions [11]. In our study, unlike the studies cited before, no medical record was used to train the system. The algorithm compared daily data from the remote monitoring of an implantable device, similarly to the recently published study by Gregoire et al [13] that trained an ML model using Holter recordings to predict short-term AF episodes. We consider this a strength of our study as only data obtained from the remote monitoring of the implantable device were needed to estimate the risk of experiencing an arrhythmic episode, thus eliminating the need for additional information from medical records.

Although our algorithm does not compute the time before a new arrhythmic episode, it does enable the identification of patients at risk of experiencing episodes of supraventricular arrhythmias in the short term (14 days following the measurement), which would improve their medical care. Our model correctly predicted whether arrhythmias would increase in almost 75% of the cases, with 66.4% global sensitivity and 77.4% specificity. The previously mentioned study from Gregoire et al [13] predicted short-term paroxysmal AF episode onset with higher sensitivity and specificity than ours (86.6% vs 83.0%, respectively). However, it is worth mentioning that, while their approach relies on comprehensive ECG recordings from a Holter monitor, our analysis is based solely on limited, secondary data derived from pacemaker use (eg, daytime heart rate, respiratory rate, or apnea counts). Although these variables provide less information, they may still be highly informative as they are known to be correlated with arrhythmic episodes [17]. Additionally, it is noteworthy that our algorithm was trained using data obtained from a device already implanted in the patient, thereby eliminating the need for additional medical visits. A table comparing the main features of our study to those of the ones mentioned previously can be found in Multimedia Appendix 7.

In patients with no registered history of arrhythmia (232/314, 73.9%), who constitute the group most likely to benefit from early therapeutic interventions, the analysis showed higher values of sensitivity and specificity (69% and 80%,

respectively). Algorithm performance was different according to baseline arrhythmia status (higher sensitivity in patients with arrhythmia in the last 31 days and higher specificity in patients with no episodes in the same period). We think this is due to the different data distribution among these 2 groups as sensitivity and specificity heavily depend on the prevalence of the episode of interest (in this case, arrhythmia).

The fact that our algorithm predicted the occurrence of arrhythmias with a similar performance to that of the model by Tiwari et al [15] (which predicted arrhythmias in a 6-month time window based on clinical records from 2 million younger patients) with relatively few data is a promising starting point to continue enhancing AI training and, therefore, the obtained results. Similarly to Tiwari et al [15], we deem it necessary to optimize AI models to increase their sensitivity and reduce false positives. One strength of our approach is that it requires only a small amount of data for training because the implantable devices continuously monitor cardiac activity. We also used a tool to standardize variable names across devices, which allowed us to combine datasets and increase the amount of data for training, which is another strong point of this study.

It is worth mentioning some limitations of the proposed model. First, the training did not consider demographic variables. Including these factors could increase the predictive capabilities and justify the use of AI over classic risk factor predictors [18]. Moreover, it has been observed that models encompassing more than one type of variable—such as clinical data and ECGs, echocardiograms, or magnetic resonance imaging, for instance—increase prediction sensitivity [19]; this should be taken into account when designing and training future AI algorithms. Second, although the number of prediction and reality sequences was high (more than 9000), data pairs were taken from a cohort of 314 patients, which could be considered low. The size of the cohort could then be increased to augment the training database and refine the output of the model, optimizing AI training and reducing the chance of overfitting the model [20]. It is also worth mentioning that our algorithm did not have external validation as it is a first-phase development, and testing the finalized model on independent data is necessary to draw more specific conclusions on its clinical impact. Additionally, the ability of cardiac devices to differentiate arrhythmia types should be considered when using the extracted data to train the model [21,22]. On this matter, our model did not distinguish among AF, atrial tachycardia, and atrial high-rate episodes, making it hard to fully characterize the clinical relevance of the algorithm. Further research is being conducted considering minimal times, ECG information, and heart rate to fully characterize arrhythmia type. Finally, we extracted the data from devices from the same vendor, and we cannot affirm that this model can be reproducible with other commercial brands. However, fine-tuning methods can be used to train the algorithm using information from other devices. Taking all the aforementioned factors into consideration, further research could focus on increasing the prediction period and on differentiating types of arrhythmias given the clinical implications of de novo episodes of AF and the need for anticoagulation therapy.

Finally, we would like to mention the importance of an intuitive web design to present the obtained data. It has been proven that the use of mobile apps in health care is determined by how user-friendly and intuitive they are and the amount of data that must be input by users (eg, health care professionals) for the apps to function (eg, patient demographics, clinical variables, or diagnostic data) as a higher data entry burden may negatively affect usability and adoption [23]. If an application quickly displays the prediction along with the patient's arrhythmia risk percentage, it is more likely that health care professionals will use it.

In conclusion, this study provides preliminary evidence that changes in arrhythmic burden may be estimated with limited but measurable sensitivity and specificity using data derived from implantable cardiac devices. A graphical overview of the study and its main findings is provided in Multimedia Appendix 8 (Visual Abstract). The predictive performance of the model may improve with further development and validation in larger cohorts that include additional demographic and clinical variables. These elements, together with the user-friendly visualization of predictions in a simple application, suggest that this initial phase of the study may serve as a basis for future research. Further studies are warranted to determine the clinical utility of this approach for the monitoring and management of patients with implantable cardiac pacing devices.

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The authors declare that no financial support was received for this work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Inclusion criteria and patient recruitment.
[DOCX File, 23 KB - cardio_v10i1e85841_app1.docx]

Multimedia Appendix 2
Selection of input and output data.
[DOCX File, 76 KB - cardio_v10i1e85841_app2.docx]

Multimedia Appendix 3
Data volume and preprocessing.
[DOCX File, 21 KB - cardio_v10i1e85841_app3.docx]

Multimedia Appendix 4
Artificial intelligence–based prediction model.
[DOCX File, 80 KB - cardio_v10i1e85841_app4.docx]

Multimedia Appendix 5
Shapley Additive Explanations feature importance.
[DOCX File, 68 KB - cardio_v10i1e85841_app5.docx]

Multimedia Appendix 6
Confidence estimation.
[DOCX File, 97 KB - cardio_v10i1e85841_app6.docx]

Multimedia Appendix 7
Comparison of our model to other predictive models.
[DOCX File, 25 KB - cardio_v10i1e85841_app7.docx]

Multimedia Appendix 8
AI for the Prediction of Atrial Fibrillation or Atrial Tachycardia Episodes in Patients With Pacemakers.
[PNG File, 51 KB - cardio_v10i1e85841_app8.png]

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Abbreviations

AF: atrial fibrillation
AI : artificial intelligence
ECG : electrocardiogram
ML : machine learning
SHAP: Shapley additive explanations

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Technologies, Clinical Applications, and Implementation Barriers of Digital Twins in Precision Cardiology: Systematic Review

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Abstract

Background: Digital twin systems are emerging as promising tools in precision cardiology, enabling dynamic, patient-specific simulations to support diagnosis, risk assessment, and treatment planning. However, the current landscape of cardiovascular digital twin development, validation, and implementation remains fragmented, with substantial variability in modeling approaches, data use, and reporting practices.

Objective: This systematic review aims to synthesize the current state of cardiovascular digital twin research by addressing 11 research questions spanning modeling technologies, data infrastructure, clinical applications, clinical impact, implementation barriers, and ethical considerations.

Methods: We systematically searched 5 databases (PubMed, Scopus, Web of Science, IEEE Xplore, and Google Scholar) and screened 330 records. Forty-two original studies met the predefined eligibility criteria and were included. Data extraction was guided by 11 thematic research questions. Mechanistic and artificial intelligence (AI) or machine learning (ML) modeling strategies, data modalities, visualization formats, clinical use cases, reported impacts, limitations, and ethical or legal issues were coded and summarized. Risk of bias was evaluated using a custom checklist for modeling studies, the Prediction Model Risk of Bias Assessment Tool (PROBAST) for prediction models, and the Risk of Bias in Non-Randomized Studies - of Interventions (ROBINS-I) for observational studies.

Results: Most digital twins (29/42, 69%) relied on mechanistic models, while hybrid mechanistic–data-driven approaches and purely data-driven designs were less frequent (13/42, 31%). Only 18 studies explicitly described ML or AI, most often deep learning, Bayesian methods, or optimization algorithms. Personalization depended primarily on imaging (32/42, 76%) and electrocardiography or other electrical signals (18/42, 43%). Visualization was dominated (41/42, 98%) by static figures and anatomical snapshots. Clinically, digital twins were most commonly applied to therapy planning, risk prediction, and monitoring. Reported benefits focused on improved decision-making and therapy-related impacts, with occasional (8/42, 19%) reports of increased accuracy or faster diagnosis, but there was limited evidence for downstream improvements in patient outcomes. Key barriers included strong model assumptions and simplifications; high computational cost; data quality and availability constraints; limited external validation; and challenges in real-time performance, workflow integration, and usability. Explicit discussion of ethical, legal, or governance issues was rare (7/42, 17%).

Conclusions: Cardiovascular digital twins show substantial potential to advance precision cardiology by linking personalized physiological models with clinical decision support, particularly for therapy planning and risk prediction in arrhythmia and heart failure. However, real-world implementation is constrained by methodological heterogeneity, restricted data and validation practices, limited openness of code and models, and sparse engagement with ethical and governance questions. Future research should prioritize standardized evaluation frameworks, robust clinical validation, interoperable and user-centered system design, and ethically grounded, patient-centered development to realize the full clinical value of digital twin systems.

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KEYWORDS

digital twin; cardiology; personalized medicine; simulation; machine learning; clinical decision support; ethics

Introduction

In recent years, the integration of digital twin technology into health care has opened new avenues for precision medicine, particularly within the field of cardiology. A digital twin is a dynamic, virtual representation of a physical system that is continuously updated with real-time data, advanced computational models, and artificial intelligence (AI) analytics [1,2]. In the context of health care, digital twins serve as virtual replicas of patients, organs, or biological systems, encompassing multidimensional, patient-specific information to inform clinical decisions [3-5].

Cardiovascular diseases (CVDs) remain a leading cause of morbidity and mortality worldwide, underscoring the need for innovative, patient-centric approaches to diagnosis, treatment, and management [6,7]. The application of digital twins in cardiology involves the creation of virtual replicas of the human heart by integrating anatomical, physiological, and molecular data. These models are capable of simulating electrical activity [8], mechanical function, hemodynamics, and drug responses [9,10]. By combining data from cardiac imaging (eg, magnetic resonance imaging [MRI] and computed tomography [CT]), electrocardiography (ECG), hemodynamic profiles, electrophysiology recordings, electronic health records, and omics assessments, digital twin systems provide a basis for precision simulation and virtual experimentation [11].

These capabilities make cardiac digital twins uniquely positioned to support personalized treatment plans, enabling applications such as risk stratification, therapy optimization, surgical simulation, and drug safety testing. The integration of AI, particularly machine learning (ML) and deep learning (DL), has further improved the scalability and performance of digital twins in real-world applications.

However, despite promising technical progress, substantial challenges remain. These include (1) high computational costs and complex personalization pipelines; (2) data heterogeneity and interoperability limitations; (3) lack of standardized validation protocols and clinical benchmarks; and (4) ongoing concerns regarding privacy, explainability, and regulatory oversight.

While multiple reviews have surveyed digital twins in general health care [12] or addressed cardiovascular simulation from a technical standpoint [11], a comprehensive, domain-specific synthesis integrating technical, clinical, and implementation perspectives in personalized cardiology remains lacking.

To address this gap, we conducted a systematic review following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 guidelines [13,14]. This review explicitly examines original research articles on cardiovascular digital twin systems, emphasizing personalization, clinical relevance, and implementation feasibility. Our study followed a two-stage methodology:

1. Screening phase: We screened 330 articles from 5 databases (PubMed, Scopus, IEEE, Web of Science, and Google Scholar). After removing duplicates, non-English entries, and publications lacking abstracts or relevant context, 42 articles were retained.
2. Review phase: Three independent reviewers assessed full-text articles based on structured research questions (RQs). Each article was evaluated for relevance to 11 themes covering technology, data integration, clinical application, validation, ethics, and data sources.

The following RQs guided our review:

- RQ1-RQ4: What are the technological foundations of cardiovascular digital twins, including modeling strategies, AI integration, and open-source availability?
- RQ5 and RQ6: How is patient-specific data structured and visualized?
- RQ7 and RQ8: What are the clinical applications and disease targets of digital twins?
- RQ9: What clinical impacts have been reported as a result of digital twin use?
- RQ10 and RQ11: What barriers, limitations, and ethical or legal considerations are acknowledged in current studies?

The aim of this study was to systematically review the existing literature on cardiovascular digital twins to identify current technologies, clinical uses, and challenges to implementation.

Methods

Overview

This systematic review was designed and conducted following the PRISMA 2020 statement (Checklist 1). The protocol was developed in advance and used a transparent, reproducible approach to article retrieval, screening, and extraction. It was structured around 11 domain-specific RQs targeting the technological, clinical, and implementation dimensions of digital twin systems in cardiology.

Data Sources and Search Strategy

A comprehensive literature search was performed across 5 major academic databases: PubMed, Scopus, Web of Science, IEEE Xplore, and Google Scholar. These platforms were selected to ensure broad interdisciplinary coverage across biomedical, engineering, and computational sciences. The databases were searched between January and early February 2025, restricting records to publications from 2010 onwards. Only the first 115 results sorted by relevance were screened for Google Scholar due to indexing limitations. The reference lists of relevant reviews were also scanned to ensure inclusion of key foundational articles.

Data collection and initial preprocessing were streamlined using Triple-A software [15], which served as the main tool for managing and organizing the retrieved records.

The search strategy used Boolean combinations of controlled vocabulary (eg, MeSH) and free-text terms as follows: (“digital twin” OR “virtual heart” OR “patient-specific model”) AND (“cardiology” OR “cardiac” OR “heart” OR “cardiovascular”) AND (“simulation” OR “personalized medicine” OR “precision medicine” OR “in silico”).

To increase transparency, we conceptually structured the search according to the Population, Intervention, Comparison, and Outcome (PICO) framework:

- Population (P): Patients with CVDs, including arrhythmia, heart failure, ischemic heart disease, cardiomyopathy, and related conditions.
- Intervention (I): Digital twin systems designed for diagnosis, simulation, personalization, monitoring, risk prediction, or therapy planning in cardiology.
- Comparison (C): Not applicable, as the review did not evaluate digital twins against alternative interventions or standard care.
- Outcome (O): Descriptive outcomes related to modeling strategies, data infrastructure, clinical applications, reported clinical impact, implementation barriers, and ethical or governance considerations.

These PICO elements informed the design of our search and eligibility criteria, while the detailed content of the review was organized around 11 thematic RQs (RQ1-RQ11).

All search results were exported to a centralized reference manager and screened using Microsoft Excel. The complete search strings for the databases are provided in Multimedia Appendix 1.

Eligibility Criteria

Articles were included if they (1) were original empirical research studies, including journal articles, conference papers, and preprints; (2) reported on the development, implementation, or evaluation of digital twin systems in health care; (3) focused on cardiovascular applications, including anatomical, physiological, or functional heart modeling; (4) were related to individualized or personalized medicine, clinical decision-making, or patient-specific therapies; and (5) were published in English and provided a structured abstract.

Articles were excluded if they (1) were review papers, commentaries, editorials, book chapters, or theoretical position pieces; (2) did not focus on cardiovascular systems (eg, neurological or orthopedic digital twins); (3) were not available in full text or lacked an identifiable abstract; (4) were duplicate entries across databases; and (5) were published in languages other than English, including those labeled as “unspecified” or “null.”

These criteria were iteratively refined during the pilot screening of 50 records.

We did not apply the exclusion criteria based on study design, as the aim of this review was to comprehensively synthesize diverse contributions to the digital twin field, including conceptual, technical, and applied studies, without limiting the scope to any particular methodological framework.

Screening and Article Selection

The initial search returned 330 records. A multistep screening protocol was applied:

- Phase 1 (title and abstract screening): Three reviewers independently screened articles for relevance. Discrepancies were resolved by group discussion and majority vote.
- Phase 2 (eligibility review): Of 44 records identified in phase 1, 2 records were excluded. A final set of 42 articles was included in the synthesis.

Reviewers used a shared Microsoft Excel spreadsheet with predefined drop-down fields for coding decisions. Interreviewer consistency was monitored, and a senior reviewer adjudicated disagreements. The filtering questions used during study selection are presented in Table 1. The complete list of all screened records, along with their inclusion or exclusion status, is provided in Multimedia Appendix 2.

Table . Filtering questions used during study selection for the systematic review of cardiovascular digital twin research.

Screening question[a]	Decision criteria
Filtering question 1: Does the study relate to digital twins in health care or medicine?	Include if the study discusses digital twins applied in health care contexts.
Filtering question 2: Does the study specifically address the use of digital twins in cardiology?	Include if the study focuses on cardiovascular applications of digital twins.
Filtering question 3: Does the study involve personalized or patient-specific applications in cardiology?	Include if the study discusses patient-specific or precision medicine approaches.

[a]Each question aligns with predefined inclusion and exclusion criteria applied across titles, abstracts, and full texts.

RQs and Data Extraction

Data extraction was organized around 11 RQs, which were structured into six thematic categories:

1. Technological foundations: modeling methods (RQ1), mechanistic model types (RQ2), ML algorithms (RQ3), and open-source availability (RQ4)
2. Data infrastructure and visualization: patient-specific data (RQ5) and visualization formats (RQ6)
3. Clinical applications and conditions: clinical use cases (RQ7) and cardiovascular conditions addressed in digital twin studies (RQ8)
4. Clinical impact: reported outcomes and benefits (RQ9)
5. Implementation challenges: technical and validation barriers (RQ10)
6. Ethical considerations: legal, privacy, and governance issues (RQ11)

Each reviewer used a structured extraction form, built in Excel, to code articles across multiple predefined categories (eg, “FEM,” “ECG,” and “Heart Failure”) using a controlled

vocabulary. Note fields allowed for contextual elaboration and inductive theme discovery.

Categories were not mutually exclusive, allowing multiple responses per article. The full data extraction form is provided in Multimedia Appendix 3.

Data Extraction Process

Data extraction followed a structured workflow as follows:

1. Full-text review: Each selected study was fully reviewed to extract methodological details and research contributions.
2. Thematic classification: Studies were assigned to predefined thematic categories based on their focus area and objectives.
3. Double-reviewer validation: Three independent reviewers extracted data; any conflicts were resolved via discussion.
4. Database compilation: Extracted data were compiled into a structured dataset for further analysis.

Risk of Bias

The risk of bias of the included studies was assessed using the instrument most appropriate for the underlying study design. Three distinct tools were used. First, simulation-based and modeling-oriented studies, such as those involving digital twins, mechanistic models, or computational pipelines, were evaluated using a custom modeling checklist, which was developed to capture methodological risks specific to computational modeling (eg, data representativeness, validation strategy, overfitting, and reproducibility). Second, prediction-modeling studies were appraised using the Prediction Model Risk of Bias Assessment Tool (PROBAST), which evaluates risk of bias across 4 domains: participants, predictors, outcome, and analysis. Finally, observational cohort studies were assessed using the Risk of Bias in Non-Randomized Studies - of Interventions (ROBINS-I), which provides structured domain-level judgments for 7 bias domains, including confounding, selection of participants, classification of interventions, missing data, and outcome measurement.

For all tools, domain-level judgments were assigned according to published guidance or tool-specific documentation. Risk-of-bias assessments were conducted independently by multiple assessors, and any discrepancies were resolved through discussion, with arbitration applied when consensus could not be reached. Domain-level ratings were then synthesized into an overall judgment (low, unclear, or high risk of bias) based on the decision rules recommended for each tool.

Visualization of risk-of-bias judgments was performed using robvis [16], an R package and web application that supports structured display of traffic-light plots and summary plots.

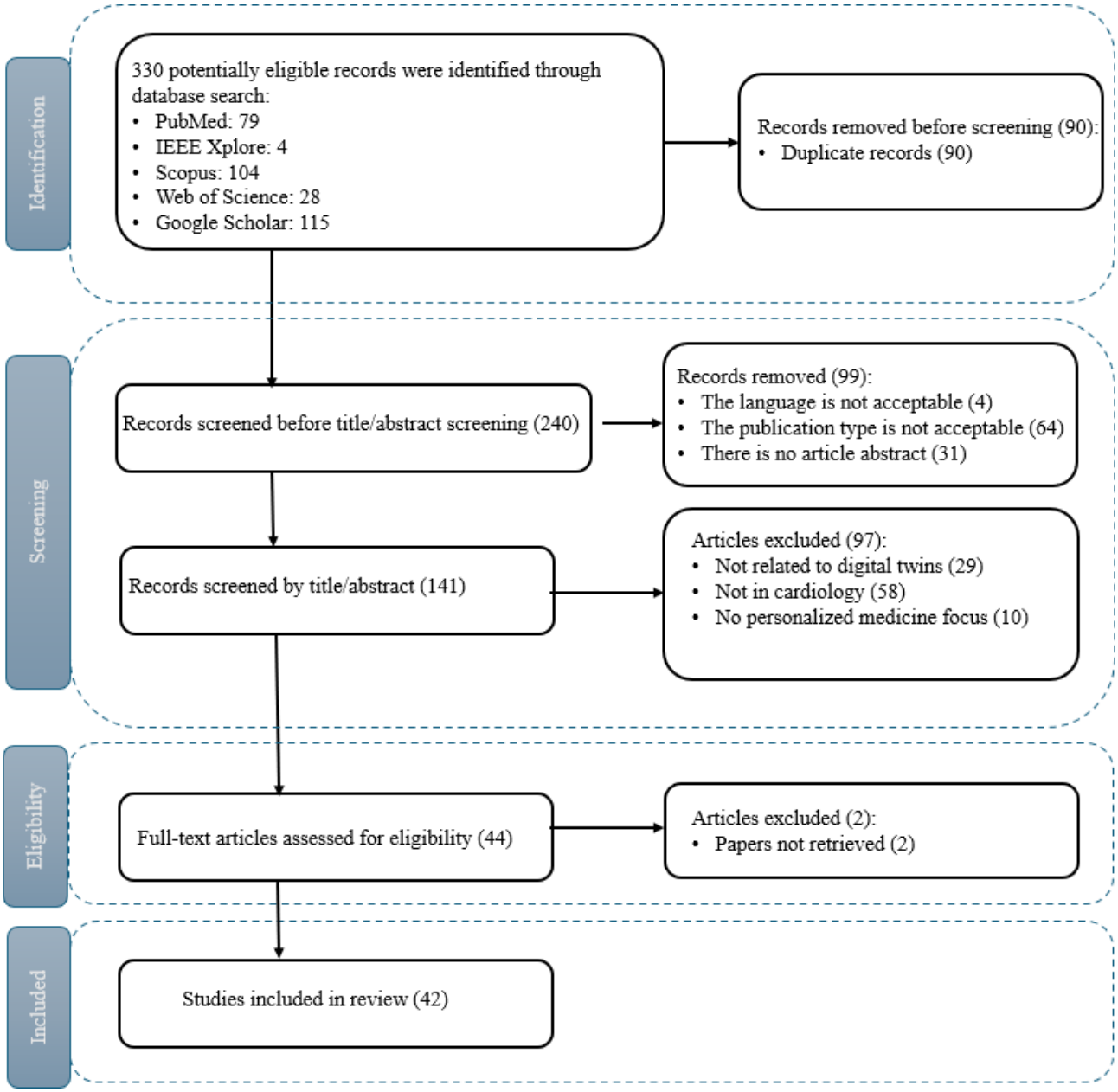
Results

Overview

We synthesized the findings from 42 original research articles on cardiovascular digital twins. The PRISMA flow diagram of the study selection process is presented in Figure 1. The results were structured around 11 predefined RQs, which were organized into 6 thematic domains: technological foundations, data infrastructure and visualization, clinical applications and conditions, clinical impact, implementation challenges, and ethical considerations. Each subsection follows a format: overview, key insights, and interpretation. For each RQ, we present summary patterns and cite representative studies in the main text. The complete mapping of all studies to the corresponding RQ categories is provided in Multimedia Appendix 4, and the mapping from raw extraction values to the harmonized categories used in the analyses is provided in Multimedia Appendix 5.

Funding sources were reported for a subset of studies and were most often public or academic, with a smaller number supported by mixed public-foundation or public-industry collaborations and relatively few funded solely by industry. Study-level funding details are summarized in Multimedia Appendix 4.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 flow diagram illustrating the systematic selection process for cardiovascular digital twin studies. A total of 330 records were retrieved from 5 major databases and screened using predefined eligibility criteria. After removal of duplicates and exclusion of irrelevant or nonoriginal articles, 42 studies were included in the final synthesis for qualitative and quantitative analyses.



Technological Foundations (RQ1-RQ4)

We outline the core technical elements of cardiovascular digital twin systems, focusing on modeling strategies (RQ1), types of mechanistic models (RQ2), ML applications (RQ3), and open-source availability (RQ4). Together, these RQs characterized how digital twins were constructed, personalized, and shared, revealing trends in hybrid modeling, the integration of AI, and the challenges in reproducibility.

RQ1: What Primary Modeling Approach is Used to Develop Digital Twins?

Overview

All 42 studies were classified according to their dominant modeling approach: mechanistic, hybrid, or data-driven. These categories reflect the computational core of digital twins, ranging from physics-based simulation to statistical learning and their integration.

Key Insights

The key insights are as follows:

- Mechanistic models were the most common (29 studies [8,11,17-43]), and they relied on physics-based formulations (eg, finite element modeling [FEM], electrophysiological simulation, and hemodynamic flow analysis) to generate personalized physiological representations.
- Data-driven models were noted in 7 studies [44-50], and they were primarily based on statistical learning or machine-learning approaches without explicit biophysical constraints.

- Hybrid approaches were the least common (6 studies [51-56]), and they combined mechanistic frameworks with data-driven components, for example, using ML to estimate parameters, extract imaging features, or accelerate computational solvers.

Interpretation

The predominance of mechanistic approaches highlights the central importance of physiological interpretability in cardiovascular digital twin development. Studies involving these approaches focus on replicating biophysical behavior with high fidelity, supporting diagnostic and interventional simulation tasks.

Data-driven twins, while less common, demonstrate growing interest in leveraging large clinical datasets for prediction, classification, and risk estimation. Their scope is more limited in scenarios requiring detailed physiological realism.

Hybrid methods illustrate emerging strategies that balance accuracy and computational efficiency. In studies involving these approaches, ML is commonly used to tune physiological parameters, derive boundary conditions from imaging or ECG data, or build surrogate models that reduce the computational cost of mechanistic solvers. In a subset of hybrid digital twin studies [51-56], ML components were typically embedded within a mechanistic framework rather than used in isolation. Across these studies, we observed 3 main integration patterns. First, ML is used for parameter tuning and personalization of mechanistic models, for example, by estimating subject-specific parameters or boundary conditions that are then supplied to a physics-based simulator. Second, ML algorithms are applied for feature extraction from raw clinical data, such as imaging or ECG signals, and the extracted features are subsequently used to initialize or constrain the mechanistic model. Third, in a small number of cases, ML serves as a surrogate or complementary model that approximates the behavior of a more complex mechanistic solver or is combined with mechanistic equations in a joint statistical-mechanistic framework. Together, these hybrid strategies illustrate how data-driven methods can enhance mechanistic digital twins by improving personalization, leveraging high-dimensional data, and reducing computational cost.

RQ2: If the Model is Mechanistic, What Specific Model Type is Used?

Overview

Across the 42 included studies, we identified multiple types of mechanistic models used within cardiovascular digital twin frameworks. Because individual studies often combined more than one formulation, we classified mechanistic components into 9 categories based on their predominant mathematical and physiological characteristics.

Key Insights

The key insights are as follows:

- Electrophysiology models were the most common (19 studies [11,17,18,20,21,25,27,28,30,34,35,37,39,41,43,44,46,51,54]). These models typically used monodomain, bidomain, or related reaction-diffusion formulations to simulate cardiac electrical activation, sometimes coupled to downstream mechanical effects.
- FEM-based structural or biomechanical models were used in 10 studies [8,18,19,26,27,29-31,33,37] to represent myocardial or vascular deformation, geometry, and stress-strain behavior.
- Electromechanical models, which explicitly couple electrical activation with tissue mechanics, were identified in 8 studies [22,26,30,32,33,52,53,55]. They supported integrated simulation of excitation-contraction processes.
- Simplified or system-level models, which are most often lumped-parameter formulations, were noted in 7 studies [24,29-31,33,36,53]. They provided compact descriptions of global hemodynamics or chamber-level dynamics, particularly when large-scale or long-duration simulations were required.
- Multiscale models were reported in 7 studies [11,22,30,33,41,44,53], linking processes across spatial or temporal scales (eg, from cellular electrophysiology to organ-level function).
- Computational fluid dynamics (CFD) models were used in 3 studies [40,42,55] to simulate blood flow and pressure distributions in chambers or great vessels. An additional 4 studies [19,23,24,56] used other mechanistic formulations (eg, specialized anatomical or biophysical models), and 1 study [42] used a surrogate mechanistic model that approximated a more complex solver. In 1 study [38], mechanistic modeling was reported, but the specific model type was not clearly described.

Interpretation

Taken together, the results show that electrophysiology-focused models form the backbone of mechanistic digital twin development in cardiology, with FEM-based structural models, lumped-parameter and multiscale formulations, and CFD models used in complementary roles. This diversity of model types illustrates how digital twin frameworks combine detailed biophysical fidelity with system-level abstractions to address specific clinical questions and RQs.

RQ3: If the Model Includes ML or AI, What Specific Algorithms are Applied?

Overview

Among the 42 reviewed studies, some explicitly reported using ML or AI techniques within the digital twin framework, while in others, the use or type of ML was absent or not clearly specified. Because several studies combined more than one method, we grouped algorithms into broad families, including DL, Bayesian methods, optimization algorithms, classical (statistical) ML, and other ML approaches.

Key Insights

The key insights are as follows:

- DL was the most frequently reported family of methods (9 studies [27,34,44-46,48,49,53,54]). These approaches included architectures, such as convolutional neural

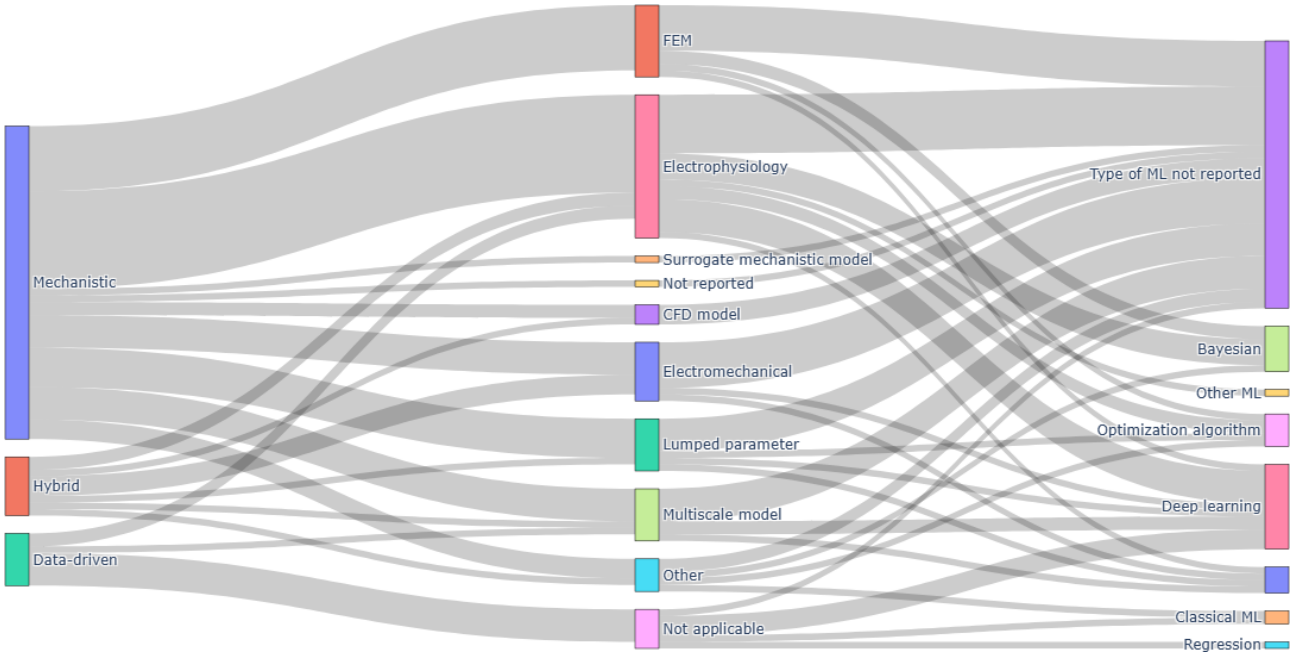
networks, neural operators, latent neural ordinary differential equation models, and related deep architectures, used for tasks like feature extraction, representation learning, or surrogate modeling.
- Bayesian methods were used in 5 studies [17,19,25,37,51], typically in the form of approximate Bayesian computation, Bayesian optimization, or Gaussian process–based models for probabilistic parameter estimation and uncertainty quantification.
- Optimization algorithms were noted in 4 studies [19,21,36,51]. These approaches included gradient-based schemes and metaheuristics that were used to tune model parameters, personalize simulations, or search over high-dimensional design spaces; in some cases, these optimizers were tightly integrated with Bayesian frameworks.
- Classical ML methods were identified in 2 studies [50,56]. These approaches included techniques, such as decision tree and logistic or linear regression, to model interpretable relationships between inputs and outcomes.
- Regression was explicitly highlighted as the primary approach in 1 of the studies [50]. One study used other ML strategies that did not fit neatly into the above categories but still relied on data-driven learning to support digital twin construction or personalization [46].

Interpretation

Overall, DL has emerged as the dominant explicitly reported ML family in cardiovascular digital twin research, supporting tasks such as feature extraction, surrogate modeling, and high-dimensional inference. Bayesian and optimization-based methods play a complementary role by enabling parameter estimation and uncertainty-aware personalization. Classical ML and regression, although less common, provide more interpretable models in selected use cases.

Figure 2 provides an integrated visualization of how primary modeling approaches, mechanistic model types, and ML or AI families co-occur across the included studies.

Figure 2. Relationships among modeling approaches, mechanistic model types, and machine learning (ML) or artificial intelligence (AI) methods in cardiovascular digital twin studies. Sankey diagram summarizing links among primary modeling approaches (research question [RQ] 1), mechanistic model types (RQ2), and ML or AI algorithm families (RQ3) across the 42 original research articles on cardiovascular digital twins included in this systematic review. The left column shows the dominant modeling approach for each study (mechanistic, hybrid, or data-driven). The middle column groups mechanistic model types into electrophysiology, finite element modeling (FEM), lumped parameter, electromechanical, computational fluid dynamics (CFD), other mechanistic models, and "not reported." The right column shows ML or AI families (deep learning, Bayesian methods, optimization algorithms, classical ML, regression, other ML, and "type of ML not reported"). The width of each flow is proportional to the number of studies combining the corresponding categories.



RQ4: Is the Framework or Model That is Created or Used Open-Source?

Overview

We evaluated the extent to which cardiovascular digital twin frameworks were shared as open-source resources. Code availability is a key indicator of scientific transparency and reproducibility, enabling independent validation and extension by other researchers and clinicians.

Key Insights

The key insights are as follows:

- Across the 42 included studies, 16 explicitly reported that their framework or model was available as open-source code [17-20,25,26,30,35,37,38,41,48,51,53,54,56].
- Two studies clearly stated that the code was not publicly released or that the implementation was proprietary [22,39].
- For the remaining 24 studies, code availability was either not mentioned or not described in sufficient detail to determine whether the implementation was accessible. Thus,

less than half of the studies (16/42, 38%) provided explicit evidence of open-source sharing, and in many cases, information on code availability was incomplete.

Interpretation

Despite increasing attention to reproducibility and open science, most studies in this review did not make their digital twin implementations publicly available. A lack of open-source code hinders transparency, reproducibility, and reusability. The few repositories that were shared provide valuable resources and serve as exemplars for future cardiovascular digital twin research.

Data Infrastructure and Visualization (RQ5 and RQ6)

The design and utility of cardiovascular digital twin systems depend heavily on how patient-specific data are structured, how outputs are visually communicated, and who the intended users are. This section addresses RQ5 and RQ6 by examining the types of data used to build or personalize digital twins, the formats used to present model outputs, and the target users of these visualizations. Together, these elements shaped the usability, interpretability, and clinical relevance of digital twin systems in practice.

RQ5: What Types of Patient-Specific Data are Used to Build or Personalize Digital Twins?

Overview

Patient-specific data underpin cardiovascular digital twin systems by enabling individual-level modeling. We explored the distinct categories of data used to personalize these models, ranging from electrical signals and anatomical imaging to omics and wearable-derived data. To facilitate interpretation, the data were grouped into consistent, semantically meaningful categories.

Key Insights

The key insights are as follows:

- Imaging data were the most commonly used (32 studies [8,11,17-19,21,22,24-27,29-31,33-40,42-44,46,48,49,51,53-55]). These data typically included modalities, such as MRI, CT, and other structural imaging, used to reconstruct patient-specific anatomy. Echocardiography was explicitly reported in 2 of these studies as a dedicated imaging source.
- Signal-based electrical data, primarily ECG, were used in 18 studies [8,17,21,25,27,33,36-39,43,46,48-51,53,54], reflecting its central role in modeling cardiac electrophysiology and conduction abnormalities.
- Vital signs were used in 12 studies [17,24,26,28,29,31,33,45,48,49,53,55], and demographics, such as age and sex, were reported in 9 studies [17,24,27,28,33,45-48], often to support model initialization, risk stratification, or cohort characterization.
- More detailed clinical information appeared in several categories: omics data were used in 4 studies [22,23,49,55], lab results were used in 4 studies [22,28,49,55], and general clinical data (such as clinical histories and visit summaries) were used in 3 studies [49,52,55]. Diagnosis [33,47,48] and treatment-related data [33,47,48] (eg, information on interventions or therapies) were each reported in 3 studies.
- Sensor-based and longitudinal monitoring information was less common: 3 studies used data from sensors [46,49,55], and 2 studies used activity tracker data [45,49], illustrating the early integration of wearable or home-based measurements into digital twin personalization. Synthetic patient data were explicitly used in 1 study [56].

Interpretation

Overall, there is a strong reliance on imaging and ECG data to define anatomy and electrophysiological behavior in cardiovascular digital twins, complemented by vital signs and demographic information for basic personalization. Omics, lab results, richer clinical records, and wearable or sensor-derived data are beginning to appear but remain less common, suggesting that truly multimodal, longitudinal personalization is still emerging. The presence of synthetic and other less conventional data sources indicates ongoing experimentation with alternative data strategies.

RQ6: What is the Primary Format Used to Visually Present Digital Twin Outputs?

Overview

We examined how digital twin outputs were visualized in cardiovascular studies, an essential aspect for interpretation, user interaction, and eventual clinical integration. Each study could use more than one visualization format, so outputs were classified into standard categories such as static figures, anatomical renderings, tables, dashboards, and interactive media.

Key Insights

The key insights are as follows:

- Static figures were the most common visualization format (41 studies [8,11,17-47,49-56]). These typically included plots, error curves, comparative graphics, and screenshots of simulations, and were primarily designed for inclusion in scientific publications.
- Two- or three-dimensional anatomical views were reported in 27 studies [8,11,17-19,21,22,24-27,29-31,33-35,37,39,40,42-44,46,51,54,55], where patient-specific geometries or simulated fields (eg, activation times, strain, and flow patterns) were mapped onto cardiac or vascular structures. These views served to visually link model predictions to underlying anatomy.
- Tabular formats were used in 7 studies [19,22,24,35,36,45,49] to report numerical outputs such as performance metrics, parameter values, and summary statistics.

Interpretation

Overall, visualization of cardiovascular digital twins remains dominated by static, publication-oriented formats such as figures and anatomical snapshots, with limited support for dynamic, interactive, or dashboard-based exploration. While anatomical views help contextualize outputs in patient-specific geometry, the scarcity of dashboards, animations, and interactive interfaces suggests that user-centric and real-time visualization capabilities are still underdeveloped. Enhancing interactive and clinically oriented visualization tools may be crucial for translating digital

twins from research prototypes into practical decision-support systems.

Clinical Applications (RQ7 and RQ8)

We explored how digital twins were applied in clinical cardiology (RQ7) and which cardiovascular conditions they targeted (RQ8). It highlighted current use cases, such as diagnosis, planning, and monitoring, and categorized the conditions based on thematic grouping identified during full-text analysis.

RQ7: What is the Main Clinical Application or Use Case of Digital Twin Systems?

Overview

We explored the primary clinical applications of cardiovascular digital twin systems, revealing the core motivations behind their development and deployment. Use cases ranged from therapy planning and risk prediction to monitoring, drug testing, and more exploratory clinical applications. Individual studies could contribute to multiple application categories.

Key Insights

The key insights are as follows:

- Therapy planning was the most common application (28 studies [8,11,17,19,20,22-25,29-34,36-39,41,45-47,49,51,54-56]). In these studies, digital twins were used to support the selection, personalization, or optimization of interventions, including device configuration, ablation strategies, or other patient-specific treatment plans.
- Risk prediction was noted in 11 studies [20,28,40,41,46-50,52,55], where digital twins were used to estimate the likelihood of adverse events, treatment responses, or disease trajectories, often to support patient stratification. Diagnosis-focused applications were identified in 7 studies [11,45,46,48-50,54], using digital twins to assist in identifying underlying pathophysiology or classifying clinical conditions.
- Surgical and device simulation was reported in 6 studies [36,38,42,46,51,55], in which digital twins provided virtual testbeds to explore procedural strategies or evaluate device performance in patient-specific anatomies. Another 6 studies used digital twins for drug testing [17,20,28,32,36,37].
- Monitoring applications were noted in 6 studies [45,48-50,52,55], where digital twins contributed to disease tracking or follow-up by integrating longitudinal data or repeated assessments. Disease progression modeling was explicitly highlighted in 3 studies [36,42,55], and a single study focused primarily on prognosis [55].

Interpretation

Overall, cardiovascular digital twins are most frequently positioned as tools for therapy planning and risk prediction, emphasizing their role in personalizing and optimizing clinical interventions. Diagnosis, surgical or device simulation, drug testing, and monitoring collectively demonstrate a broad range of applications along the care pathway, from early risk assessment to procedural planning and follow-up. As digital twin technologies mature, a clearer definition and reporting of clinical applications will be important for understanding their real-world impact.

RQ8: What Cardiovascular Conditions Are Studied Using Digital Twin Systems?

Overview

We examined the range of cardiovascular conditions addressed by digital twin systems, providing a disease-centered perspective on where digital twin technologies are currently being applied. Conditions were grouped into clinically meaningful categories, and the classification was reviewed by a physician on the research team to ensure clinical relevance and consistency.

Key Insights

The key insights are as follows:

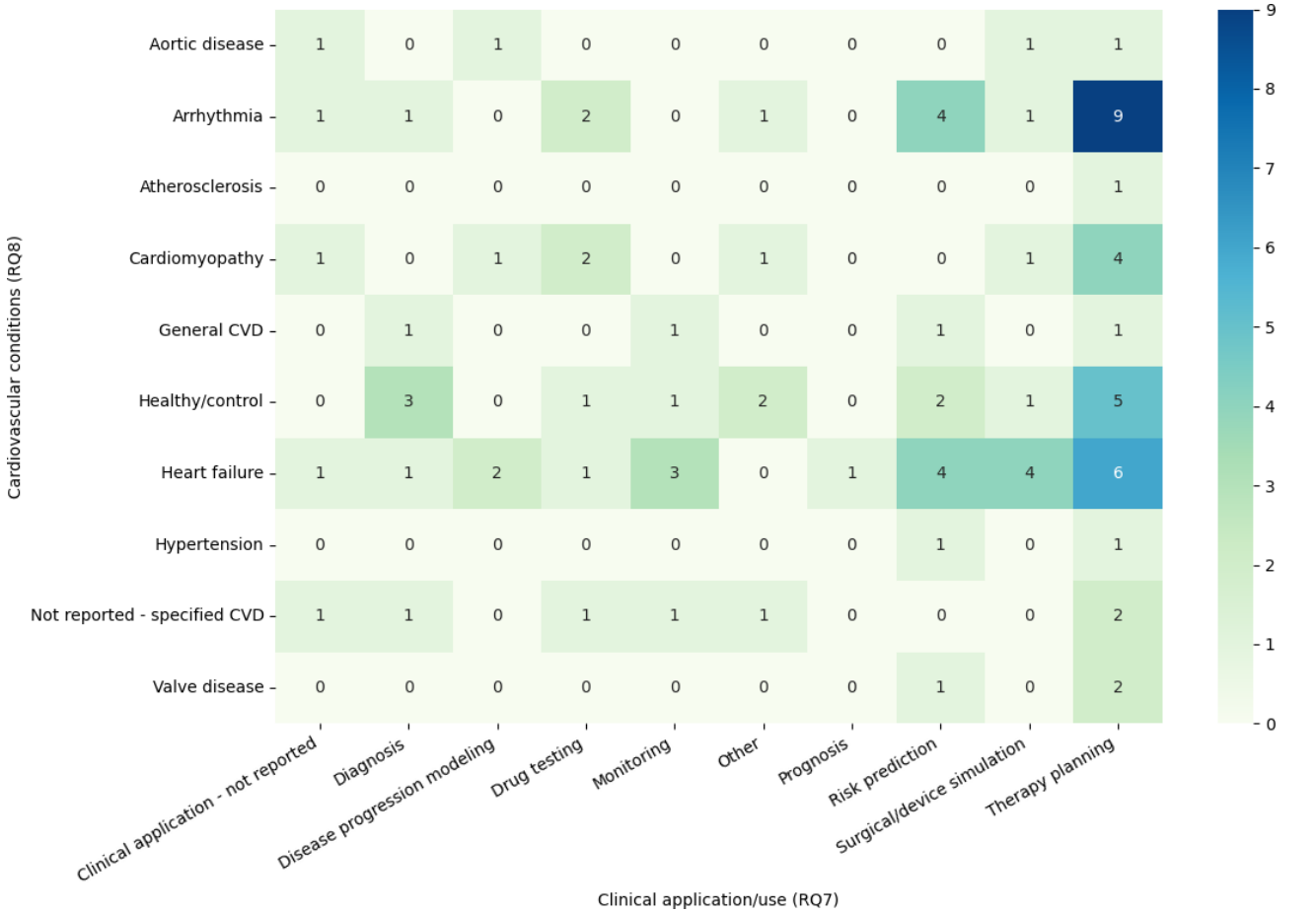
- Arrhythmia was the most frequently studied condition (13 studies [8,11,18,20,25,28,30,34,38-41,43]). The studies predominantly focused on atrial fibrillation and other rhythm disorders, reflecting the suitability of digital twins for simulating electrophysiological mechanisms and guiding rhythm-related interventions.
- Heart failure was investigated in 9 studies [33,36,38,41,48,51-53,55], often in the context of global cardiac function, ventricular remodeling, or device-based therapies. Cardiomyopathies, including hypertrophic cardiomyopathy and other structural myocardial diseases, were the primary focus in 5 studies [19,22,32,35,44], where digital twins were used to explore patient-specific mechanics and electrophysiology.
- Six studies centered on healthy or control populations [17,43,46,49,54,56], using digital twins to represent normal physiology, establish reference behaviors, or provide baselines for comparison with diseased states. Aortic disease was the focus in 3 studies [26,29,42], typically involving patient-specific modeling of the aorta for flow, wall stress, or device evaluation.

Interpretation

The distribution shows a strong emphasis on arrhythmia and heart failure, conditions in which digital twins can leverage detailed electrophysiological and hemodynamic modeling to support diagnosis, therapy planning, and risk assessment. Cardiomyopathies, aortic disease, and valvular disease are also emerging areas of application, particularly where structural and flow abnormalities can be represented in patient-specific models. By contrast, hypertension, atherosclerosis, and some other common cardiovascular conditions are only sporadically represented, and several studies do not clearly specify the underlying disease focus. These gaps suggest opportunities for expanding digital twin applications into a broader spectrum of cardiovascular conditions and for improving the clarity of disease reporting in future work.

Figure 3 summarizes how clinical applications are distributed across cardiovascular conditions. As shown in Figure 3, therapy planning and risk prediction are concentrated in arrhythmia and heart failure, whereas other conditions and applications are represented by only a small number of studies, underscoring the uneven distribution of digital twin work across CVDs.

Figure 3. Heatmap of cardiovascular conditions (research question [RQ] 8) versus clinical applications (RQ7) in cardiovascular digital twin studies. Rows show the primary cardiovascular condition modeled (eg, arrhythmia, heart failure, cardiomyopathy, aortic and valve disease, hypertension, atherosclerosis, general cardiovascular disease [CVD], healthy/control, and not reported). Columns show the main clinical applications (eg, diagnosis, disease progression modeling, drug testing, monitoring, prognosis, risk prediction, surgical or device simulation, and therapy planning). Cell color and numbers indicate how many of the 42 included studies reported each condition-application combination (darker cells indicate a higher number of studies).



Impact on Clinical Practice (RQ9)

We identified the reported clinical benefits of cardiovascular digital twin systems, including improved accuracy, personalization, therapy planning, and patient outcomes. The findings were organized into key impact categories to highlight where digital twins showed practical value in care delivery.

RQ9: What Clinical Impacts are Reported as a Result of Using Digital Twins?

Overview

We examined the concrete clinical or clinically relevant impacts attributed to cardiovascular digital twin systems. Rather than focusing on intended use alone, we captured reported effects where the use of a digital twin was described as influencing decision-making, therapy, diagnostic performance, or other aspects of care. Reported impacts were grouped into categories such as improved decision-making, therapy-related benefits, increased accuracy, and other specific outcomes.

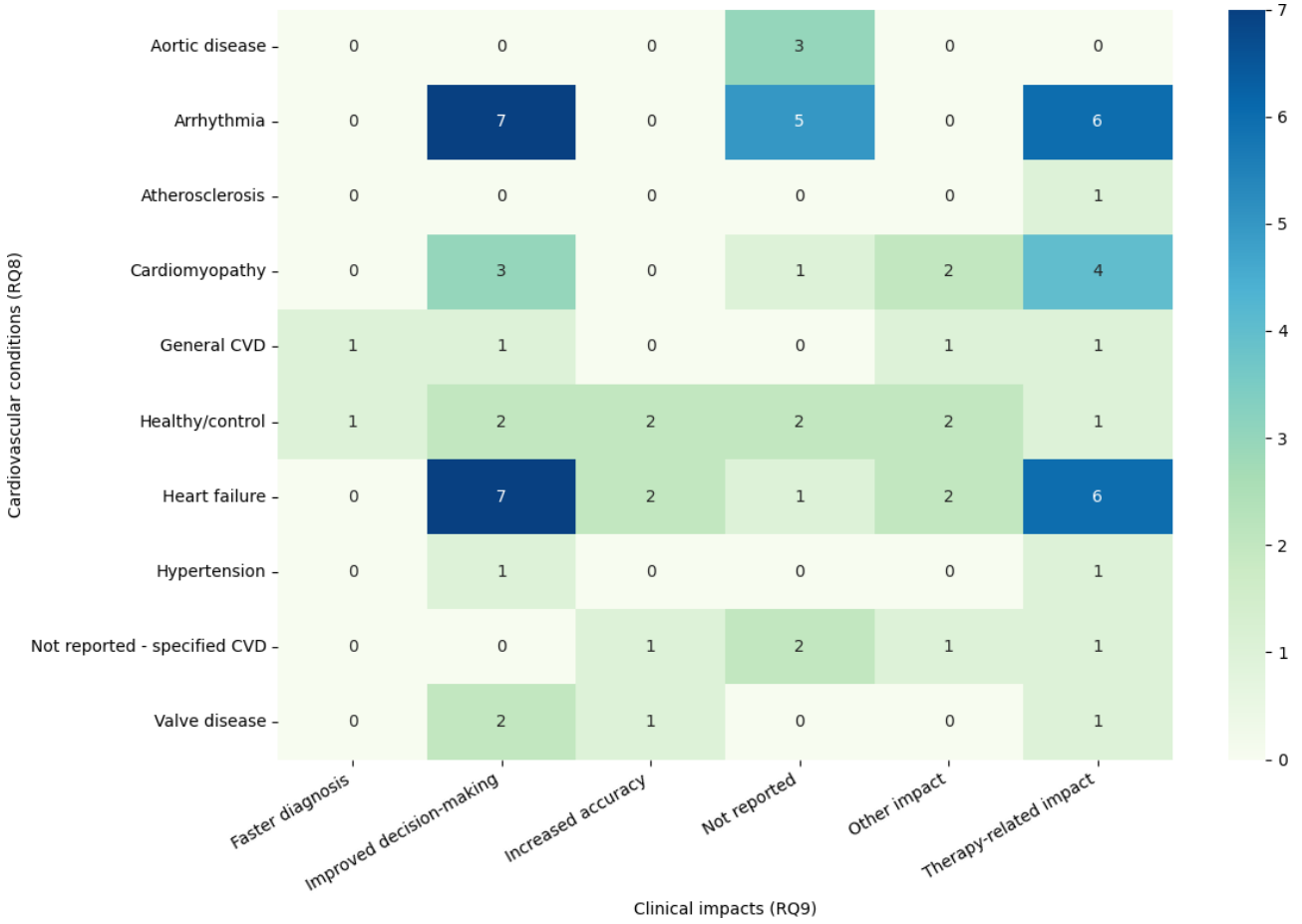
Key Insights

The key insights are as follows:

- Improved decision-making was the most frequently reported impact (19 studies [22,24,28,30-34,36,38-41,47-49,51,55,56]). In these cases, digital twins were described as helping clinicians compare alternative strategies, understand patient-specific mechanisms, or select interventions with greater confidence.
- Therapy-related impacts were reported in 18 studies [19,22-25,32,34,36,38-41,45,47-49,51,55], including optimization of device settings, refinement of ablation targets, adjustment of pharmacologic regimens, and more tailored procedural planning based on virtual simulations.
- Increased accuracy was explicitly identified in 6 studies [31,45,48,49,54,55], referring to improvements in predictive performance, better correspondence between simulations and measured clinical data, or more faithful reproduction of patient-specific physiology. Two studies [49,50] reported a faster diagnostic process, where digital twin–supported workflows were associated with quicker identification or clarification of clinical conditions.

Figure 4 illustrates how reported clinical impacts are distributed across cardiovascular conditions. Improved decision-making and therapy-related impacts were concentrated in arrhythmia and heart failure, whereas many other condition-impact combinations were represented by only one or two studies, highlighting the uneven evidence base across disease areas.

Figure 4. Heatmap of cardiovascular conditions (research question [RQ] 8) versus reported clinical impacts (RQ9) in cardiovascular digital twin studies. Rows represent the primary cardiovascular condition modeled by the digital twin (eg, arrhythmia, heart failure, cardiomyopathy, aortic and valve disease, hypertension, atherosclerosis, general cardiovascular disease [CVD], healthy/control, and not reported). Columns represent impact categories reported by study authors (faster diagnosis, improved decision-making, increased accuracy, impact not reported, other impact, and therapy-related impact). Cell color and numbers indicate how many of the 42 included studies reported each condition-impact combination (darker cells indicate a higher number of studies).

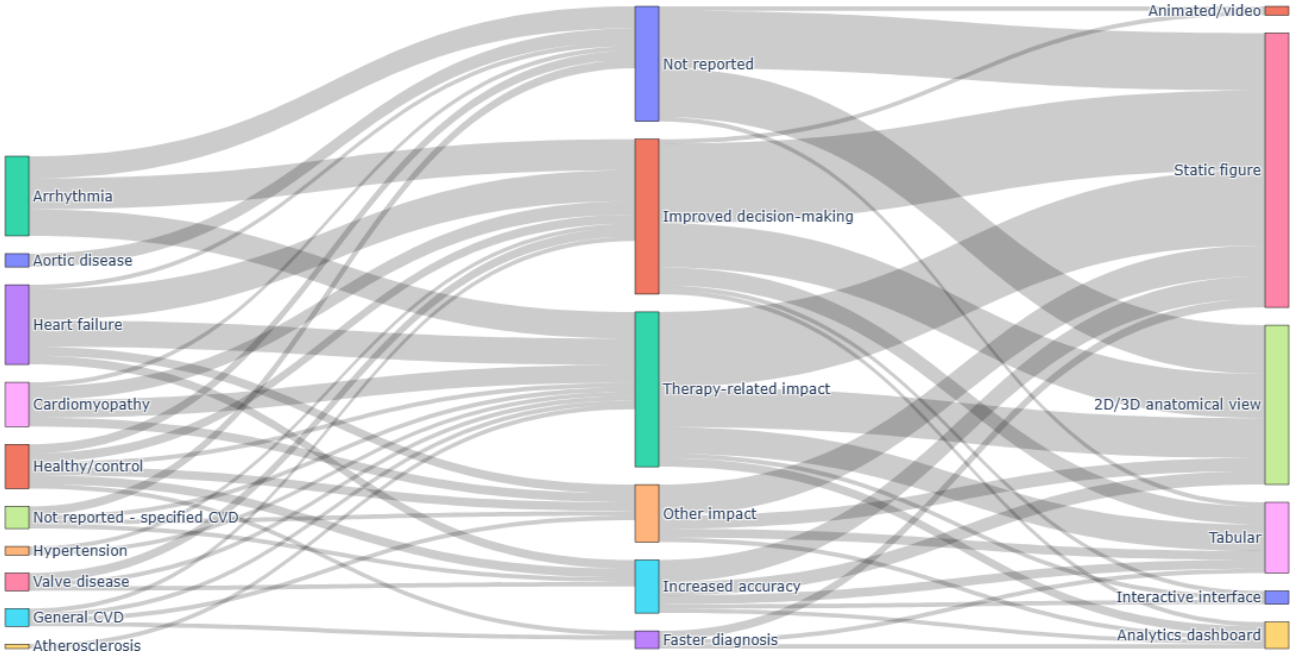


Interpretation

The most commonly reported benefits of cardiovascular digital twins relate to improved clinical decision-making and therapy-related impacts, suggesting that these systems are beginning to influence how clinicians choose and personalize interventions. Explicit gains in accuracy and diagnostic speed are less frequently reported but point toward the quantitative advantages of model-based approaches when they are carefully evaluated. At the same time, the substantial number of studies with no clearly articulated clinical impact indicates that much of the current literature remains focused on technical feasibility and validation rather than demonstrated downstream effects on care processes or patient outcomes. Strengthening the evidence base around measurable clinical benefits, such as improved decision quality, optimized therapy, and better outcomes, will be essential for wider clinical adoption.

Figure 5 shows that improved decision-making is the dominant reported impact across most cardiovascular conditions, particularly heart failure and arrhythmia, and that these impacts are almost always communicated through static figures and 2D or 3D anatomical views rather than dashboards, animations, or interactive interfaces. Therapy-related impacts and gains in accuracy are more sparsely reported and similarly rely on conventional publication-style visualizations, underscoring the limited development of user-facing, real-time visual tools, even in high-risk clinical scenarios.

Figure 5. Relationships among cardiovascular conditions, reported clinical impacts, and visualization formats in cardiovascular digital twin studies. Sankey diagram summarizing links among cardiovascular conditions (research question [RQ] 8), reported clinical impacts (RQ9), and primary visualization formats (RQ6) across the 42 original research articles on cardiovascular digital twins included in this systematic review. The left column shows the main conditions modeled by the digital twins (eg, heart failure, arrhythmia, valve disease, cardiomyopathy, hypertension, atherosclerosis, general cardiovascular disease [CVD], and healthy/control populations). The middle column displays impact categories reported by the authors (eg, improved decision-making, therapy-related impact, increased accuracy, faster diagnosis, and other impact). The right column shows the dominant visualization formats used to present model outputs (static figures, 2D/3D anatomical views, tabular displays, analytics dashboards, animated/video outputs, and interactive interfaces). The width of each flow is proportional to the number of studies combining the corresponding categories.



Barriers to Implementation and Ethical Considerations (RQ10 and RQ11)

We examined the key challenges limiting the adoption of cardiovascular digital twins, including technical barriers (RQ10) and ethical or legal concerns (RQ11). These issues highlighted the need for improved scalability, transparency, and responsible use in clinical settings.

RQ10: What Limitations or Practical and Technical Barriers are Described?

Overview

We identified the limitations and implementation barriers of cardiovascular digital twin systems as reported by the included studies. Rather than listing every individual issue, reported limitations were grouped into conceptually meaningful categories, such as model assumptions, computational constraints, data-related challenges, and integration or usability problems. This categorization helped highlight systemic obstacles that recur across the field.

Key Insights

The key insights are as follows:

- Model assumptions and structural simplifications were the most frequently cited limitations (26 studies [8,11,17,19-22,24,25,27-33,35,36,39,41,43,44,46,47,51,53]). These concerns included oversimplified anatomy or physiology, restrictive boundary conditions, and reduced model complexity that may limit generalizability or omit important mechanisms.
- Computational cost was highlighted in 21 studies [11,17,21,22,26,27,29-31,33,36,37,39,41,42,46,49,51,53,54,56], where authors noted long simulation times, high hardware requirements, or overall computational burden that can impede large-scale studies and real-time or near–real-time clinical use.
- Data-related challenges were prominent, with 16 studies [19,22,25,27-30,36,39,40,43,45,47,50,55,56] reporting issues with data quality or availability, such as incomplete or noisy clinical inputs, limited access to high-resolution or longitudinal data, and difficulties in acquiring truly personalized datasets. Limited validation was also mentioned in 16 studies [24,25,27-29,31,33-36,39,40,45,47,53,55], reflecting concerns about small sample sizes, restricted cohorts, synthetic data, or a lack of robust testing in real-world clinical environments.
- More specific barriers included a lack of real-time performance in 5 studies [33,42,50,54,55], indicating that even when models were accurate, their latency or compute demands were not compatible with time-sensitive clinical workflows. Workflow integration problems were identified in 4 studies [30,47,51,55], focusing on the challenges of embedding digital twins into existing clinical systems and processes. Clinician usability challenges were noted in 3 studies [45,49,55], where interfaces or outputs were considered difficult to interpret or not well aligned with clinical practice. High infrastructure cost was noted in 2 studies [49,53], and data security or privacy concerns were explicitly mentioned in 1 study [49].

Interpretation

The most common limitations—strong model assumptions, high computational cost, and data and validation constraints—reflect the technical and methodological complexity of deploying cardiovascular digital twins in practice. Simplifying assumptions and limited data can undermine generalizability, while computational burden and lack of real-time performance can restrict clinical usability. Integration issues, usability challenges, infrastructure demands, and security concerns, though mentioned less often, highlight important practical barriers that will become more pressing as digital twins move closer to clinical deployment. Addressing these limitations through improved model design, better data infrastructure, efficient algorithms, and user-centered integration will be essential for scalable, clinically viable digital twin systems.

RQ11: What Legal, Ethical, or Data Governance Issues are Raised Regarding Digital Twins?

Overview

We explored the ethical, legal, and data governance concerns raised in studies involving cardiovascular digital twin systems. Potential issues included privacy protection, regulatory compliance, informed consent, algorithmic transparency, and fairness. Reported concerns were grouped into categories to highlight common themes and gaps in current practice.

Key Insights

The key insights are as follows:

- Only a small subset of studies explicitly discussed legal, ethical, or governance issues. Privacy and data protection were the most frequently mentioned topics, identified in 4 studies [47,49,50,55], with references to compliance frameworks, such as General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA), and concerns about safeguarding sensitive patient data in the context of high-dimensional digital representations.
- Some studies raised other specific issues. Two studies discussed ethical or legal challenges in general terms [30,47], while another identified potential algorithmic bias, described problems or open questions around informed consent, and highlighted concerns about model transparency and the need for explainable or interpretable digital twin behavior [55].

Interpretation

Overall, explicit discussion of legal, ethical, and data governance aspects remains limited in the cardiovascular digital twin literature. While privacy and regulatory compliance are beginning to appear as concrete concerns, far fewer studies engage with broader questions around algorithmic bias, transparency, informed consent in the context of complex modeling, or downstream legal responsibilities. As digital twin systems move closer to clinical deployment and real-world decision support, more systematic attention to these dimensions, including fairness, accountability, liability, and data stewardship, will be critical to ensure trustworthy and responsible adoption.

Risk of Bias Assessment

The risk of bias was assessed for all included studies using the tool corresponding to the underlying study design. Among the 42 studies evaluated, 38 were computational or simulation-based studies assessed using the custom modeling checklist [8,11,17,18,19,20,21-27,28,29,30,31,32-34,35,36,37,38,40,41,42,43,44,45,46,48,51-53,54,55,56], 2 were prediction-modeling studies evaluated using the PROBAST [49,50], and 2 were observational cohort studies evaluated using the ROBINS-I [39,47].

Table 2 summarizes the distribution of overall risk-of-bias judgments across the 3 tools. For simulation and digital twin modeling studies, “unclear” was the most frequent overall rating (22/38, 58%), followed by “high risk” (16/38, 42%). The domains contributing most frequently to elevated risk included data representativeness, validation strategy, and sample size/overfitting. No modeling study received an overall low-risk judgment, reflecting commonly observed methodological limitations in data availability, external validation, and reproducibility practices across computational literature.

Table . Summary of overall risk-of-bias judgments across the included studies.

Tool	Total studies (N=42), n	Unclear risk, n (%)	High risk, n (%)
Custom modeling checklist	38	22 (58)	16 (42)
PROBAST[a]	2	0 (0)	2 (100)
ROBINS-I[b]	2	1 (50)	1 (50)

[a]PROBAST: Prediction Model Risk of Bias Assessment Tool.

[b]ROBINS-I: Risk of Bias in Non-Randomized Studies - of Interventions.

Both prediction-modeling studies assessed with the PROBAST were rated as having a high risk of bias, predominantly due to concerns in the analysis and outcome domains, including insufficient handling of model calibration, unclear predictor specification, and absence of prespecified analysis protocols.

Among the 2 observational cohort studies evaluated using the ROBINS-I, one was judged as having a high risk of bias, primarily due to serious confounding and selective reporting, while the other was rated as unclear.

Figures 6 and 7 present the traffic-light and summary plots, respectively, for all 38 modeling studies assessed using the custom modeling checklist. These visualizations highlight consistent methodological limitations across key domains, particularly external validation and representativeness of data inputs. Traffic-light and summary plots for the PROBAST and

ROBINS-I assessments are provided in Figures 8 and 9, respectively.

A structured visualization workflow was implemented using the robvis tool, which standardizes the graphical representation of domain-level and overall judgments and supports transparent reporting of risk-of-bias evaluations.

Figure 6. Risk of bias assessment (traffic-light plot) for modeling studies [8,11,17,18,19,20,21-27,28,29,30,31,32-34,35,36,37,38,40,41,42,43,44,45,46,48,51-53,54,55,56]. Traffic-light plot for the 38 simulation/digital twin modeling studies assessed using the custom modeling checklist. Domain-level judgments are categorized as low, unclear, or high. The plot has been generated using the robvis tool [16].

Figure 7. Risk of bias assessment (summary plot) for modeling studies [8,11,17,18,19,20,21-27,28,29,30,31,32-34,35,36,37,38,40,41,42,43,44,45,46,48,51-53,54,55,56]. Summary plot for the 38 simulation/digital twin modeling studies assessed using the custom modeling checklist. Domain-level judgments are categorized as low, unclear, or high. The plot has been generated using the robvis tool [16].

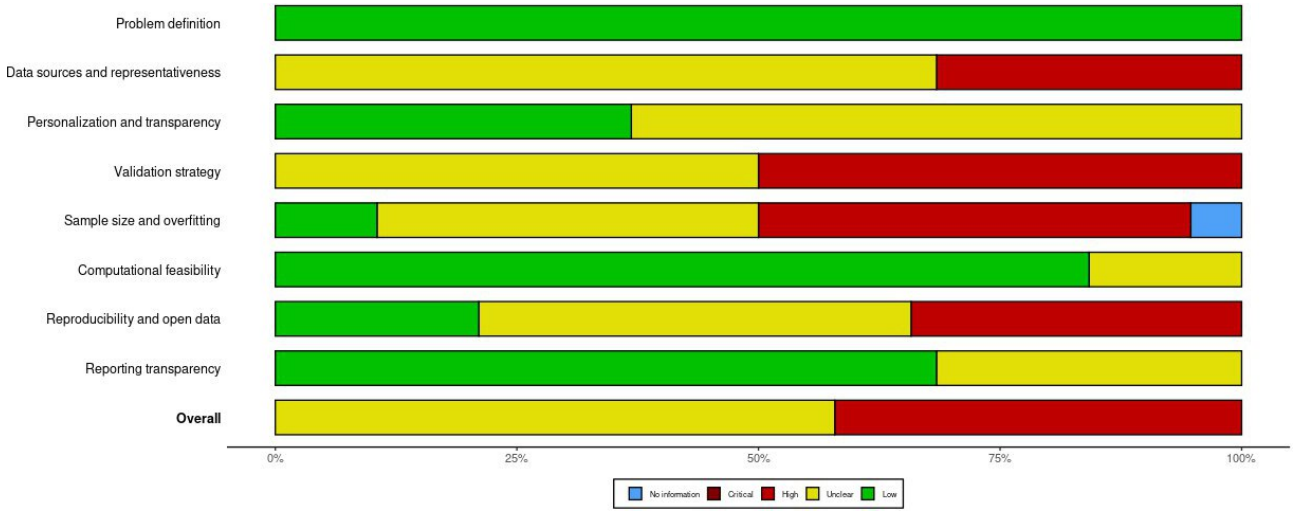
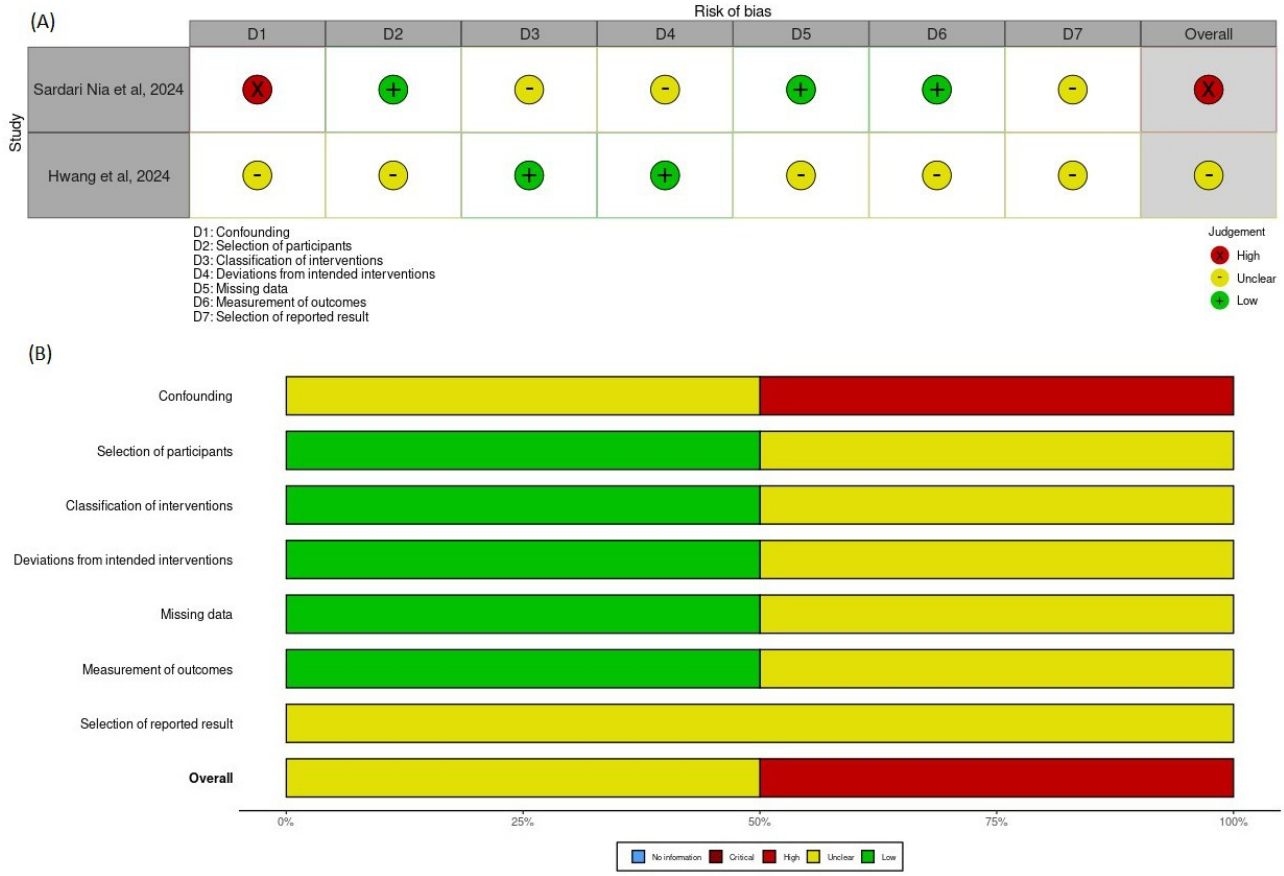


Figure 8. Risk of bias assessment for prediction-modeling studies (Prediction Model Risk of Bias Assessment Tool [PROBAST]) [49,50]. Traffic-light plot (A) and summary plot (B) for the 2 prediction-modeling studies evaluated using the PROBAST instrument. Judgments are shown across the 4 PROBAST domains (participants, predictors, outcome, and analysis) and the overall study-level rating. Visualizations are created using the robvis tool [16].

Figure 9. Risk of bias assessment for observational cohort studies (Risk of Bias in Non-Randomized Studies - of Interventions [ROBINS-I]) [39,47]. Traffic-light plot (A) and summary plot (B) for the 2 observational cohort studies evaluated using the ROBINS-I tool. Judgments are shown across the 7 ROBINS-I bias domains and the overall risk-of-bias rating. Visualizations are created using the robvis tool [16].



Discussion

Principal Findings

This systematic review synthesized findings from 42 studies and showed that cardiovascular digital twin technology is progressing rapidly but remains largely preclinical and methodologically heterogeneous. Most systems relied on mechanistic models, with a smaller subset incorporating explicit ML or hybrid mechanistic–data-driven designs. Applications clustered around arrhythmia (13/42, 31%), heart failure (9/42, 21%), and therapy planning (28/42, 67%), yet relatively few studies reported real-world clinical deployment, rigorous validation (16/42, 38%), or patient-level outcomes, underscoring the gap between technical innovation and routine clinical use.

Across 11 RQs spanning modeling foundations, data infrastructure, clinical applications, clinical impact, and implementation challenges, the review identified steady technical progress alongside persistent limitations in data quality, external validation, usability, and ethical governance. Our structured risk-of-bias assessment further highlighted that most modeling and prediction studies were judged as having unclear or high risk of bias, particularly in relation to data representativeness, validation strategies, and analysis procedures. Together, these findings suggest that cardiovascular digital twins are scientifically promising but not yet ready for widespread clinical translation.

Technological Foundations and Modeling Strategies

Mechanistic models form the backbone of current cardiovascular digital twins. Electrophysiology, finite-element structural modeling, lumped-parameter formulations, multiscale frameworks, and CFD-based flow simulations were frequently combined to capture different physiological scales and processes. The predominance of mechanistic approaches reflects the central importance of physiological interpretability and explicit biophysical assumptions in cardiology, where understanding causal mechanisms is often as important as prediction performance.

Hybrid designs and explicit ML or AI integrations were present but less common than might be expected given the broader trends in digital health. Only a minority of studies (18/42, 43%) clearly described ML algorithms, with DL (9/42, 21%), Bayesian methods (5/42, 12%), and optimization algorithms (4/42, 10%) used for tasks such as parameter estimation, feature extraction, surrogate modeling, and uncertainty quantification. Many other papers referred to “ML” or “AI” without specifying algorithm families or training procedures, limiting reproducibility and comparability. Open-source dissemination was also limited; less than half of the studies (16/42, 38%) provided accessible code, constraining independent verification, reuse, and benchmarking.

Data Infrastructure and Visualization

Personalization of cardiovascular digital twins relied heavily on structural imaging (32/42, 76%) and electrical signals (18/42,

43%). Imaging data (most often MRI or CT, with occasional echocardiography) enabled patient-specific anatomical reconstruction, while ECG and related electrical measurements supported modeling of activation patterns and conduction abnormalities. Vital signs (12/42, 29%) and demographic variables (9/42, 21%) were commonly used as basic covariates, but richer data sources appeared in only a subset of studies (omics: 4/42, 10%; lab results: 4/42, 10%; detailed clinical records: 3/42, 7%; and wearable/sensor streams: 4/42, 10%). This pattern suggests that many digital twins remain anchored in traditional imaging and electrophysiology pipelines, with multimodal, longitudinal data integration still in an early stage.

Visualization practices were predominantly static and publication-oriented. Most studies communicated digital twin outputs through static figures (41/42, 98%), anatomical overlays (27/42, 64%), or tables summarizing simulation results (7/42, 17%). Only a few described dashboards, dynamic animations, or interactive interfaces that would support real-time exploration or clinical decision-making. As a result, the "front end" of many digital twin systems remains geared toward researchers rather than clinicians or patients, which may hinder adoption even when the underlying models are sophisticated.

Clinical Applications and Target Conditions

Clinically, cardiovascular digital twins were most frequently positioned as tools for therapy planning (28/42, 67%), risk prediction (11/42, 26%), and monitoring (6/42, 14%), with additional roles in diagnosis (7/42, 17%), surgical or device simulation (6/42, 14%), and drug testing (6/42, 14%). Conditions, such as atrial fibrillation and other arrhythmias (13/42, 31%), heart failure (9/42, 21%), cardiomyopathy (5/42, 12%), and aortic disease (3/42, 7%), were most commonly represented, reflecting both their high burden and the suitability of these conditions for simulation-based assessment. Several studies (6/42, 14%) used digital twins to model healthy or control populations, providing physiological baselines and enabling comparison with diseased states.

At the same time, important cardiovascular domains remain underrepresented. Hypertension, atherosclerosis, congenital heart disease, and some valvular pathologies appeared relatively rarely or were only indirectly addressed, despite their major contribution to global cardiovascular morbidity. Furthermore, in some studies (4/42, 10%), the underlying clinical condition was not clearly specified, blurring the line between generic modeling exercises and disease-focused digital twin applications. This uneven coverage limits our ability to generalize digital twin findings across the broader spectrum of CVD.

Impact on Clinical Practice

Reported clinical impacts aligned with the conceptual promise of digital twins but were often indirect or inferred. The most commonly cited benefits were improved decision-making (19/42, 45%) and therapy-related impacts (18/42, 43%), including better selection of interventions, refined device configurations, and more personalized procedural planning. Some studies (6/42, 14%) reported increased accuracy of predictions or simulations, and a small number of studies (2/42, 5%) documented faster diagnosis or workflow advantages.

However, very few studies (4/42, 10%) linked digital twin use to robust patient-level outcomes such as mortality, hospitalization, and long-term symptom burden. Most evidence came from retrospective analyses, in silico comparisons, or small proof-of-concept applications rather than prospective, real-world evaluations. Consequently, while digital twins appear to enhance mechanistic understanding and may plausibly improve decision quality, the causal pathway from digital twin use to improved patient outcomes remains largely hypothetical. This observation was reinforced by the risk-of-bias assessments, which highlighted frequent limitations in sample size, external validation, and outcome measurement.

Barriers to Implementation and Ethical Considerations

Several recurring barriers emerged across the included studies. Strong model assumptions and structural simplifications, while often necessary for tractability, raise questions about generalizability to broader populations or clinical settings. High computational cost and limited real-time performance constrain scalability and integration into time-sensitive workflows, particularly in acute care or interventional environments. Data-quality issues, including incomplete or noisy inputs and limited access to comprehensive, longitudinal datasets, further restrict personalization and increase uncertainty.

Workflow integration and clinician usability remain significant challenges. Only a minority of studies (4/42, 10%) described how digital twin systems might be embedded within electronic health records, imaging systems, or existing decision-support tools, and even fewer studies (3/42, 7%) reported formal usability testing with clinicians. Ethical, legal, and governance issues were discussed explicitly in only a small subset of articles (4/42, 10%), primarily in relation to privacy and data protection frameworks such as GDPR and HIPAA. Isolated studies mentioned algorithmic bias, informed consent, or transparency concerns (1/42, 2%), but systematic engagement with liability, accountability, data ownership, and equity was rare, despite their importance for future clinical deployment.

Sources and Implications of Heterogeneity

Across the included studies, we observed substantial heterogeneity in how cardiovascular digital twins were conceptualized, implemented, and evaluated. This variability spanned multiple dimensions, including the definition and scope of the "digital twin," the underlying modeling strategies (eg, electrophysiology, finite-element, lumped-parameter, multiscale, CFD, and hybrid ML-mechanistic designs), the types and combinations of data modalities used for personalization, the clinical applications and disease targets, and the choice of validation approaches and outcome metrics. As a result, the findings are difficult to compare directly across studies, and a quantitative synthesis or meta-analysis is not appropriate. This heterogeneity also limits the generalizability of individual results and makes it challenging to derive standardized performance expectations for cardiovascular digital twins. Future work will benefit from clearer definitions, minimum reporting standards, and shared benchmarks to enable a more systematic comparison and aggregation of evidence.

Implications and Future Directions

The findings of this review suggest that cardiovascular digital twins are technically promising but not yet consistently validated, standardized, or integrated into routine care. Heterogeneity in modeling approaches, data inputs, validation strategies, and reporting practices limits comparability and makes it difficult to draw firm conclusions about real-world effectiveness.

Future work should focus on strengthening clinical validation in real-world settings, ideally through prospective and multisite studies that link digital twin use to patient outcomes and workflow changes. In parallel, clearer definitions of what constitutes a digital twin; shared performance metrics; and minimum reporting standards for models, data, and validation would support meaningful comparisons and regulatory assessments. Methodological transparency and user-centered design are also essential. Explainable or interpretable modeling pipelines and clinician-oriented interfaces are likely to be critical for trust and adoption.

Finally, ethical and equity considerations need to be addressed proactively. Most existing studies draw on narrow populations and rarely examine algorithmic bias, informed consent for complex modeling, or long-term data governance. Future research should deliberately include diverse populations and care settings; evaluate generalizability across subgroups; and embed privacy protection, transparency, and fair data use into the design and deployment of digital twin systems. Closer collaboration with regulators and health care organizations will be important to ensure that these technical and ethical advances translate into safe, accountable, and clinically useful tools.

Limitations of This Review

While comprehensive, this review may have missed relevant studies, especially studies published in non-English sources or proprietary implementations outside academic literature. Reporting heterogeneity also limited the comparability of validation and outcome data. As the field evolves rapidly, some emerging developments may not have been captured in the included studies.

Although we conducted a structured risk-of-bias appraisal using a custom modeling checklist for simulation studies, the PROBAST for prediction models, and the ROBINS-I for observational cohort studies, these tools were not originally designed for all types of cardiovascular digital twin research and required judgment-based adaptation. In addition, the substantial heterogeneity in study designs, data sources, and evaluation strategies precludes quantitative synthesis and indicates that our risk-of-bias judgments should be interpreted as broad indicators of methodological robustness rather than definitive ratings for individual studies.

This review was based on searches of major bibliographic databases and Google Scholar but did not include dedicated, systematic searches of clinical trial registries (eg, ClinicalTrials.gov), conference proceedings, or specialized grey-literature repositories (eg, dissertation or technical report databases). Although Google Scholar can index some gray literature and conference outputs, our screening was not designed to comprehensively capture these sources. As a result, ongoing trials, conference-only presentations, and nontraditionally published or proprietary digital twin implementations may be underrepresented in this synthesis.

Finally, the review protocol was not registered on a public platform, such as the Open Science Framework (OSF), which may limit reproducibility and transparency. Future work would benefit from prospective protocol registration to reduce the risk of selective reporting and enhance methodological rigor.

Conclusion

This systematic review mapped the technological, clinical, and implementation landscape of cardiovascular digital twin systems across 42 original studies. We found that most digital twins are grounded in mechanistic modeling, with limited but growing use of hybrid and AI-driven approaches. Personalization relies predominantly on imaging and electrical signals, and applications are concentrated in therapy planning, risk prediction, and monitoring for arrhythmia and heart failure. Although the reported impacts on decision-making and therapy optimization are promising, evidence for downstream patient-level benefits remains sparse.

At the same time, substantial heterogeneity in model architectures, data modalities, clinical use cases, and validation strategies—combined with incomplete reporting of algorithms, data, and code—limits comparability across studies and precludes quantitative synthesis. Key barriers to clinical translation include strong modeling assumptions; high computational cost; constrained data quality and availability; and limited real-time performance, workflow integration, and usability. Ethical, legal, and governance issues are only rarely addressed explicitly, with most attention focused on privacy and data protection.

Taken together, these findings suggest that cardiovascular digital twins are technically mature enough to support sophisticated, patient-specific simulations but are not yet ready for routine care. Realizing their potential for precision cardiology will require coordinated progress in standardized evaluation and reporting, rigorous clinical and external validation, user-centered and explainable design, robust data governance, and engagement with regulators and health systems. With the strengthening of these elements, digital twins may evolve from exploratory research tools into trusted, clinically integrated assets for individualized cardiovascular diagnosis, risk assessment, and treatment planning.

Funding

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Data Availability

All data analyzed in this systematic review were extracted from publicly available publications. The complete list of screened records and their inclusion/exclusion status are provided in Multimedia Appendix 2. The full data extraction matrix for all included studies is provided in Multimedia Appendix 3, and detailed study characteristics (including research question categories, risk-of-bias judgments, and funding information) are summarized in Multimedia Appendix 4.

Authors' Contributions

Conceptualization: FSR, EB, MJ
Data curation: FSR, MJ
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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOC File, 29 KB - cardio_v10i1e78499_app1.doc]

Multimedia Appendix 2
Screened records.
[DOCX File, 70 KB - cardio_v10i1e78499_app2.docx]

Multimedia Appendix 3
Data extraction form.
[DOCX File, 19 KB - cardio_v10i1e78499_app3.docx]

Multimedia Appendix 4
Research question categories.
[XLSX File, 37 KB - cardio_v10i1e78499_app4.xlsx]

Multimedia Appendix 5
Mapping of raw extraction values to harmonized research question categories.
[XLSX File, 23 KB - cardio_v10i1e78499_app5.xlsx]

Checklist 1
PRISMA checklist.
[PDF File, 213 KB - cardio_v10i1e78499_app6.pdf]

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Abbreviations

AI: artificial intelligence
CFD: computational fluid dynamics
CT: computed tomography
CVD: cardiovascular disease
DL: deep learning
ECG: electrocardiography
FEM: finite element modeling
GDPR: General Data Protection Regulation
HIPAA: Health Insurance Portability and Accountability Act
ML: machine learning
MRI: magnetic resonance imaging
PICO: Population, Intervention, Comparison, and Outcome
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROBAST: Prediction Model Risk of Bias Assessment Tool
ROBINS-I: Risk of Bias in Non-Randomized Studies - of Interventions
RQ: research question

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Applications of Smart Textiles for Ambulatory Electrocardiogram Monitoring: Scoping Review of the Literature

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Abstract

Background: Smart textiles (ie, electronic textiles) offer a promising solution to ease continuous electrocardiogram (ECG) monitoring, but their real-world clinical application has been limited.

Objective: This review comprehensively examines the current state of research on textile-based ECG monitoring systems, synthesizing current evidence with respect to performance (ie, signal quality, function under static and dynamic conditions), user experience, and current challenges.

Methods: A systematic literature search across the PubMed, MEDLINE, and Embase databases from 2000 to 2025 identified 34 research papers eligible for inclusion.

Results: Textile-based ECG electrodes demonstrated good signal quality and comfort, particularly under static conditions. Nonetheless, integration into clinical practice requires addressing critical issues, which include greater efforts at validating these technologies in clinical settings and populations, as well as ensuring data security, cost-effectiveness, user-friendliness, and data interoperability.

Conclusions: Considering the prominence of feasibility research, the successful clinical integration of textile-based ECG monitoring systems requires comprehensive efforts at establishing a clinical evaluation research base (via clinical trials) and developing regulatory policies.

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KEYWORDS

cardiac monitoring; smart textiles; electrocardiogram; ECG; remote patient monitoring; wearable; Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PRISMA

Introduction

Cardiovascular disease is a leading cause of morbidity and mortality globally, necessitating the development of improved diagnostic and management tools. In recent years, driven by advances in wearable sensors, wireless connectivity, and cloud computing, there have been substantial developments in large-scale ambulatory collection, transmission, and monitoring of various physiological and clinical outcomes [1-3]. As integrated in telemedicine and remote patient monitoring solutions, these advances offer significant improvements to cardiovascular disease care, where continuous monitoring is crucial for early disease detection and timely intervention [1,2]. Among wearable technologies, electronic textile sensors have emerged as a promising solution for unobtrusive, continuous physiological monitoring in free-living environments [3,4], including in ambulatory electrocardiogram (ECG) monitoring [5,6].

ECG monitoring relies on the detection of the heart's electrical activity via surface electrodes (placed on the skin), and subsequent transmission of the signal for analysis [7]. Long-term ECG monitoring is vital for the early detection of cardiac arrhythmias, enabling the prompt treatment and prevention of severe complications. Advanced textile–based ECG systems, often termed "smart clothing" or "smart textiles," integrate sensors and electronics within wearable garments [8-10]. These systems offer the potential for continuous ECG monitoring using dry electrodes, which are embedded in conductive fabrics or textiles [11]. This approach avoids the discomfort and limitations of conventional gel (Ag or AgCl) electrodes and conductive gels [11,12], providing a convenient method for long-term monitoring [5,11,13]. Smart textiles can additionally reduce the need for invasive monitoring modalities (eg, loop

and event monitors) and provide a better diagnostic yield (due to the ease of wearing).

Despite enthusiasm, however, adoption of textile-based ECG monitoring in clinical practice remains limited. While extensive research supports the technology's technical feasibility in measuring ECG [5,6,10], few clinical studies have assessed the validity of this technology in real-world settings [14]. Challenges hindering widespread clinical adoption include the lack of rigorous clinical validation research and compliance with stringent regulatory requirements (eg, data privacy and security, data interoperability with electronic health records [EHRs]). It is important to acknowledge that the successful translation of textile-based ECG monitoring from research prototypes to widely adopted clinical and consumer applications also hinges on the development of user-friendly technologies and user acceptance. On the technical front, maintaining adequate electrode-skin contact pressure for reliable signal acquisition and ensuring the preservation of garment integrity and performance through repeated washing cycles are critical considerations. While addressing these aspects is not the primary focus of this review, technical developments represent active areas of research, closely linked with user comfort and the long-term viability of textile-based ECG systems. This review aims to map and synthesize the existing scientific literature on textile-based ECG monitoring systems, as integrated in clothing and garments.

Methods

This review aims to map the scientific literature on textile-based ECG monitoring systems integrated into clothing and garments. Research studies, published in the English language between 2000 and 2025, that investigated the use of textile-based wearable technologies for ambulatory ECG monitoring in humans were included in this scoping review. Studies were excluded if they focused solely on nontextile wearables. The search time frame (2000-2025) was chosen to capture recent advances in smart textiles, excluding outdated technologies. The language restriction was applied to ensure feasibility and maintain the consistency of data interpretation. The results were reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist (Checklist 1).

The search strategy used a combination of keywords and controlled vocabulary terms (MeSH and Emtree) across PubMed, MEDLINE, and EMBASE (via OVID) databases. The details of the search are described in Multimedia Appendix 1. Key terms included "Smart textile," "e-textile," "smart clothing," "textile electrode," "wearable technology," "biosensors," "cardiac rehabilitation," "remote monitoring," "ambulatory monitoring," "Holter," "cardiovascular diseases," "arrhythmia," "atrial fibrillation," "heart disease," and "cardiac disorders." Filters for human studies and publication year limits were subsequently applied to ensure adherence with the specified inclusion criteria.

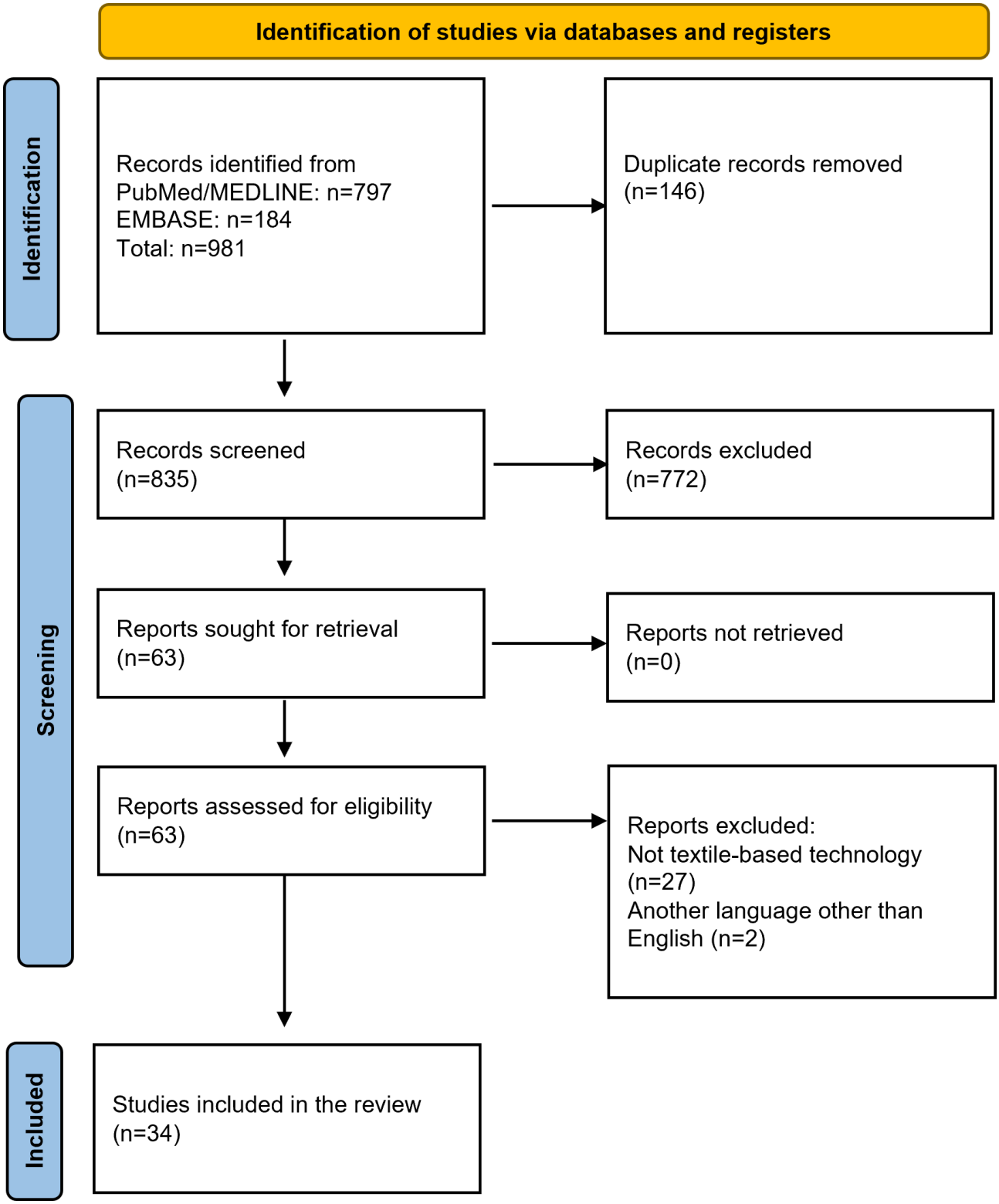
The selection process involved 3 stages. First, all identified records were checked for duplicate publications. Second, following the removal of duplicate records, titles and abstracts of the remaining records were screened for relevance to the research question and the eligibility criteria. Third, full-text papers of potentially relevant studies were reviewed to confirm eligibility. Any discrepancies were resolved through discussion among the review team members. This process ensured a rigorous selection of studies appropriate for inclusion in the scoping review. In total, across 981 records identified across databases, 63 records were selected for full-text review of eligibility. Following this review, 34 studies were selected for inclusion (Figure 1).

Given the limited number of published randomized clinical trials focusing on textile-based ECG in real-world clinical settings, this scoping review included feasibility studies, with a focus on ECG signal quality and user comfort as key outcome measures. This methodological choice acknowledges potential limitations in generalizability. It emphasizes the need for further research that incorporates diverse populations and real-world conditions to fully evaluate the clinical utility of this technology. The limited number of studies reporting on clinical outcomes directly reflects the current state of research in this area. The 34 studies were then comprehensively synthesized with respect to 3 key areas of research in smart textile–based ECG monitoring:

1. Comparative signal quality: To evaluate the signal quality of smart textile electrodes to traditional gel electrodes in evaluating various ECG indices (ie, QRS complex, P-wave, T-wave, R-peak).
2. Performance in static and dynamic conditions: To evaluate the performance of textile electrodes under static (eg, resting) and dynamic (eg, movement) conditions, examining the impact of motion artifacts on signal quality.
3. User experience: To evaluate user comfort, which is a critical factor for long-term adoption and use of smart textile–based ECG monitoring platforms, considering factors such as fabric type, electrode placement, and overall wearability.

Finally, this review outlines a roadmap for key clinical research priorities, together with highlighting the challenges that hinder the wider adoption and integration of textile-based ECG monitoring systems.

Figure 1. Flowower diagram of search strategy.



Results

Research Landscape

Between 2000 and 2025, smart textile technologies for ECG monitoring have seen steady progress, with research efforts predominantly based on prototype development [15-33] and observational research studies [34-44]. Smart textile technologies reviewed here use a range of conductive materials (eg, silver, copper, stainless steel, and metal inks), as incorporated into different garment types (eg, knitted patches, bands, vests, t-shirts, and bras). Among key design challenges for e-textiles is reliable electrode adhesion, particularly given the contrasting properties of metallic electrodes and the nonmetallic nature of clothing. To address this, various integration techniques are used, including direct knitting or weaving of electrodes into the fabric, embroidery of conductive yarns, adhesive bonding with specialized durable adhesives, or

printing with conductive inks requiring encapsulation. Garment design, such as the use of compression garments, and material selection, prioritizing rough electrode surfaces for improved mechanical interlocking, also play crucial roles. Different electrode materials and garment designs influence the contact pressure between the electrode and the skin. Contact pressure has an important role in ensuring the proper placement of the wearable and providing comfort. Excessive pressure can improve signal quality but can also increase discomfort and cause skin damage, while insufficient pressure can compromise the device's functionality [40]. Some studies have investigated compression garments to enhance contact pressure, while others have focused on optimizing electrode design to distribute pressure evenly. While these techniques offer promising solutions, the long-term durability of these adhesion methods and their resistance to repeated washings remains a key focus for future research. Wash durability is a critical consideration for textile-based ECG systems. Repeated washing cycles can degrade conductive materials, alter garment shape, and compromise electrode-skin contact. Research is ongoing to identify durable and washable electrode materials, as well as garment construction techniques that minimize performance degradation over time [45].

Although recent reviews, such as that by Xu et al [46], have explored the landscape of smart textiles in sports and health care, this work distinguishes itself by providing a focused analysis of textile-based systems specifically engineered for ECG monitoring, with a particular emphasis on clinical translation and utility. As evidenced by the analysis in Table 1 (static conditions) and Table 2 (dynamic conditions), the selection of electrode type significantly influences the performance and applicability of these systems. This segmentation by static and dynamic conditions is crucial because static conditions provide a controlled environment to assess basic electrode performance, while dynamic conditions, which introduce motion artifacts and other real-world challenges, are essential for evaluating the true utility of these systems. For example, silver-coated yarns are widely used in static settings, but their susceptibility to motion artifacts can be a limiting factor in dynamic environments. Novel materials, such as conductive polymers, hold promise for improved flexibility and signal stability, though further research is needed to validate their long-term performance in both static and dynamic scenarios. This highlights the importance of carefully considering the intended application and monitoring environment when selecting the optimal electrode technology for textile-based ECG monitoring.

Table . Studies summarized by static monitoring setting.

Author	Study type	Sample size	Electrode type	Findings	Condition
Mestrovic et al [26] (2007)	Observational	31	Textile-based piezoresistive transducer (vest)	Readable signals in cardiac inpatients lying	Static
Vojtech et al [30] (2013)	Prototype or concept	1	Silver-coated polyester and cotton nanoparticles	The amplitude of the individual waves of ECG signal obtained using the textile electrodes was smaller than the reference signal	Static
Dai et al [21] (2016)	Prototype or concept	6	Flexible polypyrrole textile electrodes	Heart rate accuracy of each subject was more than 95%	Static
Kannaian et al [29] (2012)	Prototype or concept	3	Embroidered the conductive yarn on polyester fabric	Electrocardiogram signal from the textile electrode was similar to the gelled electrode	Static
Pandian et al [20] (2008)	Prototype or concept	25	Sensors (silicon rubber with pure silver fillings)	RR[a] intervals presented good stability	Static
Tsukada et al [36] (2019)	Observational	66	T-shirts for men and brassieres for women with textile electrodes	P-wave, QRS, and T-wave were comparable between the textile and conventional electrodes	Static
Nigusse et al [19] (2020)	Prototype or concept	6	Silver-printed textile electrodes	The signals collected by silver-printed textile electrodes showed clear R-peaks without missing and false peaks, indicating good waveforms	Static
Arquilla et al [35] (2020)	Observational	8	Textile electrodes (silver thread) were sewn in a chest-mounted configuration	The sewn electrodes produced clean data, allowing the measurement of beat-to-beat variability and average heart rate	Static
Fouassier et al [25] (2020)	Feasibility or pilot	30	Smart t-shirt composed of 13 textiles electrodes made of silver yarns and hydrogel pads that released water vapor	A sinus rhythm was distinguished for all recordings obtained with both smart textile and reference system for all 3 static conditions	Static

[a]RR: R-R interval.

Table . Studies summarized by dynamic monitoring setting[a].

Author	Study type	Sample size	Electrode type	Findings	Condition
Hsu et al [24] (2019)	Prototype or concept	3	Noncontact dry electrodes in an elastic chest vest and attached with Velcros (not embedded)	ECG signal quality obtained by the noncontact electrode was similar to the conventional gel electrode. ECG signal quality was also good while walking.	Dynamic
Paradiso et al [15] (2005)	Prototype or concept	1	Fabric with strain sensors	Metal-based fabric electrodes reliably recorded bioelectric potentials.	Dynamic
Perez de Isla et al [39] (2011)	Feasibility or pilot	31	Noncontact dry electrodes in an elastic chest vest	Good intermethod agreement for common ECG parameters. Nubo shirt allowed pretest and posttest echocardiography. The system offers continuous, noninvasive, remote monitoring. The initial device had frequency limitations (0.5-100 Hz), affecting ST-segment analysis.	Dynamic
Trindade et al [17] (2016)	Prototype or concept	5	T-shirts comprised of 5 skin-contact textile electrodes	T-shirt prototypes provided adequate performance in standing states. Motion artifact interference, mainly caused by friction between the textile electrodes and the skin, considerably limited the performance of the prototypes in mobile contexts.	Dynamic
Pola et al [27] (2007)	Prototype or concept	4	Silver electrodes	Jogging caused the biggest problem in measurements.	Dynamic
Gonzales et al [31] (2015)	Prototype or concept	Not reported	T-shirt with 3 dry silver-based electrodes	Good efficacy of dry electrodes even in a high-motion environment.	Dynamic
Li et al [18] (2020)	Prototype or concept	1	Textile electrodes (silver-coated nylon yarns) knitted into a T-shirt	The smart clothing showed good performance for measuring ECG signals.	Dynamic
Ghahjaverstan et al [43] (2023)	Feasibility pilot	20	Dry electrodes made from conductive yarns, knitted within an elastic chest band	HR[b] measurements comparable to the reference system across all tasks, including exercising.	Dynamic

Author	Study type	Sample size	Electrode type	Findings	Condition
Romagnoli et al [47] (2014)	Observational	12	Smart textile system (GOW) with embedded textile electrodes in shirt, transmitting data to an electronic module	Excellent agreement between GOW and ECG for RR[c] intervals (LoAs[d] around ±3 ms). Good agreement for MeanRR, SDNN[e], SD2. Poor agreement for RMSSD[f], HF[g], LF/HF[h], HFnu[i], and SD1 (wide limits of agreement). The GOW system showed overall good accuracy for HR but limited accuracy for many HRV[j] parameters.	Dynamic
Coyle et al [38] (2010)	Prototype or concept	Not reported	Piezoresistive sensor	ECG signals gathered during rest showed high quality.	Dynamic
Di Rienzo et al [16,41] (2005, 2006)	Prototype or concept; observational (development phases for the same system)	1; 31	Textile-based piezoresistive transducer (vest)	Readable signals in cardiac inpatients pedaling.	Dynamic
Di Rienzo et al [48] (2013)	Observational	40	Textile vest with knitted conductive-fiber electrodes (single-lead ECG)	Readable ECG 95.9% vs 82.7% (traditional); artifact rate 4.1% vs 17.3%; arrhythmia detection sensitivity 99.7%, specificity 99.9%; PQ/QRS comparable; RR interval error ~1 ms	Dynamic
Weder et al [32] (2015)	Prototype or concept	12	Two Ag- or Ti-coated polyethylene terephthalate electrodes embedded into a chest belt	The embroidered electrodes presented signals comparable with Ag or AgCl gel electrodes	Dynamic
Pani et al [33] (2016)	Prototype or concept	10	Patch of textile electrodes made by treating conventional fabrics with a highly conductive solution of PEDOT:PSS	Textile electrodes showed similar performance, or even better, in wet conditions	Dynamic
Alizadeh Meghrazi et al [13] (2020)	Prototype or concept	6	Silver-plated nylon yarns and carbon-coated nylon yarns knitted in a waistband	ECG signals were reliably obtained from different locations on the waist	Dynamic
Fukuma et al [49] (2019)	Feasibility or pilot	100	Textile electrodes (Hitoe fabric with PEDOT-PSS) embedded in a t-shirt	The system was suitable for lifestyle or sports activities, demonstrating AF[k]-detection performance similar to that of other wearable devices	Dynamic
Pagola et al [50] (2023)	Feasibility or pilot	163	Textile electrodes in a garment	The textile wearable Holter monitoring detected pAF[l] in 35.37% of patients	Dynamic

Author	Study type	Sample size	Electrode type	Findings	Condition
Teferra et al [34] (2021)	Feasibility or pilot	1	Textile electrodes embedded in a smart ECG vest	Performance was comparable to a traditional 3-lead Holter monitor	Dynamic
Machino et al [42] (2023)	Randomized controlled trial	67	Dry textile electrodes (PEDOT-PSS and nanofiber) embedded in a garment	Garment ECG (2-week) detected AF recurrence in 18% of patients, significantly higher than 24-hour Holter (6%)	Dynamic
Amami et al [44] (2022)	Feasibility or pilot	31	Silver textile electrodes embedded in an undershirt	Wearable undershirt electrode demonstrated abilities comparable to Holter ECG for ECG monitoring and arrhythmia detection	Dynamic
Olmos et al [51] (2014)	Observational	31	nECG SHIRT: Biomedical shirt with integrated textile electrodes (BlendFix) for ECG signal acquisition	Excellent correlation between Nuubo system and conventional tilt table test for commonly assessed ECG parameters during tilt testing	Dynamic
Yu et al [52] (2017)	Cohort study	5	Wearable 12-lead ECG T-shirt with 10 dry textile electrode patches (Shieldex Medtex P180) and active electrodes	Average per-lead signal coverage ranged from 20.9% to 56.3%. After combining data from all leads (temporal fusion), overall coverage improved to up to 81.9%. A 3-stage artifact detection algorithm effectively identified artifacts from 50-Hz noise and motion.	Dynamic
Pagola et al [22] (2018)	Feasibility or pilot	146	Three-lead ECG vest and 1-lead ECG chest band	Both garments were similarly comfortable during the day and night. However, the vest group presented a longer time of compliance and time analyzed than the chest band. The percentage of missed signal was lower in the vest group. The rate of undiagnosed AF detected with textile Holter was 21.9%	Dynamic
Steinberg et al [23] (2019)	Prototype or concept	15	Bra or shirt with integrated sensors recording a single-lead ECG	The wearable ECG sensor's signal quality and accuracy were equivalent to Holter monitoring. Signal coverage of R-R intervals showed a very close overlay between the wearable sensor and Holter signals. The wearable sensor presented high wearing comfort and minimal risk of skin irritation.	Dynamic

Author	Study type	Sample size	Electrode type	Findings	Condition
Neri et al [53] (2024)	Observational	30	Crop top garment with embedded polymer–based electrodes	YouCare System showed 70% "Good," 12% "Acceptable," and 18% "Not Readable" ECG signals	Dynamic

[a]Prototype or concept: Early engineering or technical validation studies, often with small samples or bench testing. Feasibility or pilot: Preliminary human studies assessing usability, signal quality, or performance in real-world conditions. Clinical studies: Observational, cohort, or randomized controlled designs.

[b]HR: heart rate.

[c]RR: R-R interval.

[d]LoA: limits of agreement.

[e]SDNN: standard deviation of NN intervals.

[f]RMSSD: root mean square of successive differences.

[g]HF: high-frequency component.

[h]LF/HF: low-frequency/high-frequency ratio.

[i]HFnu: normalized high-frequency component.

[j]HRV: heart rate variability.

[k]AF: atrial fibrillation.

[l]pAF: paroxysmal atrial fibrillation.

Comparative Signal Quality of Textile-Based ECG Monitoring and Standard Gel Electrodes

The standard ECG signal comprises morphological features (ie, P-wave, QRS, and T-wave), reflecting atrial and ventricular depolarization and repolarization, and temporal features (ie, PR, QRS, QT, and R-R intervals), representing durations between these events [5]. These features provide key insights into cardiovascular physiology and pathology, making continuous long-term ECG monitoring essential for detecting cardiovascular disorders and abnormalities [54].

Traditionally evaluated over the long term using Holter monitors, ambulatory ECG monitoring relies on adhesive gel (Ag or AgCl) electrodes, which provide excellent signal quality [24,35]. However, long-term use is often limited by skin irritation, gel drying, and electrode detachment due to perspiration [24,35,55]. Smart textile electrodes offer a potential solution to these issues by using conductive fabrics, materials, or metals to acquire ECG signals without the need for gels [11].

The demonstration of the accuracy and reliability of smart textile–based ECG monitoring platforms is essential to enhance their adoption in clinical settings. In relation to identifying morphological and temporal ECG features, most studies have focused on the QRS complex, P-wave, T-wave, and R-peak amplitude variations and smart textiles' signal-to-noise ratio. For example, in an early demonstration of the feasibility of textile-based ECG monitoring, Di Rienzo et al [16,56] used a conductive fiber vest to accurately detect arrhythmias and heart rate compared to a traditional ECG recorder, while Paradiso et al [15] showed comparable results with a metal-yarn vest. Further research investigated various conductive materials (eg, silver-coated nylon, stainless steel yarn [26]), electrode placement (chest bands, t-shirts, wristbands [26,27,29,30]), and different textile constructions, demonstrating good signal quality in many studies in agreement with reference devices [13,19,21,23,26,29,30,35,42-44,47,50,52]. However, some studies reported issues, such as noise from dry skin [27], signal amplitude discrepancies due to electrode placement [30], and waveform irregularities [18]. While many studies focused on signal quality and accuracy, and some incorporated signal processing algorithms to improve data quality [15,16,39,57], few addressed the integration of textile-based ECG data into clinical practice [34,42-44,50,58-61].

Several studies demonstrated good textile-based ECG signal quality [20,21,26,29,32,34,36,38,46,52,57], highlighting the technology's promise for long-term monitoring. However, limitations remain: data transmission methods (eg, Bluetooth, Wi-Fi) often require extensive postprocessing; most studies were conducted in controlled laboratory settings with healthy participants and did not use fully integrated wearable form factors; and the clinical validation and long-term feasibility remain insufficiently explored. Future research should address these limitations through more comprehensive real-world studies incorporating diverse populations and integrated clinical workflows to ensure reliable and meaningful data.

Textile-Based ECG Monitoring Performance During Static and Dynamic Conditions

The division of studies based on monitoring setting (static vs dynamic) reveals key trends in the field of textile-based ECG monitoring. As demonstrated in Table 1, 9 of the reviewed studies focused on static conditions, likely reflecting the initial stages of development and validation for these technologies. The rationale for this segmentation lies in the fundamentally different challenges presented by each scenario. The static setting allows for the controlled assessment of signal quality and electrode performance, minimizing the confounding effects of motion artifacts and providing a baseline for evaluating the system's potential. However, the number of studies in the dynamic category demonstrates a growing interest in the application of these systems in real-world scenarios. This shift introduces new challenges, as the dynamic setting often leads to increased motion artifact and greater variability in

electrode-skin contact impedance. Examining the types of activities within the dynamic setting (walking, jogging, cycling, etc) further highlights these challenges, with activities involving more vigorous movement generally resulting in lower signal quality.

The inherent flexibility of textile-based ECG systems introduces challenges related to motion artifacts. Di Rienzo et al [48] explored the impact of dynamic conditions, examining the impact of motion artifacts on signal quality in telemedicine applications. The electrode-skin interface is particularly susceptible to disruption during dynamic movements, leading to noise and signal degradation, especially with dry or hairy skin [11,19,33,37]. Numerous studies have investigated the impact of both static (sitting, lying, standing) and dynamic (eg, walking, jogging, sit-to-stand) activities on ECG signal quality [17,20,24,25,31,32,34,36,38,39,41,52]. For example, Perez de Isla et al [39] evaluated a dynamic ECG monitoring system (Nuubo's dynamic ECG) against a conventional treadmill–based ECG monitoring system during exercise electrography and found comparable performance between the 2 systems on baseline and peak heart rates. Similar results were also seen by Olmos et al [51] for heart rate and maximum PR interval on the tilt table test between Nuubo's technology ECG shirt and conventional ECG monitoring.

In relation to other ECG parameters, Di Rienzo et al [48,57] also observed adequate QRS complex detection during walking and pedaling, while Pandian et al [20] reported good consistency in R-R, QRS, and QT intervals during walking with a textile vest. However, Trindade et al [17] noted higher noise amplitude with textile electrodes compared to gel electrodes during walking, and Tsukada et al [36] observed increased motion artifacts with trunk twisting. Studies included various strategies to mitigate motion artifacts, including the optimization of electrode placement, use of compression bands to enhance electrode-skin contact, and application of skin moisturizers or humidification techniques [11,17,33]. The use of a wetting device was also shown to improve signal quality in both static and dynamic conditions [32].

User Comfort

Wider clinical adoption of textile-based ECG monitoring requires user acceptance, which is linked to comfort and ease of use [11,62]. While high signal quality and accuracy are crucial, a comfortable and unobtrusive system is essential for encouraging prolonged wear and consistent data acquisition [6]. However, user comfort has been under-investigated, with only a few studies addressing this critical aspect as a secondary outcome [22,23,35,44,63].

These studies offer key insights into user perceptions. Pagola et al [22] found that patients with stroke preferred the e-textile vest over a conventional chest band for long-term use, with comparable comfort levels across day and night. Wu et al [62] reported that an e-textile t-shirt was more comfortable than traditional gel electrodes. Neri et al [53], comparing an e-textile–based ECG device to a standard Holter monitor, reported significantly greater patient comfort in the e-textile monitor, compared to the standard monitor. Steinberg et al [23] also noted greater comfort and low skin irritation with e-textile sensors, integrated into bras and shirts during 24-hour monitoring, while Arquilla et al [35] found no significant comfort difference compared to traditional electrodes. Similarly, Montazeri Ghahjaverstan et al [43] reported that all pediatric participants found the textile-based chest band easy to wear, nonirritating, and generally comfortable, with 95% rating the design as appropriate and 75% willing to use it for continuous monitoring at home.

Discussion

This review highlights the significant progress, as well as the challenges faced in optimizing e-textile–based ECG monitoring. Our findings address pertinent issues related to the optimal design and adoption of textile-based ECG monitoring technologies with respect to signal quality, static and dynamic performance, and user comfort.

Signal Quality

In relation to signal quality, the reviewed studies primarily evaluated ECG signal quality of e-textiles in healthy participants within controlled laboratory settings. The current proof-of-concept studies and feasibility testing [64,65], though essential for establishing minimum viable products, do not address the complexities of adopting e-textile–based ECG monitoring in clinical practice. Therefore, definitive conclusions about the effective use and integration of e-textiles in clinical practice cannot be drawn. Still, these studies achieved reliable ECG signals in e-textiles compared to standard adhesive electrodes and clarified key requirements to achieve reproducible ECG signals in e-textiles. These included consistent electrode placement, stable contact, supported by optimized electrode design, appropriate garment fit, garment care, and wash durability. Overall, these findings point to the need for evaluations of e-textile–based ECG monitoring in everyday life and clinical settings against standard modalities (ie, Holter monitors), incorporating diverse populations, health conditions, and standardized testing protocols.

Static and Dynamic Performance

E-textile–based ECG monitoring is particularly susceptible to motion artifacts, which disrupt ECG signals and degrade signal quality. The majority of studies included monitored ECG in static conditions, likely reflecting the initial validation efforts. While these studies indicated equal-to-superior performance for static e-textile–based ECG assessment [20,26,29,30,38,57], fewer studies included dynamic e-textile–based ECG assessment. Despite the lack of standardized protocols, many studies demonstrated the satisfactory detection of QRS complexes and rhythm abnormalities during moderate dynamic activity [20,34,38,52,57]. Nonetheless, motion artifacts significantly impacted signal quality during more strenuous activities [17,25,33,36]. A limitation of the current literature in relation to dynamic e-textile–based ECG assessment is the lack of standardized protocol, making it difficult to directly compare results across studies. Furthermore, studies in realistic, uncontrolled dynamic environments are still relatively scarce, highlighting the need for further research to address the practical challenges of implementing textile-based ECG monitoring in everyday life. In addition to factors that influence signal quality

(mentioned previously), further advancements in signal processing and machine learning are needed to reliably extract clinically meaningful data during dynamic conditions [39,60,61].

User Comfort

Although some feasibility and prototype studies report that textile electrodes may improve comfort compared to traditional gel electrodes [17,21], evidence remains limited and heterogeneous. Independent studies [22,23,35,63] have noted favorable comfort outcomes, while 1 study from our group [43] found the textile band to be "generally comfortable." These findings should be interpreted with caution given the potential for bias and the small sample sizes involved. Overall, comfort remains an underresearched area, and further independent clinical evidence is needed to confirm these preliminary observations. Future research should prioritize standardized assessment of user experience using validated tools and include diverse populations, as comfort and ease of use are critical for long-term adoption.

Clinical Integration

The potential for greater use and clinical integration of e-textiles is promising, yet significant challenges remain. These include interoperability with existing EHR systems, clinical validation, patient privacy, cost-effectiveness, timely feedback mechanisms, and user-friendliness. Effective workflow integration also requires clear standards for data review frequency, protocols for urgent findings, and sustainable reimbursement models. Frameworks, such as the ABCD model [58]—which evaluates device accuracy, clinical utility, regulatory approval, and cost—can guide adoption. Importantly, these frameworks must incorporate both clinician and patient perspectives [66-68] to ensure usability and adherence.

Recent clinical investigations provide encouraging evidence of feasibility and diagnostic value in real-world settings. Fukuma et al [49] demonstrated that a t-shirt with PEDOT-PSS electrodes was suitable for lifestyle and sports activities, achieving atrial fibrillation (AF) detection performance comparable to other wearables; although this study was included in our review, it primarily involved asymptomatic participants with cardiovascular risk factors rather than patients with established disease. Pagola et al [50] reported that intensive 90-day textile Holter monitoring detected paroxysmal AF in 35.37% of patients, underscoring the benefit of extended monitoring. Machino et al [42] showed that a 2-week garment ECG detected AF recurrence in 18% of patients—significantly outperforming 24-hour Holter monitoring (6%). Similarly, Amami et al [44] found that an undershirt with silver textile electrodes provided ECG monitoring and arrhythmia detection comparable to conventional Holter devices. Collectively, these findings indicate promising feasibility and signal quality; however, conclusions about clinical robustness cannot be drawn without formal quality assessment and larger trials.

Recommendations

The rapid evolution of telemedicine and digital health tools presents significant opportunities to improve cardiovascular disease management [69-71]. Smart textiles offer a promising pathway toward enhanced remote patient monitoring, providing benefits for patients, health care providers, and the overall health care system. However, successful integration requires addressing several key aspects.

1. Wearable data acquisition: This pillar focuses on developing robust and reliable wearable systems capable of accurately monitoring, collecting, and preprocessing ECG data from textile-based sensors. This includes considerations, such as sensor design, electrode placement, and signal quality under various conditions.
2. Data transmission and communication: The seamless and secure transmission of ECG data from the wearable device to a remote monitoring center (smartphone or PC) is crucial. This necessitates robust and reliable data communication networks, addressing issues such as signal strength, data security, and bandwidth limitations.
3. Cloud-based data analytics and clinical integration: A powerful cloud-based analytics platform is needed to process, analyze, and interpret ECG data efficiently, providing clinicians with readily accessible, accurate, and clinically relevant information [2,6,9]. This platform must facilitate timely alerts for acute events, support offline data access, and seamlessly integrate with existing EHRs. Data processing and analysis techniques are essential components of this system, requiring sophisticated algorithms to filter noise, identify key patterns, and provide meaningful interpretation [72,73]. The scalability and reliability of the backend infrastructure, including data storage and retrieval, are essential factors determining the system's performance.

Clinicians require user-friendly clinical portals to visualize and manage this data effectively, enabling timely diagnosis and intervention. Patients and caregivers should have access to relevant information for their self-management and remote health monitoring (Figure 2). Finally, user training and education are critical, particularly for individuals with low digital literacy [74]. Addressing these 3 pillars will be key to realizing the full potential of smart textiles in improving cardiovascular care.

Figure 2. Smart textiles data workflow and integration in clinical practice. Textile-based sensors embedded in clothes or garments continuously measure electrocardiogram (ECG) signals.

Current Issues and Challenges

While textile-based ECG technology shows promise in terms of signal quality, several challenges must be addressed to facilitate its broader adoption in clinical practice. This section outlines key obstacles across 3 interconnected areas: technology, data management, and clinical workflow integration (Figure 3, Table 3).

Figure 3. Challenges for smart textile integration into clinical practice.

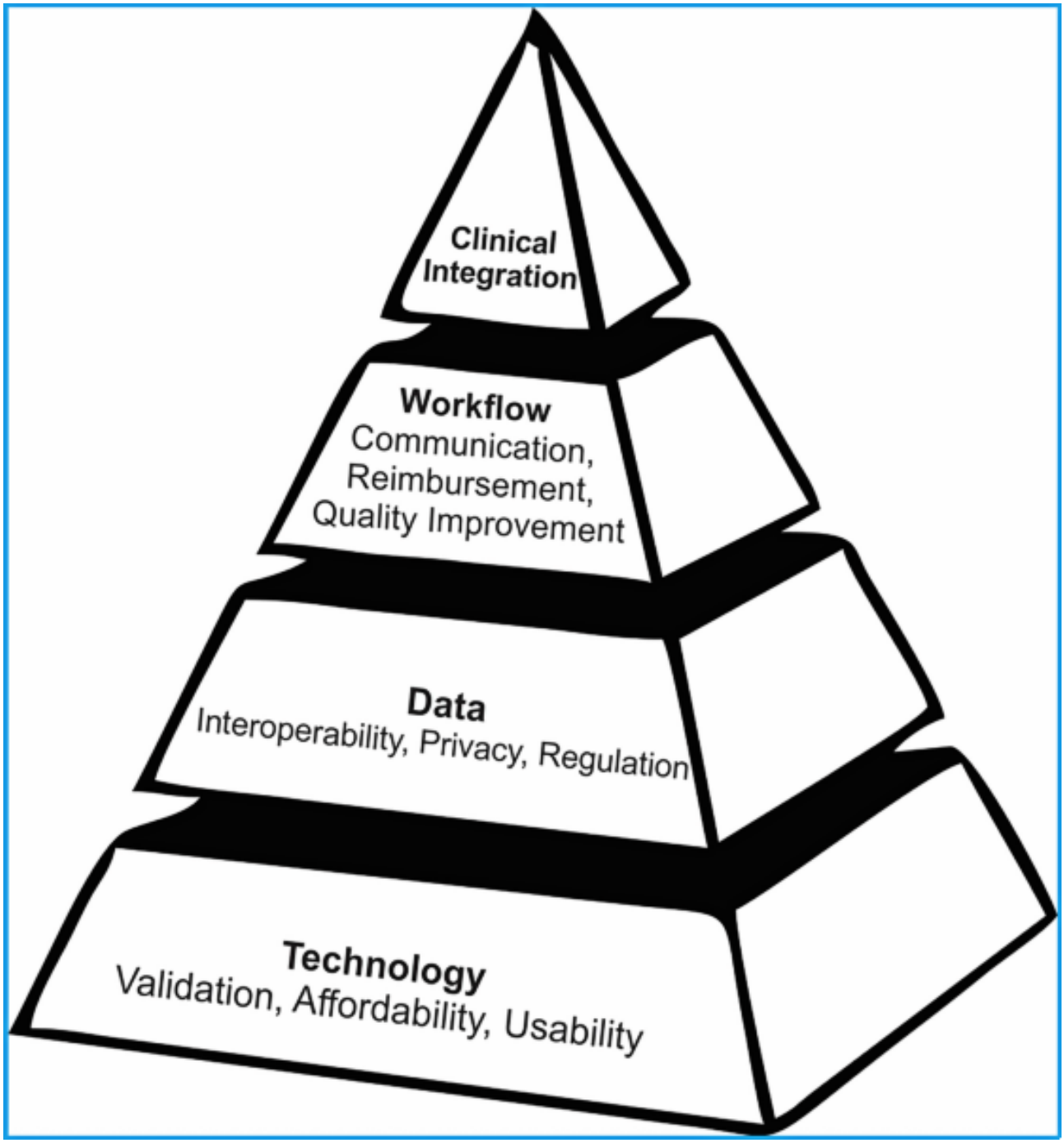


Table . Challenges and recommendations for smart textile integration into clinical practice.

Theme	Challenges for clinical integration	Recommendation
Technology	• Lack of clinical validation of smart textiles for ECG[a] monitoring. Poor data validity hampers the repeatability of measurements and impairs interoperability and data exchange. • Affordability and cost may limit the uptake of the smart textile for ECG monitoring. • Absence of information about user needs, perception, and acceptance of the smart textile for ECG monitoring.	• Extensive clinical validation regarding the safety, effectiveness, and performance of the smart textile to monitor physiological data over long periods in free-living conditions. • Private insurance companies and government may partially support the cost of smart textiles for ECG monitoring. • A comprehensive understanding of users' perceived value, perceived usefulness, perceived ease of use, and satisfaction must be met by health care professionals and users for the widespread adoption of smart textile devices. Surveys, interviews, and focus groups to address the user acceptability issue.
Data	• User privacy and security concerns related to the misuse of personal health information during data transfer and real-time data streaming. • Inefficient interoperability among devices, applications, systems, and domains. • Absence of clear regulatory policies governing smart textile for ECG monitoring.	• Clear guidelines providing the privacy, confidentiality, and proper use of electronic medical information. Ensure that users feel comfortable and confident sharing a significant amount of data with data analytic companies, health care providers, and insurance companies. • Uniform and straightforward data formats; standard communication protocols for information exchange between smart textiles and other platforms. • Adopt devices cleared or approved by regulatory agencies (i.e., FDA[b]). Expansion of HIPAA[c] policies aligned with remote patient monitoring technologies, such as smart textiles.
Clinical workflow	• Efficient processes for communicating actionable or urgent data between health care providers, patients, and caregivers are not yet well defined. In particular, the appropriate frequency of data review and the personnel responsible for monitoring incoming data still need to be established. Without clear workflows, there is a risk of data overload, which can delay timely and appropriate clinical responses. • Reimbursement structures are not fully implemented for remote patient monitoring using smart textiles technologies. • Challenges using digital health data gathered from electronic health record systems, personal health records, and other systems (eg, smart textile) for clinical quality improvement.	• Development of a clinical dashboard for data reporting. Operationalize and triage the data and define realistic response time. Health care providers can review regularly acquired ECGs during in-person or virtual visits. Timely feedback can be guaranteed if the platform allows the health care provider to set customizable notifications, for example, in case an abnormal event is detected. • Clear reimbursement models addressing remote monitoring and data review. More studies to assess the costs and cost-effectiveness of remote monitoring are necessary to determine reasonable reimbursement rates. • Clear regulations to use the smart textile data, allowing it to be aggregated, linked with other forms of data, and leveraged to generate new knowledge and promote clinical quality improvement.

[a]ECG: electrocardiogram.

[b]FDA: Food and Drug Administration.

[c]HIPAA: Health Insurance Portability and Accountability Act.

Technological Challenges

Technological challenges include the following:

- Clinical validation: While numerous studies demonstrate the feasibility of textile-based ECG electrodes in terms of signal quality, none have yet achieved routine clinical adoption (technological readiness level 9). A substantial body of clinical data is needed to validate the technology's

fidelity, interoperability, safety, and effectiveness as intended [75].

- Affordability and cost: While smart textiles could potentially reduce health care costs through optimized patient management and early intervention [61], this remains unsubstantiated. The cost-effectiveness of this technology needs further investigation, considering both initial investment and long-term operational costs [76-78]. Reimbursement policies from insurance companies and governments are crucial for broader accessibility [66,79].
- Usability and acceptability: Limited research exists on user perceptions and acceptance of smart textile ECG monitoring. Factors, such as comfort (thermal, tactile, style, pressure), ease of use, perceived value, and the ability to share data with health care providers, significantly influence user adoption [66,67,69,80,81]. Further research using user-centered design methodologies (surveys, focus groups, interviews) is essential [82,83], using frameworks, such as the technology acceptance model to understand user behavior [67,80].

Data-Related Challenges

Data-related challenges include the following:

- Privacy and security: The collection and transmission of sensitive physiological data through smart textiles raise significant privacy and security concerns [84]. Robust data protection measures, secure data storage, and transparent data usage policies are essential to safeguard patient information and ensure compliance with relevant regulations [4,58,85]. Informed consent and authorized user access are paramount.
- Interoperability: The seamless integration of smart textile ECG data with existing EHRs and other health care systems is essential for efficient remote patient monitoring [64,86,87]. This requires consistent data formats, standard communication protocols, and a cloud-based architecture that ensures data exchange and interoperability across different service providers [88].
- Regulatory policy: The rapid evolution of smart textile technology necessitates a review and update of existing regulatory frameworks [86]. Clear standards and guidelines are needed to ensure safety and effectiveness, particularly concerning data privacy and security, in accordance with regulations like Health Insurance Portability and Accountability Act and Food and Drug Administration guidelines [89]. Transparent policies regarding data collection, usage, and sharing are crucial for building trust and facilitating adoption [90].

Clinical Workflow Challenges

Clinical workflow challenges include the following:

- Communication and feedback: Effective communication and feedback between patients and health care providers are vital components of remote patient monitoring [91]. User-friendly clinical dashboards, timely alerts, and efficient reporting mechanisms are required to ensure timely intervention and improve clinical decision-making [64,73,74]. However, challenges include potential delays due to data loss, network issues, and data overload [8,70].
- Reimbursement: Clear and well-defined reimbursement pathways are essential to ensure the financial viability of smart-textile–based ECG monitoring within the health care system [74,76]. To support adoption, the cost-effectiveness of these smart wearable systems must be demonstrated, and sustainable reimbursement models need to be developed, taking into account factors such as monitoring duration and clinical service provision [92,93]. Evidence from clinician surveys also indicates support for a shared-cost approach, where expenses are distributed among patients, insurance providers, and government payers [94].
- Quality improvement: Integrating smart textile data into established clinical workflows enables continuous learning and improvement through feedback loops and data-driven insights [63,95-98]. This requires robust data analysis methods, the development of meaningful clinical indicators, and a strong focus on data-driven decision-making within the health care system. A structured approach to quality improvement, including infrastructural and organizational changes, is crucial for maximizing the benefits of smart textile technology.

Limitations

This scoping review provides a current overview of e-textile–based ECG monitoring but has several important limitations. First, our search strategy did not explicitly include ECG-specific keywords (eg, “ECG,” “EKG,” “Electrocardiogram”), which may have restricted the retrieval of engineering-focused studies emphasizing signal fidelity, such as QRS detection algorithms. While cardiovascular disease terms (eg, “Arrhythmia,” “Atrial Fibrillation”) and monitoring concepts (eg, “Holter,” “ambulatory monitoring”) were expected to capture most relevant literature, omitting explicit ECG terms could have excluded technical performance studies that do not reference disease-specific terminology. Future reviews should incorporate ECG-related keywords and engineering databases to ensure comprehensive coverage of signal processing and hardware design research.

Second, the evidence base is dominated by feasibility and proof-of-concept studies, reflecting the early developmental stage of this technology. These studies often involve small sample sizes and controlled laboratory environments, limiting generalizability to real-world clinical settings. While such controlled conditions are valuable for assessing baseline performance, they may not fully capture usability and reliability under everyday conditions. Furthermore, the absence of standardized testing protocols for key metrics, such as signal quality, wearability, and durability, makes cross-study comparisons challenging. We did not conduct a formal risk of bias assessment, so the findings should be interpreted with caution.

Third, the scope of this review was primarily focused on signal quality, performance under static and dynamic conditions, and user experience. Wash durability, a critical factor for long-term usability, was outside the main scope. Future reviews should evaluate standardized laundering protocols and durability

metrics, as these factors are essential for practical implementation and regulatory approval.

Despite these limitations, textile-based ECG monitoring demonstrates compelling potential benefits that conventional ECG methods cannot easily replicate. These include improved access to care for remote or underserved populations, continuous monitoring for the early detection of subtle cardiac changes, enhanced patient comfort and adherence due to increased wearability, and potential cost savings through earlier intervention. While further clinical validation and standardization are necessary, these advantages underscore the transformative potential of smart textiles in cardiac care.

Conclusion

In conclusion, smart textiles offer the potential for the valuable long-term monitoring of ECG parameters, improving the detection of transient events and reducing intervention times. Further, their capacity for unobtrusive, remote monitoring and seamless integration with other health metrics offers unique advantages over conventional ECG. However, widespread support and adoption within clinical workflows depend on addressing the identified limitations, incorporating user feedback, and demonstrating the clinical utility and cost-effectiveness of this technology. Only with reliable and meaningful data can textile-based ECG monitoring serve as a valuable diagnostic tool to guide care, provide a more complete picture of heart health, and improve treatment decisions.

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Conflicts of Interest

CPS is a former employee of Myant Health Corp. She also held a MITACS internship at Myant Health Corp during her postdoctoral fellowship at the University of Toronto. GC is an employee of Myant Health Corp. BM is a former employee of Myant Health Corp. MP is currently employed by Myant Health Corp. EML is a former employee of Myant Health Corp. MA-M is an employee of Myant Health Corp. SB is a former employee of Myant Health Corp.

Multimedia Appendix 1
Database search details.
[DOCX File, 20 KB - cardio_v10i1e74261_app1.docx]

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 31 KB - cardio_v10i1e74261_app2.docx]

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Abbreviations

AF: atrial fibrillation
ECG: electrocardiogram
EHR: electronic health record
MeSH : Medical Subject Headings
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Mindfulness-Based Self-Management Program Using a Mobile App for Patients With Pulmonary Hypertension: Single-Arm Feasibility Study

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Abstract

Background: Mindfulness-based interventions have been applied across various chronic illnesses, but no tailored program exists for individuals with pulmonary hypertension (PH).

Objective: This study aimed to develop and evaluate the feasibility of a mindfulness-based self-management program for patients with PH, delivered online to accommodate their limited mobility.

Methods: A single-arm pre-post study was conducted using an 8-session, weekly videoconference program incorporating PH self-management education and elements of mindfulness-based cognitive therapy. A mobile app linked to an Apple Watch was used to support symptom monitoring and mindfulness awareness. Outcomes included PH-related symptoms, quality of life (emPHasis-10), depression (Patient Health Questionnaire-9 [PHQ-9]), anxiety (Generalized Anxiety Disorder 7-item scale [GAD-7]), resilience (Connor-Davidson Resilience Scale [CD-RISC]), and loneliness (UCLA Loneliness Scale–short version). Assessments occurred at baseline, week 4, and program completion. Exit interviews explored perceived changes and experiences.

Results: Twelve participants (mean age 41.8, SD 10.5 years; range 26 - 56 years) were enrolled, and 9 completed the program (75% retention). Participants valued the online format and Apple Watch integration, while noting a need for optional on-demand sessions. Qualitative analysis identified themes such as increased self-awareness, use of meditation for pain management, and enhanced self-compassion. Quantitative analysis showed significant changes across 3 time points (baseline, week 4, and week 8) for emPHasis-10 (χ^2_2 =9.74; *P*=.008) and CD-RISC (χ^2_2 =7.27; *P*=.03). Trends toward change were observed for PHQ-9 (χ^2_2 =4.75; *P*=.09) and GAD-7 (χ^2_2 =5.07; *P*=.08), but week 12 data were limited (n=5). No significant changes in loneliness were observed.

Conclusions: The program appeared to support patients with PH in managing symptoms and emotions and suggested potential improvements in quality of life. These preliminary findings warrant evaluation in a future randomized controlled trial.

Trial Registration: UMIN Clinical Trials Registry UMIN000044075; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000050319

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KEYWORDS

mindfulness; mindfulness-based intervention; pulmonary hypertension; self-management; digital health

Introduction

Pulmonary hypertension (PH) is a progressive disease characterized by shortness of breath as the primary symptom. Although recent advances in treatment have dramatically improved the prognosis of the disease [1], patients with PH may face various physical symptoms and may experience limitations in their activities and social roles. Self-management at home has become increasingly complex owing to the use of medications with various mechanisms of action and with various routes of administration [2]. Furthermore, side effects of

pulmonary vasodilative medications, such as headache, jaw pain, plantar pain, diarrhea, and nausea, may occur. These symptoms are more pronounced in continuous intravenous and subcutaneous infusion therapies. There is a certain level of risk for sudden death in severe PH cases with right heart failure; thus, patients with PH are forced to live with uncertainty.

Therefore, it is not surprising that patients with PH tend to experience high anxiety and depression. Past studies demonstrated that 21.9% - 56% of PH patients are comorbid with depressive symptoms [3-14], 10.7% - 62% with anxiety symptoms [3-6,8,12,13], and 27.6% - 40% with stress-related symptoms [4,11]. These findings suggest the need for psychological care for patients with PH.

Mindfulness has been described as "paying attention in a particular way—on purpose, in the present moment, and nonjudgmentally" [15]. Mindfulness-based interventions have gained increasing attention as a method of psychological care for patients with physical illnesses. The two major programs are mindfulness-based stress reduction (MBSR) [16] and mindfulness-based cognitive therapy (MBCT) [17]; however, flexible modifications of the program to fit with target populations, such as providing information on nutrition [18], grief care [19], and advance care planning [20,21], have been implemented.

Conventional mindfulness-based programs have been delivered on a face-to-face basis; however, in recent years, web-based programs have been developed and implemented quite widely [22,23]. In the field of cardiovascular disease, mindfulness interventions are being developed for patients with coronary artery disease and heart failure [24-26].

However, to the best of the authors' knowledge, there has been no mindfulness-based program that has been developed specifically for PH. Modification of the program may be needed for patients with PH to avoid physical overload that may worsen right ventricular function. For example, yoga, a standard component of MBSR and MBCT, could lead to cardiopulmonary overload. Furthermore, since patients with PH often have limited mobility, web-based programs, instead of on-site programs, are likely to be preferred.

Therefore, in this study, we developed and tested the feasibility of an online mindfulness-based self-management program for patients with PH using a smartphone app on Apple Watch. The intervention aimed to improve the quality of life (QOL) and resilience and to reduce depression, anxiety, and pain (a side effect of the treatment) of patients with PH.

Methods

Study Design

This study used a mixed methods, single-group, pre-post design.

Participants

Inclusion and Exclusion Criteria

The inclusion and exclusion criteria are shown in Textbox 1.

Textbox 1. Inclusion and exclusion criteria.

The inclusion criteria for this study were as follows:

- A confirmed diagnosis of pulmonary hypertension (PH) [27].
- Age 20 - 75 years.
- The ability to attend at least six of the eight 60-minute online sessions.
- The ability to operate the self-administered mobile app on an iPhone or iPad and an Apple Watch.

The exclusion criteria were as follows:

- Severe physical symptoms, including but not limited to decompensated right-sided heart failure, as assessed by the attending physician.
- Patients with an active psychiatric disorder who were currently under psychiatric care or receiving psychotropic treatment. These individuals were excluded for safety reasons, as the program was delivered entirely online, and timely in-person support could not be ensured if psychological distress or other adverse emotional reactions were to occur during the intervention.
- Cognitive impairment or other conditions that, in the attending physician's judgment, would make it difficult for the patient to understand or participate in the program, based on routine clinical assessments and information in medical records.
- Individuals deemed by their attending physicians to be clinically unstable or otherwise inappropriate for participation.
- Individuals who had previously participated in structured mindfulness-based programs such as mindfulness-based cognitive therapy (MBCT) or mindfulness-based stress reduction (MBSR).

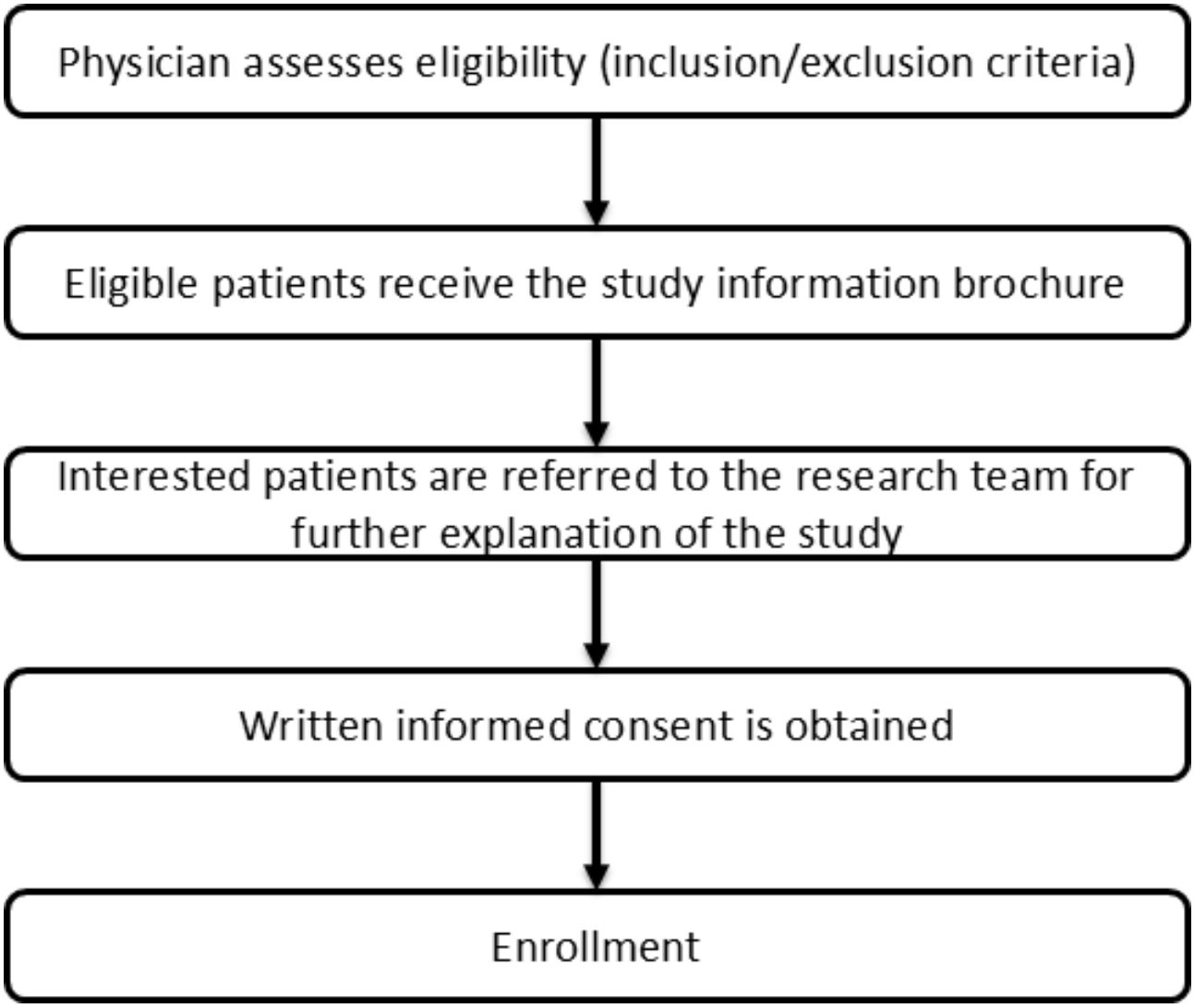
Individuals aged 18 - 19 years were not included, because at the time this study was initiated (December 2020), persons ages 20 years and younger were not considered adults for the purpose of providing independent informed consent under Japanese ethical guidelines, and thus, were unable to consent without guardian approval [28].

Recruitment and Screening Procedures

Participants were recruited through a structured, stepwise process. First, physicians screened patients during routine clinical visits to ensure they met the inclusion criteria and did not meet any exclusion criteria. Eligible patients were then provided with an informational brochure describing the study. Patients who expressed interest were referred to the research team, who provided a detailed explanation of the study

procedures. Written informed consent was obtained from all patients before enrollment. The overall recruitment and screening process is shown in Figure 1.

Figure 1. Flowchart illustrating the recruitment and screening.



Sample Size Justification

As this was a feasibility study, the primary aim was to evaluate acceptability, adherence, and operational feasibility rather than to test statistical efficacy; therefore, a formal power calculation was not required. We chose a target sample size of approximately 12 participants, which is comparable to previous feasibility studies of meditation or mindfulness-based interventions in cardiovascular populations that enrolled about 10 - 15 participants [29,30].

Intervention

Program Contents

The conceptual framework and content of the program are presented in Figure 2 and Table 1. We developed this program based on the findings of our previous research, which showed that the key elements of distress for patients with PH were the loss of the past and the threat of disease progression, including rumination about the past and concern about the future [14]. The fundamentals of the intervention were based on MBCT, which addresses rumination and has been proven effective for both physical and psychological symptoms in patients with critical illnesses [17]. Furthermore, we added psychoeducation and self-management skill-building as essential components, as the distress of patients with PH derives from PH-specific symptoms (eg, breathlessness) and the adverse effects (eg, pain or nausea) and difficulties associated with the treatment (eg, home oxygen therapy).

Figure 2. Conceptual framework of the mindfulness-based intervention program for patients with pulmonary hypertension.

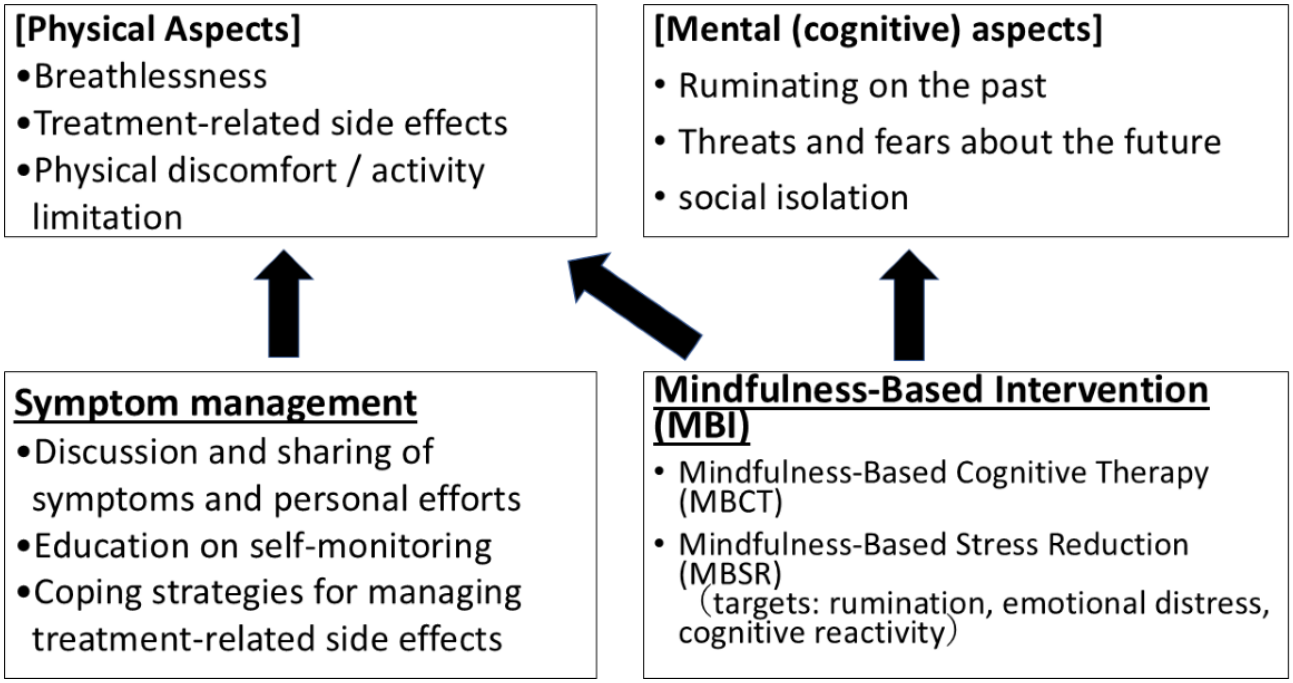


Table . Program content structured based on the results of previous research.

Elements of distress	Program content and expected effects
“Isolation from my surroundings”	Prevent isolation and reduce loneliness by regularly connecting with others and sharing thoughts and feelings through weekly online meetings.
“Loss of myself” and “Fear of illness progression or deterioration”	By reflecting on their physical and mental conditions through mindfulness practice and homework, participants become aware of their thought patterns and feelings, such as loss of abilities, regret regarding the past, and anxiety about the future; promoting meta-cognition stops rumination, thereby alleviating mood swings and anxiety.
“Hassle associated with oxygen therapy,” “Suffering from side effects,” and “Rumination on illness due to breathlessness”	Learning and sharing the basic knowledge and practical tips required for self-management and enhancing the ability to self-manage activities, shortness of breath, side effects, and other issues.

Program Structure

Table 2 presents the outline of the program. The basic structure of the program was similar to that of MBCT. To lessen the potential physical and psychological burden of the patients, we adapted an online format. We shortened the length of each session to 1 hour. We eliminated yoga, which has been supposed to be an integral component in conventional MBCT, for safety reasons, since patients with PH are at risk of circulatory collapse owing to direct right ventricular stress caused by increased pulmonary artery pressure, which could be exacerbated by physical exercise.

Table . Schedule and homework for the self-management mindfulness program for patients with pulmonary hypertension.

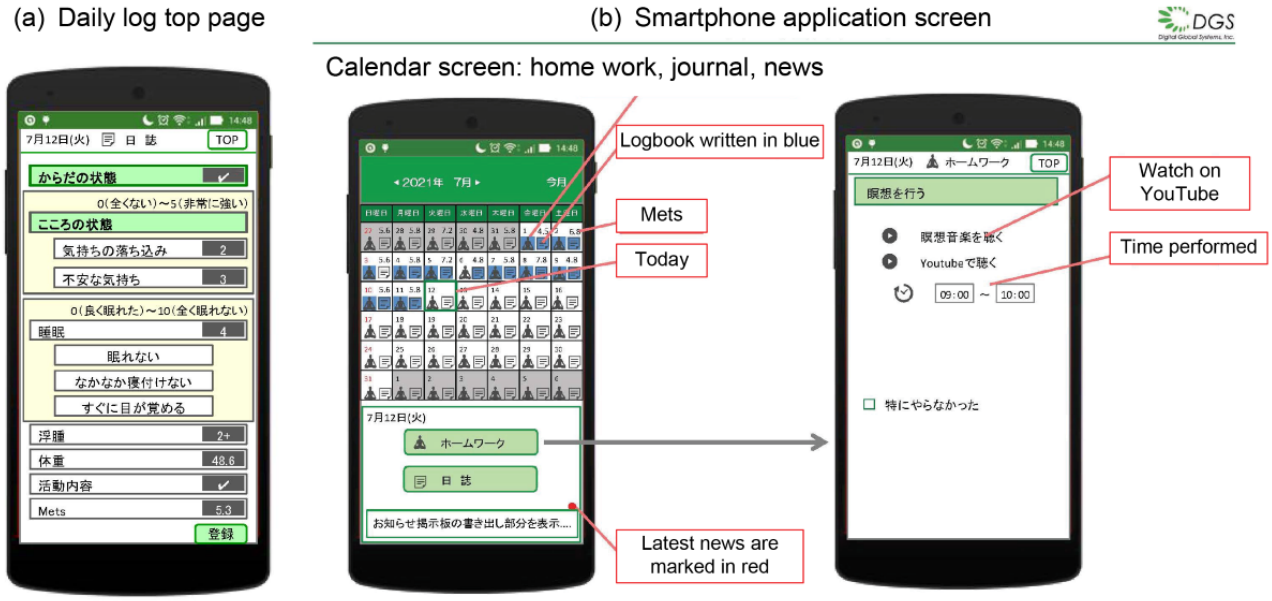
Session	Theme	Contents	Homework
1	Start the program	• What is mindfulness? • How to use the self-management app? • Short breathing meditation	• Using self-management app
2	Become aware of automatic reactions	• Short breathing meditation • Symptom management of pulmonary hypertension	• Mindful daily living
3	Focus on your body	• Body scan (meditation) • Cognitive strategies for managing treatment-related side effects	• Body scan
4	Focus on breathing	• Mindfulness meditation of breathing and body • Pleasant and unpleasant mode	• Pleasant and unpleasant life diary
5	Focus on your body and adjust it	• Short meditation • Adjustment of pulmonary hypertension activities	• Meditation • Focus on your pulse during activity
6	Thoughts are not facts	• Mindfulness meditation with sound and thought • Cognitive strategies for managing thoughts and emotions (guided imagery practice) • 3-step breathing space method	• Using 3-step breathing space method when feeling uncomfortable
7	Caring for yourself	• Compassion meditation • Positive habits	• Meditation • Appreciation list
8	Use skills for your future	• Meditation • Reflection on the past • Looking toward the future	• —[a]

[a]Not applicable.

The program was delivered in a group format once a week over a period of 8 weeks via video conference. The program was facilitated by the lead author, a nurse with 6 years of experience in practice and the teaching of mindfulness interventions. Each session lasted 60 minutes, which included 10- to 30-minute meditation practice, which was facilitated with the facilitator. At the beginning of each session, a reflection on homework was conducted, and an inquiry session was held after each meditation practice. Homework included daily mindfulness practice (eg, breathing meditation and body-scan meditation) and reflection journaling on emotional and physical experiences. Video lectures on the meaning of mindfulness, the pleasant and unpleasant mode, and mindfulness meditation were provided by a clinical psychologist and a nurse who had been a mindfulness provider for over 10 years. Pleasant mode and unpleasant mode involve mindfully reflecting on pleasant and unpleasant experiences in daily life, noting the physical sensations, emotions, and thoughts that arose at the time, thereby cultivating awareness.

To facilitate self-management skills, we developed a mobile app, which enabled users to record their daily physical conditions and to monitor their activity status using an Apple Watch (Figure 3). The mobile app (Self-management App, developed in collaboration with DGS Co Ltd) stored data on secure encrypted servers; all identifying information was anonymized and replaced by unique participant codes. For participants who did not own an Apple Watch, a device was lent to them free of charge for use during the study period. Participants were advised to use this mobile app throughout the program.

Figure 3. Screenshots of the self-management smartphone app used in the study.



Outcome Measures

Demographic Data

Demographic and clinical information, including age, sex, diagnosis, disease classification (World Health Organization functional class), duration of illness, and treatment status, were collected at baseline through participants' self-report and review of medical records. Demographic information was obtained to characterize the study sample and was used only for descriptive analyses.

Feasibility and Acceptability

The feasibility of the intervention was evaluated with participation and completion rates for the program. Acceptability was assessed by collecting and evaluating feedback from the program through interviews. The interviews included questions about changes in symptoms, self-management skills, and mental health conditions before and after the program. Furthermore, the participants were asked to describe the perceived benefits of the program, what should be changed, what they liked and disliked, and obstacles and facilitators for implementation of the program.

Secondary Outcomes

Secondary outcome measures comprised emPHasis-10, a disease-specific patient-reported outcome measure for evaluating the QOL of patients with PH [31]; the Patient Health Questionnaire (PHQ-9) for depression [32]; the Generalized Anxiety Disorder 7-item (GAD-7) scale [33]; the Connor-Davidson Resilience Scale (CD-RISC), a measure of one's ability to recover from various difficulties such as illness, emotional pressure, and pain [34]; and the UCLA Loneliness Scale-short version [35]. In addition, interviews were conducted regarding changes in awareness and behaviors related to self-management. These measures were obtained at baseline, 4 weeks after the program, and at the end of the program. The questionnaire was administered at four time points (baseline, week 4, week 8, and week 12). All questionnaires were provided in paper format, completed by participants at each time point, and returned by mail.

Analytical Methods

Content analysis was used to analyze the qualitative data from the interviews [36]. The characteristics and results of the participants were summarized using descriptive statistics, with median (range) for continuous variables and frequency (percentage) for categorical variables. The score changes between time points for each participant were plotted as line graphs for each scale. The Friedman test was conducted to evaluate the differences in scores across time points. This nonparametric test was chosen owing to its suitability for comparing repeated measures or related samples without assuming normality. Significance was set at $P<.05$. IBM SPSS (version 28) for Windows was used for all statistical analyses. MAXQDA (VERBI Software GmbH) was used for qualitative data analysis.

Ethical Considerations

This study was approved by the ethics review committees of Tokyo Kasei University and Kyorin University School of Medicine (SKE2020-11, number 1631) and was conducted in accordance with the ethical standards of the Declaration of Helsinki and relevant national guidelines.

All participants received a written explanation of the study's purpose, procedures, potential risks, and their right to withdraw at any time without disadvantage. Written informed consent was obtained from all participants prior to study participation.

To ensure privacy and confidentiality, all data were anonymized and assigned participant identification codes at the time of collection. No personally identifiable information was included in the datasets used for analysis. Data were securely stored on a password-protected hard disk drive.

Participants did not receive monetary compensation but were provided with the mindfulness program free of charge as part of the study.

No identifiable images or personal information of participants are included in this paper or the supplementary files.

The study was registered in the UMIN Clinical Trials Registry (UMIN000044075).

Results

Participant Characteristics

Participants' baseline characteristics are shown in Table 3.

Table . Participant characteristics at baseline (n=12).

Characteristics	Results
Age (years), mean (SD)	41.8 (10.5)
Age (years), range	26 - 56
Sex, n (%)	
Male	3 (25)
Female	9 (75)
Program completed, n (%)	9 (75)
PH[a] type, n (%)	
PAH[b]	11 (92)
CTEPH[c]	1 (8)
MeanPAP[d] (mmHg), median (range)	32.5 (20-47)
Treatment (pharmacological therapy), n (%)	
Epoprostenol (IV[e])	5 (42)
Treprostinil (IV)	2 (2)
Treprostinil (SC[f])	1 (8)
Only oral medicine[g]	4 (33)
Interventional history, n (%)	
Post BPA[h]	1 (8)
Therapeutic support, n (%)	
Oxygen therapy	3 (25)
Symptoms, n (%)	
Dyspnea on exertion	10 (83)
Fatigue	10 (83)
Palpitations	3 (25)
Pain	8 (67)
Nausea	3 (25)
Diarrhea	5 (42)
QOL[i] (emPHasis-10[j]), mean (SD), range	33.6 (10.1), 16 - 46
Depression (PHQ-9[k]), mean (SD), range	14.1 (6.6), 2 - 24
Anxiety (GAD-7[l]), mean (SD), range	11.1 (5.5), 1 - 18
Resilience (CD-RISC[m]), mean (SD), range	17.8 (8.0), 3 - 29
Loneliness (UCLA Loneliness Scale), mean (SD), range	26.6 (5.9), 13 - 34

[a]PH: pulmonary hypertension.
[b]PAH: pulmonary arterial hypertension.
[c]CTEPH: chronic thromboembolic pulmonary hypertension.
[d]MeanPAP: mean pulmonary arterial pressure.
[e]iv: intravenous injection therapy.
[f]sc: subcutaneous injection therapy.
[g]Including the 1 participant with post-BPA status.
[h]BPA: balloon pulmonary angioplasty (only applies to patients with CTEPH).
[i]QOL: quality of life.
[j]emPHasis-10: disease-specific patient-reported outcome (PRO) measures for evaluating quality of life in patients with pulmonary hypertension.
[k]PHQ-9: Patient Health Questionnaire-9.

[l]GAD-7: Generalized Anxiety Disorder 7-item scale.

[m]CD-RISC: Connor-Davidson Resilience Scale.

Feasibility

Of the 12 participants who agreed to participate in this study, 9 completed the program (75% retention rate). The 3 individuals dropped out due to hospitalization for exacerbation of hemoptysis, hospitalization for treatment of comorbidities, and catheter infection.

Acceptability of Program Structure

The responses by the 9 participants who completed the program are shown in Table 4. Furthermore, the following comments were received regarding the program's structure:

> *The weekly online real-time program made me feel as though I were back at work again, and it refreshed me and made me feel lively and excited.*
>
> *The Apple Watch helped me understand my physical condition better through objective numbers and data, and it gave me the opportunity to face my illness properly. Just experiencing symptoms can be vague, and they are easily forgotten, but being able to check the numbers and monitor my condition is really helpful.*
>
> *I didn't know anything about mindfulness at first, so I felt hesitant. I think it would be much easier to engage if I could learn why mindfulness is applied to this illness.*
>
> *I take diuretics every day, so it would be helpful if there were an on-demand option that allows me to participate calmly without worrying about needing to urinate.*

Table . Feedback on the number of sessions, duration per session, and session intervals (n=9).

Variable	Sample, n (%)
Number of programs (8 in total)	
Too many	2 (22)
Appropriate	6 (67)
Too few	1 (11)
Time per session (60 minutes per session)	
Too long	0 (0)
Appropriate	9 (100)
Too short	0 (0)
Program interval (once per week)	
Too long	0 (0)
Appropriate	7 (78)
Too short	2 (22)

Changes and Awareness After the Program

The qualitative content analysis identified 10 categories (Table 5).

Table . Qualitative analysis results: categories reflecting changes and awareness after the program.

Category	Frequency, n
Being able to objectively consider one's thoughts and feelings and not be bothered by them	14
Peace of mind from facing one's mind and body	13
Reduced pain and handling side effects	12
Being compassionate toward oneself	10
Focusing on one's body and conducting activities	10
Awareness of the importance of breathing	6
Increased happiness and positive feelings	4
Realization that actions during illness until the present were not erroneous	4
Reduced fatigue	3
Acquiring methods of thinking and coping when feeling anxious or restless	2

Being Able to Objectively Consider One's Thoughts and Feelings and Not Be Bothered by Them

Participants were able to understand that their mental instability was due to their poor physical condition.

> *I used to struggle to accept it, but now I can think, 'My physical condition is bad today, so it's natural [for my feelings to also decline]. It can't be helped.' […] And I can tell myself, 'It's the illness that makes me feel this way, so it can't be helped.'* [ID7]

Reduced Pain and Handling Side Effects

They experienced how meditation can help relieve pain and heartburn.

> *I had been having a headache for a long time, but while I was doing the body scan meditation, the pain disappeared… It's really strange, but the pain seems to move around. I always wonder why.* [ID5]

Being Compassionate Toward Oneself

Even when thoughts and feelings came to mind, they were able to observe them objectively and respond more adaptively. Consequently, they felt that this positive change reduced self-blame and harsh self-criticism.

> *I really felt that the number of times I thought, 'Oh no, this is terrible,' had decreased...I really felt that the number of times I thought.* [ID2]

Focusing on One's Body and Conducting Activities

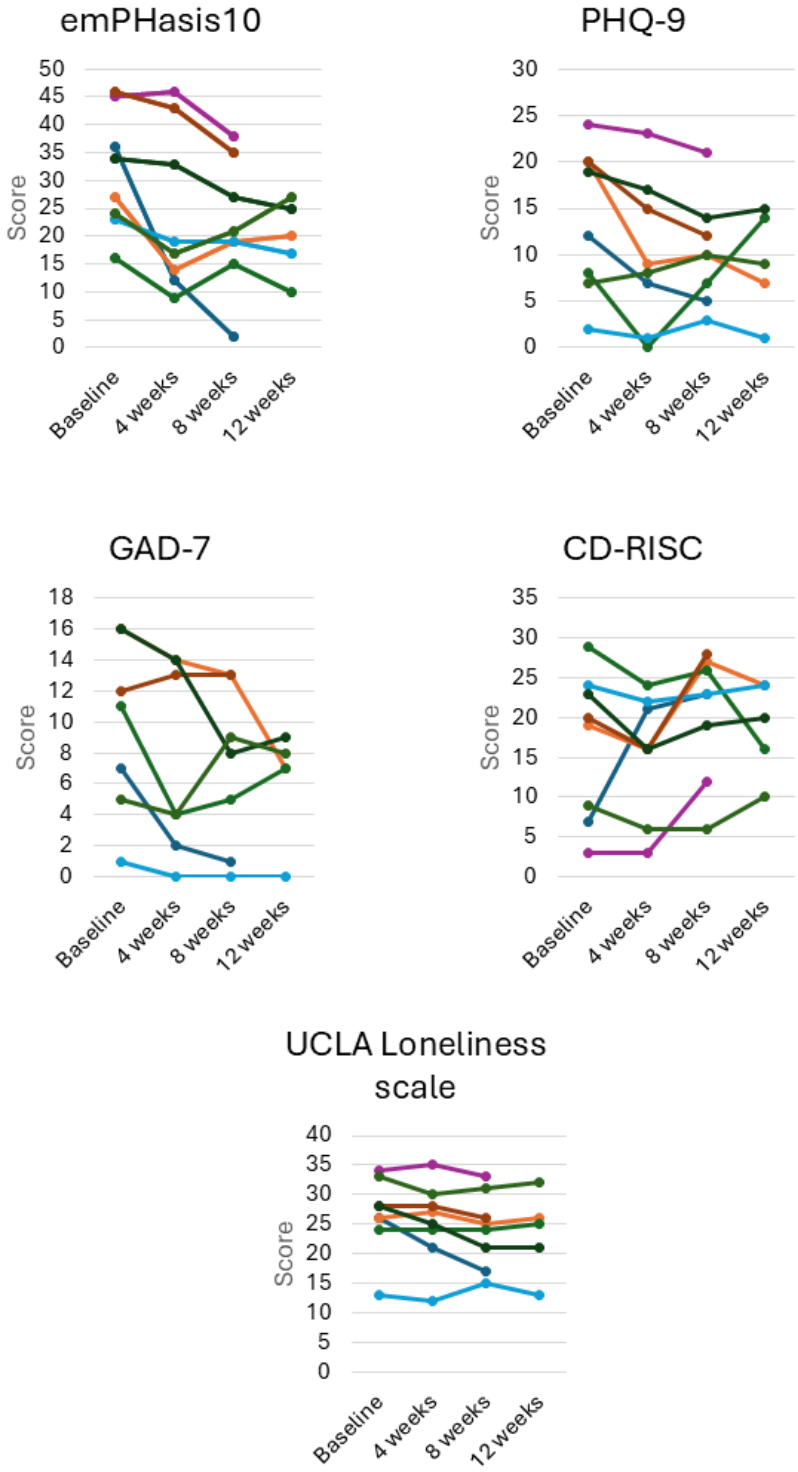
By focusing on bodily sensations and intentionally attending to their internal states during daily activities, participants reported reduced pain.

> *At night, after eating dinner and taking my medication, my heart used to start pounding faster. But now, after I finish eating, I take a moment and tell myself, 'Let's breathe slowly and take a little rest,' and the breathlessness goes away.* [ID4]

Secondary Outcomes

Although 9 participants completed the program (75% completion rate), the week 8 quantitative analysis—the primary endpoint—included data from 8 participants (67% data retention rate) because one completer did not return the postprogram questionnaire. Figure 4 shows score trends from baseline, week 4, week 8, and week 12. At week 12 (one month after the end of the program), responses were obtained from 5 participants (56% response rate).

Figure 4. Individual trajectories of patient-reported outcome measures across the four assessment time points (baseline, 4 weeks, 8 weeks, and 12 weeks). The figure displays individual-level changes in 5 psychosocial and clinical measures used in this study: the emPHasis-10 (disease-specific quality of life), PHQ-9 (depressive symptoms), GAD-7 (anxiety symptoms), CD-RISC (resilience), and the UCLA Loneliness Scale (loneliness). Each colored line represents a single participant's score over time. These descriptive data illustrate variability in symptom patterns and potential trends in psychological well-being during and after the mindfulness-based intervention. CD-RISC: Connor-Davidson Resilience Scale; GAD-7: Generalized Anxiety Disorder 7-item scale; PHQ-9: Patient Health Questionnaire-9.



The emPHasis-10 (χ^2_2=9.74; *P*=.008) and CD-RISC (χ^2_2=7.27; *P*=.03) scores showed significant differences at baseline (preprogram), 4 weeks (during the program), and 8 weeks (postprogram; n=8). The significant differences were not maintained at 12 weeks (follow-up). In addition, although no significant difference was found, a trend toward improvement in the PHQ-9 (χ^2_2=4.75; *P*=.09) and GAD-7 (χ^2_2=5.07; *P*=.08) was observed. Moreover, a few participants showed sudden deterioration in QOL and experienced depressive and anxiety symptoms a month after the program; however, they reported

that this coincided with the timing of replacing the subcutaneous Treprostinil injection needle. No significant changes were observed in feelings of loneliness. Individual score trajectories are shown in Figure 4.

Discussion

Principal Findings

This study evaluated the feasibility, accessibility, and preliminary psychological changes associated with an online mindfulness-based program designed for patients with PH. The program achieved good retention, with a completion rate of 75% (9/12), and was generally well accepted by participants. Quantitative analyses revealed positive changes in QOL, depression, anxiety, and resilience scores, while qualitative findings indicated that participants experienced greater bodily awareness, emotional regulation, and self-compassion through mindfulness practice. Together, these results suggest that an online mindfulness-based intervention is both feasible and acceptable for patients with PH and may have the potential to improve their psychological well-being and symptom management.

Feasibility and Accessibility

With a completion rate of 75% (9/12), the program demonstrated a relatively high level of retention. However, the primary reason for participant dropout was hospitalization due to physical deterioration associated with underlying or comorbid conditions. As PH progresses, patients may develop worsening right heart failure or experience hemoptysis, necessitating hospitalization. Therefore, future implementations of the program should target individuals with stable PH and take into account the potential for physical decline during participation.

The 60-minute session length appeared appropriate; however, participants indicated that the total number of sessions (n=8) was excessive and that the weekly interval was too short. Additionally, some participants expressed a desire for on-demand sessions, citing difficulties caused by frequent urination due to diuretic use. These findings suggest the need to reconsider the program's frequency and delivery format.

The program consisted of eight 60-minute real-time sessions conducted weekly via an online conferencing system. For PH patients who experience challenges leaving their homes, this online delivery format effectively reduced their physical burden. Nevertheless, the requirement to connect online at a fixed time each week imposed an additional burden that may have negatively affected retention. Conversely, participants who had stopped working due to illness reported a sense of fulfillment and accomplishment from attending regularly scheduled sessions.

As discussed above, offering the entire program on an on-demand basis could further reduce participant burden and improve retention. However, inquiry—a central element of mindfulness—requires real-time interaction between instructors and participants. Inquiry, also referred to as mindful dialog, provides participants with opportunities for self-reflection through guided conversation. To preserve this essential component, at least part of the program should be conducted synchronously rather than fully on-demand. Although traditional MBSR and MBCT programs comprise 8 sessions, recent studies have developed and validated shorter mindfulness-based interventions [37-40]. Based on these findings, we propose a hybrid format that reduces the total number of sessions and delivers approximately half of them on demand. This approach may lessen participant burden while maintaining the feasibility and therapeutic integrity of the intervention. Nevertheless, some patients may require individualized support to manage specific physical symptoms, treatment-related side effects, or emotional distress. Therefore, it may be necessary to consider implementing individual consultations before the program or during the intervention period to provide tailored support for such patients.

Furthermore, this intervention was implemented as an individual program. Expanding individual programs to a larger population poses logistical challenges and limits generalizability. Future studies should therefore examine the effectiveness of group-based formats. In addition, since mindfulness interventions require trained facilitators, the current shortage of qualified personnel represents a barrier to broader dissemination. To promote scalability, two approaches may be considered: (1) developing on-demand mindfulness modules that can be facilitated by health care professionals without formal mindfulness training, or (2) establishing training programs to cultivate health care providers capable of delivering mindfulness interventions.

Although the response rates for pre- and midprogram questionnaires were high, those at program completion and 4 weeks postcompletion were notably low. In this study, paper-based questionnaires were distributed and returned by mail. For PH patients who find it burdensome to leave home, this method likely contributed to the low response rate. Therefore, future studies should employ web-based questionnaires that allow participants to respond online, thereby reducing the response burden and improving data collection rates.

Qualitative Findings: Psychological and Physical Experiences During the Program

Qualitative analysis identified themes such as "finding peace of mind through connecting with the body and mind" and "recognizing the importance of breathing." Interoception refers to perceiving, accessing, and evaluating internal bodily signals [38]. In mindfulness meditation, participants focus nonjudgmentally on present-moment bodily sensations. Rumination arises when attention drifts toward the past or future; mindfulness meditation helps disengage from rumination by redirecting awareness to the present body and activating interoceptive processing [41]. In this program, body-scan and breath-focused meditations enhanced participants' interoceptive awareness, helping them notice their breathing patterns, bodily reactions during activities, and the thoughts and emotions arising in their minds. Through nonjudgmental observation, participants experienced decentering, which enabled them to view their situations from a distance, thereby reducing rumination and perceived pain.

In addition, lectures and cognitive-behavioral activities addressing emotions and physical symptoms related to treatment side effects provided opportunities to learn coping strategies and methods for engaging with these symptoms. By increasing bodily awareness and practicing mindful engagement during activities, participants reported decreased fatigue and pain. These observations suggest that, in addition to mindfulness practice itself, learning management strategies tailored to PH-related side effects and adaptive coping methods may contribute to reducing treatment-related discomfort and improving activity tolerance.

Breathing was a key element of mindfulness meditation. Before the study, there was concern that focusing on breathing might exacerbate dyspnea in PH patients. Contrary to expectations, meditation focusing on breathing appeared to lessen perceived breathlessness. For individuals experiencing daily dyspnea, increasing awareness of breathing helped them recognize shallow breathing patterns and intentionally breathe more deeply and slowly, which may have contributed to reduced shortness of breath during exertion.

Furthermore, improvements in self-compassion, well-being, and positive emotions were observed after program participation. Many PH patients tend to blame themselves, thinking, “If only I had sought treatment earlier,” or “I became sick because I was weak.” Mindfulness may have helped reduce self-critical thinking by fostering objective awareness of mental states and thought patterns, encouraging nonjudgmental observation, and supporting more positive self-recognition. Overall, these findings suggest that the program may have a favorable influence on mental health and emotional well-being, though further investigation in larger, controlled studies is needed.

Comparison With Previous Work

Changes observed in QOL, depression, anxiety, and resilience scores suggest that the intervention may have the potential to support improvements in psychological well-being. However, immediate effects on rapidly worsening physical symptoms should not be expected. In this study, standardized self-administered questionnaires were conducted at four time points (baseline, week 4, week 8, and week 12). Because this was a feasibility study with a small sample size and a low response rate at week 12, statistical analyses across all time points were limited. Analyses of the first three time points (baseline, week 4, and week 8) indicated preliminary improvements in QOL, with several participants demonstrating downward trends in depression and anxiety scores. While these findings are not sufficient to determine efficacy, they suggest possible patterns of change that merit further investigation in future controlled trials.

Previous studies of mindfulness-based interventions in cardiovascular populations provide context for interpreting these findings. A randomized controlled trial (The Stress Reduction, Meditation, and Mindfulness Program) targeting patients with chronic heart failure reported reductions in perceived stress and improvements in clinical outcomes [26]. Similarly, a meta-analysis of randomized controlled trials in patients with coronary artery disease demonstrated significant reductions in depression, anxiety, and stress following mindfulness-based interventions [25]. Although the present study focused on patients with PH, the observed trends—increased emotional regulation, decreased rumination, and enhanced self-compassion—are consistent with mechanisms reported in these previous studies.

The mean CD-RISC score in this sample was lower than that reported in patients with cancer (29.3) [42] or multiple sclerosis (26.8) [43], suggesting relatively low baseline resilience in participants. While the small sample size limits interpretation, the observed changes in resilience scores suggest that mindfulness-based programs may hold potential for supporting resilience in PH populations. These preliminary findings align with previous literature indicating that mindfulness practice may contribute to improvements in adaptive coping and emotional well-being across diverse chronic illness populations.

Limitations

This study has several limitations that should be acknowledged.

First, as a single-arm feasibility study, it did not include a control group. Without a comparison to usual care or another intervention, it is difficult to determine whether the observed improvements in quality of life or psychological measures were attributable to the program itself or to other factors, such as natural adaptation or social interaction with facilitators. To mitigate this, standardized self-report measures were used at multiple time points to examine within-participant changes. Future studies should include a randomized controlled design to allow more robust evaluation of efficacy.

Second, the sample size was small, which limits the statistical power and generalizability of the findings. Because of the limited number of participants, subgroup analyses could not be performed, and some trends may have gone undetected. Nevertheless, the study provided valuable preliminary data on feasibility and participant experiences, which will help inform sample size estimation and stratification criteria for future trials.

Third, the study duration was relatively short, and no long-term follow-up was conducted. Consequently, it remains unclear whether the improvements observed immediately after the intervention can be sustained over time. Future studies should incorporate follow-up assessments to examine the persistence of psychological and physical benefits and to identify factors that influence continued engagement with mindfulness practice.

Fourth, response rates for the postprogram and 4-week follow-up questionnaires were low, possibly because of the paper-based mailing method, which may have introduced response bias. Participants who continued responding may have been those more motivated or satisfied with the program. To improve response rates and minimize bias, future research should use web-based data collection methods to facilitate participation and reduce the burden on patients with PH.

Future Directions

Based on these findings, several future directions for research and program development can be proposed. First, future studies should conduct randomized controlled trials with larger and more diverse samples to verify the program’s efficacy and assess its long-term impact. Longitudinal follow-up is necessary to

evaluate whether the psychological and physical benefits observed in this feasibility study can be sustained over time. Multisite or decentralized clinical trial designs may also facilitate participation among patients with PH who face difficulties traveling to research facilities.

Second, refinement of the program content is warranted. Adjustments to session frequency and duration, as well as partial incorporation of on-demand components, may help reduce participant burden and improve accessibility. Developing a group-based version of the program could further enhance social connectedness and scalability.

Third, to promote broader dissemination and generalization of mindfulness-based interventions, it will be important to develop and implement educational programs that train cardiovascular health care professionals to practice and facilitate mindfulness. Increasing the number of qualified practitioners is expected to contribute to the sustainable delivery and expansion of such programs in clinical and community settings. In addition, future efforts should focus on expanding the availability of mobile apps across different digital platforms and, ultimately, adapting and implementing the program in international settings. Such developments may facilitate broader accessibility and cross-cultural validation of mindfulness-based interventions for patients with chronic cardiopulmonary diseases.

Conclusions

This feasibility study suggests that an online mindfulness-based self-management program may help patients with pulmonary hypertension engage more effectively with symptoms, treatment-related side effects, and emotional distress. Participants reported preliminary improvements in perceived pain and aspects of quality of life, indicating potential psychological benefits. Further refinement of the program and evaluation in larger randomized controlled trials are needed to determine its efficacy and long-term impact.

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Data Availability

The raw data analyzed qualitatively will not be disclosed to maintain the confidentiality of the responses, but the quantitatively analyzed datasets may be provided by the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: YT (lead), DF (equal), SP (equal)
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Formal analysis: YT (lead), JM (equal)
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Supervision: DF (lead), SP (equal)
Validation: YT (lead), SP (equal), AG (equal), JM (supporting), DF (supporting)
Visualization: YT (lead), SP (supporting), JM (supporting), DF (supporting)
Writing – original draft: YT
Writing – review & editing: DF (lead), TK (supporting), MK (supporting)

Conflicts of Interest

TI receives lecture fees from MSD and Bayer outside the submitted work. YT receives lecture fees from MSD and Mochida Pharmaceutical and serves as an advisor for an international meeting organized by MSD, outside the submitted work. The other authors declare no conflicts.

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Abbreviations

CD-RISC: Connor-Davidson Resilience Scale
GAD-7: Generalized Anxiety Disorder 7-item scale
MBCT: mindfulness-based cognitive therapy
MBSR: mindfulness-based stress reduction
PAH: pulmonary arterial hypertension

PH: pulmonary hypertension
PHQ-9: Patient Health Questionnaire-9
QOL: quality of life

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Machine Learning Models for Mortality Prediction in Intensive Care Unit Patients With Ischemic Stroke Associated With Intracranial Artery Stenosis: Retrospective Cohort Study

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Abstract

Background: Mortality prediction in intensive care unit (ICU) patients with ischemic stroke complicated by intracranial artery stenosis or occlusion remains difficult. Conventional scoring systems often lack discriminatory power and fail to provide individualized risk estimates. Machine learning approaches have been increasingly explored to integrate diverse clinical features for prognostic modeling.

Objective: This study aims to develop and evaluate machine learning models for individualized mortality prediction in ICU patients with ischemic stroke associated with intracranial artery stenosis or occlusion.

Methods: Using the Medical Information Mart for Intensive Care IV (MIMIC-IV) database, we conducted a retrospective cohort study including 5280 adult ICU patients identified through *International Classification of Diseases, Ninth and Tenth Revision* (*ICD-9/10*) codes. Mortality status was determined based on the presence of a recorded date of death (dod) in the MIMIC-IV database. Patients with a documented dod were classified as deceased, whereas those without a recorded dod were classified as nondeceased. The primary outcome was all-cause mortality as recorded in the MIMIC-IV database, defined by the presence of a documented dod. Patients were randomly split into training (n=3696, 70%) and testing (n=1584, 30%) cohorts. Missing value imputation, correlation reduction, and multistep supervised feature selection (gradient boosting, BorutaShap, recursive feature elimination with cross-validation, LassoCV, and chi-square analysis) were performed exclusively within the training set and subsequently applied to the test set, resulting in 35 retained predictive features. Eight machine learning models—including light gradient boosting machine (LightGBM), Bagging (bootstrap aggregating), random forest, logistic regression, support vector machine, gradient boosting, adaptive boosting, and k-nearest neighbors—were trained with hyperparameter optimization using RandomizedSearchCV. Model performance was evaluated using area under the curve, accuracy, recall, precision, F_1-score, and calibration curves. Shapley additive explanations were used for global and individual-level interpretability.

Results: LightGBM, Bagging, and logistic regression demonstrated comparable discrimination, achieving an area under the curve of approximately 0.82 - 0.83 and accuracy above 73% on the independent test set. LightGBM demonstrated balanced performance (recall 0.70; precision 0.72) and good calibration. Shapley additive explanations analysis identified acute physiology score III, suspected infection, Charlson comorbidity index, age, weight on admission, and red cell distribution width as the most influential predictors. Overall, higher physiological severity, greater comorbidity burden, and older age were consistently associated with increased observed mortality risk.

Conclusions: Machine learning models—including LightGBM and Bagging—provide interpretable predictions of all-cause mortality in ICU patients with ischemic stroke and intracranial arterial disease. These models highlight key prognostic features and may support mortality risk stratification. External validation and evaluation of workflow integration are warranted before clinical implementation.

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KEYWORDS

ischemic stroke; intracranial arterial stenosis; critical care; machine learning; mortality prediction; explainable artificial intelligence; intensive care unit; ICU outcomes

Introduction

Cerebrovascular diseases, particularly those associated with intracranial artery stenosis or occlusion, are major contributors to morbidity and mortality among critically ill patients [1]. In the intensive care unit (ICU), these conditions often lead to acute neurological deterioration, secondary complications, and poor clinical outcomes, posing significant management challenges. Despite the widespread use of traditional clinical scoring systems, accurate and individualized mortality prediction remains difficult.

Recent advances in machine learning (ML) offer promising approaches to address this challenge [2]. ML algorithms can process large-scale, high-dimensional clinical data to detect complex, nonlinear relationships that conventional methods may overlook [3]. Such tools have shown potential in critical care settings, particularly for mortality prediction, risk stratification, and outcome modeling in severe illnesses including stroke and sepsis.

The Medical Information Mart for Intensive Care IV (MIMIC-IV) database [4] is a publicly accessible ICU dataset containing detailed records of over 350,000 ICU admissions, including demographics, diagnoses, physiological measurements, laboratory tests, and treatments. This rich resource facilitates the development of robust, data-driven predictive models [5].

In this study, we leveraged the MIMIC-IV database to develop and evaluate ML models for predicting in-hospital and post-discharge mortality in ICU patients diagnosed with ischemic stroke associated with intracranial artery stenosis or occlusion. We used advanced feature selection techniques—including gradient boosting classifier, BorutaShap, recursive feature elimination with cross-validation (RFECV), and LassoCV—to optimize the input variables [6]. Additionally, Shapley additive explanations (SHAPs) were integrated to enhance model interpretability and transparency, providing insight into the contribution of each feature to individual predictions [7].

Although several ML-based models have been developed for predicting outcomes in patients with ischemic stroke [8-10], most existing studies have focused on general stroke cohorts or emergency department populations and have rarely examined critically ill patients with intracranial artery stenosis or occlusion. Moreover, prior models typically target in-hospital mortality alone, rely on limited variable sets, or lack transparent feature-interpretation methods. In contrast, our study incorporates a large and granular ICU cohort from the MIMIC-IV database, applies a multistep feature selection pipeline, evaluates multiple ML algorithms under a unified framework, and uses SHAP to provide clinically interpretable insights. By including both in-hospital and postdischarge deaths recorded in the database, our model provides a pragmatic assessment of observed all-cause mortality risk in ICU patients, reflecting real-world outcome documentation in large critical care registries.

Our aim was to establish an interpretable and high-performing prognostic model to support timely and informed clinical decision-making for ICU patients with ischemic stroke. The following sections describe our methodology, present the results, and discuss the clinical implications and future research directions.

Methods

Study Design and Data Source

This retrospective cohort study was conducted using the publicly available MIMIC-IV database, which contains detailed clinical data from over 350,000 ICU admissions at the Beth Israel Deaconess Medical Center between 2008 and 2019. The database includes a comprehensive range of variables, such as demographic characteristics, vital signs, laboratory results, diagnoses, medications, and procedures.

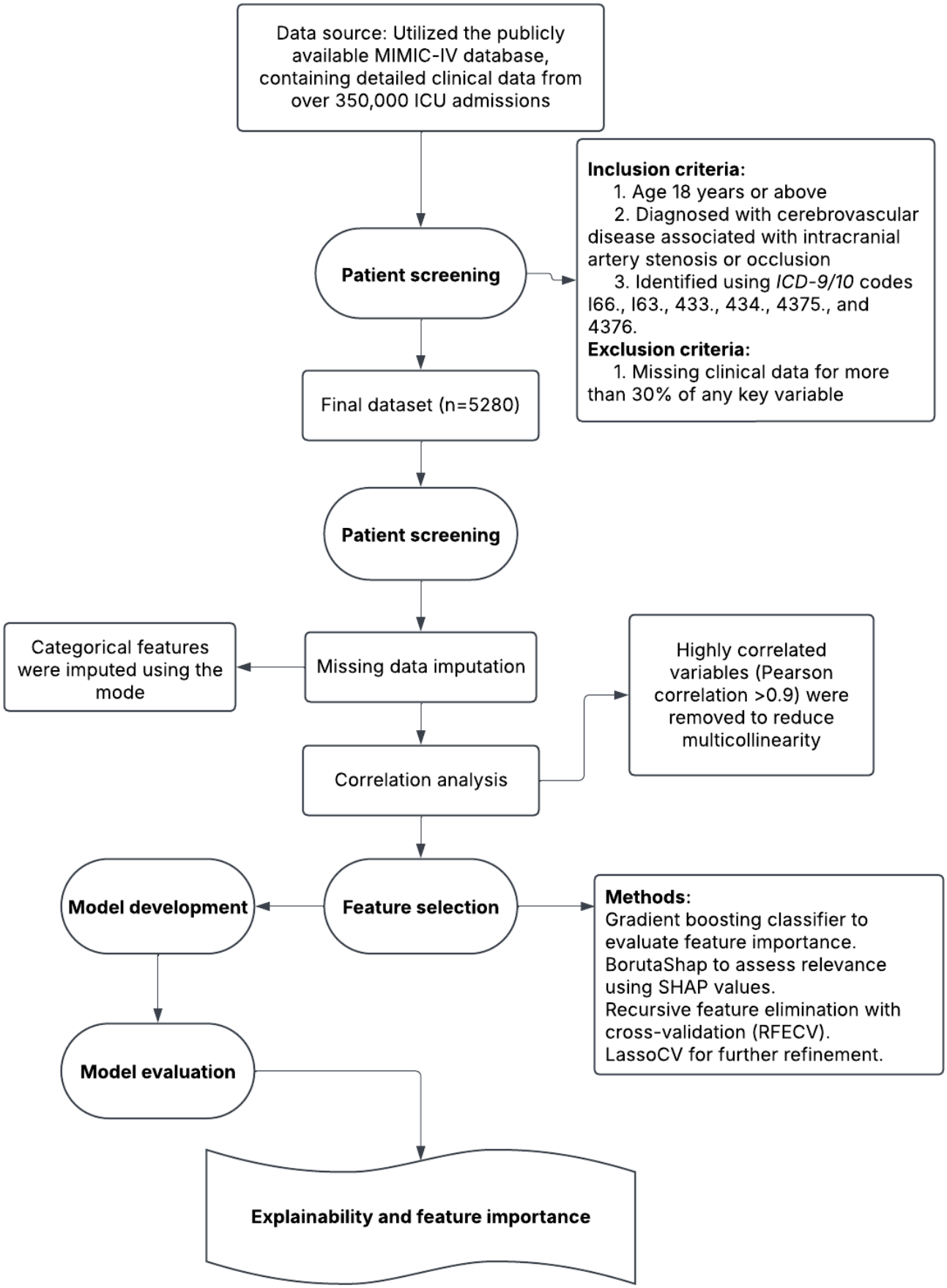
Mortality outcomes were ascertained using the publicly available MIMIC-IV database (version 3.1; released on October 11, 2024). Mortality status was determined based on the presence of a recorded date of death (dod) in the database. Patients with a documented dod were classified as deceased, whereas patients without a recorded dod were classified as alive. This definition captures all-cause in-hospital mortality as well as postdischarge mortality when documented in MIMIC-IV. The primary outcome was all-cause mortality, defined by the presence of a recorded dod in the MIMIC-IV database. Patients with a documented dod were classified as deceased, whereas those without a recorded dod were classified as nondeceased. No additional time-window restriction was applied.

This study focused on adult ICU patients diagnosed with ischemic stroke associated with intracranial artery stenosis or occlusion. Patients were identified using *International Classification of Diseases, Ninth and Tenth Revision* (*ICD-9/10*) codes corresponding to cerebrovascular pathology, specifically: I66., I630-I637, 433., 434.*, 437.5, and 437.6. Because cohort selection was not restricted to the principal diagnosis, the study population included critically ill patients in whom ischemic stroke may have been either the primary diagnosis or a significant comorbid condition.

A total of 8437 patient records were initially identified with relevant cerebrovascular diagnoses. To ensure data integrity and minimize redundancy, only the first ICU admission for each patient was considered. After excluding individuals with multiple admissions or incomplete records, the final study cohort comprised 5280 patients aged 18 years or older.

The primary outcome was all-cause mortality, defined by the presence of a recorded dod in the MIMIC-IV database. The patient selection process is illustrated in Figure 1.

Figure 1. Flowchart of the study design and methodology. *ICD-9/10*: *International Classification of Diseases, Ninth and Tenth Revision*; ICU: intensive care unit; MIMIC-IV: Medical Information Mart for Intensive Care IV; SHAP: Shapley additive explanations.



Inclusion and Exclusion Criteria

Patients were included if they met the following criteria: (1) aged 18 years or older; (2) diagnosed with ischemic stroke associated with intracranial artery stenosis or occlusion, identified using *ICD-9/10* codes from MIMIC-IV, including I66., I630-I637, 433., 434., 437.5, and 437.6; and (3) had documented mortality status based on the presence or absence of a recorded dod in the MIMIC-IV database. From all 364,627 patients in MIMIC-IV, a total of 8437 hospitalization records fulfilled the cerebrovascular diagnostic criteria. For patients with multiple admissions, only the first ICU admission was retained to avoid duplication, resulting in a final cohort of 5280 adult ICU patients.

Outcome Definition

The primary outcome was observed all-cause mortality, defined by the presence of a recorded dod in the MIMIC-IV database. This outcome reflects mortality events documented during hospitalization and after discharge when available. The absence of a recorded dod was interpreted as survival within the observation window. This definition was applied consistently across the entire cohort and all modeling stages.

Variables and Features

A comprehensive set of variables was included, comprising:

- Demographic variables: age, sex, height, and weight.
- Clinical parameters: vital signs (eg, heart rate, blood pressure, respiratory rate), laboratory findings (eg, hemoglobin, white blood cell count, glucose, calcium, creatinine).
- Scoring systems: sequential organ failure assessment, acute physiology and chronic health evaluation III (APS-III), and Glasgow Coma Scale.
- Clinical history: Clinical history variables included the Charlson comorbidity index, presence of malignancy, suspected infection (defined algorithmically based on antibiotic administration and body fluid culture collection), use of mechanical ventilation, and pharmacological treatments (eg, anticoagulants and antihypertensive agents).

To ensure adequate data quality, any variable with more than 30% missing values was excluded from further analysis. This criterion was applied to variables only, and no patients were excluded based on this step. Following preprocessing, 151 features were retained for further analysis. To ensure early risk stratification and avoid look-ahead bias, all predictive features were extracted exclusively from the early phase of ICU admission. Demographic characteristics were obtained at baseline, and all laboratory variables were defined as the first available measurement after ICU admission. Physiological parameters, clinical scores, and treatment-related indicators (including mechanical ventilation status and suspected infection) were derived from data recorded within the first 24 hours following ICU admission. No information collected beyond this predefined early time window was used for feature construction, model training, or prediction.

Data Preprocessing and Feature Selection

To minimize the risk of data leakage, all preprocessing and feature selection procedures were conducted strictly within the training data only.

The dataset was first randomly split into a training set (n=3696, 70%) and an independent testing set (n=1584, 30%). Missing data imputation was performed by fitting the imputation strategy exclusively on the training set. Continuous variables were imputed using the median values derived from the training data to reduce the influence of outliers, while categorical variables were imputed using the mode. The fitted imputation parameters were then applied unchanged to the testing set.

To reduce multicollinearity, Pearson correlation analysis was conducted within the training set. Features with a correlation coefficient greater than 0.9 were excluded, including variables such as “dbp,” “hematocrit,” “rbc,” and “mechvent_score.” The same feature exclusion rules were subsequently applied to the testing set.

Feature selection was performed using a multistep strategy applied exclusively to the training data. This process included (1) gradient boosting classifier–based feature importance ranking; (2) BorutaShap, which integrates SHAP values with the Boruta algorithm for robust supervised feature selection; (3) RFECV; (4) LassoCV for regularization-based feature shrinkage; and (5) chi-square tests to assess statistical associations (P<.05).

To enhance robustness and reduce method-specific bias, a consensus feature selection strategy was adopted. Only features consistently selected across multiple methods were retained. This approach resulted in the identification of 35 predictive features with the highest and most stable importance, including “inr_max,” “calcium,” “spo2,” “oasis_x,” “suspected_infection,” and “anchor_age.” The final selected feature set was fixed after training and applied unchanged to the independent testing set.

Validation Strategy

In addition to the conventional random split, we performed a temporal validation to assess model generalizability across different calendar periods and to minimize potential information leakage due to long study duration. Specifically, patients were grouped according to the MIMIC-IV anchor_year_group variable. Admissions from earlier calendar periods were used for model training, while more recent admissions were reserved for testing. This temporal split mimics a real-world deployment scenario, in which models trained on historical data are applied to future patients. All preprocessing steps, feature selection procedures, and hyperparameter tuning were performed exclusively within the temporally defined training set, and the finalized models were evaluated on the temporally independent test set using the same performance metrics as in the random split analysis.

Model Development and Hyperparameter Optimization

The training set was used exclusively for model development and hyperparameter tuning, while the testing set was reserved for final performance evaluation. Prior to model training, feature

standardization was performed using *z*-score normalization, with scaling parameters estimated from the training data and subsequently applied to the testing data.

Multiple ML classifiers were trained, including light gradient boosting machine (LightGBM), Bagging (bootstrap aggregating), k-nearest neighbors, logistic regression, support vector machine (SVM), random forest, adaptive boosting (AdaBoost), and gradient boosting.

Hyperparameter optimization for each model was conducted using RandomizedSearchCV within the training set, using cross-validation to identify optimal parameter combinations. This training-only optimization strategy ensured that no information from the testing data influenced model selection or tuning. All cross-validation procedures were conducted exclusively within the training set.

Model performance was evaluated using several metrics, including:

- F_1-score: The harmonic mean of precision and recall.
- Precision: The proportion of predicted positives that were positive.
- Recall: The proportion of actual positives that were correctly identified.
- Area under the receiver operating characteristic curve (ROC AUC): A performance measurement for classification problems at various threshold settings.
- Accuracy: The proportion of correctly classified instances.

The performance of each model was visualized through ROC curves to assess classification ability. Confusion matrices were also generated to assess the number of true positives, false positives, true negatives, and false negatives for each model. Calibration performance was assessed using both calibration curves and quantitative metrics, including the Brier score, calibration slope, and calibration intercept, to provide a comprehensive evaluation of the reliability of predicted probabilities.

Decision Curve Analysis

To evaluate the clinical utility and net benefit of the predictive models, we performed decision curve analysis (DCA). DCA quantifies the net benefit of using a model to guide clinical decisions across a range of threshold probabilities, which reflects the trade-off that clinicians and patients are willing to make between the benefits of a true positive and the harms of a false positive. The net benefit was calculated for our top-performing models (LightGBM, Bagging, extreme gradient boosting (XGBoost), random forest, and AdaBoost) and compared against 2 default strategies: “treat all” (assuming all patients are classified as high risk) and “treat none” (assuming no patients will die). A model with a higher net benefit across a range of thresholds is considered to have greater clinical utility.

Model Interpretability

To interpret model predictions, we applied SHAP, which quantifies the contribution of each feature to individual predictions. SHAP summary and scatter plots were generated for the best-performing model, LightGBM, offering visual insights into key mortality predictors.

Statistical Analysis

Chi-square tests were used to determine associations between categorical features and mortality, with a significance level of $P<.05$. The Kolmogorov-Smirnov test was applied to compare the distribution of continuous features between survival and mortality groups.

Ethical Considerations

This study used the data from the publicly available and fully deidentified MIMIC-IV database. Because the dataset contains no identifiable private information and all patient data are anonymized, this retrospective analysis is exempt from institutional review board approval. The use of MIMIC-IV data complies with all relevant ethical guidelines and the data use agreement required for access to the database. No direct patient contact or intervention occurred, and therefore informed consent was not required.

Results

Patient Characteristics

A total of 5280 ICU patients diagnosed with cerebrovascular disease and intracranial artery stenosis or occlusion were included. The cohort had a mean age of 69.1 years (SD 14.6), and 52.4% (n=2765) were male. Table 1 summarizes key demographic, clinical, and laboratory characteristics.

Table . Demographic, clinical, and laboratory characteristics stratified by mortality status (recorded death date vs no recorded death date)[a].

	Total (N=5280)	No recorded date of death (n=2952)	Recorded date of death (n=2328)	*P* value
Demographic characteristics				
Age (y), mean (SD)	69.09 (14.61)	66.09 (14.92)	72.89 (13.26)	<.001
Male, n (%)	2765 (52.4)	1178 (50.6)	1587 (53.8)	.02
Female, n (%)	2515 (47.6)	1150 (49.4)	1365 (46.2)	.02
Race or ethnicity, n (%)				
White	3495 (66.2)	1973 (66.8)	1522 (65.4)	—[b]
Black	533 (10.1)	264 (8.9)	269 (11.6)	—
Hispanic or Latino	156 (3)	95 (3.2)	61 (2.6)	—
Asian	144 (2.7)	82 (2.8)	62 (2.7)	—
Other or unknown	952 (18)	538 (18.2)	414 (17.8)	—
Comorbidities				
Hypertension, n (%)	1655 (31.3)	959 (32.5)	696 (29.9)	.05
Diabetes mellitus, n (%)	1799 (34)	874 (29.6)	925 (39.7)	<.001
Dyslipidemia, n (%)	1964 (37.2)	797 (34.2)	1167 (39.5)	<.001
Suspected infection, n (%)	3874 (73.4)	1876 (63.6)	1998 (85.8)	<.001
Dementia, n (%)	251 (4.8)	79 (2.7)	172 (7.4)	<.001
Malignant cancer, n (%)	438 (8.3)	118 (4)	365 (15.7)	<.001
Charlson comorbidity index, median (IQR)	6 (4-8)	5 (3-7)	7 (5-9)	<.001
Laboratory parameters				
LDL-C[c] (mg/dL), mean (SD)	85.8 (33.2)	88.6 (34.2)	82.3 (31.5)	<.001
Triglycerides (mmol/L), mean (SD)	131.3 (128.8)	130.0 (117.7)	133.0 (141.5)	.12
Blood glucose (mg/dL), mean (SD)	134.1 (60.2)	127.6 (53.0)	142.3 (67.5)	<.001
RDW[d]	14.8 (2.1)	14.4 (1.9)	15.4 (2.3)	<.001
BUN[e]	24.8 (18.5)	20.5 (13.6)	30.3 (22.1)	<.001
Clinical scores				
SOFA[f] score, mean (SD)	1.5 (1.9)	1.3 (1.8)	1.8 (2.1)	<.001
APS-III[g] score, mean (SD)	42.7 (19.9)	36.6 (16.1)	50.4 (21.4)	<.001
SAPS-II[h], mean (SD)	36.4 (13.2)	32.1 (11.3)	41.8 (13.4)	<.001
GCS[i], mean (SD)	13.8 (2.2)	14.2 (2.0)	13.7 (2.5)	<.001
In-hospital mortality				
Mortality, n (%)	669 (12.7)	0 (0)	669 (28.7)	<.001

[a]Race or ethnicity was reported as recorded in the electronic health record and aggregated for descriptive purposes only.

[b]Not available.

[c]LDL-C: low-density lipoprotein cholesterol.

[d]RDW: red cell distribution width.

[e]BUN: blood urea nitrogen.

[f]SOFA: sequential organ failure assessment.

[g]APS-III: acute physiology and chronic health evaluation III.

[h]SAPS II: Simplified Acute Physiology Score II.

[i]GCS: Glasgow Coma Scale.

The most common comorbidities were hypertension (n=1655, 31.3%), diabetes mellitus (n=1799, 34%), and dyslipidemia (n=1964, 37.2%). Based on the MIMIC-IV recorded dod, 2328 (44.1%) patients were classified as deceased, while 2952 (55.9%) patients had no recorded dod and were classified as nondeceased. The in-hospital mortality rate was 12.7% (n=669), representing a subset of deaths captured by the recorded dod in the MIMIC-IV database.

Compared with patients classified as nondeceased, those classified as deceased were significantly older (mean age: 72.9, SD 13.3 y vs mean age: 66.1, SD 14.9 y; P<.001) and had higher Charlson comorbidity index scores (median 7, IQR 5-9 vs median 5, IQR 3-7; P<.001). They also had higher incidences of suspected infection (1998/2328, 85.8% vs 1876/2952, 63.6%; P<.001) and dementia (172/2328, 7.4% vs 79/2952, 2.7%; P<.001). Group differences were observed for laboratory variables such as low-density lipoprotein cholesterol and red cell distribution width (both P<.001), whereas triglycerides did not differ significantly (P=.12).

Feature Selection

Following imputation and correlation filtering, 107 features were included. After applying the feature selection pipeline (gradient boosting, BorutaShap, RFECV, LassoCV, and Chi-square testing), 35 features were consistently identified as significant. These features were retained for model development. The full list of selected features is available in Multimedia Appendix 1.

Model Performance

Eleven ML classifiers were trained and evaluated using the selected features. Table 2 presents the performance metrics, and Figure 2 illustrates ROC curves for each model.

Table . Performance metrics of machine learning models.

Classifier	Accuracy	ROC AUC[a]	Recall	Precision	F_1-score
Logistic regression	74.18	0.82	0.65	0.73	0.69
SVM[b]	74.31	0.82	0.66	0.73	0.69
KNN[c]	72.29	0.82	0.51	0.78	0.62
Decision tree	69.70	0.75	0.67	0.65	0.66
Random forest	72.92	0.82	0.66	0.70	0.68
AdaBoost	74.12	0.82	0.67	0.72	0.69
Gradient boosting	73.30	0.81	0.65	0.72	0.68
XGBoost[d]	73.42	0.82	0.68	0.70	0.69
LightGBM[e]	74.87	0.82	0.70	0.72	0.71
Bagging	73.93	0.82	0.72	0.70	0.71
Voting	72.98	0.83	0.61	0.73	0.66

[a]ROC AUC: area under the receiver operating characteristic curve.

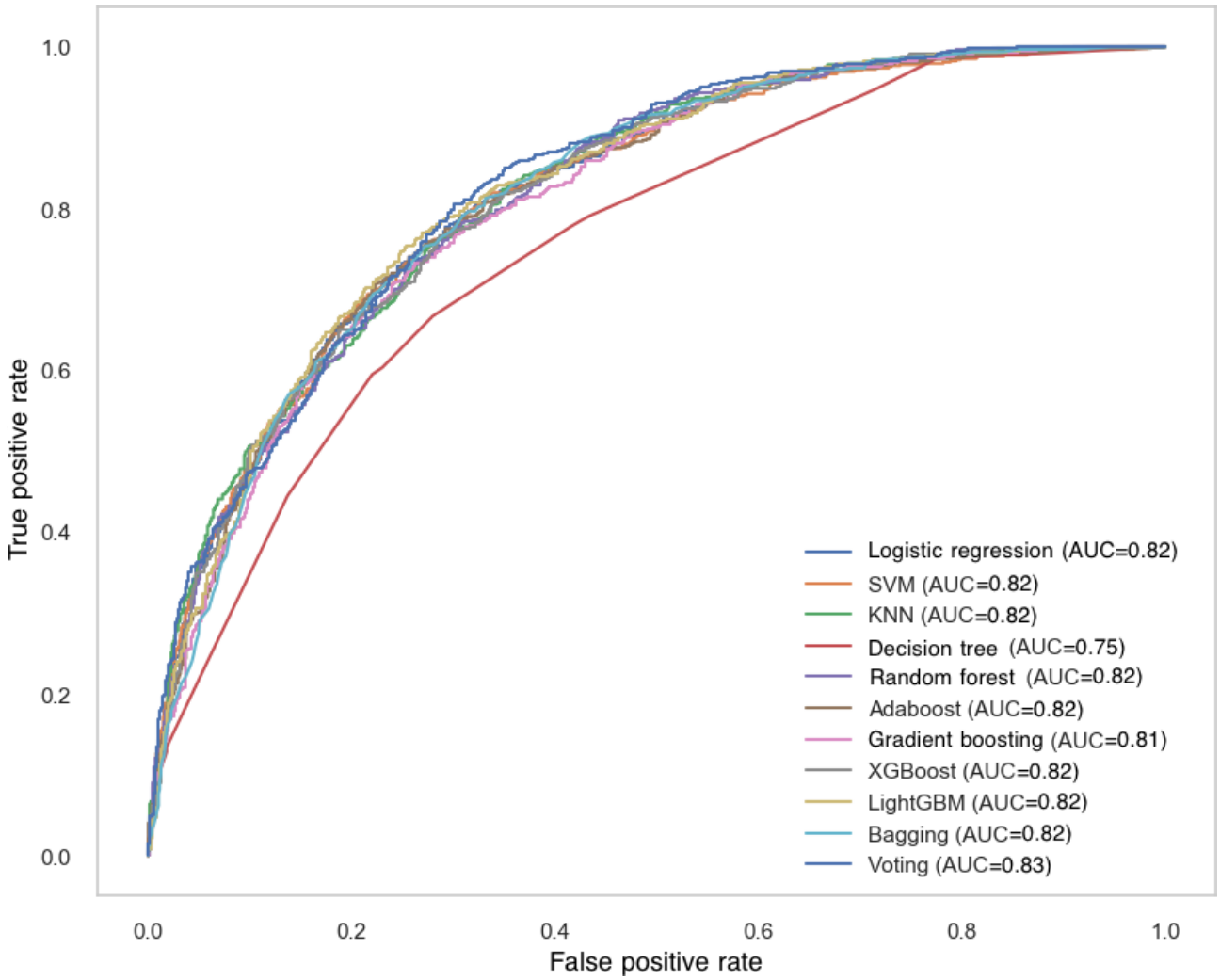
[b]SVM: support vector machine.

[c]KNN: k-nearest neighbors.

[d]XGBoost: extreme gradient boosting.

[e]LightGBM: light gradient boosting machine.

Figure 2. Receiver operating characteristic (ROC) curves and area under the curve (AUC) values for various classification models in predicting mortality outcomes in intensive care unit (ICU) patients with cerebrovascular diseases. KNN: k-nearest neighbors; LightGBM: light gradient boosting machine; SVM: support vector machine.



LightGBM demonstrated strong overall performance, achieving an accuracy of 74.87% and an ROC AUC of 0.82, a recall of 0.70, a precision of 0.72, and an F_1-score of 0.71. This model demonstrated robust performance across all evaluation metrics and was highly effective in discriminating between classes and minimizing false positives.

Bagging performed similarly to LightGBM, with an accuracy of 73.93%, ROC AUC of 0.82, recall of 0.72, precision of 0.70, and an F_1-score of 0.71. It also provided balanced performance but with slightly lower precision compared to LightGBM.

XGBoost and AdaBoost showed competitive performance with an accuracy of around 73.5%, both achieving an ROC AUC of 0.82. XGBoost had a recall of 0.68 and F_1-score of 0.69, while AdaBoost exhibited a slightly higher recall of 0.67 but a slightly lower precision (0.72) compared to XGBoost.

SVM and random forest both showed promising performance, with accuracy values of 74.31% and 72.92%, respectively. These models also achieved similar ROC AUC scores of 0.82, with SVM yielding a slightly higher recall of 0.66 compared to random forest (0.66). Both models displayed well-balanced performance, with SVM achieving the highest recall.

Logistic regression, a widely used baseline model for binary classification, achieved an accuracy of 74.18%, an ROC AUC of 0.82, and a recall of 0.65, demonstrating discriminative performance comparable to that of ensemble-based models such as LightGBM and Bagging.

K-nearest neighbors performed well in terms of ROC AUC (0.82) but had a relatively lower recall of 0.51, which affected its F_1-score (0.62). This highlights its ability to discriminate classes well but with a tendency to miss true positive cases.

Decision tree performed the worst, with an accuracy of 69.70%, an ROC AUC of 0.75, and relatively low precision (0.65) and recall (0.67), making it less suitable for this classification task when compared to other models.

After restructuring the experimental pipeline to ensure that imputation and feature selection were performed exclusively on the training data, model performance remained largely stable. The LightGBM model achieved an ROC AUC of 0.81 on the independent test set, indicating that the original performance estimates were not substantially inflated by data leakage.

In summary, ensemble models—particularly LightGBM and Bagging—demonstrated the best balance between sensitivity and specificity.

Temporal Validation Analysis

To further evaluate the robustness and temporal generalizability of the proposed models, we conducted a temporal validation using anchor_year_group to separate training and testing cohorts. Models trained on earlier admission years and tested on later years demonstrated stable discriminative performance. The LightGBM model achieved an AUC of 0.85, with an accuracy of 0.78, recall of 0.75, and F_1-score of 0.71. Logistic regression showed comparable performance (AUC=0.85), while the Bagging model demonstrated slightly lower discrimination (AUC=0.84). These results suggested that model discrimination remained stable when applied to temporally independent data; however, performance estimates in the temporal test set should be interpreted with caution due to potential under-ascertainment of out-of-hospital mortality in more recent calendar years of the MIMIC-IV database.

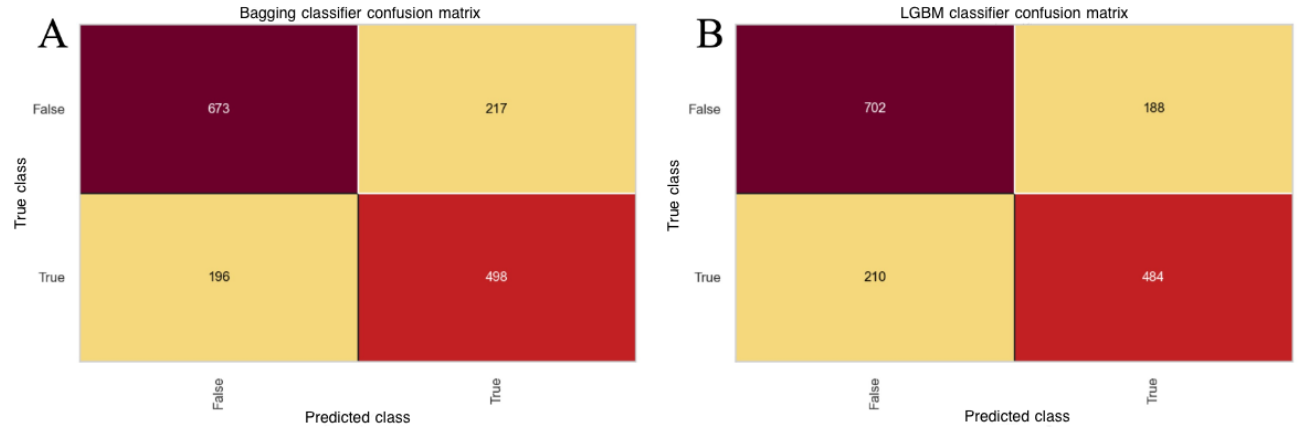
Performance Comparison With Conventional ICU Severity Scores

When evaluated as standalone predictors on the independent test set, conventional ICU severity scores demonstrated moderate discrimination. Simplified Acute Physiology Score II (SAPS-II) achieved the highest performance among traditional scores (ROC AUC=0.73; accuracy=0.65), followed by APS-III (ROC AUC=0.72; accuracy=0.66), Oxford Acute Severity of Illness Score (ROC AUC=0.66), and Logistic Organ Dysfunction System (ROC AUC=0.66). In comparison with these rule-based ICU severity scores, the LightGBM model demonstrated higher discrimination on the same test set (ROC AUC=0.83; accuracy=0.75). DeLong testing confirmed that LightGBM significantly outperformed APS-III as a standalone predictor (ΔAUC=0.12, P<.001), indicating meaningful incremental prognostic value beyond conventional ICU severity scoring systems. Notably, when compared with a fully specified multivariable logistic regression model trained on the same feature set, LightGBM showed comparable discriminative performance, highlighting that both linear and nonlinear modeling approaches can achieve similar discrimination in this setting. The added value of ensemble ML models was primarily reflected in calibration performance, DCA, and the ability to capture complex feature interactions. Importantly, this comparable performance persisted under temporal validation, indicating that both linear and nonlinear models maintained stable discrimination when applied to future patient cohorts.

Confusion Matrix and Calibration Curve

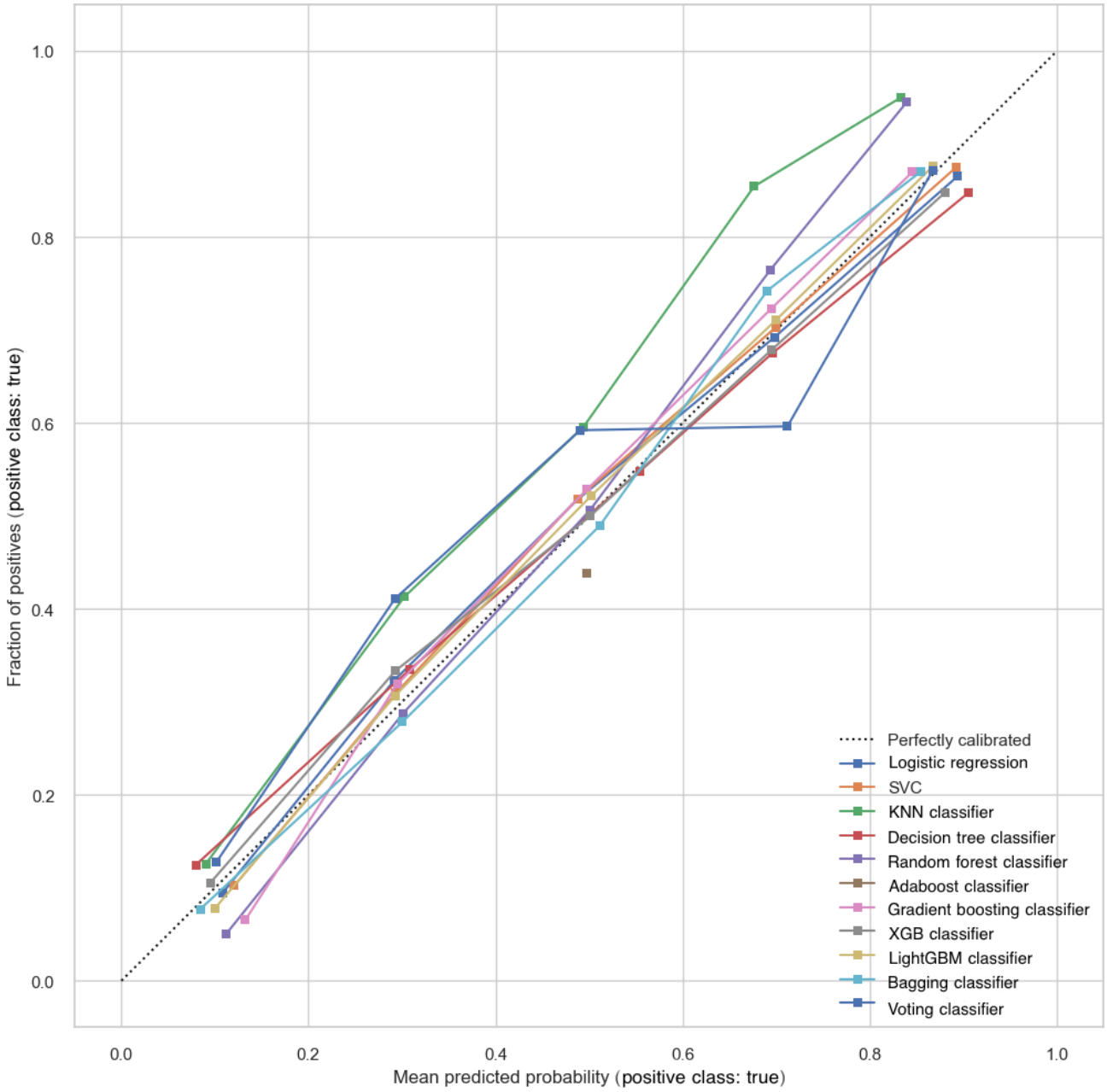
The confusion matrix for the top-performing models (LightGBM and Bagging) demonstrated high accuracy in predicting both positive (mortality) and negative (survival) outcomes (Figure 3). Bagging exhibited a strong balance between sensitivity and specificity, with a true positive rate of 0.72 and a true negative rate of 0.76.

Figure 3. Confusion matrices for the Bagging and light gradient boosting machine (LightGBM) classifier models in predicting mortality outcomes in intensive care unit (ICU) patients with cerebrovascular diseases. (**A**) Confusion matrix for the Bagging classifier model. (**B**) Confusion matrix for the LightGBM classifier model. In the confusion matrices, darker red cells indicate higher counts, whereas lighter yellow cells indicate lower counts.



Calibration curves (Figure 4) were plotted to evaluate the agreement between predicted and observed mortality risk. Both LightGBM and Bagging demonstrated good calibration, with predicted probabilities closely aligning with actual outcomes across the full risk spectrum. To complement the visual assessment, quantitative calibration metrics were also computed. LightGBM achieved the lowest Brier score (0.171), indicating the best overall probability accuracy, and showed a calibration slope close to 1 (1.14) with a small intercept (0.057), suggesting minimal systematic over- or underestimation. Bagging also demonstrated strong performance with a low Brier score (0.174), a calibration slope of 1.12, and an intercept of 0.021. Together, these results indicate that LightGBM and Bagging provided well-calibrated and reliable mortality risk predictions.

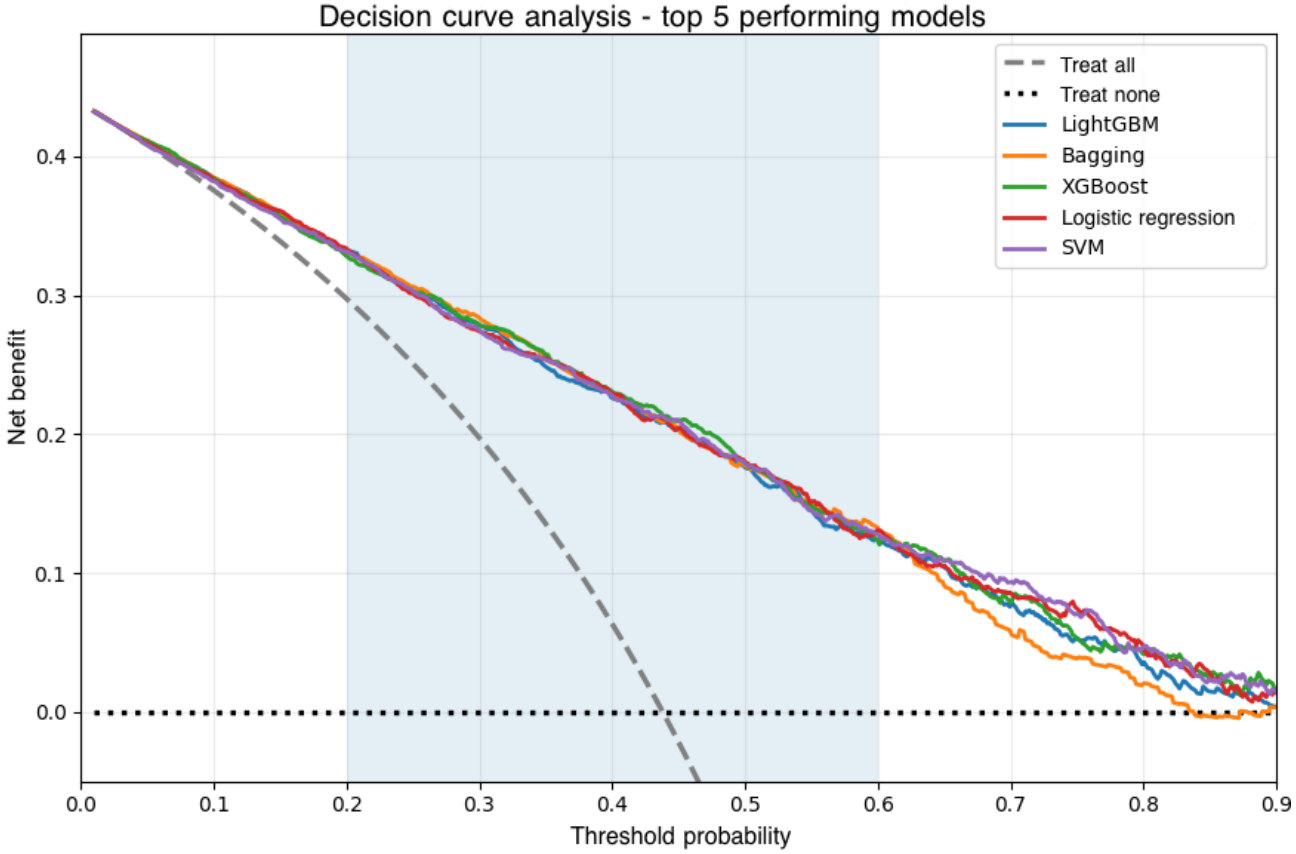
Figure 4. Calibration curves for different classification models in predicting mortality outcomes in intensive care unit (ICU) patients with cerebrovascular diseases. KNN: k-nearest neighbors; LightGBM: light gradient boosting machine; SVC: support vector classifier; XGB: extreme gradient boosting.



DCA and Clinical Utility

The clinical utility of the top 5 predictive models was evaluated using DCA. As shown in Figure 5, all models demonstrated a higher net benefit than the "treat none" strategy across a broad range of clinically relevant threshold probabilities. When compared with the "treat all" strategy, the ML models provided additional net benefit primarily at moderate-to-higher threshold probabilities (approximately 0.4 - 0.8), whereas at lower thresholds, their net benefit largely overlapped with the "treat all" approach.

Figure 5. Decision curve analysis (DCA) of the top five machine learning models for mortality prediction. The DCA illustrates the net benefit of using 5 predictive models (light gradient boosting machine [LightGBM], Bagging, extreme gradient boosting [XGBoost], logistic regression, and support vector machine [SVM]) across a range of threshold probabilities. The dashed gray curve represents the "treat all" strategy, which was calculated using the standard DCA definition, whereby the net benefit at a threshold probability of zero equals the observed event prevalence and decreases with increasing threshold probability. The dotted horizontal line represents the "treat none" strategy. Shaded areas indicate clinically relevant threshold probability ranges. A model with a higher net benefit at a given threshold is considered to have greater potential clinical utility.



Across this clinically relevant range, LightGBM generally showed the most favorable net benefit, with Bagging and XGBoost exhibiting closely comparable performance. Logistic regression and SVM also demonstrated consistent net benefit above the baseline strategies. Overall, these findings indicate that the proposed models may be most useful for guiding more selective clinical decisions—such as identifying high-risk patients for intensified monitoring or intervention—rather than for low-threshold scenarios where treating all patients may already be appropriate.

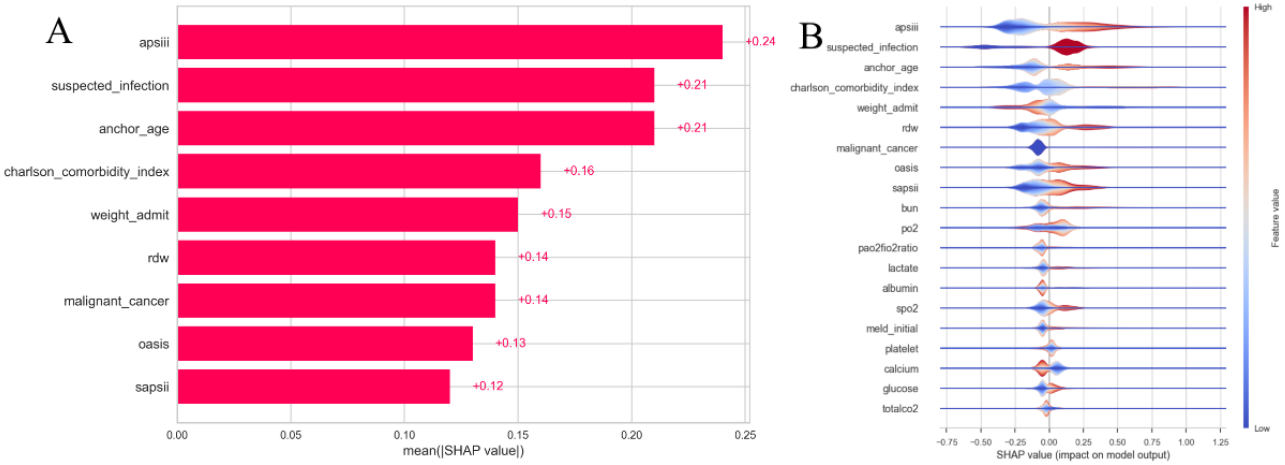
SHAP Analysis and Feature Importance

We performed SHAP analysis to interpret individual features' influence on the model's predictions. SHAP values provide a quantitative way to understand how much each feature contributes to the model's predictions. We used 2 complementary visualizations—a SHAP bar plot and a layered violin plot—to explore global feature importance and the detailed impact of each feature.

Key Insights From SHAP Analysis

The SHAP bar plot (Figure 6A) and layered violin plot (Figure 6B) both highlight the most influential features in the model. The bar plot shows the average absolute SHAP values for the top features, while the violin plot reveals the distribution of SHAP values for each feature, providing a more nuanced view of how each feature impacts the model's predictions. For clarity of visualization, the aggregated "sum of remaining features" term was excluded from the SHAP bar plot, allowing direct comparison of the relative importance of individual predictors.

Figure 6. Shapley additive explanation (SHAP) plots illustrating the impact of key features on model predictions. (**A**) Bar plot showing the average absolute SHAP values for the most influential features. (**B**) Layered violin plot displaying the distribution of SHAP values for the top features, with color indicating feature values (red for high, blue for low).



The top 5 features with the highest average SHAP values are as follows (key observations):

- “apsiii” (acute physiology score III) is the most important feature, with an average SHAP value of 0.24 (SD 0.17). This feature has a broad range of SHAP values, both positive and negative, indicating its complex impact on the model’s output depending on the severity of the patient’s condition.
- “suspected_infection” and “anchor_age” both have a mean SHAP value of 0.21 (SD 0.19 and 0.15, respectively), signifying their strong positive influence on the model’s predictions. Higher values of suspected_infection (indicating suspicion of infection) and anchor_age (older age) are associated with a higher likelihood of adverse outcomes.
- “charlson_comorbidity_index” shows a more balanced SHAP value distribution (mean SHAP value of 0.16, SD 0.19), suggesting that comorbidities have a mixed influence on the model, with both positive and negative impacts depending on the values of the index.
- “weight_admit” and “rdw” both show a strong positive contribution to the model, with average SHAP values of 0.15 (SD 0.16) and 0.14 (SD 0.13), respectively. Higher values for these features correlate with a higher probability of adverse outcomes.
- “malignant_cancer” and “oasis” also demonstrate strong positive contributions, with SHAP values predominantly concentrated in the positive range.

Feature Impact Analysis

The layered violin plot (Figure 6B) provides a deeper understanding of how the distribution of feature values influences the model’s predictions. The plot shows that the SHAP values for most of the top features are concentrated in the positive range, indicating that higher values for these features generally lead to higher predicted risks. For example, “suspected_infection,” “anchor_age,” and “weight_admit” all have SHAP values that are predominantly positive, meaning that higher values of these features are associated with a higher likelihood of adverse outcomes.

However, some features, such as “apsiii” and “charlson_comorbidity_index,” show more variability in their SHAP values, with both positive and negative values present. This indicates that these features have a more complex relationship with the model’s predictions, contributing in both directions depending on the specific values.

Overall, the visualizations help us understand which features are most important in the model’s decision-making process and how the value of each feature affects the predictions.

Summary of Key Findings

This study analyzed 5280 ICU patients with cerebrovascular diseases and found that older age, higher comorbidity scores, suspected infection, and dementia were associated with higher mortality. Feature selection identified 35 significant factors, and ML models were trained using these features. LightGBM and Bagging performed best, with LightGBM achieving 74.87% accuracy and an ROC AUC of 0.82. SHAP analysis highlighted key features such as acute physiology score III, suspected infection, and age as the most influential predictors of mortality. These models offer reliable tools for predicting all-cause mortality as recorded in the MIMIC-IV database and identifying high-risk patients in critical care settings.

Discussion

Principal Findings

This study demonstrates the potential of ML models to predict all-cause mortality among ICU patients with cerebrovascular diseases, using mortality outcomes as recorded in the MIMIC-IV database. Recent studies have shown that ML approaches can enhance prognostic accuracy in stroke and cerebrovascular disease populations, outperforming traditional clinical scores and improving individualized risk stratification [11,12]. Using the extensive MIMIC-IV database, we developed and evaluated several ML algorithms, identifying LightGBM and Bagging models as top performers across multiple metrics, consistent with the findings from recent ML-based stroke outcome prediction research [13]. These findings highlight the robustness of these models and underscore the value of ML in supporting

clinical decision-making for critically ill patients with complex cerebrovascular conditions [14].

Key Findings and Clinical Implications

Critical predictors of all-cause mortality identified in this cohort included suspected infection, age, Charlson comorbidity index, and malignancy. These factors align with prior research emphasizing the influence of comorbidities and infections on stroke outcomes [15,16]. Notably, suspected infection was highly prevalent in this cohort (73.4%), reflecting the high burden of infectious complications among critically ill patients with cerebrovascular disease admitted to the ICU, emphasizing the need for the timely recognition and management of infections—especially pneumonia—which significantly worsen stroke prognosis [17,18]. Age remains a well-established prognostic factor, with older patients facing higher mortality risk [19]. The Charlson comorbidity index further confirms the elevated risk among patients with multiple comorbid conditions, such as diabetes and hypertension [20]. SHAP analysis elucidated the relative importance of these variables, providing actionable insights for clinicians during risk assessment.

The SHAP analysis highlighted APS-III, suspected infection, comorbidity burden, and age as the most influential predictors of mortality, which is consistent with established stroke prognostic literature [21]. APS-III reflects the overall physiological severity on ICU admission, and higher scores have been strongly associated with increased mortality risk in critically ill stroke patients [22]. Infection status—particularly early respiratory or systemic infections—is a well-recognized complication that substantially increases mortality risk following ischemic stroke [23]. Similarly, a higher Charlson comorbidity index captures chronic disease burden, such as cardiovascular disease, diabetes, or malignancy, all of which worsen poststroke prognosis [24]. Age is one of the most robust and widely validated predictors of mortality and functional decline after ischemic stroke. The prominence of these variables in our SHAP results reinforces the biological plausibility of the model and indicates apparent alignment with clinical knowledge, supporting the reliability and interpretability of the ML predictions [25].

It is noteworthy that “suspected infection” was defined based on clinical interventions, including antibiotic administration and body fluid culture collection, rather than solely on physiological confirmation. As such, this feature may partially reflect clinicians’ perception of illness severity and concern for systemic infection, functioning as a process-of-care proxy rather than an independent biological marker. The considerable contribution of this variable in SHAP analyses suggests that the model may be learning from real-world clinical decision-making patterns embedded in ICU workflows. This characteristic is inherent to retrospective critical care datasets and highlights the importance of cautious interpretation when incorporating intervention-derived features into predictive models.

It should be noted that APS-III is a composite severity score derived from age and multiple physiological variables [26]. In the present models, APS-III was included alongside individual components, such as anchor_age and specific physiological measurements (eg, blood urea nitrogen and heart rate). Consequently, collinearity exists between APS-III and its constituent variables, and the contribution of age and physiological severity may be distributed across both the composite score and individual features in the SHAP-based importance rankings. Therefore, the prominence of APS-III in the SHAP analysis should be interpreted as reflecting overall illness severity rather than an independent effect separate from demographic or physiological factors, and the relative importance of these variables should be considered collectively.

Although established ICU severity scores such as APS-III and SAPS-II demonstrated reasonable predictive performance, the proposed ML models demonstrated higher discrimination than individual conventional ICU severity scores, while showing comparable performance to multivariable logistic regression models trained on the same feature set. Notably, APS-III, which represents one of the most comprehensive and widely used severity scores in critical care, was identified as the most influential individual predictor in the SHAP analysis.

Despite this, the LightGBM model provided a statistically significant improvement over APS-III alone, suggesting that the ML approach integrates complementary clinical information beyond conventional scoring systems. These findings support the role of ML as an enhancement to, rather than a replacement for, traditional ICU risk stratification tools.

Our results suggest that ML models, particularly LightGBM and Bagging, offer fairly accurate, individualized mortality predictions, enabling ICU clinicians to identify high-risk patients early. This capability could facilitate better resource allocation and more targeted interventions, ultimately improving patient outcomes where timely decision-making is critical.

In addition to predictive accuracy, the practical integration of the proposed models into clinical workflows is an important consideration. Because all input features used by the LightGBM and Bagging models are routinely collected in the ICU and are available within electronic health records, the models could be embedded into existing clinical decision support systems to generate real-time mortality risk estimates. Such integration would allow clinicians to identify high-risk patients shortly after ICU admission, prioritize monitoring intensity, optimize resource allocation, and guide discussions regarding prognosis. The use of SHAP-based explanations further enhances transparency by enabling clinicians to understand the key factors driving each patient’s prediction. Future work will focus on implementing and evaluating these models in prospective clinical settings to assess usability, workflow impact, and real-world clinical benefit.

Comparison With Existing Literature

Consistent with previous studies, our findings indicate that ML models can provide incremental prognostic value beyond conventional bedside severity scores for ICU patients with stroke-related conditions [27]. In our cohort, commonly used ICU severity scores showed moderate discrimination when evaluated as standalone predictors on the same independent test set (eg, SAPS-II AUC=0.73; APS-III AUC=0.72; Oxford Acute Severity of Illness Score AUC=0.66; Logistic Organ Dysfunction System AUC=0.66). In contrast, the best-performing ML model (LightGBM) achieved substantially

higher discrimination (AUC=0.83), and DeLong testing confirmed a statistically significant improvement over APS-III alone (ΔAUC=0.12, $P<.001$). These results suggest that the ML approach integrates complementary information beyond established scoring systems, supporting enhanced early risk stratification.

Our focus on patients with intracranial artery stenosis or occlusion extends the literature by providing detailed insights into this understudied subgroup. The large, publicly available MIMIC-IV dataset enabled robust analysis of more than 5000 patients, improving generalizability. The inclusion of mortality occurring after hospital discharge, as captured in the MIMIC-IV database, and a broad set of early clinical features, including biochemical markers and physiological severity indices, provide a comprehensive assessment of mortality risk compared with many prior studies limited by smaller samples or narrower feature sets.

Beyond traditional performance metrics, DCA demonstrated the clinical utility of the proposed models under specific decision thresholds. As shown in Figure 5, LightGBM and Bagging provided higher net benefit than the "treat none" strategy across a broad range of threshold probabilities and demonstrated clear advantage over the "treat all" strategy primarily at moderate-to-high risk thresholds. This pattern is expected given the relatively high prevalence of the outcome and indicates that the models may be particularly useful for guiding more selective clinical decisions.

In this context, incorporating these models into ICU workflows could support improved resource allocation by more accurately identifying patients at higher risk who may benefit from intensified monitoring or intervention. Together with model interpretability using SHAP, these findings support the potential for targeted, real-world application of our ML approach rather than indiscriminate use across all clinical scenarios.

Importantly, the robustness of the findings was further supported by temporal validation. When models were trained on earlier admission years and evaluated on later years, performance remained stable, with no meaningful degradation in discrimination or calibration. This temporal evaluation reduces concerns regarding information leakage inherent to random splitting in long-term retrospective datasets and supports the potential real-world applicability of the proposed models in contemporary ICU populations.

Strengths and Limitations

Key strengths include the use of multiple advanced feature selection methods (gradient boosting classifier, BorutaShap, RFECV) to isolate the most relevant predictors and the integration of SHAP for model interpretability, which fosters clinical trust and facilitates implementation.

Mortality status in this study was determined solely based on the presence or absence of a recorded dod in the MIMIC-IV database. As a result, deaths occurring outside the capture scope of the database—particularly out-of-hospital deaths in more recent calendar years—may not have been recorded. Accordingly, the absence of a documented dod should not be interpreted as confirmed long-term survival. Because mortality ascertainment relied on registry-based death records rather than active longitudinal follow-up, longer-term outcomes, such as functional recovery or late mortality beyond what was captured in the database, could not be assessed.

A related observation in this cohort was the marked discrepancy between in-hospital mortality and overall recorded mortality, indicating that a substantial proportion of deaths occurred after hospital discharge. In critically ill patients with advanced age, high comorbidity burden, malignancy, or severe physiological derangement, such postdischarge mortality may reflect transitions to hospice or comfort-focused care rather than unexpected physiological deterioration alone. Because explicit indicators of goals-of-care decisions—such as do not resuscitate status or comfort measures only orders—are not consistently captured in the public MIMIC-IV database, these factors could not be directly modeled. Consequently, the predictive models may partially capture clinical trajectories associated with end-of-life decision-making in addition to underlying illness severity. This limitation is particularly relevant in the context of temporal validation, as the incomplete capture of out-of-hospital mortality in more recent calendar years may introduce outcome misclassification, potentially inflating apparent model performance when the absence of a recorded death reflects missing data rather than true survival.

Moreover, all predictors were derived exclusively from the data available within the first 24 hours of ICU admission, prior to most formal goals-of-care decisions. However, the MIMIC-IV database does not provide reliable "present on admission" indicators for stroke diagnoses. As a result, some patients may have developed ischemic stroke after ICU admission rather than being admitted primarily for acute stroke, introducing potential temporal misclassification between disease onset and feature extraction. This limitation may affect the specificity of the cohort and should be considered when interpreting the model's applicability to strictly acute stroke populations. This design suggests that the models primarily reflect early physiological severity and comorbidity burden rather than downstream treatment choices. From a clinical perspective, the early identification of patients at extremely high risk of mortality—regardless of whether death occurs following aggressive treatment or comfort-focused care—remains highly relevant for prognostic communication, care planning, and resource allocation in the ICU.

Another important limitation is the absence of direct measures of neurological stroke severity, such as the National Institutes of Health Stroke Scale (NIHSS), which is not systematically available in the MIMIC-IV database. Without the NIHSS, the model cannot distinguish between patients with mild neurological deficits and severe systemic illness versus those with large, devastating strokes. Accordingly, the model may be better interpreted as predicting mortality among critically ill patients with stroke-associated conditions ("death with stroke") rather than mortality driven exclusively by cerebrovascular injury itself ("death from stroke"). The prominence of APS-III and other systemic physiological markers in the SHAP analysis supports this interpretation and reflects the clinical reality of ICU stroke populations, in whom outcomes are often driven by multiorgan dysfunction and comorbidity burden. Therefore, the

proposed model should not be viewed as a replacement for stroke-specific prognostic tools used in acute neurological decision-making, but rather as a complementary instrument for global mortality risk stratification in critically ill patients with stroke-associated conditions.

In addition, the feature "suspected infection" was operationally defined based on clinical actions (antibiotic administration and body fluid culture collection) rather than microbiological confirmation alone. As such, this variable may partially act as a proxy for clinician concern or illness severity, introducing potential circularity whereby the model learns from care processes rather than purely independent physiological risk factors. This reflects real-world ICU practice but warrants cautious interpretation of its predictive contribution. Although race and ethnicity were available in the database and are reported in the descriptive characteristics, this study did not perform formal subgroup or fairness analyses to evaluate potential differential model performance across demographic groups. Given known disparities in critical care delivery and the use of process-of-care–derived features such as suspected infection, algorithmic bias cannot be excluded and should be addressed in future validation studies.

The final key limitation of this study is the absence of an external validation cohort. Although rigorous internal validation was performed using an independent hold-out test set, the generalizability of the model to other institutions, populations, and clinical environments remains uncertain. Moreover, all data were derived from a single academic medical center, and institutional practices regarding discharge disposition, hospice referral, and comfort-focused care may differ substantially across health systems. As a result, the model may partially reflect center-specific end-of-life care workflows, potentially limiting its applicability to settings with different palliative care practices. At the time of this study, no external ICU dataset contained sufficiently detailed information on intracranial artery stenosis or occlusion together with reliable mortality outcomes to enable external validation. Future studies should validate these findings in multicenter datasets or prospective clinical cohorts.

Future Directions

Future research should aim to integrate these ML models into clinical workflows for real-time risk stratification. The incorporation of additional data types, such as imaging and genetic information, may further improve predictive accuracy. Prospective validation in diverse clinical settings is needed to confirm generalizability and assess impact on patient outcomes. Combining ML models with established clinical scores like NIHSS and sequential organ failure assessment could enhance predictive power and support decision-making.

In conclusion, this study supports the use of ML models to provide personalized mortality risk assessments for ICU patients with cerebrovascular disease associated with intracranial artery stenosis or occlusion, with potential to improve critical care management and patient prognosis.

Conclusions

ML models, especially LightGBM and Bagging, demonstrate comparable performance in predicting all-cause mortality in ICU patients with cerebrovascular diseases involving intracranial artery stenosis or occlusion. By leveraging routinely collected clinical data and identifying key risk factors, such as suspected infection, age, and comorbidities, these models offer valuable support for early risk stratification and clinical decision-making in critical care. Further external validation and real-world implementation studies are warranted to confirm their generalizability and clinical impact.

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Data Availability

The datasets generated and/or analyzed during this study are available from the publicly accessible Medical Information Mart for Intensive Care IV database repository. The raw data used in the analysis, as well as the processed data, can be found in Multimedia Appendix 1. Additional datasets or analysis scripts are available upon request from the corresponding author.

Authors' Contributions

Conceptualization: KZ
Data analysis: KZ
Data collection: RC
Data curation: RC
Data interpretation: CM

Investigation: CM
Methodology: KZ
Project administration: LL
Resources: XL
Statistical analysis: YY
Supervision: LL
Validation: YY
Visualization: YY
Writing – original draft: KZ
Writing – review & editing: XL, RC, XL, JY
Writing – review & editing (text revision): PL, GX
All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Pearson correlation matrix of the final selected features.
[CSV File, 25 KB - cardio_v10i1e82042_app1.csv]

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Abbreviations

AdaBoost: adaptive boosting
DCA: decision curve analysis
dod: date of death
***ICD-9/10*:** *International Classification of Diseases, Ninth and Tenth Revision*
ICU: intensive care unit
LightGBM: light gradient boosting machine
MIMIC-IV: Medical Information Mart for Intensive Care IV
ML: machine learning
NIHSS: National Institutes of Health Stroke Scale
RFECV: recursive feature elimination with cross-validation
ROC AUC: area under the receiver operating characteristic curve
SAPS II: Simplified Acute Physiology Score II
SHAP: Shapley additive explanation
SVM: support vector machine
XGBoost: extreme gradient boosting

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Perceived Potential and Challenges of Supporting Coronary Artery Disease Treatment Decisions With AI: Qualitative Study

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Abstract

Background: Coronary revascularization decision-making for patients with coronary artery disease (CAD) can be complex and challenging. Artificial intelligence (AI) has the potential to improve this decision-making by bringing data-driven insights to the point of care.

Objective: We aimed to elicit, collect, and analyze various stakeholders' perceived potential and challenges related to developing, implementing, and adopting AI-based CAD treatment decision support systems.

Methods: A facilitated small-group discussion method, known as a World Café, was conducted with general cardiologists, interventional cardiologists, cardiac surgeons, patients, caregivers, health system administrators, and industry representatives. One-on-one interviews were conducted for participants who could not attend the World Café. Perceived potential and challenges of AI-based CAD treatment decision support systems were solicited by asking participants three broad questions: (1) What is most challenging about revascularization decision-making? (2) How could an AI tool be integrated into the existing clinical workflow? (3) What are the critical components that need to be considered when developing the AI tool? Thematic analysis was performed to identify themes from the data.

Results: Nine participants completed the World Café, and 3 participants completed the one-on-one interviews. Five main themes emerged: (1) evidence-based care, (2) workload and resources, (3) data requirements (subthemes: patient-centered approach, evidence-based AI, and data integration), (4) tool characteristics (subthemes: end user built; generation and presentation of decision support information; user-friendliness and accessibility; and system logic, reasoning, and data privacy), and (5) incorporation into clinical workflow (subthemes: AI as an opportunity to improve care and knowledge translation).

Conclusions: While health care providers aim to provide evidence-based care, CAD treatment decision-making can often be subjective due to the limited applicability of clinical practice guidelines and randomized controlled trial evidence to individual patients. AI-based clinical decision support systems may be an effective solution if the development and implementation focus on the issues identified by end users in this study (patient preference, data privacy, integration with clinical information systems, transparency, and usability).

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KEYWORDS

coronary artery disease; clinical decision support; artificial intelligence; technology adoption; implementation science; stakeholder engagement

Introduction

Coronary artery disease (CAD) is characterized by reduced blood flow to the heart muscles caused by plaques in the coronary arteries. The gold standard diagnostic procedure for CAD is coronary angiography performed in cardiac catheterization laboratories, using radiocontrast agents and x-rays to diagnose the disease. Typically, the treatment decision involves determining whether the problematic coronary arteries need to be revascularized via either percutaneous coronary intervention or coronary artery bypass graft (CABG) surgery,

or whether the most appropriate treatment is medical therapy only.

While clinical practice guidelines based on randomized controlled trials exist [1], coronary revascularization decision-making can be complicated by complex CAD (eg, multivessel disease), challenging coronary anatomies, comorbidities, unique patient characteristics, and patient preferences. Although multidisciplinary Heart Team approaches, where diverse specialists, including general cardiologists, interventional cardiologists, and cardiac surgeons, discuss the patient case and formulate the best treatment as a group, are recommended for revascularization decision-making for complex CAD [2,3], they are neither standardized nor evidence-based, making it difficult to operationalize complex treatment decision-making systematically.

Artificial intelligence (AI) has the potential to support coronary revascularization decision-making via data-driven insights. By leveraging patterns and relationships learned from a large amount of patient data, AI models can generate and present personalized decision support insights at the point of care. However, even if AI models with good performance are available for deployment, their technical and operational implementation in real-world clinical environments remains challenging and requires adoption from a variety of stakeholders, including patients, clinicians, health system administrators, health care payors, researchers, and developers [4]. Understanding the barriers and enablers to adopting AI-based clinical decision support systems (CDSS) is critical to developing and implementing such systems in clinical practice.

This study aimed to understand the perceptions of how an AI-based CDSS can facilitate CAD treatment decision-making.

Methods

Study Design and Setting

A World Café [5] was used to elicit and collect stakeholder perceptions about the use of an AI-based CDSS for CAD treatment decision-making. A World Café is a formal, semistructured method that engages diverse stakeholders through multiple rounds of small group discussions, each guided by a targeted question. It is designed to create an open, café-style atmosphere that encourages equitable participation and the flow of ideas across groups. This method enables intimate discussions among participants with varied perspectives, supporting the identification of themes relevant to a topic.

This study intended to complete a single World Café; however, some of our key end users (clinician participants) were unable to attend the World Café due to unexpected urgent patient cases. To ensure that these participant perspectives were captured in the dataset, 3 additional one-on-one interviews were conducted at a later date using the same semistructured protocol and targeted questions used in the World Café.

The World Café and interviews took place in Alberta, Canada, from May 2, 2022, to July 18, 2022, using the videoconferencing and online meeting platform, Zoom (Zoom Communications). Only participants and researchers were present during the meetings and interviews.

Participants and Recruitment

Study participants were recruited in Alberta and included: (1) clinicians involved in the care of patients with CAD including general cardiologists, interventional cardiologists, and cardiac surgeons; (2) health system administrators; (3) private-sector representatives from the cardiovascular information system industry; and (4) patients and caregivers (individuals aged 18 y and older with CAD, or caregivers supporting individuals with CAD).

All clinician participants were practicing physicians within Alberta Health Services (AHS), which is one of the largest fully integrated provincial health systems in North America. AHS oversees centralized delivery of acute care, emergency medical services, diagnostics, and many community-based programs for over 4.4 million Albertans. Although Alberta operates within Canada's universal, publicly funded health care system, its structure differs from many jurisdictions in Canada and abroad by unifying services under a single provincial authority rather than regionally or privately administered systems [6].

Participants were identified using purposive sampling to maximize variation in backgrounds and sex differences. Potential participants (World Café participants [WCPs] and one-on-one interview participants [OIPs]) were recruited using our research network and invited to participate via email. Once potential participants indicated an interest, the consent script was sent to them via email. They were provided with multiple opportunities to ask questions before completing the oral consent process. The consenting process occurred before the World Café and one-on-one interviews.

Data Collection

Consistent with the World Café methodology [7], data were collected through facilitated discussion on broad questions. Three questions were posed to both the WCPs and OIPs sequentially: (1) What is most challenging about revascularization decision-making? (2) How could an AI tool be integrated into the existing clinical workflow? (3) What are the critical components of the AI tool that need to be considered when developing the tool?

A facilitator guided the discussion and used prompts to generate discussion for each question. A note-taker collected field notes to document the context of the discussion (eg, the physical environment and individuals' nonverbal communication) and captured a summary of the discussion, which was shared with the participants at the end of the session (member checking). The World Café session and interviews were digitally recorded and transcribed verbatim, and the field notes were incorporated into the transcripts for analysis.

Reflexivity

The World Café and interviews were conducted by trained, experienced male and female facilitators who had formal graduate-level and experiential training in qualitative methodology and interview facilitation. Several members of the research team, including the facilitators and principal

investigators, had pre-existing professional and nonprofessional relationships with some participants, which may have influenced rapport and data interpretation. One principal investigator was a family member of a patient with CAD who had recently been diagnosed and had an urgent CABG. During the analysis phase, these pre-existing relationships and researchers' personal backgrounds were explicitly discussed during team meetings to reflect on how personal experiences, disciplinary backgrounds, and expectations may shape data interpretation and the construction of final themes.

Data Analysis

Transcripts from both the World Café and one-on-one interviews were uploaded, managed, and analyzed using NVivo (version 12.0, Lumivero). The Clarke and Braun [8] approach to thematic analysis was used to analyze the data. An inductive approach was used to identify codes and themes from the data. A first analyst familiarized themselves with the data and identified and established codes in a coding book as a reference. A second independent analyst then familiarized themselves with the data and reviewed the preliminary codes identified by the first analyst, revising and adding new codes while interpreting the data as a circular process that moved back and forth between smaller parts of the transcript and the whole text. This iterative coding process was applied as new themes emerged, and the transcripts were reread to verify that the codes and themes were not missed. These coding "nodes" were discussed among the research team and then consolidated into themes [8]. Coding discrepancies between analysts were addressed through discussion and joint review of the relevant transcript segments. Consensus was achieved through iterative comparison of interpretations, and any disagreements were resolved collaboratively to ensure consistent application of codes across the dataset.

In contrast to the group dynamic characteristic of the World Café, individual interviews may elicit more detailed and individualized reflections. To reconcile these methodological differences and enable direct comparison between formats, all transcripts were coded using the same unified coding framework. Codes and themes were examined for convergence and divergence, and only themes supported by patterns across both data sources were used in the final analysis. Although the one-on-one interviews were conducted following the World Café, the interview guide was not refined or modified based on World Café findings, and the same semistructured protocol was used across formats.

Trustworthiness

Various strategies were used to ensure the trustworthiness of the findings [9]. The transcripts were reviewed by the World Café and interview facilitators for accuracy before analysis. We used member checking at the end of the World Café and each interview by summarizing the discussion and asking participants if we accurately captured the discussion. Regular peer debriefing and discussion took place between members of the research team about the representation of this study's population, recruitment, data collection strategies, and data analysis, from the data coding process to the emerging themes, to enhance the accuracy of the results. The results were reviewed and refined by all authors, some of whom were participants.

Ethical Considerations

The University of Calgary Conjoint Health Research Ethics Board approved this study (REB20-1879). Before participation, explicit oral informed consent was sought and obtained from all study participants. The privacy and confidentiality of participants' data and identity were maintained by following the approved research data security and privacy protocol. Participants were not compensated. Additionally, this paper follows the COREQ (Consolidated Criteria for Reporting Qualitative Research) guideline (Checklist 1) [10].

Results

Overview

The World Café was conducted on May 2, 2022, and the interviews were conducted between June 15 and July 18, 2022. The World Café lasted about 120 minutes, and each interview ranged from 45 to 60 minutes. The participants (9 male; 3 female) were cardiologists (n=4), interventional cardiologists (n=2), cardiac surgeons (n=2), health system administrators (n=1), patients and caregivers (n=2), and an industry representative (n=1). Clinician participants (n=8) included early-career (n=3), middle-career (n=4), and senior professionals (n=1).

Five overarching themes emerged from the data: (1) evidence-based care, (2) workload and resources, (3) data requirements (subthemes: patient-centered approach, evidence-based AI, and data integration), (4) tool characteristics (subthemes: end user built; generation and presentation of decision support information; user-friendliness and accessibility; and system logic, reasoning, and data privacy), and (5) AI incorporation into clinical workflow (subthemes: AI as an opportunity to improve care and knowledge translation). Each theme is described in detail in the ensuing sections, with example quotes tabulated in Tables 1-5 for each theme. Quotations are identified by stakeholder group and by data collection source (ie, WCPs or OIPs).

Table . Example quotes related to evidence-based care (theme 1).

Description	Example quotes
The importance of evidence-based clinical practice.	• "We need more evidence when the areas we do have evidence still aren't standardized… Could more evidence help standardize things? And I do want to say that there are areas, certainly, that we need more evidence, but just like the counterbalance, there is, there are areas where we have evidence, and it still hasn't standardized practice." [OIP #1, surgeon] • "It certainly does. And I think it would for everybody. Everybody should be thinking of the guidelines, but it's kind of a starting point because it's often the nuances, or there's the other clinical variables that aren't in the classic guidelines that are important considerations." [OIP #3, interventionalist] • "It can be challenging identifying which patients you're going to want to proceed with revascularization versus proceeding with medical therapy… it does become somewhat knee-jerk that a person has in anginal symptoms or they have a non-invasive test that's suggestive of ischemia, and automatically they get sent to the cath lab with the thought that they're going to be revascularized. Now, the existing literature and the existing guidelines don't actually support that… it can be challenging…" [OIP #2, interventionalist]
Uniform and standardized decision-making between clinicians: different priorities based on their values & success rates (PCI[a] vs CABG[b]).	• "I think most decisions for revascularization are made ad hoc, on the spot, and I think that's reasonable for most of the time, but it really is the setup for a practitioner dependent practice… I think all of us see variation in practice, and I think all of us see that there's areas that aren't standardized… It would be nice if things were standardized, it simplifies things and allows everyone to ensure that we're aligned or at least the expectations are clear." [OIP #1, surgeon] • "I think there is variation in practice. But, say, between different surgeons, there's definitely variability. But, ultimately, say, if it's in the middle of the night, then it's basically what my preference or opinion is, I guess, at that point. What my colleagues might do might be different, but it doesn't really affect my decision process at that point." [OIP #3, interventionalist]

[a]PCI: percutaneous coronary intervention.

[b]CABG: coronary artery bypass grafting.

Table . Example quotes related to workload and resources (theme 2).

Description	Example quotes
The impact of decision-making process due to workload and physician burnout. Lack of time to explore and discuss patient information due to high volume of work.	• "When I have been burnt out, of course that impacts my practice, of course that impacts my decision making. I imagine that each of these... I think there's a very high resiliency rate within each of these groups, and I think, a lot of self-awareness to monitor burnout. It's impossible for me to quantify the impact, I'd just be speculative, but I think that all of us have to be mindful of that impact in decision making." [OIP #1, surgeon] • "When we're burnt out and we're overloaded sometimes, there's a tendency towards the path that's going to give us a more definitive answer more quickly." [OIP #2, interventionalist] • "The other considerations are the timing of revascularization. Is there active ischemia at the time? Is it an emergency that needs to be done right away? Or is it something that can wait until something else is optimized, either antiplatelet strategies or anticoagulation or other patient variables? Clinical status? Timing on like ... Is it emergency or not? Or is it urgent? Or is it elective?" [OIP #3, interventionalist] • "I was thinking about time as being one of the biggest issues for me and also acuity. So, I find that you have more time to weigh those risks and benefits and do your own cost-benefit analysis in the more stable scenario. But, in the acute phase, that time to do that goes at the side of trying to get the intervention going and the case started… It should be standardized for all patients, regardless of the presentation. But in my own individual experience, I find that time is really an issue, and it depends on the urgency of the scenario." [WCP #6, cardiologist] • "One is synthesizing all of the data that comes in. So, whether it's the anatomy, the patient comorbidities presentation, and what everyone's perspective on feasibility of getting a good result, whether it's by angioplasty or bypass surgery. So, I think it's putting everything together… you're trying to get through all of these patients, being comfortable that you've gathered all the relevant data to make the right decision is quite difficult…" [WCP #5, interventionalist] • "We might get a mailing list the day before…, you might spend a little bit of time in the evening reviewing the angiogram films. And the next day they might only spend five minutes on a patient… So, you're trying to get through all of these patients, being comfortable that you've gathered all the relevant data to make the right decision is quite difficult, given the fact that a lot of times you have never met the patient… So, certainly that you can get time pressure and not discuss patients thoroughly enough." [WCP #5, interventionalist]

Description	Example quotes
Considering cost of care (PCI[a] vs CABG[b]) vs value of care.	• "Back to our patient's perspective, I think we do look at risks of the non-discussed pieces of it when we make our decisions with patients. So, obviously as clinicians, we talk about death or MI stroke, but there are a lot of other things that go into the decision-making like time in hospital, recovery status… we would want to discuss with the patient to make sure they understand. So, at 10 years you may have a slightly better risk of death, but in the meantime, you've got a recovery period that would be hard to manage. So, cost may be less so than the patient discussions, but as the healthcare system tightens, cost will become more and more important in the future." [WCP #4, interventionalist] • "We do talk about value, defining value as outcome over cost. So, it's not that the cost doesn't matter. And I think the system is willing to pay the cost as long as the outcome achieved from that cost makes sense. So, I think in our system, we would talk more about value" [WCP #3, administrator] • "When you're pressed for beds if the results are close enough between bypass and PCI, does your resource limitation push you more towards one or the other?... And so, certainly we did have those discussion... you just deal with one or the other either with surgery or angioplasty, then the fact that five years down the road they might be back for a second procedure. But you just try to keep the resources freed up in the system, whether it's time or money or beds." [WCP #5, interventionalist] • "Everything that we're talking about is incredibly expensive… I would think, in the scheme of budget for this, this would be relatively small, and anything that makes things more efficient probably will save money more than whatever it costs." [OIP #3, interventionalist]
Considering resources (e.g., cost, investment), and willingness to invest and implement the AI[c] tool.	• "If we want these tools to be adopted, they have to be purchased… a lot of the times we are making those arguments as a return on investment, essentially saying that if they pay this much for this software, it will save them time, it will lead to improvements in quality for value-based reimbursement or these sorts of things… So, I do think there's the clinical perspective in terms of, directly with the patient and beds and everything. And then there's also the administrative perspective around time and resources and whether they are willing to put in the effort to implement this in practice in order to actually see the results. I think it's an important consideration, even this early on in the process." [WCP #9, industry partner]

[a]PCI: percutaneous coronary intervention.

[b]CABG: coronary artery bypass grafting.

[c]AI: artificial intelligence.

Table . Example quotes related to data requirements (theme 3).

Subtheme and description	Example quotes
Patient-centered approach	
Complex patients with multimorbidity	• "I think one of the bigger challenges that's happening more and more now is our patients are older. They're more complex. They have more comorbidities. The risks of everything are higher. Their disease is getting more complex. There are sometimes not reasonable PCI options… And so, you are not infrequently trying to treat a patient who has complex multi-vessel disease, who is a poor candidate for surgical revascularization, or a very high-risk candidate for surgical revascularization, who is equally a high-risk candidate for percutaneous revascularization." [OIP #2, interventionalist] • "There are the anatomic things like the coronary anatomy. There are the other comorbidities are a big role... I guess the factors that relate to their potential benefits. Are they potentially receiving a symptom or a survival benefit? And then what are their risk factors?... Because it's always a balance of benefit versus risk." [OIP #3, interventionalist]
Understanding patient expectations and preferences	• "If you give the patients a choice, they'll all pick PCI. And PCI is great for a lot of them, but it's not right for everybody. And that's where that education has to come in, and then they can make their decision." [OIP #3, interventionalist] • "I chose a course of treatment that had the lowest chance of incontinence over the others. So, it's weird, I'm not sure patients really think exactly like clinicians in this situation. I was opting for quality of life over other factors, and it served me well… But those would be important to me." [WCP #2, patient] • "Nobody wants to have surgery, but people are interested in their long-term outcomes. They don't want repeated heart attacks… the second one is also understanding what the patient's preference is and how much of that weighs on the decision. So, if it's 60% in favor of bypass and 40% in favor of angioplasty from a clinician standpoint, but what if the patient feels very strongly that they want to have angioplasty and you would need to tell them various substantial risk… or substantial benefit of bypass surgery. So, understanding what the patient preference is based upon what would happen if they were presented with the data." [OIP #3, interventionalist]
Evidence-based AI[a]	
Representation of diverse patients in the data used to develop the model	• "I think that making sure that you want the largest pool of data possible, but making sure that data represents a wide cross-section of demographics, and that you're not trying to ultimately end up generalizing it to populations that haven't been involved in generating the model. That's really important." [OIP #2, interventionalist]

Subtheme and description	Example quotes
Complementing and improving upon the existing clinical practice and evidence	• "I would love to see both strengths of AI put to work… there are a lot of things we know, and honestly, I think we're maybe not that bad at this, but it would be great to see if AI comes up with information or predictors that we didn't know, which would be the real beauty of this model." [WCP #4, interventionalist] • "You're going to do the standard stuff that we all think about, age, diabetes, hypertension, dyslipidemia, frailty, down the list, but the black box approach where you basically ask the computer to tell us what's in the model, I think would be very interesting and potentially the validation moving forward would be very exciting." [WCP #4, interventionalist] • "AI-based technologies is to be able to give us information that some standard studies don't give us… It may be possible that by applying more complex machine learning, you might actually be able to find an answer that we haven't been able to find so far in our existing evidence. So, I think that you have to be aware of what the existing evidence is, but if you find a different answer using new technology, well, I don't think you adopt it wholeheartedly and ignore what we have figured out already, but I think you need to integrate that in." [IP #2, interventionalist] • "The evidence is coming typically from trials that have a lot of nuances to them. Applying guidelines or a specific trial to a specific patient can be real challenge because they don't always directly apply. That's where the clinical judgment and oversight and gestalt, I think, play a role and is trying to say, well, the evidence that we have ... How well does it apply to this patient? And that's where they don't always directly apply." [IP #3, interventionalist]
Data integration	

Subtheme and description	Example quotes
Ethics, privacy, and confidentiality	• "I think that from a patient privacy perspective, that's going to be a really important thing to have a really good grasp on the ethics before that happens, because machine learning can be used to generate all sorts of models for all sorts of risks. And whether those things in the future are going to... Say, my EMR is plugged into machine learning, and it's able to automatically generate a detailed risk for, for cardiac death over the next 10 years, is that going to affect my patient's ability to get insurance? So, there needs to be a consent aspect in there for sure." [OIP #2, interventionalist] • "Obviously, confidentiality and privacy are massive when it comes to medical information. It certainly would have to be secure." [OIP #3, interventionalist]
Integration with the EMR[b].	• "Something that can be incorporated directly into the EMR, so you can just say, 'Oh, well, I want to calculate the whatever score for this patient,' so you can click on it and it can pull in whatever data that it needs. I think that the simpler you make it, the more likely you're going to see uptake." [OIP #2, interventionalist] • "When we talk about how this could be integrated in the existing workflow, I think we have to consider Connect Care as part of this…, Healthcare institutions have put significant investment into the implementation of electronic medical record systems… which opens up an opportunity for us, if we can integrate with those systems and make it fairly seamless experience." [WCP #9, industry partner]
Integration of comprehensive data elements	• "The critical components one is, as everyone's mentioned, is the APPROACH CARAT diagram and all the different components of it, whether it's the anatomy or the jeopardy score, lesion characteristics, previous stents, the comorbidities that are the classic comorbidities, whether it's renal failure or diabetes, left ventricular dysfunction, patient age, BMI, whether it's super high or super low. The ones that are harder to capture, I think, beforehand… other one is frailty… it's something that's really hard to capture, but I think the frailty piece is really important." [WCP #5, interventionalist]

[a]AI: artificial intelligence.

[b]EMR: electronic medical record.

Table . Example quotes related to tool characteristics (theme 4).

Subtheme and description	Example quotes
End user built	
Engaging end users throughout the development and implementation processes	• "When developing something that is intended to be used as a tool for someone, that person is the stakeholder and they should be engaged and heavily involved in all aspects of the development, training, implementation, and subsequent follow up and iterations. It's hard for me to imagine a step a clinician shouldn't be involved…" [OIP #1, surgeon] • "Physicians and patients would be the end-users for those models that are generated. So, matter of asking what more information the end-users actually need." [OIP #2, interventionalist] • "I think something like this could be complicated enough that, without a physician or surgeon or an interventionist… clinical feedback would be important in order to tailor it to what the clinicians need to see." [OIP #3, interventionalist] • "What data are available, what data are easy to get, which ones would require the physician to do extra steps? And maybe prioritizing ones that are accessible or prevalent versus ones that might require extra work and therefore prevent adoption. So, I think that's, figuring out what we can do with Connect Care or very similar systems is important here." [WCP #9, industry partner]
Engaging patients throughout and capturing patients' voices	• "If the AI tool was developed with the patient-centered focus with patient researchers actually involved in developing the tool. And it might provide a communication roadmap for some of your colleagues… and coach them in both the language and what the patient is actually looking from their clinician to provide in the way of information, so that the discussion is actually much more robust." [WCP #4, interventionalist] • "Asking the patients how they're doing, their mobility, quality of life, frailty, we know from other research that's been done that PROMs are quite predictive of outcomes, and they come out, when you run the AI with all the different features, PROMs often come out as contributing to that final prediction." [WCP #9, industry partner]
Family physicians as potential end users	• "Is that possible that it could be starting with a family physician instead of specialist cardiologist? I don't know where else it potentially could start. That way, it's an easier conversation for the family physician to have with the patient." [WCP #1, patient] • "I would fully agree with that (integrating AI in PHC)… The only thing is that some family physicians are overwhelmed by the breadth of knowledge they need to know about your diabetes, your heart's arteries, your medical therapy, and they really look to the cardiologists and the surgeons, where appropriate… the intricacies of decision-making." [WCP #4, interventionalist]
Generation and presentation of decision support information	

Subtheme and description	Example quotes
Need for scores as a way to summarize granular information for easy interpretability and communication	• "Making decisions about revascularization would be the development of more complex risk-prediction models… through machine learning, there would be the ability to generate a more sophisticated model for helping to estimate risk. And again, you're not going to ultimately have an AI making the decision about whether or not you're going to proceed with revascularization, but to be able to go into an interaction with a patient and be able to give them more granular information about what their risks are, that could be helpful." [OIP #2, interventionalist] • "I think it'll be determining what all risk factors need to go into this tool (AI) and what weight are you going to give to each risk factor and does presentation…, How do you give mobility a number, and comorbidities… but some of these risk factors are going to be a little bit difficult to try to quantify." [WCP #7, cardiologist] • "My first thought was on the APPROACH diagram, there's a jeopardy score and the jeopardy score is used, to a degree, to guide our revascularization decisions. It would almost make sense that this prediction tool puts some sort of either score or recommendation was my first thought." [WCP #4, interventionalist] • "Overlay how AI has actually helped populate the data in the various columns of chart data. That, to me, I think would be perhaps a good marriage of data… on the various success factors that you're striving towards by each treatment option. And then that would provide a good discussion basis for the physician and the patient and their family… if you stack them all together, you would have what would logically be the optimal treatment plan, just because the higher score and whatever it would add up, it would be ably demonstrated… it's easy to explain at the bedside, I think would be a big benefit rather than talking in clinical jargon." [WCP #2, patient]
Importance of data quantity and quality	• "I think that's how you would harness the true power of AI and machine learning. As much data as you could get in, I think that's how you could really…harness the power of this method." [OIP #1, surgeon] • "In order to get high quality information out of any machine learning system, it's entirely based on the volume of data you're able to provide it… I think the broader the data you're able to plug into a machine learning system, the better, because one of the big issues that I'm aware of with machine learning is just the impact of the bias of the information that you put in." [OIP #2, interventionalist] • "As a surgical resident who's doing a lot of research with clinical data, being able to extract that data efficiently would be key... I think we've struggled a little bit with the comprehensiveness of data and the efficiency of it." [WCP #8, surgeon]
User-friendliness and accessibility	

Subtheme and description	Example quotes
Importance of an easy-to-use, intuitive user interface and automation.	• "User interface are really important… I'm not still clear how to evaluate an algorithm… I don't have a good sense as to how to actually perform due diligence on a product or algorithm. And in the absence of the ability to do that, it's very difficult to know how much weight you would put on the response from an algorithm. So, I think that a bit of knowledge translation, or trying to validate an AI model in a manner that's understandable to clinicians is critical." [OIP #1, surgeon] • "I think a lot of what it comes down to is really just convenience, and speed, and ease of use… certainly, automated measurements, automated tracing of the left ventricle and calculation of, for example, a 3D left ventricular ejection fraction. These are areas that accuracy is improved… so I think usability becomes really, really important, particularly at a time when technology has in certain areas of medicine, led to a lot of added complexity with an unclear value proposition. And so I think that really providing an easy to use interface and easily digestible material is our answers, is really helpful." [OIP #1, surgeon] • "When I think about kind of AI tools, they're going to be things that physicians reach for when they want them… you're going to be reaching for every patient… for something as simple as like MDCalc to put in someone's Framingham risk score. So, you would want something that is easily accessible, something that is smartphone-based, or even something that can be incorporated directly into the EMR, so you can just say, 'Oh, well, I want to calculate the whatever score for this patient,' so you can click on it and it can pull in whatever data that it needs. I think that the simpler you make it, the more likely you're going to see uptake" [OIP #2, interventionalist] • "In general, surgeons aren't very technically or at least computer savvy. The simpler, the better, for sure. Because not too many surgeons will commit to a lot of learning for something like that, computer work, or have a lot of time to commit to it. Actually, it is quite important that it's something that's intuitive or easy to work with. Being user friendly, for sure, is important. Being accessible. Something that we can use remotely is important because that's when, I think, it'd be pretty useful. And then just current, I guess. Data or information that's real time." [OIP #3, interventionalist]
System logic, reasoning, and data privacy	

Subtheme and description	Example quotes
Transparency and accountability	• "I think that there does need to be some sort of transparency in how the tool is working… For decisions, an overall gestalt is used a lot... is this person a candidate for this? Is this person ... Would it be ... Would they do well with this? And so, the gestalt is an important part. With artificial intelligence, I don't know if gestalt is a part of it. That would be a challenge, I would think. Having some transparency, though, in how the algorithms or whatever it is that are making recommendations or decisions or things like that ... A transparency so that people can see how this tool comes to these conclusions." [OIP #3, interventionalist] • "I think the only thing that we have to be fully aware of and cognizant of… from a medical legal point of view, having a statement that X is the desired outcome without all of the qualifying pieces, if the Y procedure is done and the patient has a bad outcome, which may or may not be predictable, usually not predictable, it may lead to a medical legal nightmare… So, we just have to be cognizant of that and decide where this decision tool lands in terms of its availability and to who." [WCP #4, interventionalist]
Living documents and real-time feedback	• "From a workflow perspective, AI really needs to be almost synchronous with the test itself and providing real time feedback or near time feedback to be really clinically useful." [OIP #1, surgeon] • "I think it needs to be part of the living document and available at the time we do the angiogram to be most valuable. I would say that 90% of the time the revascularized option, which is anatomically best for the patient and comorbidly best for the patient, taking their patient profile is obvious 90% of the time. It's either a straightforward stent, we deal with it, move on. It's either ongoing medical therapy, we optimize that and move on, or it's a clear-cut patient that should be moved forward for bypass..." [WCP #4, interventionalist] • "Being user friendly, for sure, is important. Being accessible. Something that we can use remotely is important because that's when, I think, it'd be pretty useful. And then just current, I guess. Data or information that's real time." [OIP #3, interventionalist]
Data privacy and confidentiality	• "I think that from a patient privacy perspective, that's going to be a really important thing to have a really good grasp on the ethics before that happens, because machine learning can be used to generate all sorts of models for all sorts of risks. And whether those things in the future are going to... Say, my EMR is plugged into machine learning, and it's able to automatically generate a detailed risk for, for cardiac death over the next 10 years, is that going to affect my patient's ability to get insurance? So, there needs to be a consent aspect in there for sure." [OIP #2, interventionalist] • "Obviously, confidentiality and privacy are massive when it comes to medical information. It certainly would have to be secure." [OIP #3, interventionalist]

Table . Example quotes related to AI[a] incorporation into clinical workflow (theme 5).

Subtheme and description	Example quotes
AI as an opportunity to improve care	
Considering AI as an opportunity in the existing clinical workflow.	• "For sure, there's many opportunities… I think risk stratifying the lesion or identifying high risk lesion characteristics… identifying a culprit lesion, the predicted success of revascularization or subsequent stent complications. In another way of saying that would be determining what method of revascularization. I think those are all-important real-time feedback that an operator could receive… It would be really nice to pair that with non-invasive cardiac diagnostics, which would include echo, MRIs… Those are all areas that I think will be very, very interesting." [OIP #1, surgeon] • "I think that having some artificial intelligence to make suggestions is helpful. And like I said, to provide supporting information like risk profiles and stuff like that, but I think that ultimately, the conversation between the physician and the patient is always going to be a pretty big driving force for what path we go down." [OIP #2, interventionalist]
Knowledge translation	
The importance of knowledge translation among end users.	• "One of the challenges for us in knowledge translation here, trying to translate something that's extremely technical. And in fact, we're front-runners in the industry into something that's useful for both patients and caregivers. So, I don't think it's a game stopper, it's just something we have to be aware of and be knowledgeable about." [WCP #2, patient] • "You guys do such important work, really the patient should be knowing this stuff, like what's going on with their body at a doctor's visit, at a family physician. So, I think if this information's being shared." [WCP #1, patient] • "I don't have a good sense as to how to actually perform due diligence on a product or algorithm. And in the absence of the ability to do that, it's very difficult to know how much weight you would put on the response from an algorithm. So, I think that a bit of knowledge translation, or trying to validate an AI model in a manner that's understandable to clinicians is critical." [OIP #1, surgeon]

[a]AI: artificial intelligence.

Theme 1: Evidence-Based Care

Overview

All participants emphasized the importance of evidence-based guidelines to minimize variation in care and unify the Heart Team that makes treatment decisions for patients with CAD. The clinician participants explained that their clinical practice was based on their clinical knowledge and experiences, as well as existing medical evidence (including clinical practice guidelines). They stated that although there are some clinical guidelines, many are of low quality and endorsed the need for better guidelines. They also noted that while evidence and experience are foundational, CAD treatment decisions tend to be biased by the opinion of a single clinician and that each clinician has different priorities and experiences.

The clinician and health system administrator participants noted that, in addition to the evidence informing treatment decisions, factors such as the urgency of the case, provider workload, patient preferences, and time of day also influence treatment decisions. This led to comments related to timely and complete patient data (medical history and comorbidities), which is discussed in greater detail under theme 3 (data requirements).

Contrasting Perspectives

While all participants endorsed the importance of evidence-based care, clinicians primarily framed the issue as a challenge of guideline clarity and individual bias. In contrast, it was suggested that administrators may instead focus on the broader system-level influences that contribute to variability in revascularization decisions (explored in further detail in theme 2).

Theme 2: Workload and Resources

Overview

Most clinician participants stressed that time is a significant issue for making treatment decisions around revascularization. They stated that due to the high volume of cases, there is minimal time available to comprehensively review patient information and discuss the patient. This challenge, combined with the urgency required to revascularize patients with CAD, makes it difficult to fully assess all the risks and benefits of each treatment approach and consider patient preferences. All participants endorsed the challenges related to the current strain on the health care system and clinicians.

There was also discussion about physician burnout due to persistently high workloads. Clinician participants expressed that when they are overloaded and burnt out, there is a chance they will make a treatment decision more quickly, without fully considering all factors.

Participants suggested that having access to all relevant information for making treatment decisions in one, easily accessible spot would facilitate decision-making, which might help to improve patient outcomes and resource use. This is further discussed in theme 5 (AI incorporation into clinical workflow). Further noted by the patient participants was the importance of also considering patient preferences, which is discussed under themes 3 - 5 below.

Furthermore, there was some discussion about the cost of care vs the value of care (outcomes). Most of the clinician participants emphasized that they valued results over cost when making decisions about revascularization. However, they did suggest that long-term resource consumption should be considered before making treatment decisions, provided the evidence for effectiveness is comparable (eg, CABG vs percutaneous coronary intervention). The health care system administrator also discussed the issue of the value of care, especially in the current context of a resource-strained health care system.

Considerations of the cost and resources of implementing a new AI system into clinical workflow were discussed. It was noted that adopting AI in the clinical workflow is expensive and needs investment (time and money). However, participants suggested that the investment in AI may be relatively small if it eventually saves time and improves the quality of care. The industry participant expressed the importance of engaging and understanding health system administrators' willingness to invest (time and resources) and implement the AI technology into practice from the early stages of the development process.

Contrasting Perspectives

Although all participants acknowledged the strain created by limited time and resources, clinicians emphasized how high workload, case urgency, and burnout directly affect their ability to thoroughly review patient information and weigh treatment options. Patients highlighted the importance of ensuring that their preferences are considered despite time constraints, whereas administrative concerns remained focused on the value of care despite resource limitations. From an industry perspective, attention was drawn to the investment required to implement AI tools and the willingness of administrators to support such adoption.

Theme 3: Data Requirements

Patient-Centered Approach

All participants agreed that patient characteristics were the most critical factor in making a revascularization decision. The clinician participants indicated that making decisions around revascularization is particularly difficult for complex patients with multimorbidity.

Understanding and considering patient preference was another key factor in making revascularization decisions. The clinician participants indicated that giving patients a choice or following their preferences can be challenging, because the patient's preference can sometimes be highly divergent from the evidence-based recommendation.

All participants agreed that respecting patient preference is important, and a conversation between the clinician and the patient, including hearing the patient's perspective while educating patients about the risks and benefits of each intervention, should guide the decision-making process. It was noted that an AI-based CDSS could facilitate this discussion.

Evidence-Based AI

Participants stated that AI-based tools are expected to be based on evidence. The clinician participants emphasized that integrating existing evidence is important. They were intrigued by data standardization that could help AI to address real and predictable risks efficiently and consistently.

In addition, the clinician participants wondered if AI-based recommendations would differ from the current evidence and how they would reconcile such discrepancies. Despite this concern, they also expressed their excitement toward practicing data-driven revascularization decision-making.

Data Integration

Participants voiced the importance of integrating patient data into AI-based CDSSs. Participants stated that AI tools integrated with the electronic medical record could facilitate the clinical use of large volumes of patient data more efficiently and precisely. All participant groups also stated that integrating all critical patient data, including a comprehensive list of risk factors (eg, patient history, comorbidities, anatomical presentation, and frailty), is essential for AI-based CDSSs. Given the size and comprehensiveness of the data involved, some participants raised concerns regarding ethics, privacy, and confidentiality.

Contrasting Perspectives

All participants emphasized both the importance and the challenges of incorporating patient perspectives into revascularization decision-making. Clinicians suggested that an integrated AI-based CDSS may facilitate clinician-patient discussions and enhance decision-making; however, they also raised concerns regarding patient confidentiality and the potential unintended consequences of risk profiling that may adversely affect patients.

Theme 4: Tool Characteristics

End User Built

All participants emphasized the importance of meaningfully involving all key end users when developing the tool. All participant groups stressed that end users should be involved not only in tool development but also in training, implementation, and evaluation. Furthermore, the patient and clinician participants noted that a patient-centered approach that captures patient voices and their perspectives about clinicians' use of AI-based tools would lead to effective communication between patients and care providers. Some participants identified family physicians as potential end users as well.

Generation and Presentation of Decision Support Information

Participants were interested in the possibility that AI-based CDSSs have the capacity to provide a comprehensive score or recommendation that takes into account patient characteristics to optimize treatment plans and have the ability to interact with patients and families. Summary risk scores were preferred for easy interpretability and communication. Conversely, participants expressed concerns about the validity of the CDSS and including a comprehensive list of potential risk factors. Comprehensive data that integrated patient medical history and comorbidities were perceived as core components for successful AI-based CDSSs.

User-Friendliness and Accessibility

A user-friendly interface and being accessible beyond a networked computer (eg, mobile access) would increase uptake. In addition, participants stated that the CDSS needs to be intuitive and integrated seamlessly within the existing clinical workflow. Technical support would improve the usability and implementation of a CDSS, which would also address the concern about resources and workload associated with the tool (discussed in theme 2). The clinician participants also stressed that revascularization decisions require a high-level summary of accurate information, which must be easy to navigate and access.

System Logic, Reasoning, and Data Privacy

Most of the clinician and patient participants focused on the importance of the transparency of the CDSS and knowing how the CDSS works and generates treatment recommendations, including its logic and limitations.

Some participants also expressed their concern about regulatory compliance, liability, and accountability of the CDSS before implementation can be considered. This concern was based on medical ethics and legal perspectives. However, some participants also felt that if data privacy standards could be met, there was excitement about leveraging the advantages of AI.

Similarly, another major concern expressed by many participants was data privacy, particularly whether the AI-based CDSS could maintain the required confidentiality and privacy of health information. They pointed out that CDSS developers should be aware of various regulatory requirements that protect health information privacy. The patient participants were worried that AI recommendations could have unintended consequences on other health-related issues.

Contrasting Perspectives

Although all stakeholder groups agreed that AI-based CDSSs should be user-friendly, accessible, and developed with meaningful end user involvement, clinicians emphasized medico-legal considerations and the desire for such tools to support real-time decision-making and seamlessly integrate into clinical workflow. In contrast, patients may be more likely to view such tools as a means to facilitate discussion with care providers rather than solely functioning as a real-time decision aid. Both clinicians and patients emphasized the importance of validity and transparency of an AI-based CDSS; however, similar to theme 3, concerns remain regarding patient data privacy.

Theme 5: AI Incorporation Into Clinical Workflow

AI as an Opportunity to Improve Care

Most participants perceived AI as an opportunity in the clinical workflow. They were quite positive and supportive about the development of AI-based CDSSs for revascularization decision-making. The clinician participants felt that AI would add support to their decision-making process, provided that recent scientific evidence is incorporated into the CDSS. Many participants mentioned that integration between the electronic medical record and AI, and end user engagement with both clinicians and patients, would be crucial to integration into the clinical workflow.

Knowledge Translation

Participants underlined knowledge translation as one of the core components required before integrating AI into the clinical workflow. For instance, the clinician participants were intrigued by how AI algorithms work, how comprehensive AI-based risk scores can be, as well as the system logic, reasoning, benefits, and limitations of the technology. However, many participants expressed that they still lacked knowledge about how AI works and suggested that continuous knowledge translation would be helpful.

Participants also noted that identifying end users is critical before integrating AI into the clinical workflow. For instance, a patient participant questioned whether AI-based CDSSs could be integrated into not only cardiac care but also primary care. The participant further expressed that integrating AI into primary care would facilitate conversations between patients and their primary care providers.

Contrasting Perspectives

While some clinicians emphasized the potential role of AI-based CDSSs as real-time supports within existing clinical workflows, others highlighted their value in supporting clinician-patient conversations across care settings. Differences in perspectives were most apparent in relation to knowledge translation, with clinicians emphasizing their desire for a deeper understanding of AI system functionality and validity, while other participants highlighted the importance of making AI-derived information simple and accessible to patients and primary care providers.

Discussion

Principal Results

This study provides an exploratory examination of AHS stakeholder perspectives on the use of an AI-based CDSS for CAD treatment strategy. Across stakeholder groups, participants emphasized that delivering evidence-based care when making coronary revascularization decisions for patients with CAD is often challenging due to conflicting or inadequate clinical practice guidelines. Although AI has the potential to improve the current state of CAD treatment decision-making, the need for timely access to comprehensive patient data through integration with hospital information systems, clinicians' heavy

workloads, data privacy concerns, and end users' desire for transparency regarding how the AI generated a particular recommendation may complicate the successful development, deployment, and adoption of AI-based CDSSs. The likelihood of successful adoption can be enhanced by incorporating scientific evidence and patient preference into decision support information, involving end users (both patients and clinicians) in the entirety of technology development, designing systems that are intuitive and easy to use, and presenting information in a succinct and easy-to-understand manner. In addition, this study's participants also raised the importance of systemic issues, including regulatory requirements, the need for resource commitments from health systems, and health care cost considerations.

Despite these challenges, the participants expressed excitement about AI's potential to improve CAD care. Many acknowledged that they had limited AI knowledge and wanted to be educated in an ongoing manner. They felt that although substantial investments may be required to develop, implement, and adopt AI-based CDSSs, the potential cost savings and improved patient outcomes will likely make it a worthwhile endeavor.

Contrasting Perspectives

Across themes, consistent patterns emerged in how different stakeholder groups framed the challenges and opportunities associated with AI-supported revascularization decision-making. Clinicians primarily focused on the practical realities of care delivery, emphasizing limitations in guideline clarity, time pressure, workload, and difficulties with synthesizing large amounts of data. Many described how an AI-based CDSS could help synthesize complex data, enhance clinical efficiency, and support real-time decision-making. Clinician concerns centered on liability and accountability of implementing AI-based tools, how to reconcile AI recommendations with clinical judgment, and emphasized the importance of patient data security and privacy. While clinicians often focus on mitigating long-term mortality and major adverse event risk, patients emphasized the importance of considering both short and long-term risks and benefits, valuing AI-based CDSS as a tool to help facilitate communication between clinicians and care providers. Industry perspectives highlighted the potential challenges surrounding an AI-based CDSS implementation, emphasizing the need for early alignment with administrative priorities, investment considerations, and demonstrable value to support adoption. Health system administrative perspectives, in contrast, tended to frame decision-making through a system-level lens, prioritizing standardization and value of care, viewing an AI-based CDSS as a short-term cost with potential long-term benefits and cost savings. Finally, differences were evident in expectations around knowledge translation, with clinicians seeking a deeper understanding of transparency, validation, and functionality of AI-based systems, while other participants emphasized the importance of making AI-derived information accessible to patients and primary care providers. Together, these contrasting perspectives highlight that the successful implementation of AI-based CDSSs requires not only technical accuracy but also careful alignment with the distinct priorities, responsibilities, and expectations of diverse stakeholder groups.

Comparison With Prior Work

The potential of AI in improving CAD or cardiovascular care at large has previously been discussed [11,12], and a number of machine learning models have been developed in this space for a variety of clinical use cases (eg, in other studies [13-17]). Although much of this research has focused on the technical aspects of development, rather than implementation and adoption [18], many of the themes that emerged from the World Café are echoed in the existing literature. Challenges introduced by the availability, quality, and standardization of data are consistently raised in discussions surrounding the use of AI in health care [19-21], and concerns about data privacy and security are also common [22,23]. Many studies investigating clinician uptake of AI-based CDSSs emphasize the importance of providing evidence-based decision support information [21,24-27], using development data that are reflective of the patient populations the AI is intended to support [28-30], and increasing the transparency of model reasoning as important facilitators to adoption [22-24,31]. These studies also underline the issues resulting from an absence of AI education in the current medical curricula and call for increased knowledge translation efforts to build trust and credibility with clinicians [24,32]. It is worth noting that several issues discussed by the participants, including time constraints and the need for intuitive and user-friendly applications, are pervasive issues in health care that are not necessarily unique to the adoption of AI-based tools [33,34]. Indeed, with a greater than 50% failure rate among many types of CDSS [35], the need for end user involvement in development has been highlighted as crucial to successful implementation [35,36].

While many of the issues identified in this study appear to be universal across health care, contextual idiosyncrasies remain. For example, the WCPs often stressed the importance of patient preference in CAD treatment decision-making and suggested that an AI-based CDSS may help facilitate patient discussions. In contrast, some prior studies have reported concerns about AI-based CDSSs negatively impacting the patient-clinician relationship, suggesting that using such systems could reduce the amount of time available for patient interaction or, in extreme cases, cut out contact altogether should clinical interactions be shifted to a digital format [22,25]. However, one of these studies interviewed only general practitioners [25], whose responsibilities are arguably more conducive to digitization than coronary revascularization decision-making. Similarly, other studies have discussed technical barriers beyond data requirements, including insufficient computing resources and inconsistent access to Wi-Fi, which are more pervasive in low-to-middle-income countries [28,37]. Thus, the importance of this work also lies in understanding the context within which the AI-based CDSS will be implemented, which is essential for successful adoption [38-41].

Finally, although AI-based clinical tools are increasingly being evaluated for their potential to enhance clinical decision-making and efficiency [42], their utility should be met with both optimism and caution. Recent evidence suggests that while AI-based systems can accurately perform specific clinical tasks and support information delivery, these capabilities may not necessarily translate into improved patient or system-level

outcomes [43,44]. Indeed, despite substantial investment and academic efforts, there remains limited prospective evidence demonstrating that AI-based tools have improved patient outcomes at scale [45]. Concerningly, among approved medical devices that use AI, clinical validation studies are inconsistently reported, and when reported, rarely include prospective and randomized evaluations [46,47]. Accordingly, while the technical performance of AI-based tools remains important, prospective randomized controlled trials are needed to demonstrate true clinical benefit. In parallel, future investigations should explicitly evaluate the fairness and equity of these tools and aim to determine whether such tools can alleviate clinician burden rather than add to cognitive or administrative loads [48].

We hope the diverse contextual factors described here can serve as a helpful foundation for the future development and implementation of CDSSs for CAD treatment decision-making.

Limitations

This study has several limitations. First, 3 clinician participants were unable to attend the World Café, and they were engaged in one-on-one interviews instead. Although efforts were made to engage these participants using comparable prompts and facilitation techniques, inherent differences between one-on-one and group-based World Café discussions may have influenced the data generated. As a result, some themes may reflect methodological differences despite efforts to reconcile findings across formats. Second, within our relatively small sample size, clinicians outnumbered the other stakeholder groups (8 vs 4), and their opinions may have dominated the discussions and results. For instance, some patient perspectives were articulated by clinicians rather than patients directly and may not necessarily represent the views or priorities of the patients themselves. Third, all participants were recruited in Alberta, limiting the generalizability of our findings to other jurisdictions. As the overall structure of AHS, including the clinical flow of patients and delivery of care, may not mirror that of other health care systems, some of the themes identified in the current investigation may be unique to this publicly funded and integrated health care system. Accordingly, while the themes and perspectives derived from this investigation provide valuable insight into the intricacies of implementing AI-based CDSS into practice, future work incorporating larger and more heterogeneous participant populations, balanced stakeholder representation, consistent data collection formats, and diverse health care system contexts may provide additional insights.

Conclusions

Various stakeholders, including patients and clinicians, believe that current coronary revascularization decision-making for patients with CAD is only partially evidence-based. AI-based CDSSs have the potential to improve this, leading to improved patient outcomes and health care cost savings. The successful development and implementation of such AI-based CDSSs hinges upon extensive end user involvement, data integration, data privacy protection, incorporation of patient preference, alignment with scientific evidence, and great usability. Integrating end user co-design and iterative usability testing may help support these priorities in future work.

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Authors' Contributions

KS designed and oversaw this study and wrote the manuscript. BB conducted this study, analyzed the data from the World Café and interviews, synthesized findings, and wrote the manuscript. CvR edited and revised the manuscript. BH and RW participated in the World Café and validated the main findings from this study. JL oversaw this study, provided resources, and prepared the manuscript. All authors proofread and approved the manuscript.

Conflicts of Interest

JL is a cofounder and major shareholder of Symbiotic AI, Inc. BH is a minor shareholder of Symbiotic AI, Inc. CvR is a paid independent contractor or consultant for Symbiotic AI, Inc. RW is an interventional cardiologist.

Checklist 1
COREQ checklist.
[PDF File, 432 KB - cardio_v10i1e81303_app1.pdf]

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Abbreviations

AHS: Alberta Health Services
AI: artificial intelligence
CABG: coronary artery bypass grafting

CAD: coronary artery disease
CDSS: clinical decision support system
COREQ: Consolidated Criteria for Reporting Qualitative Research
OIP: one-on-one interview participant
WCP: World Café participant

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Multilingual Video Education for Hospitalized Patients With Myocardial Infarction (EDUCATE-MI): Single-Arm Implementation Study

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Abstract

Background: Clinical guidelines recommend the early initiation of secondary prevention strategies prior to hospital discharge for patients with myocardial infarction (MI) to reduce morbidity and mortality, but implementation is resource-intensive. Multilingual videos can deliver information in diverse preferred languages and literacy levels, but their impact on MI knowledge among hospitalized patients remains unclear.

Objective: This study aims to assess whether the delivery of a multilingual educational video to hospitalized patients with MI can improve patient MI knowledge before hospital discharge.

Methods: We conducted a single-arm pre-post study with embedded formative implementation evaluation from December 2023 to October 2024 in a tertiary hospital. The intervention was a video on post-MI management, available in English, Arabic, Hindi, and Mandarin (with Simplified Chinese subtitles). The intervention was delivered via a tablet provided by the research assistant. The primary outcome was the change in patient knowledge of MI, measured by comparing the mean number of correct responses before and after the intervention using a 2-tailed paired *t* test. We assessed early-stage implementation using 2 prespecified elements from the Proctor implementation outcomes framework: acceptability and fidelity of the video delivery. We performed content analysis on the notes taken from participants' feedback to improve the video.

Results: We recruited 129 participants (mean age of 59.4, SD 12.6 years) for this study. English was the preferred language (n=96, 74.4%) and Hindi was the predominant non-English language (n=17, 13.2%). Of the 129 participants enrolled, 128 completed follow-up immediately postintervention (1 lost interest). The average number of correct responses out of 10 was 5.4 (SD 2.7) at baseline and 7.2 (SD 2.5) postintervention (mean difference=1.9, 95% CI 1.6-2.2; P<.001; Cohen d_{rm} for paired change=0.72). The educational video was well-accepted, with 83.6% (107/128) of participants finding it easy to understand, 74.2% (95/128) engaging, and 87.5% (112/128) useful. Participants' feedback for improvement highlighted content complexity and a preference for conversational language and dialects. Fidelity of the intervention was subjectively assessed as reasonably achieved, given that the core components of the intervention (ie, animations and educational content conveyed through the audio and subtitles) were delivered as intended. Fidelity of the implementation strategy was similarly assessed as reasonably achieved because there were no technology issues preventing delivery of the intervention as intended, through video display from a weblink embedded in REDCap, using a tablet with internet connection.

Conclusions: A short educational video may improve patient knowledge of MI before discharge. Further scaled research is needed to evaluate the effectiveness and implementation of this intervention in additional languages and diverse populations.

This study highlights the need for culturally and linguistically tailored resources in clinical settings, informing future research and policy on inclusive patient education.

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KEYWORDS

myocardial infarction; health education; diversity, equity, inclusion; DEI; multilingual video

Introduction

Cardiovascular disease (CVD), a group of diseases affecting the heart and blood vessels, remains the leading cause of death worldwide [1]. Most CVD mortality is due to atherosclerotic causes, including acute myocardial infarction (MI) secondary to plaque rupture (type 1 MI), accounting for 38% to 44% of all CVD-related deaths worldwide [2]. After the acute phase, the risk of death from another cardiac event remains high [3].

International guidelines recommend the early initiation of secondary prevention strategies prior to hospital discharge to reduce the risk of morbidity and mortality [4], but there are challenges in implementation. A key component of secondary prevention is adherence to various medications, including long-term aspirin and dual antiplatelet therapy [5]. However, adherence to these medications remains suboptimal [6] due to barriers including psychological factors and the complexity of the drug regimen [7]. Patient education is key to addressing MI knowledge gaps and suboptimal medication adherence, but inpatient education delivery relies on time-pressured frontline clinicians and may fail to accommodate the needs of diverse populations [8].

Educational videos can help deliver evidence-based health information to diverse populations and accommodate different language preferences and literacy levels, including people with limited reading ability or those who are illiterate [9,10]. A systematic review (59 experimental studies, n=9789) of video-based educational interventions reported improved knowledge in 75 % (30/40) of the assessed outcomes in people with chronic diseases [9]. Previous studies evaluating inpatient video interventions for patients post-MI [11,12] have shown improvements in patient knowledge, but the videos in these studies were delivered in 1 predominant language. To date, no studies have evaluated the impact of multilingual educational videos delivered during admission on patient knowledge post-MI. Assessing knowledge during hospitalization and before discharge is important as distress in the acute period of an MI can interfere with understanding and recalling clinical information [13].

The aim of this study was to assess whether the delivery of a multilingual educational video to hospitalized patients with MI can improve their patient knowledge of MI before hospital discharge.

Methods

Study Design

We conducted a single-arm pre-post study with embedded formative implementation evaluation in a tertiary teaching hospital in Sydney, Australia. The protocol is available on Open Science Framework (registered on April 12, 2024) [14]. Reporting of this study follows the StaRI (Standards for Reporting Implementation Studies; Checklist 1), TIDieR (Template for Intervention Description and Replication; Checklist 2) guidelines, and TREND (Transparent Reporting of Evaluations with Non-Randomized Designs; Checklist 3) [15-17].

Patient and Public Involvement

Members of the public were not involved in the design of the study or the interpretation of the findings. There are plans to disseminate the results of the research to study participants and the community via our institute's monthly newsletter.

Participants and Setting

Patients were invited to participate if they were aged 18 years or older, had been admitted for inpatient services at Westmead Hospital for a type 1 MI [18], had undergone coronary angiography, and understood 1 of the 4 available languages: English, Arabic, Hindi, or Mandarin (with Simplified Chinese subtitles; Multimedia Appendix 1).

Participants who were unable to consent to the study in 1 of 4 four languages or who were unable to complete the video due to cognitive or visual impairments were excluded.

Intervention and Implementation Strategy

The intervention was a single video with subtitles, approximately 5 minutes long, with voiceovers performed by native speakers in English, Hindi, Arabic, and Mandarin (Simplified Chinese subtitles) to ensure linguistic appropriateness. The video included different animations and focused on explaining the disease process leading to a type 1 MI (ie, acute coronary atherothrombosis) and the importance of different medications post-MI. The video was developed by a consultant cardiologist and a cardiology advanced trainee based on the latest clinical guidelines, using whiteboard animation software, with input from a multidisciplinary team. The development and description of the video is described following the TIDieR checklist in [16].

The implementation strategy was the delivery of the intervention via a tablet with an internet connection, provided by the research assistant. The video was embedded in REDCap (Research Electronic Data Capture; Vanderbilt University) surveys (accessed via a weblink) and hosted online.

Recruitment and Data Collection

Eligible participants were identified through discussion with their care team and approached at the patient's bedside. Participants were informed that they could withdraw at any time. We did not approach participants who were clinically unstable, as indicated by the ward clinicians. A research assistant

conducted the consent process and stayed with the patient while they watched the video. Patients were encouraged to provide feedback on the video during and after visualization; the research assistant took notes of patients' comments and feedback. At baseline, sociodemographic data and MI knowledge were collected. MI knowledge was assessed immediately postintervention and at a 1-month follow-up (the latter being optional, for participants who opted to provide an email address for this purpose), as well as data on the acceptability of the video. Sociodemographic data, MI knowledge, and acceptability data were collected via self-reported electronic questionnaires hosted on the REDCap platform.

Study Outcomes

The prespecified primary outcome was prospectively defined as the average number of correct responses on the MI knowledge questionnaire immediately after the intervention, compared to baseline. Given the lack of validated questionnaires assessing MI knowledge [19], one of the investigators (AT) developed the MI knowledge questionnaire with contributions from other clinicians. The tool is a 10-item multiple-choice (5 options with 1 correct answer per question) questionnaire that assesses general MI knowledge, with questions on the causes of MI and post-MI medications (with the total number of correct responses ranging from 0="no correct answers" to 10=" all answers to the 10 questions were correct"; Multimedia Appendix 1).

A prespecified secondary outcome was the average number of correct responses in the MI knowledge questionnaire at 1 month. Exploratory post hoc outcomes included the proportion of participants who improved their total number of correct responses from baseline to postintervention, the proportion meeting the knowledge target (defined as 7 or more correct responses out of 10) or medication knowledge target (defined as correctly answering all 7 medication questions), and the proportion of correct responses for each of the 10 individual questions postintervention compared to baseline.

To assess early-stage implementation, we evaluated two prespecified elements from the Proctor implementation outcomes framework [20]: (1) acceptability of the intervention and (2) fidelity of the intervention and implementation strategy (ie, delivery of the intervention via a tablet with an internet connection). Acceptability of the intervention was assessed through content analysis of participants' feedback (described in the "Data Analysis" section) and via a questionnaire asking participants to rate 3 different statements on a 5-point scale from strongly disagree to strongly agree ("The information delivered in the video was easy enough to understand," "I found the video engaging," and "I found the information useful") and asking whether they would be interested in receiving similar videos in the future (yes or no).

Fidelity of the intervention was subjectively assessed by the investigators based on whether the core components of the intervention (ie, video animations and educational content conveyed through the audio and subtitles) were delivered as intended across the 4 different language versions. For this assessment, perspectives from the translators involved in the study were sought regarding the extent to which the translated content matched the English version. Fidelity of the implementation strategy was subjectively assessed by the investigators based on deviations from the intended mode of delivery (ie, video display from a weblink embedded in REDCap, using a tablet with internet connection).

Data Analysis

Data analysis followed a statistical analysis plan developed a priori (Open Science Framework) [14]. A sample size of 119 participants was estimated to provide 90% power to detect a moderate effect size (d=0.3) in knowledge difference pre-post, considering a 2-sided type 1 error of 0.05.

We expressed descriptive data as proportions and means with SD. The prespecified primary outcome was analyzed using a 2-tailed paired *t* test, measuring the mean difference in patient knowledge before and after the intervention, reported with 95% CIs, and Cohen d_{rm} for paired change (Multimedia Appendix 1). An exploratory McNemar test was used to assess changes in the proportion of participants who met knowledge targets before and immediately postintervention, as well as the proportion of correct responses for each of the 10 individual questions postintervention compared to baseline. A prespecified 2-tailed paired *t* test was used to measure the mean difference in patient knowledge before and 1 month postintervention. To test the homogeneity of the treatment effect across subgroups, we used ANCOVA (postadjusted for baseline) to assess the change in the average number of correct responses by age (≤65 y and >65 y), sex (male and female), language (English and non-English), and education (prior to secondary education completion and postsecondary education; Multimedia Appendix 1). We report the proportion of participants who improved their total number of correct responses from baseline to postintervention and implementation measures of acceptability descriptively immediately postintervention and at 1-month follow-up.

Analyses were conducted using R statistical software (version 4.4.0; R Project for Statistical Computing). *P* value was 2-sided, and statistical significance was set at *P*=.05. Data were analyzed from October 2024 to November 2024. Participants with missing data at follow-up were excluded from the analysis. Two researchers performed content analysis on the notes taken from participants' feedback. We were interested in understanding the participants' perspectives on the content of the video in the different languages and their suggestions for improving the videos. Themes were reviewed and discussed with 2 other investigators to clarify, explore, and refine interpretations.

Ethical Considerations

Ethical approval (2021_ETH00983_v3) was obtained from the Western Sydney Local Health District Human Research Ethics Committee. Participant information and consent forms were available in English, Arabic, Hindi, and Mandarin (Simplified Chinese subtitles). Informed consent was obtained in the participants' preferred language. All documents and content in the intervention were translated by the multicultural unit in the Western Sydney Local Health District by a qualified health interpreter. Data were collected and stored on secure servers accessible only to approved study personnel. All data were

deidentified for data analysis and publication. No compensation was offered to the participants.

Results

Between December 2023 and October 2024, a total of 150 patients were assessed for eligibility. Of these, 130 were approached (20 were deemed by a clinician as not medically fit to be approached for the study), and 129 were enrolled (Figure 1). Of the 129 participants enrolled, 128 completed follow-up immediately postintervention (1 lost interest). Of the 89 participants who provided their email address for the 1-month survey, 18 responded (Figure 1). The baseline characteristics of participants are summarized in Table 1. The mean participant age was 59.4 (SD 12.6) years and 20.2% (26/129) were female. In our sample, 24.8% (32/129) were South Asian and 76% (98/129) completed secondary education or above. The majority of our participants listed English as their preferred language (96/129, 74.4%), followed by Hindi (17/129, 13.2%), Arabic (10/129, 7.8%), and Mandarin (with Simplified Chinese subtitles; 6/129, 4.7%).

Figure 1. Flow diagram of participants in the single-arm pre-post study.

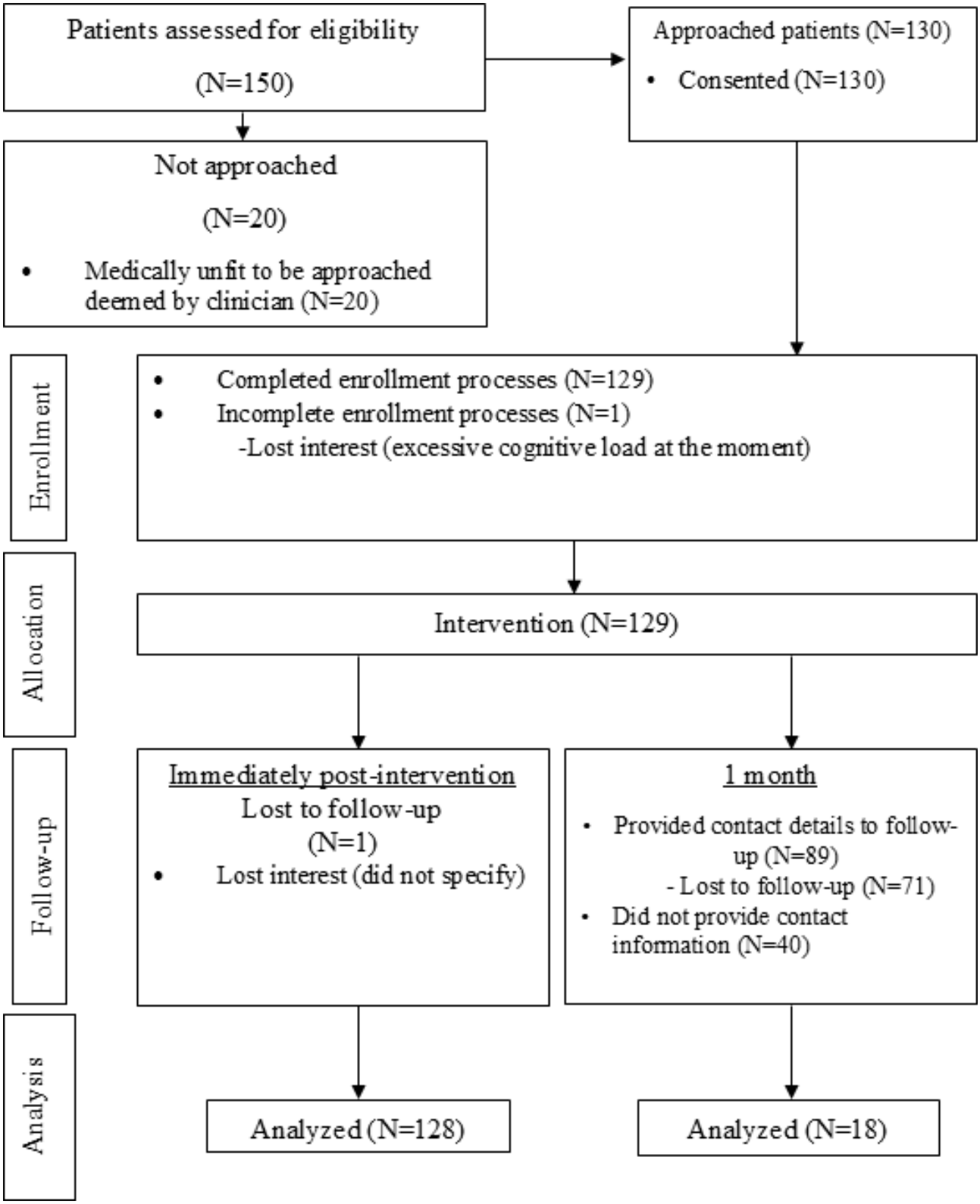


Table . Baseline sociodemographic and clinical characteristics of participants (N=129).

Characteristics[a]	Value
Sex, n (%)	
Female	26 (20.2)
Age (y; missing=3), mean (SD)	59.4 (12.6)
Ethnicity, n (%)	
Aboriginal or Torres Strait Islander	3 (2.3)
Australian or New Zealander	25 (19.4)
Polynesian	1 (0.8)
European	29 (22.5)
American (North, Central, and South)	1 (0.8)
South Asian (Bangladesh, India, Nepal, Pakistan, and Sri Lanka)	32 (24.8)
East Asian (China, Japan, and Taiwan)	8 (6.2)
South-East Asian (Vietnam, Cambodia, Laos, Burma, Malaysia, Singapore, Philippines, Thailand, Indonesia, and East Timor)	8 (6.2)
Middle East and North African	19 (14.7)
Sub-Saharan Africa	1 (0.8)
Pacific Islander	2 (1.6)
Other	0 (0)
Preferred languages, n (%)	
English	96 (74.4)
Arabic	10 (7.8)
Hindi	17 (13.2)
Mandarin (with Simplified Chinese subtitles)	6 (4.7)
Education level, n (%)	
Never attended school	1 (0.8)
Primary	7 (5.4)
Secondary school without completion certificate	23 (17.8)
Secondary school graduate	25 (19.4)
Technical or vocational qualifications	10 (7.8)
University undergraduate	47 (36.4)
University postgraduate	16 (12.4)
Risk factors, n (%)	
Diabetes	48 (37.2)
Hypertension	74 (57.4)
High cholesterol	66 (51.2)
Smoker (or recently quit <12 mo)	47 (36.4)

[a]All data are self-reported.

In the primary outcome analysis, the average number of correct responses was 5.4 (SD 2.7) at baseline and 7.2 (SD 2.5) postintervention (mean difference=1.9, 95% CI 1.6-2.2; *P*<.001; Cohen d_{rm} for paired change=0.72; Table 2). At 1 month postintervention, there were 18 completed responses (Multimedia Appendix 1). Overall, 72.7% (93/128) of the participants showed higher scores in their total number of correct responses postintervention compared to baseline (Multimedia Appendix 1). The proportion of participants who met the MI knowledge target postintervention increased from 47/129 (36.4%) to 93/128 (72.7%; *P*<.001; Figure 2). For each of the individual questions, the proportion of correct responses increased from baseline to postintervention, except for 1 question (question 7; Multimedia Appendix 1).

Regarding the acceptability of the intervention, most participants reported that they agreed or strongly agreed that the information delivered in the video was easy to understand (107/128, 83.6%), engaging (95/128, 74.2%), and useful (112/128, 87.5%); additionally 84.4% (108/128) reported they would like to receive similar videos in the future (Multimedia Appendix 1).

Table . Mean difference in myocardial infarction (MI) knowledge before and immediately after the multilingual video intervention in hospitalized patients with MI prior to discharge (n=128).

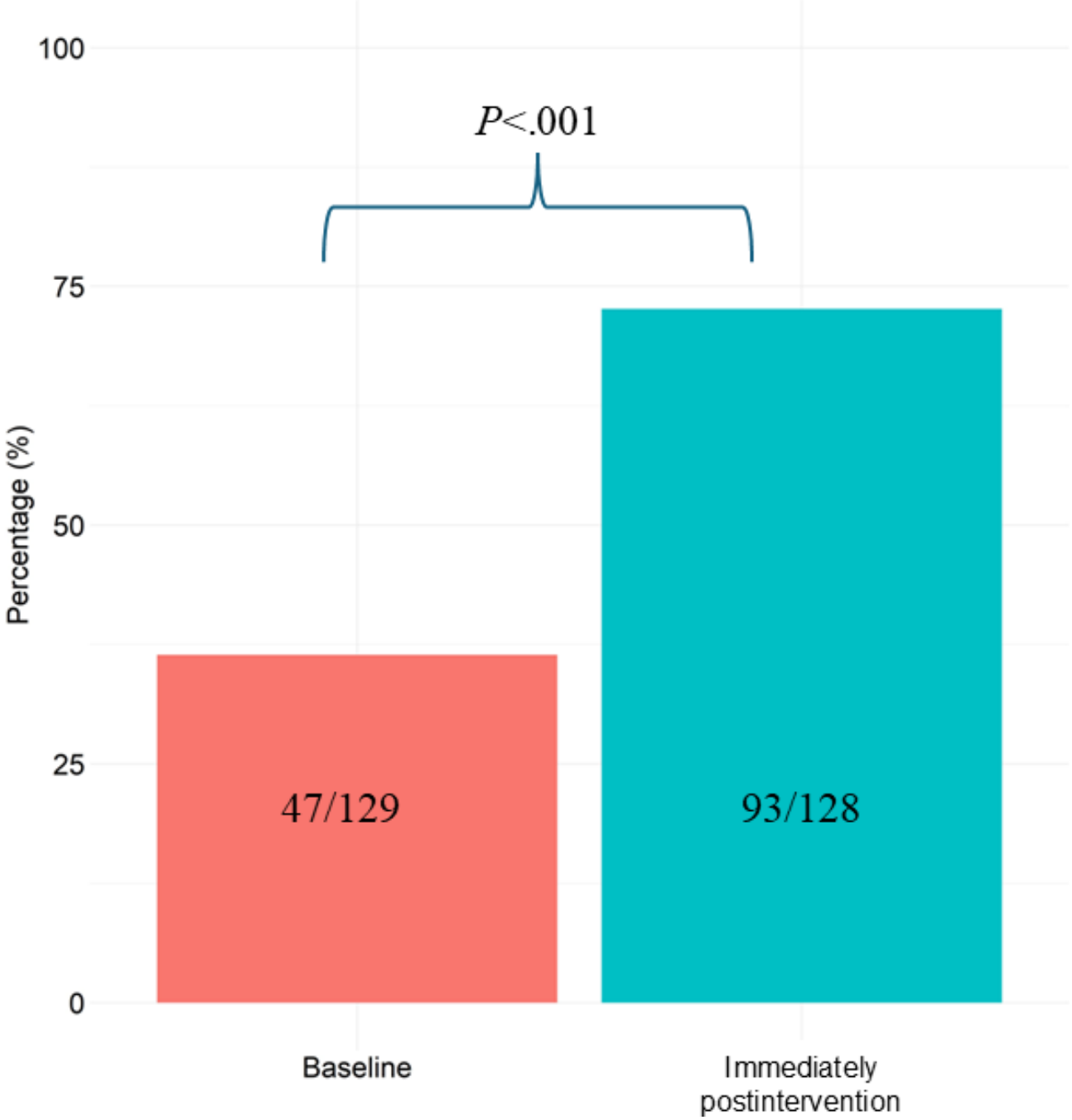
	Baseline, n=129	Immediately postintervention, n=128	Mean difference, n=128[a] (95% CI)	*P* value	Cohen d_{rm}[b]
Mean number of correct responses[c], mean (SD)	5.4 (2.7)	7.2 (2.5)	1.9 (1.6-2.2)	<.001	0.72

[a]Analyzed using 2-tailed paired *t* test.

[b]Cohen d_{rm} for paired change - adjusted d_z estimating the "standard" between-subjects *d* by a factor of 2(1−r), where *r* is the Pearson correlation between the paired measures [21] (Supplement F in Multimedia Appendix 1).

[c]Correct responses range from 0 to 10.

Figure 2. Bar plot illustrating the proportion of participants who met the knowledge target (defined as 7 or more correct responses out of 10) before and immediately after the video intervention. Changes in the proportion of participants were assessed using a McNemar test.



Nine participants (5 Hindi-speaking, 2 Mandarin-speaking, and 2 Arabic-speaking) provided qualitative feedback on the videos. Content analysis of the feedback revealed two main themes: (1) complexity of the content and medical jargon, and (2) preference for conversational language and dialects. Regarding the complexity of the content and medical jargon, participants indicated they had difficulty understanding some terms in the videos, expressing a preference for lay language. Examples of quotes from participants grouped in this theme include:

> *The video will be too difficult to understand (for people not) familiar with the terminology.* [Study ID 125; 70‐75 years; preferred language: Hindi; educational level: university undergraduate]

> *High-order Hindi was used—needs to have less jargon.* [Study ID 30; 66‐70 years; preferred language: Hindi; educational level: university postgraduate]

Regarding the preference for conversational language and dialects, participants with Hindi as their preferred language reported that a macaronic-hybrid language was commonly used to communicate and would be preferred for the video. Participants with Arabic as their preferred language mentioned that they would prefer the video to be in their specific dialect. Examples of quotes are presented as follows:

> *Mix of Hindi and English would have been better—conversational Hindi.* [Study ID 30; 66-70

years; preferred language: Hindi; educational level: university postgraduate]

Dialect is like Egyptian… parents would understand Nahw… (I) am bilingual—so can't read or write. [Study ID 108; 40-45 years; preferred language: Arabic; educational level: university undergraduate]

Fidelity of the intervention was subjectively assessed as reasonably achieved, given that the core components of the intervention (ie, animations and educational content conveyed through the audio and subtitles) were delivered as intended. The video animations were the same across the 4 translated versions of the educational video; only the timing between different animations changed to accommodate the audio. The educational content conveyed through the audio and subtitles was also delivered as intended, with minor differences in language between the different translations. Fidelity of the implementation strategy was similarly assessed as reasonably achieved because there were no technology issues preventing delivery of the intervention as intended through video display from the weblink embedded in REDCap, using a tablet with internet connection.

Discussion

Principal Findings

In this single-arm pre-post study with embedded formative implementation evaluation of 128 inpatients admitted for an MI, we found that a short multilingual educational video may improve patient knowledge of MI before discharge. The videos were deemed acceptable, with most participants finding them easy to understand, engaging, and useful. The core components of the intervention were delivered as intended, as the videos across the 4 languages comprised the same animations and educational content in both audio and subtitles, with only slight timing differences due to language nuances between translations. There were no deviations from the implementation strategy, with all participants watching the video through a REDCap weblink on a tablet with internet connection, as intended. Our study demonstrates that it is possible to deliver videos in different languages—English, Arabic, Hindi, and Mandarin (with Simplified Chinese subtitles)—to inpatients in a linguistically diverse context at a tertiary hospital, with modest improvement in MI knowledge before discharge.

Comparisons With Prior Work

Results from our study suggest that a single multilingual video intervention may improve patient MI knowledge in the inpatient setting. Our results are consistent with other studies evaluating inpatient video interventions for patients post-MI [11,12], although ours was the only one delivered in more than 1 language. One of these studies, a randomized controlled trial (RCT) of 68 inpatients, reported a moderate within-subject change in the intervention group (15-min video) at 3-month follow-up in the same order of magnitude that we found in our study [11]. A 2-arm quasi-experimental study (N=25) reported a 50% larger within-subject change in the intervention group at 7-day follow-up [12]. These medium to large within-subject changes also appear to persist when video interventions are delivered in a postdischarge cardiac rehabilitation setting. A pre-post study of a culturally adapted secondary prevention video education program (Simplified Chinese) for patients post-MI reported that one-quarter of patients found the information overwhelming, despite a medium within-subject change in knowledge similar in magnitude to our findings [22]. Given the competing demands during MI recovery, even the modest knowledge gains noted may be clinically meaningful and are consistent with previous findings. It remains unclear how different health literacy strategies applied to multilingual videos can influence knowledge in different populations, which should be explored in future research [23].

The mean postintervention score was 7/10, even after participants had just viewed the video, highlighting the persistent challenges of meeting patients' educational and health literacy needs. Despite efforts to adhere to readability recommendations (ie, grade 8 or below), our findings indicate additional attention is required to produce simpler content with fewer unfamiliar terms. These findings were echoed in our feedback discussions and may reflect broader barriers to comprehending health resources, such as high readability levels (ie, above the recommended grade 8 level) and the use of medical jargon [24]. Reducing readability levels prior to translation into non-English languages is important, as content complexity may be compounded during translation [24,25]. In addition, the literal translation of certain terms may not accurately convey their intended meaning, and the use of culturally equivalent terms may be preferable [25,26]. Hence, cultural adaptation is key to adequately considering the cultural aspects that may not be captured through linguistic translation alone, such as cultural equivalence, cultural appropriateness, similarity of interpretability, and item relevance [25,27].

While knowledge scores improved postintervention and the video in our study was well-accepted, further gains may be achieved with the involvement of community members in the co-design and cultural adaptation of intervention content [24,28]. Notwithstanding the importance of addressing language barriers in improving health outcomes and quality of care [29], future studies aiming to develop equitable health education interventions should also consider the nuances of social context and how language intersects with race, migration status, religion, socioeconomic position, and other social determinants of health [30-32].

Strengths and Limitations

Strengths of this study include delivering the intervention to a diverse, multicultural population (n=114, 88% non-Caucasian) in an inpatient setting. We translated the intervention into 4 different languages and adapted the medical jargon in the translations. However, there were challenges in translating medical language, and the readability of our English-language content was high, at grade 10, instead of the desired grade 8. These limitations are common in medical content, where the inclusion of specific, complex, condition-specific terminology (eg, MI) is often unavoidable and increases overall readability scores [33].

This study should be interpreted in the context of its single-arm pre-post design, which limits the evaluation of causality. Our English educational content did not meet the recommended grade 8 readability levels and was at a grade 10 level due to the

inclusion of unavoidable medical terms, which were otherwise explained in the transcript. Translations were reviewed by native speakers, but more comprehensive patient involvement in co-design and cultural adaptation will be key for future iterations, based on participant feedback. Only 34 out of 129 participants received the intervention in a language other than English, which reflects the known challenges of recruiting participants from diverse backgrounds [34,35]. Furthermore, our content analysis of patient feedback was based on researcher notes rather than verbatim transcripts of recorded feedback, limiting opportunities for in-depth analysis of participants' perspectives of the intervention. Patient knowledge may have been influenced by short-term recall in the immediate postintervention period, and the 1-month results should be interpreted with caution due to low response rates and the risk of survivor bias. Given the absence of validated patient questionnaires to assess MI knowledge, the MI knowledge questionnaire was created by clinicians in the study and was not psychometrically assessed. It may not measure actionable MI knowledge, which is key for patient empowerment and behavior change. Finally, we did not assess medication adherence, secondary prevention behaviors, health literacy, or language proficiency, which could have aided in the interpretation of the results.

Multilingual videos have the potential to reduce language barriers in the delivery of inpatient education for patients with MI prior to discharge, particularly in health care services that serve multicultural communities. We demonstrated that it is possible to improve knowledge in the short term and implement educational videos within a 5-minute timeframe for hospitalized patients with MI in a multicultural context. This offers a scalable and pragmatic strategy that may ease demands on health care staff prior to discharge. Patients report a considerable treatment burden in the first year following an MI, particularly those with lower health literacy [36], which may contribute to suboptimal medication adherence. Providing education prior to discharge may help alleviate this burden and serve as a primer for adherence to secondary prevention care. In the future, large language models and other generative artificial intelligence tools could complement video-based education by providing interactive, personalized support [37] in a patient's preferred language and at an appropriate readability level [38]. These tools could enhance health literacy and support equitable care for patients from diverse linguistic backgrounds. Future research, particularly larger RCTs with longer follow-up, should consider strategies to better engage participants with non-English language preferences, to enhance inclusivity, and evaluate the effectiveness of multilingual patient education interventions in different language groups.

Conclusions

A short educational video delivered during inpatient hospital admission for acute MI may improve patient knowledge before discharge. Our study demonstrates that it is possible to deliver videos in different languages—English, Arabic, Hindi, and Mandarin (with Simplified Chinese subtitles)—to patients in a multicultural context at a tertiary hospital. Future interventions should be culturally adapted and co-designed with patients. Further RCTs are needed to evaluate the long-term impact of this intervention on MI knowledge and secondary prevention behaviors across different settings.

Acknowledgments

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

AZ was responsible for data collection, data analysis, and writing the manuscript. AT, LL, and SKK contributed to the conceptualization and study design and critically reviewed the manuscript. EO assisted in the interpretation of the data analysis and critically reviewed the manuscript. SM assisted in the data analysis and critically reviewed the manuscript. MS, MW, JA, DM, and CKC critically reviewed and contributed to the manuscript. AT and LL are co-senior authors.

Conflicts of Interest

JA is a co-director of Health Literacy Solutions Pty Ltd. The SHeLL Editor is a research tool owned by the University of Sydney and is sublicensed to Health Literacy Solutions Pty Ltd to support broader public access and use.
CKC is a recipient of an Investigator Grant from the National Health and Medical Research Council and is an investigator on current grants funded by the Medical Research Future Fund and the National Health and Medical Research Council. CKC is a member of the Board of the Western Sydney Local Health District and the National Heart Foundation of Australia. CKC has previously received research funding or grants from NSW Health, the Australian Digital Health Agency, and Google. CKC has also previously received speaker fees from several organizations, including Novartis, Limbic, Eli Lilly and Company, Novo Nordisk, and Amgen. The George Institute for Global Health has submitted patent applications related to low fixed-dose combination products for the treatment of cardiovascular and cardiometabolic diseases. CKC is listed as one of the inventors on these applications. She reports no direct financial interests in the patent applications or related investments.
The other authors declare no conflicts of interest.

Multimedia Appendix 1
Supplementary material (Setting Details, Protocol Deviations, MI Knowledge Questionnaire, and Detailed Analyses).
[DOCX File, 94 KB - cardio_v10i1e82817_app1.docx]

Checklist 1
StaRI checklist.
[DOCX File, 55 KB - cardio_v10i1e82817_app2.docx]

Checklist 2
TiDier checklist.
[DOCX File, 276 KB - cardio_v10i1e82817_app3.docx]

Checklist 3
TREND checklist.
[DOCX File, 53 KB - cardio_v10i1e82817_app4.docx]

Checklist 4
iCHECK-DH checklist.
[DOCX File, 28 KB - cardio_v10i1e82817_app5.docx]

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Abbreviations

CVD: cardiovascular disease
MI: myocardial infarction
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
StaRI: Standards for Reporting Implementation Studies
TIDieR: Template for Intervention Description and Replication
TREND: Transparent Reporting of Evaluations with Non-Randomized Designs

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Association Between Type D Personality and Cardiovascular Disease History: Cross-Sectional Study

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Abstract

Background: Type D personality, characterized by high negative affectivity and social inhibition, has been linked to poorer mental health and heightened risk for adverse cardiovascular outcomes. Although previous studies have examined associations between type D personality, psychological distress, and cardiovascular disease (CVD), many have assessed these factors independently, relied on clinical samples, or overlooked the simultaneous assessment of psychological distress and CVD history. Consequently, less is known about how type D traits relate to emotional distress and CVD history within the general population. Understanding these relationships may support early identification of at-risk individuals and strengthen the integration of psychological screening into cardiovascular care.

Objective: This study aimed to (1) examine associations between type D personality, emotional distress (depression, anxiety, and stress), and self-reported CVD history; (2) compare distress levels among participants with and without CVD history; and (3) determine whether type D personality predicts emotional distress independent of demographic factors and CVD history.

Methods: A cross-sectional online survey was completed by 146 adults aged 30 to 85 years, recruited through convenience and snowball sampling on social media. Type D personality was assessed using the Type D Scale–14, and emotional distress was measured using the Depression Anxiety and Stress Scale-21 items. CVD history was captured through a single self-report question regarding prior diagnosis of a cardiovascular condition. Descriptive statistics characterized the sample. Two-tailed independent samples *t* tests compared distress between individuals with and without type D personality and between participants with and without CVD history. Pearson correlation coefficients examined associations among key variables. Hierarchical multiple regression assessed whether type D personality predicted emotional distress beyond age, gender, education, and CVD history.

Results: Of the 146 participants, 40 (27.4%) reported a history of CVD and 62 (42.5%) met criteria for type D personality. Individuals with type D personality exhibited significantly higher depression, anxiety, and stress levels than non–type D participants (all $P<.001$). Participants with CVD history also reported greater distress compared with those without CVD history. Hierarchical regression analyses showed that type D personality remained a strong independent predictor of emotional distress ($\beta=.46$; $P<.001$) after adjusting for demographics and CVD history. CVD history made an additional but smaller contribution to distress ($\beta=.18$; $P=.008$). These findings highlight the cumulative influence of personality traits and cardiovascular background on psychological well-being.

Conclusions: Type D personality traits have been associated with higher levels of psychological distress and with a greater likelihood of self-reported CVD history in the general population. Type D personality remained a significant predictor of distress after accounting for demographic factors and cardiovascular history, underscoring its potential role in early psychological risk identification. Incorporating brief personality and mental health screening into cardiovascular assessment may support more comprehensive care.

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KEYWORDS

type D personality; cardiovascular disease; psychological distress; depression; anxiety; stress

Introduction

Background and Rationale

Cardiovascular diseases (CVDs) remain the leading cause of mortality worldwide, resulting from a complex interplay of genetic, physiological, behavioral, and psychosocial factors [1,2]. While traditional risk factors such as age, hypertension, smoking, and dyslipidemia are well established, there is growing recognition of the contribution of psychological characteristics to cardiovascular risk and prognosis [3,4]. Among these, type D ("distressed") personality has drawn attention due to its association with poor mental health and adverse cardiac outcomes [5].

Type D personality is defined by the joint presence of negative affectivity (NA), the tendency to experience negative emotions, and social inhibition (SI), the tendency to suppress emotional expression and avoid social interactions [6]. Individuals with this personality profile are more likely to report symptoms of depression, anxiety, and stress and to experience low social support, poor quality of life, and unfavorable health behaviors [7,8]. This personality pattern is considered relatively stable over time and is found in both clinical and nonclinical populations [9]. Habibović et al [10] found that among patients with CVD, type D personality might be associated with lower social engagement, which could, in turn, partly explain its association with adverse health outcomes.

Emerging evidence suggests that type D personality is associated with an increased risk of cardiovascular morbidity and mortality, independent of traditional risk factors. Proposed mechanisms include heightened physiological stress responses (eg, hypothalamic-pituitary-adrenal axis dysregulation and inflammation), maladaptive coping strategies, and delayed health-seeking behavior [11,12]. Moreover, type D personality may interact synergistically with emotional distress to compound cardiovascular risk [13,14].

Despite increasing interest in this construct, several gaps remain. First, many studies have focused on patients with known cardiac diagnoses, limiting generalizability to broader populations. Second, type D personality and emotional distress (eg, depression, anxiety, and stress) are often examined in isolation, rather than concurrently, despite their theoretical and empirical overlap. Third, there is a lack of studies conducted in non-Western or diverse sociocultural contexts, such as Israel, where demographic and psychosocial profiles may differ.

This study addresses these gaps by simultaneously examining type D personality, psychological distress, and self-reported CVD history in a community sample. Unlike prior work focusing exclusively on clinical end points, our goal is to characterize the psychological profile of adults with and without cardiac history to assess whether type D personality is associated with greater emotional distress and cardiovascular vulnerability.

Objectives and Hypotheses

This study has two primary aims: (1) to examine whether individuals with type D personality report higher levels of depression, anxiety, and stress compared to non–type D individuals; and (2) to assess whether type D personality is an independent predictor of psychological distress after controlling for age, gender, education, and cardiovascular history.

On the basis of prior literature and theoretical models, we hypothesize the following:

- Hypothesis 1—individuals with type D personality will report significantly higher emotional distress (depression, anxiety, and stress) than those without type D traits.
- Hypothesis 2—type D personality will significantly predict psychological distress after adjusting for demographic and medical variables.

By testing these hypotheses, this study aimed to contribute to a more nuanced understanding of how personality traits relate to psychological well-being and cardiovascular history. Such knowledge may help inform early screening and targeted interventions in cardiac care settings.

Methods

Study Design

A cross-sectional, quantitative study was conducted to assess associations between type D personality, psychological distress, and self-reported cardiovascular history in a nonclinical adult sample. The study was part of a larger survey-based investigation examining personality and health factors.

Participants and Recruitment

A total of 146 participants were recruited via convenience and snowball sampling using targeted advertisements on Facebook and WhatsApp (Meta Platforms, Inc) between January and April 2022. Inclusion criteria included being aged 30 years or older, fluency in Hebrew, and access to the internet. Participants completed an anonymous online questionnaire hosted on Google Forms (Multimedia Appendix 1). Sensitivity analysis confirmed that the sample size provided sufficient statistical power for the logistic and linear regression models used.

Ethical Considerations

The study was approved by the Institutional Review Board of Ruppin Academic Center (approval code 251-L/22). Informed consent was obtained electronically from all participants before participation. All responses were anonymous. Participants received no monetary compensation. All data were deidentified before analysis.

Measures

Demographics and Health History

A background questionnaire collected data on age, gender, marital status, number of children, education level, religious identification, and self-reported cardiovascular history. CVD history was determined via the following question: “Have you ever been diagnosed with a cardiovascular condition or experienced a cardiac event (Yes/No)”?

Type D Personality

The Type D Scale–14 [8] was used to measure type D personality. The scale includes 14 items rated on a 5-point Likert scale, yielding 2 subscales: NA and SI. Participants scoring 10 or greater on both subscales were classified as type D. The scale has demonstrated good reliability in Hebrew-speaking populations (α>.80).

Psychological Distress

The Depression Anxiety Stress Scale (DASS)-21 items [13] was used to assess emotional distress. The 21 items measure depression, anxiety, and stress over the previous week using a 4-point Likert scale. Subscale scores were calculated and multiplied by 2 to match standard interpretations. Internal consistency was high (α=.87-.91).

Data Screening and Statistical Analyses

Data were screened for completeness, normality, and outliers. All variables met the assumptions for parametric testing. Descriptive statistics were computed for all variables.

Independent samples *t* tests and chi-square tests compared psychological outcomes and type D classification across demographic groups and CVD history. Pearson correlations examined associations among continuous variables.

Hierarchical linear regression was used to evaluate whether type D personality predicted psychological distress (total DASS score), after controlling for age, gender, education, and CVD history. All analyses were conducted using SPSS (version 28; IBM Corp). Two-tailed independent samples *t* tests with $P<.05$ were considered significant. Effect sizes (ie, Cohen *d*, η^2, and R^2) were reported.

Results

Sample Characteristics

Of the 146 participants, 40 (27.4%) reported a history of CVD. The sample was predominantly Jewish (140/146, 95.9%), secular (102/146, 70%), and highly educated (116/146, 80% held postsecondary degrees). Table 1 presents detailed demographic and psychological characteristics. Participants were categorized into 6 age groups: 30 to 39, 40 to 49, 50 to 59, 60 to 69, 70 to 79, and 80 to 85 years. The age distribution indicated that the majority of participants (95/146, 65%) were aged 50 to 70 years, while an additional 20% (29/146) were aged 70 to 85 years. Younger participants were less represented, with 5% (8/146) aged 30 to 39 years and 10% (15/146) aged 40 to 49 years. In total, 66% (97/146) of participants were female.

Table . Descriptive statistics and internal consistency of psychological measures among Israeli adults (N=146).

Variable	Values, mean (SD)	Cronbach α
Negative affectivity	11.4 (6.7)	0.89
Social inhibition	13.2 (6.1)	0.92
Depression	14.6 (5.8)	0.87
Anxiety	12.7 (5.4)	0.89
Stress	15.9 (6.5)	0.91
Distress (total)	43.2 (14.9)	0.94

Prevalence of Type D Personality

On the basis of the Type D Scale–14, 42% (62/146) of participants met the criteria for type D personality . Type D participants were more likely to report a history of CVD (54/146, 36.9%) than non–type D participants (29/146, 20.2%; $\chi^2_1=4.5$; $P=.03$).

Group Differences in Psychological Distress

Participants with type D personality scored significantly higher on depression (mean 19.2, SD 5.0) than non–type D participants (mean 11.3, SD 4.5; $P<.001$; Cohen $d=1.72$), indicating a large effect size. Similarly, anxiety (mean 16.5 vs 9.7, SD 4.6 vs 3.9; $P<.001$; Cohen $d=1.63$) and stress (mean 21.0 vs 12.1, SD 5.3 vs 4.8; $P<.001$; Cohen $d=1.76$) were markedly higher in type D participants, reflecting strong group differences. Psychological distress differed between the study groups, as shown in Table 2.

Table . Group differences in depression, anxiety, and stress between participants with and without type D personality, based on summed Depression Anxiety Stress Scale–21 items subscale scores (range 0 - 21; N=146).

Variable	Type D (n=62), mean (SD)	Non–type D (n=84), mean (SD)	*t* value (*df*)	*P* value
Depression	19.2 (5.0)	11.3 (4.5)	8.12 (144)	<.001
Anxiety	16.5 (4.6)	9.7 (3.9)	7.89 (144)	<.001
Stress	21.0 (5.3)	12.1 (4.8)	8.48 (144)	<.001

Associations With Cardiovascular History

Participants with CVD history had higher mean type D scores (mean 1.42, SD 0.61) and higher levels of psychological distress than those without CVD. Depression, anxiety, and stress were significantly elevated among those with CVD (all $P<.05$).

Regression Analysis

A 2-step hierarchical regression evaluated predictors of psychological distress. Step 1 included demographics and CVD history and explained 14.6% of the variance ($F_{4,141}=6.05$; $P<.001$). Step 2 added type D personality and accounted for an additional 15.1% of variance ($\Delta F=29.64$; $P<.001$), with the final model explaining 29.7% of total variance ($F_{5,140}=14.87$; $P<.001$).

Type D personality was the strongest predictor ($\beta=.46$; $P<.001$), followed by CVD history ($\beta=.18$; $P=.008$). Age, gender, and education were not significant.

Discussion

Principal Findings

This study found that type D personality was strongly associated with elevated depression, anxiety, and stress in a community-based Israeli sample, with effects persisting after adjustment for age, gender, education, and CVD history. Participants with CVD also had higher type D scores and distress, although personality traits showed a stronger effect. The prevalence of type D (62/146, 42%) exceeded global community estimates, potentially reflecting cultural or contextual factors. This unusually high prevalence may reflect specific cultural, societal, or psychosocial characteristics within the Israeli context, such as collectivist norms, social stressors, or health awareness, highlighting the importance of considering local sociocultural factors when interpreting type D personality prevalence and its psychological correlates. These results align with epidemiologic evidence showing shifts in cardiovascular determinants and the growing role of psychosocial risk factors [15-17], as well as updates highlighting stress pathways in CVD pathophysiology [16]. Depression levels in participants with type D personality were in the moderate range (mean 19.2, SD 5.0), consistent with literature linking depressive symptoms to increased cardiac risk via behavioral, autonomic, inflammatory, and platelet activation mechanisms [18,19]. Such clustering of distress in individuals with type D personality mirrors psychocardiology findings that integrate psychological traits with cardiovascular biology and epidemiology [20].

By jointly examining type D personality, psychological distress, and CVD history, this study extends previous work focused mainly on clinical cardiac populations, demonstrating similar associations in nonclinical adults. Mechanistically, high NA and SI may limit social support, encourage maladaptive coping, and promote biological dysregulation, all of which can contribute to cardiovascular vulnerability [16,18]. The findings suggest potential value in community and primary care screening for type D traits and distress, in line with clinical reviews emphasizing early psychosocial intervention to improve cardiac outcomes [19,21]. Although the cross-sectional design limits causal inference, and the sample's demographic profile may affect generalizability, these results support a multifactorial model where stable personality traits, affective states, and cardiovascular history interact within the broader epidemiologic trends in CVD [15-17,20].

It should be noted that because type D personality includes NA and the outcome measure (DASS-21) assesses depression, anxiety, and stress—all facets of negative affect—our analysis may partly reflect conceptual overlap rather than an independent predictive effect, highlighting a tautological limitation that warrants careful interpretation.

Limitations

Several limitations warrant discussion. First, the use of self-reported CVD history introduces potential misclassification and recall bias. Although we included examples in the survey question, objective verification (eg, medical records) was not feasible. Additionally, the use of a single self-report item for CVD history limits granularity and may affect associations with type D personality and psychological distress.

Second, the cross-sectional design precludes causal inference. While we propose that type D traits may precede emotional distress, it is also plausible that chronic distress shapes personality expression (reverse causality). Future longitudinal research is needed to disentangle these pathways. In addition, the convenience and snowball sampling may have introduced self-selection bias, as individuals with greater psychological concerns or distress may have been more likely to participate, possibly inflating type D prevalence and its association with distress.

Third, the sample was predominantly female, Jewish (140/146, 95.9%), highly educated, and secular. This demographic specificity, along with the nonrandom recruitment strategy, limits the generalizability of the findings. The prevalence of type D personality in our sample (62/146, 42%) was higher than typically reported in community-based studies, which may reflect characteristics of the recruited population and further limits external validity.

Fourth, the overlap between type D (particularly the NA subscale) and general negative affect raises concerns about multicollinearity in statistical models. Future studies should consider examining subscale interactions or partial correlations to clarify unique contributions.

Fifth, our analyses did not account for several established cardiovascular risk factors, including behavioral factors (eg, smoking, physical activity, and diet), biomedical factors (eg, BMI, diabetes, and dyslipidemia), and broader socioeconomic variables (eg, income and employment status). These unmeasured variables may confound the observed associations between type D personality, psychological distress, and CVD history and should be considered in future research.

Future research should use longitudinal and multimethod designs to evaluate the causal relationships among personality traits, emotional distress, and cardiovascular outcomes. Clinical studies involving medically verified diagnoses, as well as diverse cultural and demographic samples, are needed to enhance external validity. In addition, the development and validation of brief screening tools for type D personality in primary care and cardiology settings could facilitate early identification. Intervention studies should examine whether reducing emotional distress in individuals with type D personality leads to improvements in cardiovascular outcomes.

Recommendations

Future studies should further explore the clinical implications of incorporating psychological screening, such as type D personality, into cardiovascular care. Additional research is warranted to evaluate how integrating psychological assessment into routine practice may contribute to more personalized prevention and intervention strategies.

Conclusions

This study demonstrates that type D personality is significantly associated with elevated psychological distress and a history of CVD, even within a community sample. These findings

highlight the importance of considering psychological factors when examining cardiovascular health outcomes.

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Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: KG
Data collection: KG, YS
Formal analysis: KG
Methodology: KG
Supervision: KG
Writing – original draft: KG, YS
Writing – review and editing: KG, YS
All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey of the study (in Hebrew).
[DOCX File, 25 KB - cardio_v10i1e79159_app1.docx]

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Abbreviations

CVD: cardiovascular disease
DASS-21: Depression Anxiety Stress Scales
NA: negative affectivity
SI: social inhibition

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Digital Health Literacy in Elective Open-Heart Surgery Patients: Cross-Sectional Study

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Abstract

Background: Digital health solutions play a key role in health care, but their safe and effective use depends on patients' digital health literacy. While digital health solutions are beneficial for patients with cardiac disease, disparities in digital health literacy may limit access, particularly for patients undergoing cardiac surgery with complex care and psychological challenges. Unaddressed, these disparities could exacerbate inequalities in accessing beneficial digital services. Denmark's advanced digital health care system provides a unique context to evaluate digital health literacy.

Objective: This study aimed to assess digital health literacy levels in patients scheduled for elective open-heart surgery and examine associations with sociodemographic factors and concurrent health issues.

Methods: We conducted a cross-sectional survey of consecutive patients scheduled for elective open-heart surgery at 3 university hospitals covering approximately two-thirds of Denmark's population. Patients with cognitive impairment or language barriers preventing completion of the questionnaire were excluded. The questionnaire was administered in paper form by medical staff during preoperative consultations. Digital health literacy was assessed using the validated 8-item eHealth Literacy Scale (eHEALS; range 8 - 40), along with 2 additional questions from the validated Danish version assessing the perceived importance and usefulness of online health information. Sociodemographic data collected included age, gender, cohabitation status, social support for technology use, educational level, and number of concurrent health issues. Descriptive and comparative analyses examined associations between eHEALS scores and sociodemographic variables and health issues. Exploratory subscale analyses evaluated the 3 eHEALS domains—awareness, skills, and ability to evaluate online health information—to identify areas in which patients may require additional support.

Results: Of 576 eligible patients, 313 (54.3%) completed the survey between February 2024 and July 2024. Response rates varied across sites: 71.1% (133/187), 58.5% (134/229), and 28.8% (46/160) in sites 1, 2, and 3, respectively. Nonresponse was primarily due to logistical challenges during preoperative consultations, with only a few patients excluded because of cognitive impairment, language barriers, or refusal. The median eHEALS score was 30 (IQR 27 - 32), indicating generally high digital health literacy scores (cutoff score ≥26). Scores were negatively correlated with age (Spearman ρ=–0.18; P=.002) and positively associated with educational level (Kruskal-Wallis test: χ^2_2=17.0; P<.001). No substantial associations were observed for gender, cohabitation status, social support for technology use, or number of concurrent health issues. Exploratory subscale analyses suggested that patients felt least confident in evaluating the quality and relevance of online information, highlighting a potential focus for tailored support.

Conclusions: Patients scheduled for elective open-heart surgery generally reported high digital health literacy levels, but challenges remain in critically appraising digital health information. Younger age and higher educational levels were associated with higher self-reported digital health literacy, but the association was modest. This underscores the need for individual assessment to identify patients who may benefit from tailored support.

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KEYWORDS

cardiovascular diseases; thoracic surgery; elective surgical procedures; health literacy; telemedicine; computer literacy; health communication; sociodemographic factors; surveys; questionnaires

Introduction

Digital health has become an essential component of modern health care delivery. Over the past decade, digital health solutions and telemedicine have steadily evolved, transforming the way in which health care is accessed and delivered. The COVID-19 pandemic significantly accelerated this development as physical consultations were limited and the need for remote solutions intensified [1,2]. Today, digital health forms an integral part of routine health care across a range of clinical settings.

These solutions are particularly valuable in outpatient cardiac rehabilitation. They can help overcome time and travel barriers during structured programs (phase 2) and support long-term recovery and lifestyle maintenance (phase 3) [3]. Digital health literacy, defined as the ability to seek, find, understand, and appraise digital health information [4], is essential when implementing digital health solutions as low digital health literacy is associated with reduced awareness and use of digital services [5]. Moreover, addressing patients' digital health literacy may be important to ensure more inclusive implementation of these solutions, enabling broader engagement and reducing inequities [6]. Digital health interventions have been associated with improvements in health-related quality of life, as measured using validated instruments such as the HeartQoL questionnaire in cardiac populations, and with increased physical activity in patients with chronic conditions [7,8]. A recent systematic review in community-dwelling older adults reported relatively low digital health literacy as measured using the eHealth Literacy Scale (eHEALS) instrument [9]. Lower socioeconomic status and self-reported lack of digital skills have also been reported to affect digital health literacy negatively [10]. This may contribute to health disparities if health care systems do not account for patients' digital health literacy when designing and implementing digital solutions. Consequently, patients with lower digital health literacy may face unequal opportunities to enhance their health and well-being [11]. Therefore, it is important to investigate whether sociodemographic factors are associated with digital health literacy in patients with cardiac disease, as identifying such associations could inform targeted strategies to support effective engagement with digital health interventions.

In this study, we aimed to assess digital health literacy levels in patients scheduled for open-heart surgery and examine differences across sociodemographic factors and concurrent health issues.

Methods

Design, Study Setting, Population, and Data Collection

This cross-sectional survey collected data via a questionnaire administered at Aarhus University Hospital, Aalborg University Hospital, and Odense University Hospital, covering 3 regions that together represent approximately two-thirds of the Danish population. Adult patients scheduled for elective open-heart surgery between February 8, 2024, and July 5, 2024, were invited to participate. Nurses or medical secretaries distributed the questionnaire in paper form to eligible patients during their preoperative consultation and collected it anonymously the day before surgery. Inclusion criteria were patients aged ≥18 years scheduled for elective open-heart surgery. Patients unable to read or understand Danish or deemed by staff to be cognitively unable to complete the questionnaire were excluded. The responsible staff members assessed whether patients were suitable to participate.

The reporting of this study follows the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [12].

Questionnaire Measures: Digital Health Literacy, Sociodemographics, and Data on Health Issues

The questionnaire consisted of 2 sections: one assessing patients' self-reported digital health literacy and the other gathering their sociodemographic information and data on health issues.

We used the eHEALS to assess self-reported digital health literacy [13]. The eHEALS has been validated in multiple languages, including Danish, and applied across various demographic groups [14]. The eHEALS consists of 8 items that assess the patient's self-perceived ability to access, evaluate, and apply health information found on the internet [15]. Respondents rate each item on a 5-point Likert scale ranging from "strongly disagree" (1 point) to "strongly agree" (5 points). Scores for each item are summed, yielding a total score of 8 to 40 points. A higher score indicates a higher level of digital health literacy, with ≥26 considered the cutoff between high and low digital health literacy levels [16-18]. Two supplementary items included in the validated Danish eHEALS assessed patients' perceived importance and usefulness of digital health (not included in the total score) to provide contextual information on attitudes toward digital health. Furthermore, we analyzed the digital health literacy assessment according to the 3-factor model as defined by Sudbury-Riley et al [16]: "awareness of internet health resources" (items 1 and 2), "skills and behavior needed to access health information" (items 3-5), and "self-belief in ability to evaluate health resources" (items 6-8). This domain-specific approach allows for a more nuanced evaluation of patients' competencies in accessing, using, and appraising online health information rather than relying solely on a total eHEALS score [16].

The second section of the questionnaire included questions on self-reported sociodemographic factors and health issues and was developed based on known risk factors associated with low digital health literacy in patients with cardiac disease [17-19]. Sociodemographic factors included age, gender, educational level, cohabitation status, and social support for technology use.

Patients were also asked to specify any health issues beyond the cardiac disease. Educational levels were categorized according to the International Standard Classification of Education as high school (0-2 years of post–high school education), undergraduate (3-4 years of post–high school education), and postgraduate (>4 years of post–high school education) [20]. Cohabitation status was determined as either being a cohabitant or living alone. Social support for technology use was defined as the availability of help from friends or family in addressing technological challenges when necessary. Health issues beyond the primary cardiac diagnosis were represented by a checklist of the most common health issues, including diabetes, pulmonary disease, vascular disease, back and muscle pain, asthma, rheumatoid arthritis, osteoporosis, migraine or severe headache, and chronic kidney disease [21]. Patients could specify any additional diseases in a free-text field. Health issues were categorized as "none," "one," or "two or more."

Data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University), hosted by Aarhus University [22].

Statistical Methods

Patients with missing items on the eHEALS were excluded to prevent underestimation of the score. On the basis of prior studies, a nonnormal distribution of eHEALS scores was anticipated, and therefore, nonparametric tests were expected to be appropriate. Normality of the data was visually assessed before selecting the statistical approach. Log transformation was attempted but did not normalize the distribution; thus, nonparametric tests were applied.

We assessed differences in eHEALS scores using the Mann-Whitney *U* test for dichotomous variables and the Kruskal-Wallis test for categorical variables with 3 levels. The correlation between age and eHEALS scores was evaluated using the Spearman rank correlation, with values interpreted as weak (0.10 - 0.30), moderate (0.31 - 0.50), or strong (>0.50), consistent with commonly accepted conventions in the literature [23]. The 3 subscales of the digital health literacy assessment were analyzed by calculating medians and IQRs for each subscale.

All analyses were performed using the R statistical software (version 4.1.2; R Foundation for Statistical Computing) and RStudio (version 2024.12.0; Posit PBC).

Ethical Considerations

The questionnaire included a preamble outlining the study's objectives, the voluntary nature of participation, and the confidentiality and anonymity of respondents. Participants were informed that no personally identifiable data (eg, name, civil registration number, or contact information) were collected. All data were collected and stored in a secure environment accessible only to members of the research team and handled in accordance with the General Data Protection Regulation and institutional data protection policies. Data were analyzed and reported in aggregate form only, ensuring that individual participants could not be identified. Informed consent was implied through completion and submission of the questionnaire. Participants were informed that they could discontinue participation at any time before submission without any consequences and that, due to the anonymous nature of the survey, withdrawal after submission would not be possible. No financial or other compensation was provided for participation. This study was conducted in accordance with the Declaration of Helsinki. The Research Ethics Committee of the Danish Regions waived the need for study approval as the study was exempt from registration under Danish law (Danish Committee Act on Research Ethics Review of Health Research Projects §14 subsection 2; case number: 2400348) [24].

Results

General Characteristics

In total, 54.3% (313/576) of the eligible respondents were included. Separate response rates among eligible patients at the 3 sites were 71.1% (133/187), 58.5% (134/229), and 28.8% (46/160). Baseline characteristics of the study population are summarized in Table 1.

Table . Sociodemographic characteristics and eHealth Literacy Scale (eHEALS) score of study participants (n=313).

Participant characteristic	Values
Sociodemographics	
Age (y), mean (SD)	65.8 (11)
Gender (missing: 2; n=311), n (%)	
Male	232 (74.6)
Female	79 (25.4)
Educational level (missing: 8; n=305), n (%)	
High school	92 (30.2)
Undergraduate	170 (55.7)
Postgraduate	43 (14.1)
Cohabitation status (missing: 0), n (%)	
Living alone	78 (24.9)
Cohabiting	235 (75.1)
Close relationships (missing: 3; n=310), n (%)	
Reported close personal relationships	276 (89.0)
No close personal relationships	34 (11.0)
Concurrent health issues (missing: 16; n=297), n (%)	
Number of health issues	
None	135 (45.5)
1	102 (34.3)
≥2	60 (20.2)
Digital health literacy level, median (IQR)	
eHEALS score (8-40)	30 (27-32)

As anticipated, eHEALS data were not normally distributed (Figure 1). The median eHEALS score was 30 (IQR 27 - 32), and 91.8% (267/291) of the participants scored 26 or higher, indicating that participants generally possessed high self-reported digital health literacy levels. A total of 7% (22/313) of the questionnaires were discarded due to missing items. As a complement to the eHEALS, patients were asked about their opinions on the importance and usefulness of digital health. Just over half of the participants rated the internet as “useful” for health-related decisions (160/291, 55%) and considered access to online health information to be “important” (157/291, 54%) to them (Figure 2).

Figure 1. Distribution of total eHealth Literacy Scale (eHEALS) scores among participants (n=291).

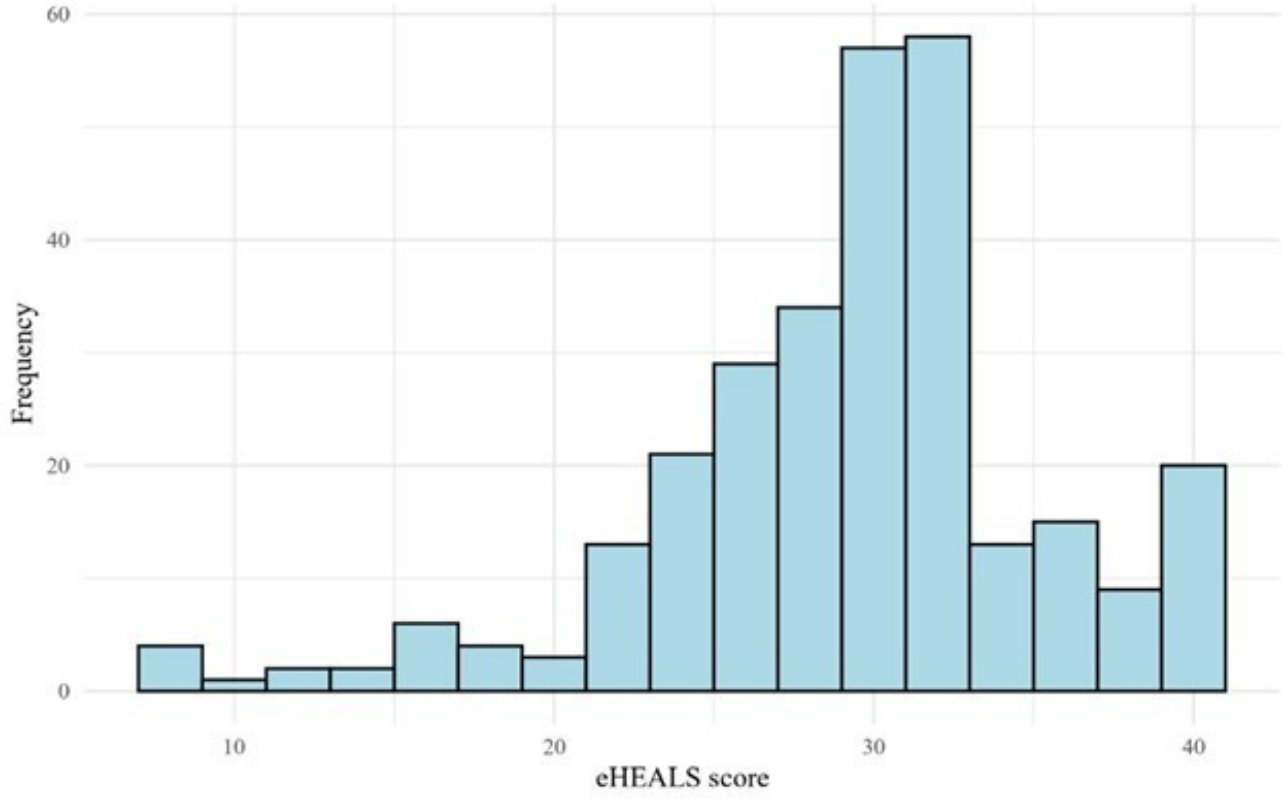
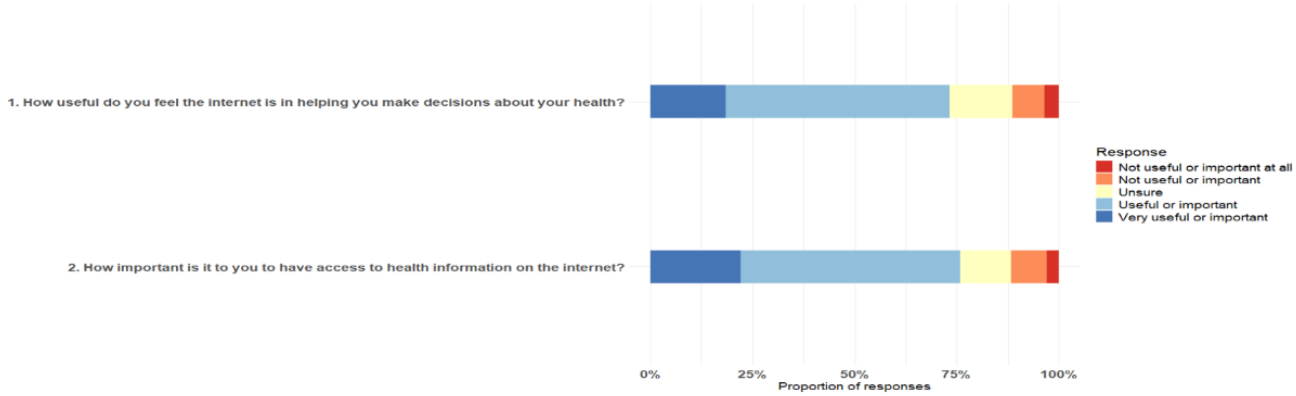
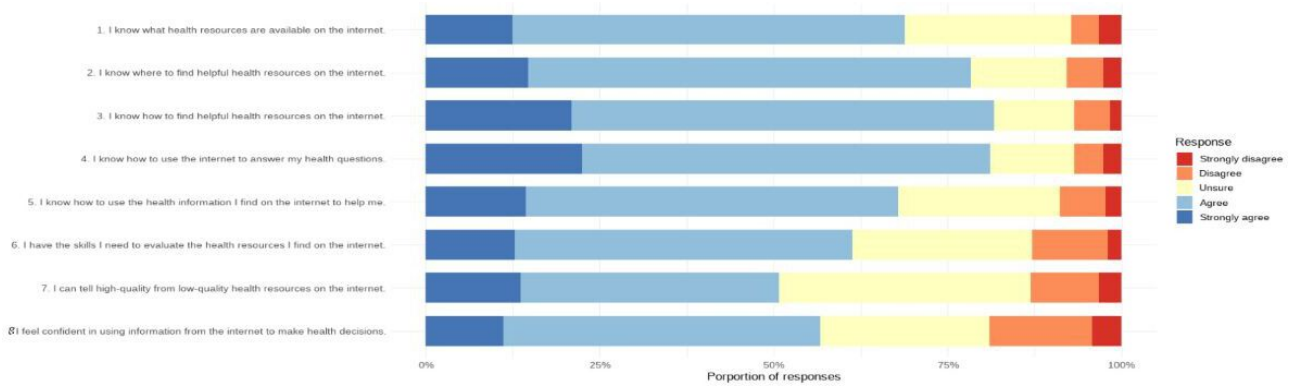


Figure 2. Distribution of responses to the 2 questions supplementing the eHealth Literacy Scale on the usefulness and importance of online health information.



The 3 subscales of the digital health literacy assessment were analyzed separately. The median scores were 8 (IQR 8-8) for "awareness" (2 items; maximum score=10), 12 (IQR 10-13) for "skills" (3 items; maximum score=15), and 12 (IQR 10-12) for "evaluate" (3 items; maximum score=15). These results indicate similar levels across all 3 domains. The proportion of responses across the 5-point Likert scale for each question is illustrated in Figure 3. Across all 8 eHEALS items, most patients selected "agree," indicating an overall high perceived digital health literacy. Response distributions across items suggest lower confidence in the "evaluate" domain. Notably, for item 7 ("I can tell high-quality from low-quality health resources on the Internet"), a substantial proportion of participants responded with "unsure," indicating limited confidence in critically appraising online health information.

Figure 3. Distribution of eHealth Literacy Scale responses grouped according to the 3-factor model: “awareness” (items 1-2), “skills” (items 3-5), and “evaluate” (items 6-8).



Sociodemographic Factors, Health Issues, and eHEALS Scores

Most participants (276/310, 89.0%) reported having close relationships that could assist them with technical issues. The most common sources of social support were children and spouses.

Age was significantly negatively correlated with eHEALS scores (Spearman ρ=–0.18; *P*=.002), reflecting a weak decline in self-reported digital health literacy as age increases. Additionally, a significant difference in eHEALS scores was observed across educational levels, with higher educational level corresponding to higher eHEALS scores (Kruskal-Wallis test: χ^2_2=17.0; *P*<.001).

No statistically significant differences in eHEALS scores were found across gender, cohabitation status, presence of close relationships, or number of health issues. The results are presented in Table 2 and as box plots and scatterplots in Multimedia Appendix 1.

Table . Impact of sociodemographic factors and health issues on self-reported digital health literacy level.

Variables	eHEALS[a] score (8-40), median (IQR)	Test statistic	*P* value
Age (y)	30 (27-32)	–0.18[b]	.002
Gender		7426.5[c]	.46
Male	30 (26-32)		
Female	30 (29-32)		
Educational level		17.0[d]	<.001
High school	29 (25-32)		
Undergraduate	31 (27-32)		
Postgraduate	33 (30-39)		
Cohabitation status		8317.5[c]	.56
Living alone	30 (27-32)		
Cohabiting	31 (27-32)		
Close relationships		3992.5[c]	.47
Yes	30 (27-32)		
No	30 (23-32)		
Health issues		0.1[d]	.94
None	31 (27-32)		
1	30 (27-32)		
≥2	30 (26-34)		

[a]eHEALS: eHealth Literacy Scale.

[b]Spearman rank correlation.

[c]Mann-Whitney *U* test (*W* statistic).

[d]Kruskal-Wallis test (chi-square value with *df* of 2).

Discussion

Principal Findings

In this cross-sectional study of patients referred to elective open-heart surgery, we found that self-reported digital health literacy was generally high, with younger age and higher educational level associated with higher eHEALS scores. No significant differences were observed for gender, cohabitation status, presence of close relationships, or number of concurrent health issues. Despite high overall eHEALS scores, many patients reported limited confidence in their ability to critically appraise online health information. To our knowledge, this is the first assessment of self-reported digital health literacy in a preoperative cardiac surgery population. Evaluating digital competencies is particularly important in this high-risk group, which faces existential threats and complex care demands. Here, digital health literacy is essential to support informed decision-making, perioperative care, and postoperative cardiac rehabilitation.

Our finding related to younger age and higher self-reported digital health literacy is consistent with prior evidence from a systematic review of 17 studies in the general population [25], as well as a cross-sectional study of individuals with moderate to high cardiovascular risk [17]. While some studies have not found an association between age and self-reported digital health literacy measured using the eHEALS, their generalizability is limited due to factors such as small, selective samples, as is the case in 2 Danish studies on patients with cardiac disease [19,26]; selection bias from motivated participants with cardiac disease in a randomized controlled trial [27]; and limited applicability to the European context of an Asian cohort from the general population [28]. Recent evidence shows a general trend toward narrowing age-related gaps in digital health literacy [9,10,18], likely due to increased digitalization and technology adoption among older adults. Our findings indicate that age-related disparities in digital health literacy persist even in Denmark, a highly digitalized country where approximately 90% of older adults use the internet and own smartphones [29]. This potential among older adults underscores the ongoing need to provide adequate support to this group to ensure that they benefit from digital health solutions [27,30].

Consistent with previous research [17,25], patients with higher educational levels reported high digital health literacy levels measured using the eHEALS. However, patients with lower educational levels also demonstrated moderately high scores, indicating less disparity in digital health competencies within this population than anticipated.

No association was found between the number of health issues and eHEALS scores. Although direct evidence is lacking, it is plausible that repeated engagement with digital health services in a highly digitalized system may help maintain or enhance digital health literacy among patients with multiple chronic conditions, potentially counteracting any negative effects of higher disease burden [31].

The findings highlight that, although certain sociodemographic factors may influence digital competencies, they do not fully explain individual variation in digital health literacy. In a health care context in which digital solutions are increasingly integrated into perioperative and rehabilitative care, awareness of these individual differences remains essential. Tailoring digital health solutions to patients' varying levels of digital competence can enhance accessibility, promote equity, and help prevent the deepening of existing health disparities [32].

Assessing digital health literacy in cardiac surgery patients is important when identifying those who may require support to effectively engage with digital health information during the preoperative and rehabilitation phases. The eHEALS was selected for its validated, concise format, which allows for practical screening in the stressful, time-constrained preoperative setting. Although it provides only a focused assessment of patients' ability to seek, find, and appraise online health information, it remains suitable for identifying patients who might benefit from additional guidance. More comprehensive instruments such as the Digital Health Literacy Instrument [33] or the eHealth Literacy Questionnaire [34] offer broader assessments but are less practical for routine clinical use.

The widely used eHEALS provides a brief assessment of perceived digital health literacy, but as it was developed in 2006, it does not reflect the competencies needed to engage with modern digital health technologies. Specifically, it does not address users' ability to interpret and use data from mobile health apps and wearables, evaluate the credibility of health information on social media and video-sharing platforms, or navigate secure patient portals to communicate with health care providers. Furthermore, it lacks items related to privacy, data security, and critical appraisal of digital sources. Therefore, high eHEALS scores may primarily reflect proficiency in health 1.0 skills (eg, searching for health information online) while masking potential gaps in the more interactive and participatory health 2.0 skills required in contemporary digital health ecosystems [35]. This highlights the need for updated instruments that capture these multidimensional competencies and remain practical for use in clinical research and routine care. Screening alone cannot address digital health disparities; effective solutions also demand enhanced digital health literacy among health care providers and system-level support [36]. However, there is a marked gap between these ambitions and clinical reality. Studies indicate that older adults and individuals with limited health or digital literacy often face structural and educational barriers, which remain inadequately addressed despite the global policy focus [37,38]. Assessing digital health literacy is only the first step in identifying patients who may benefit from tailored support and in guiding the design of digital health tools that are accessible to patients with varying levels of digital competence.

Our exploratory analysis of the 3 digital health literacy subscales ("awareness," "skills," and "evaluate") indicates that patients may particularly struggle with critically appraising digital health information. Such limitations may increase the risk of misinterpreting online content, potentially affecting patient-physician communication and informed decision-making [39]. The assessment of separate domains in the 3-factor structure can reveal nuances that the overall score might hide [16]. Our findings suggest that targeted support to enhance evaluation skills may help patients engage more effectively and safely with digital health information.

Participants generally stated that it was "important" for them to have access to online health information and that the internet was "useful" in helping them make decisions regarding their health. This self-reported confidence likely reflects the well-established digital health infrastructure in the Danish health care system, which promotes patient engagement and access to personal health data [40]. Such a digital infrastructure likely contributes to patients' perceived ability to manage their health information online. This aligns with evidence suggesting that the use of internet-based health interventions can enhance digital health literacy [41].

Strengths and Limitations

The inclusion of 3 university hospitals covering approximately two-thirds of the national population is a major strength that enhances the generalizability of our findings. However, the exclusion of patients from the Capital Region, which is characterized by a younger and more highly educated population, may result in an underestimation of overall digital health literacy and limit the completeness of national representation.

Denmark's advanced digital infrastructure makes it a "critical case" for examining the integration of digital health solutions, offering valuable insights applicable to other countries navigating the digitalization of health care [40]. However, in settings with less integrated digital health systems or lower population-level digital competence, digital health literacy levels may be lower, and engagement with digital platforms may be more limited. Previous work has emphasized that differences in digital health literacy must be addressed to avoid inequities, highlighting the importance of simplifying communication and providing flexible solutions for disadvantaged populations [6]. The all-comer design, focusing specifically on elective open-heart surgery patients, further strengthens this study by targeting a group well positioned to benefit from tailored digital health interventions during recovery.

This study also had several limitations. First, the representativeness of the sample may be limited. Overall response rates were modest across all 3 sites, with particularly low participation at one site. Staff involved in questionnaire distribution reported that nonresponse was largely random due to logistical challenges, with only a minority attributable to patient exclusions or refusals. For context, data from the Western Denmark Heart Registry, which mandatorily records all cardiac surgery procedures in the catchment areas of the 3 participating regions, show that, for the same year, the mean age (65.9, SD 10.6 years) and proportion of male individuals

(76.9%) were nearly identical to those of our sample (mean age 65.8, SD 11 years; 232/311, 74.6%), supporting reasonable representativeness. However, selection bias cannot be entirely excluded. Excluding 22 patients with incomplete eHEALS questionnaires from the analysis may also have introduced selection bias.

Second, the questionnaire was administered on the day immediately preceding major surgery. Preoperative stress and anxiety could have influenced patients' self-reported digital health literacy, potentially inflating scores through social desirability or deflating them due to impaired concentration. However, as patients routinely receive electronic preoperative information, this timing mirrors real-world clinical practice.

Third, acute and subacute patients were not included; while their baseline digital health literacy remains unclear, their capacity to engage with digital health tools may be temporarily compromised due to the urgency of their conditions.

Finally, the use of the self-reported eHEALS, which does not fully capture the rapidly evolving digital health environment, may lead to an overestimation of patients' true digital health literacy levels.

Conclusions

This study demonstrates that patients scheduled for elective open-heart surgery generally report high digital health literacy, particularly younger individuals and those with higher levels of education. However, variability exists across sociodemographic groups, and challenges remain in patients' ability to critically evaluate online health information. The findings highlight the importance of health care professionals being aware of patients' varying levels of digital health literacy to provide appropriate support. Tailoring digital interventions based on patients' capabilities is essential to ensure equitable access and optimize the integration of digital health solutions into cardiac care.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to patient confidentiality but are available from the corresponding author on reasonable request.

Authors' Contributions

RD, DSS, ISM, and TM designed and initiated the study. RD supervised the data collection at 2 of the sites, and BB and KHB supervised the collection of data at the third site. RD, DSS, and KHB entered data into REDCap (Research Electronic Data Capture). RD analyzed the data and drafted the manuscript under the supervision of ISM, TM, BB, KHB, and KAS. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Box plots and scatterplot presenting the distribution of eHealth Literacy Scale scores across gender, age, presence of close relationships, educational levels, cohabitation status, and number of health issues.
[DOCX File, 6175 KB - cardio_v10i1e83454_app1.docx]

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Abbreviations

eHEALS: eHealth Literacy Scale
REDCap: Research Electronic Data Capture
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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The HeartHealth Program: A Mixed Methods Study of a Community-Based Text Messaging Support Program for Patients With Cardiovascular Disease From 2020 to 2024

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Abstract

Background: The HeartHealth program is a 6-month SMS text messaging–based support program offered to patients with a recent cardiovascular hospitalization or recent cardiovascular clinic visit in Western Sydney, Australia. Its customized content focuses on cardiovascular risk factors, lifestyle, treatments, and general heart health information.

Objective: This study aimed to evaluate the implementation of the HeartHealth program.

Methods: A mixed methods study was conducted assessing program reach, effectiveness, implementation, and maintenance using program data, participant feedback surveys, and staff focus group discussions. Consecutive adult patients who had attended cardiology clinics or had been discharged from cardiology hospitalization at Westmead Hospital, between April 2020 and April 2024, were included in the analysis. Content analysis was used to interpret the qualitative data.

Results: A total of 23,095 patients were invited, 8804 (38.1%) enrolled into the program, and 7964 out of 8804 (90.5%) completed the 6-month duration. Participants enrolled in the HeartHealth program had a mean age of 58.6 years, 60.3% (5302/8788) were male, and 62.4% (5382/8624) were recruited from an outpatient clinic setting. A total of 851,058 SMS text messages were sent, with 99.41% (846,009/851,058) delivered successfully. A total of 3533 out of 7964 (44.4% of program completers) participants completed the postintervention survey, and 4 HeartHealth staff members participated in a focus group discussion. Among the participants who completed the survey, 60.5% (2137/3533) reported that the program improved the healthiness of their diet, 53.6% (1894/3533) reported improved physical activity levels, and 56.1% (1982/3533) reported that it helped remind them to take their medications. Content analysis of participant feedback identified that the program was effective in prompting participants to change their diet, providing emotional support, reminding them of the importance of behavior change, improving their confidence in managing their health, and keeping participants focused. Key barriers included limited personalization, language options, and SMS text messaging scheduling flexibility. Recommended adaptations focused on enhancing personalization, greater engagement by local clinical teams, and expanding program dissemination.

Conclusions: The program had a broad reach, translated to improved patient-reported health behaviors, and provided participants with needed support at low cost and low resource requirements. This analysis highlights the successful implementation and scalability of the HeartHealth program and provides key learnings for health systems that are looking to implement similar programs in the future.

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KEYWORDS

text messaging; Short Message Service; SMS; secondary prevention; implementation evaluation; cardiovascular disease; digital health intervention

Introduction

Patient education is an important element of care of patients with chronic disease, and several international agencies now have a policy focus on improving patient education to support self-management [1-3]. Smoking cessation, physical activity, diet modification, weight management, and medication management are all important in cardiovascular disease (CVD) prevention, but current models of care are limited in support for patients to address these behaviors [4]. Most current health care models' education and support are typically delivered through in-person consultation and group activities; however, this modality poses multiple barriers such as many travel requirements [5], cost [6], time, and lack of prioritization [7]. In addition, many health care services lack the resources and funding to deliver these, and programs have limited ability to cater to population diversity [8,9].

Digital health technologies present a scalable means to deliver customized patient education [10]. Several small- to medium-sized randomized controlled trials have shown mobile health texting interventions to improve patient CVD risk factors, including: low-density lipoprotein cholesterol levels [11], BMI [11], blood pressure [12], weight management [13], and smoking cessation [14]. Furthermore, these interventions report high rates of patient satisfaction [15] and usability [11]. Yet, despite the research to date, there are limited examples of real-world implementation and evaluation of large-scale digital education and support programs for cardiovascular and other chronic diseases.

In April 2020, the HeartHealth program was initiated and offered to patients with CVD discharged from cardiovascular services or clinics in Western Sydney, New South Wales. The program provides personalized cardiovascular education and support via SMS text messaging through a digital customization platform over a 6-month period and an opportunity to ask questions. This study aimed to evaluate the implementation of the HeartHealth program.

Methods

HeartHealth Program Description

The HeartHealth program was designed to reduce cardiovascular risk in patients with CVD or at high CVD risk. The HeartHealth program involved the delivery of regular semipersonalized cardiovascular education and support via SMS text message for 6 months. SMS text messages were sent approximately 3 - 4 times per week. The message bank was developed by clinicians, academics, and patients and covered the following 5 modules: smoking, diet, physical activity, COVID-19, and general cardiovascular health. Messages were written to provide advice, education, motivation, and reminders aimed at improving cardiovascular risk factors and healthy lifestyle behaviors. SMS text messages would often be supplemented with a URL link to a website to enable access to further information on the message content. Participants were able to opt out of the program at any time through alerting staff through responding to the SMS text messages. The core structure of the program content was curated based on the previously published TextMe and TextMe2 programs [11,16]. Message content development was based on a range of theoretical frameworks spanning 3 phases of development as previously described [17,18], with program content actively reviewed and updated.

At registration, participants completed a survey detailing their baseline characteristics (hypertension, diabetes mellitus, hypercholesterolemia, smoking status, and diet preference). Algorithms selected messages from the message bank based on participants' baseline characteristics, tailoring each program accordingly. Messages addressed the participants by their preferred name and provided the source of information; examples of SMS text messages have previously been outlined in program development protocols [17,18]; furthermore, Multimedia Appendix 1 provides examples of messages.

To disseminate SMS text messaging support programs at scale, our team at Westmead Applied Research Centre built a cloud-based digital platform "TextCARE" that can deliver multiple programs according to varying clinical algorithms, simultaneously. Hence, this enabled delivery of customized content to thousands of people concurrently. The HeartHealth program that started at Westmead Hospital in April 2020 continues to be deployed.

Enrollment and Eligibility

Patients were identified either following attendance at a Westmead Hospital outpatient rapid access cardiology clinic or following discharge from an inpatient cardiology admission at Westmead Hospital. Patients were eligible for HeartHealth if they were aged 18 years or older, post hospital discharge from a cardiology admission, or had recently attended an outpatient cardiology clinic. Initially, the program was designed where consecutive eligible patients from the previous week were sent a single SMS text message to enroll into the HeartHealth program. Recruitment protocols were adapted in October 2021 so that participants who did not respond to the initial SMS text messaging invitation were followed up with a phone call from a HeartHealth staff member and offered program enrollment. Consent was obtained electronically, disseminated by an SMS text message, and captured on REDCap (Research Electronic Data Capture; Vanderbilt University).

Ethical Considerations

This study was approved by the Western Sydney Local Health District Human Research Ethics Committee (approval number 2020/ETH01649). Consent for data collection was provided by participants at the time of program enrollment. All data collected are deidentified. There was no compensation provided to participants for their involvement with this study.

Study Design

This study is a retrospective observational study that evaluated the implementation of the HeartHealth program, an existing program implemented as standard of care in the Western Sydney Local Health District, New South Wales, Australia. A mixed methods design assessing the HeartHealth program "Reach," "Effectiveness," "Implementation," and "Maintenance" was used. Typically, an implementation evaluation would also assess program site "adoption"; however, as the HeartHealth program

was intended to be rolled out only at one site, this component was not assessed. Three sources of data were collected: postintervention surveys, focus group discussions with organization staff, and program-related data. Data sources used for analysis are outlined in Table 1.

Table . Descriptions of the implementation evaluation domains including the domain definition, outcome measures, and data sources.

Domain	Definition	Outcome measures	Data sources
Reach	Reach was defined as the characteristics and proportion of patients who agreed to opt into the HeartHealth program following hospital discharge or outpatient clinic visit		
		• Participant enrollment	• Program data[a]
		• Characteristics of patients who did and did not opt into the program	• Program data • Electronic medical health records (adapted with permission from Sheahen et al., [19])
		• Reasons patients did not opt into the program	• Program data
Effectiveness	Effectiveness was defined as clinical improvements following the program delivery and was assessed by participant behavior and knowledge changes		
		• Participant lifestyle behavior changes	• Postintervention survey
		• Participant health knowledge and behavior.	• Postintervention survey
Implementation and maintenance	Implementation and maintenance were defined as the extent the staff members implemented and maintained the program as intended as well as the participant's perception of appropriate program delivery		
		• Program fidelity, attrition, and organization requirements	• Program data
		• Program resources and costs	• Program data
		• Participant SMS text message interaction	• Program data
		• Program barriers (organization and individual levels)	• Focus group discussion • Postintervention survey
		• Program enablers (organization and individual levels)	• Focus group discussion • Postintervention survey
		• Program adaptations required for long-term maintenance (organization and individual levels)	• Postintervention survey • Focus group discussion
		• Program adaptations made by HeartHealth staff	• Focus group discussion • Program data

[a]Data obtained from participants and staff members during enrollment, throughout the program, and at program completion as per the programs standard practice.

Data Collection

Postintervention Surveys

All participants in the HeartHealth program were invited to complete an assessment survey at the end of the intervention (Multimedia Appendix 2). The survey was designed by The University of Sydney staff to evaluate the program, asking participants for feedback on the program's impact, such as changes in lifestyle behaviors, what they enjoyed, and what could be improved. The survey was distributed via REDCap.

Focus Group Discussion

All current HeartHealth staff members (n=4) involved with the operationalization of the HeartHealth program were invited to partake in a single focus group discussion regarding the reach, effectiveness, implementation, and maintenance of the HeartHealth program (Multimedia Appendix 3).

HeartHealth Program Data

From the onset of the HeartHealth program, staff members recorded and stored data on participant outreach, enrollment, opt-out, and responses to SMS text messages. On a weekly basis, staff members would record, categorize, and store the program data, enabling thorough and complete analysis on the reach and implementation components of our analysis. These data were stored securely on The University of Sydney Research Data Store platform.

Data or Statistical Analysis

Statistical analysis was undertaken using R statistical software (version 4.2.0; R Core Team). Categorical data, including quantitative survey data, program attrition data, and participant demographic data, are presented as frequencies and percentages. Qualitative data assessing participant and staff perspectives of program barriers, enablers, areas of required adaptations, interaction with SMS text messages, and implementation of the program are analyzed via content analysis [20]. One researcher (BS) familiarized themself with the data and inductively coded the data into themes and subthemes. Three researchers (BS, RT, and LL) then reviewed and discussed established themes and subthemes, which were repeatedly adapted until agreement was reached on final theme and subtheme formation. HeartHealth participants were excluded from the "Effectiveness" section of the analysis if they did not complete the entire 6-month program duration.

Results

Reach and Participant Enrollment

A total of 23,095 patients, who had either attended a Westmead Hospital cardiology clinic or were discharged from Westmead Hospital cardiology unit between April 2020 and April 2024, were offered the HeartHealth program. A total of 14,291 patients did not opt into the program, and 8804 patients consented to participate in the program (enrollment rate: 8804/23,095, 38.1%; Figure 1).

Most patients were invited to enroll in the program following an outpatient clinic review (59.7% vs 40.3%); consequently, the HeartHealth program cohort primarily consisted of patients recruited from a clinic setting. HeartHealth participants were slightly younger (58.6 years vs 61.7 years) than the nonenrollee patients; however, gender distribution was similar (Table 2). Extracted electronic medical record data on comorbidities were obtained for 4324 HeartHealth participants and 7218 nonenrollee patients from April 2020 to April 2022. During this period, program participants were more likely to report English as their preferred language than nonenrollee patients (82.1% vs 76.0%, respectively) and less likely to have prior CVDs than nonenrollee patients (eg, ischemic heart disease 15.2% vs 20% and heart failure 25.4% vs 32.7%, respectively; Multimedia Appendix 4—adapted with permission from Sheahen et al [19]).

Figure 1. HeartHealth program enrollment schema outlining the number of patients invited, enrolled, and completed the postintervention survey.

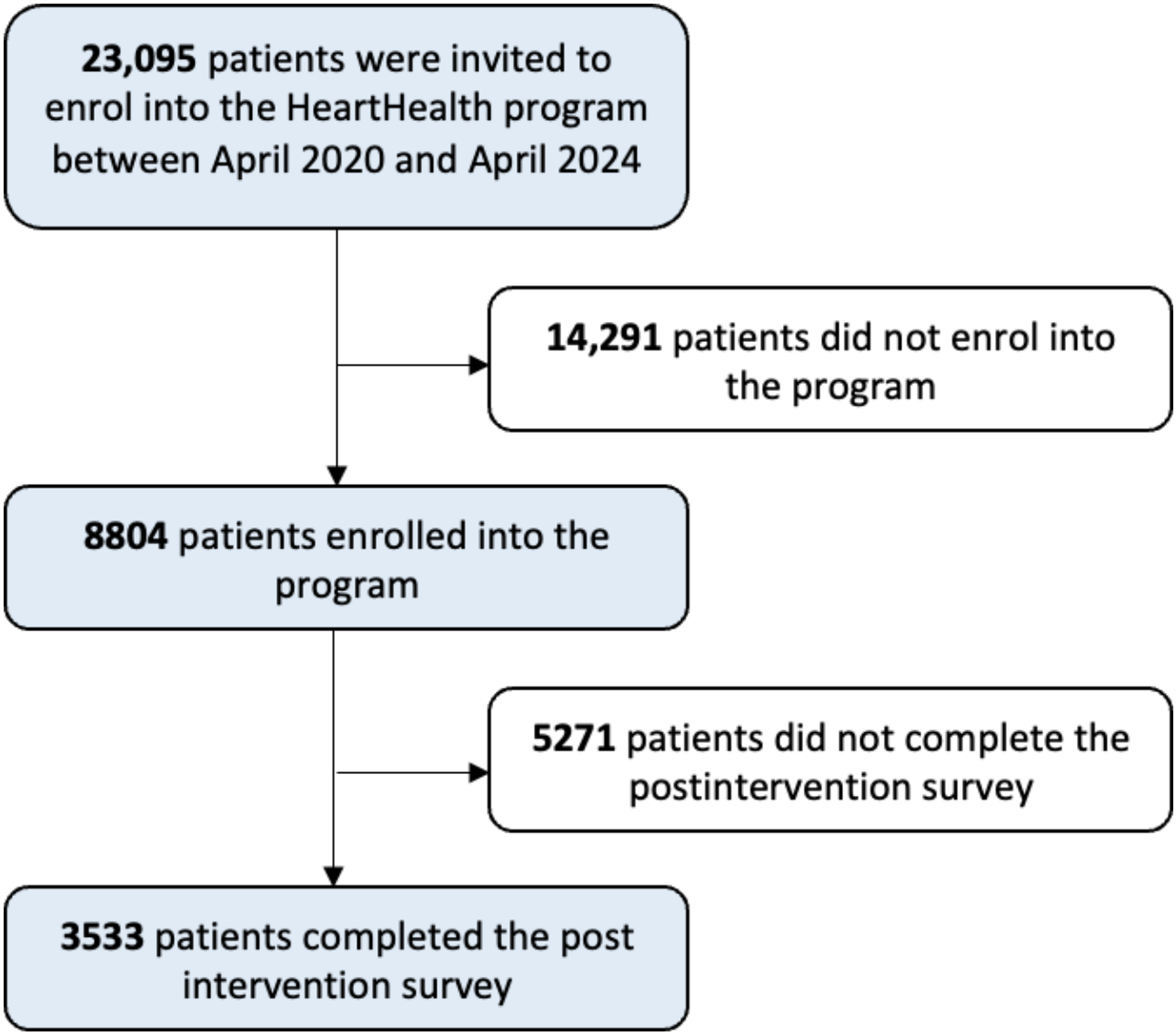

Table . Characteristics of participants who opted into the HeartHealth program and those who did not opt in (nonenrollee patients), including age, gender, and site of recruitment.

Characteristics	HeartHealth participants (n=8804)	Nonenrollee patients (n=14,291)	Overall (N=23,095)
Age (years), mean (SD)	58.6 (16.1)	61.7 (17.8)	60.5 (17.2)
Missing, n	12	10	22
Sex			
Male, n/N (%)	5302/8788 (60.3)	8647/14,263 (60.6)	13,949/23,051 (60.5)
Female, n/N (%)	3486/8788 (39.7)	5616/14,263 (39.4)	9102/23,501 (39.5)
Missing, n	16	28	44
Site of recruitment			
Hospital setting, n/N (%)	3242/8624 (37.6)	5872/14,013 (41.9)	9114/22,637 (40.3)
Clinic setting, n/N (%)	5382/8624 (62.4)	8141/14,013 (58.1)	13,523/22,637 (59.7)
Missing, n	180	278	458

Effectiveness

A total of 3533 out of 7964 (44.4% of participants who completed the program) participants completed the postintervention survey. Of those participants who completed the survey, most participants reported that the program helped them improve the healthiness of their diet (n=2137, 60.5%), increase their exercise levels (n=1894, 53.6%), and remind them

to take their medications (n=1982, 56.1%) [1]. Content analysis of participant feedback identified that HeartHealth participants reported that the program was effective in improving their overall health (Textbox 1). The first theme highlighted that the program translated into improved health behaviors through initiating lifestyle changes, empowering patients to engage in self-management of their health, and reinforcing healthy behaviors. The second theme demonstrated that the program improved patients' well-being and psychological health through improving patients' sense of care, accountability, motivation, and positivity.

Textbox 1. Themes and subthemes on participant benefits of the HeartHealth program.

Theme 1: Program translated to effective health behavior change

Initiating lifestyle change

- "Extremely useful [HeartHealth program], I've made changes to my lifestyle and feel I'm taking more control over myself."
- "Thanks to your support I am now on the right path to getting better, I first thought I wouldn't make next year . By slowly following the beginning of program and taking it slowly day by day . I didn't have any blockages in my heart, but my [myocardial infarction] was caused through either trauma or stress, so I naturally sourced methods from your program to help me."
- "The program has prompted me to reduce my salt intake. While I already knew that salt should be reduced in our diets, it was useful being prompted about it and having suggestions on how to reduce salt intake."
- "I was overweight, I didn't eat [many] vegetables, but now I do. I didn't walk much, now I walk every day . This program has changed my [lifestyle]."
- "I was pleased to be part of the trial which was a big factor in me losing 20 KG and becoming fitter."
- "The only unhealthy thing about my lifestyle is smoking cigarettes, those text reminders did make me think about quitting though – so I guess that's a positive."
- "The smoking messages encouraged me to quit smoking. 3 months [since I] quit."

Empowering people to engage in self-management

- "I found all the messages were very useful for me as it empowered me to do more activities, eat healthy, take my tablets and to stay healthy. I'm well and improved a lot beyond expectation. Thank you so much."
- "After following this program I am confident I can follow through with the activities suggested and have healthy foods in the future for improvement to my physical health and internal health."
- "Most of the messages are useful and doable. I have gained a lot of important information necessary to maintain a healthy lifestyle."

Reinforcement of healthy habits

- "Short and sharp reminders helped me re-focus especially with regard to diet and exercise."
- "Good work. I'm glad I'm doing this program. Keeps me more conscious of my lifestyle and what needs improvement for a longer and healthier life."
- "The messages keep me focused, and I review them weekly just to make sure I am on track."

Theme 2: Program supported patients' psychological health and well-being

Provided participants with a sense of care

- "I love the program. I'm single and live alone and it was nice to receive a message with helpful advice and it made me much less stressed, and I felt less alone."
- "Was nice to get messages to know someone was caring and supportive through my new transitional time."
- "The messages made me feel like there was someone checking on me and was steering me in the right direction."
- "Great program. I felt that I had daily support/companion to manage my condition."

Participant accountability

- "Keep it going. It helped me so much and made me feel that I was cared for, there was someone looking out for me and it kept me on my toes."
- "It was a good program. It kept me informed of that I was supposed to do to stay healthy. A weekly reminder, at least, does not let you forget your obligations."

Motivation and positivity

- "The messages were good motivation. It's easy to revert away from a healthier lifestyle and forget about my condition but the but the messages kept it front of mind."
- "I was glad to do it. It motivated me a lot. Kept on straight and narrow. I looked forward to receiving the massages. Thank you."
- "The increase in psychological safety was a direct result. This helped in keeping me focused and in a positive state of mind as I journeyed through regaining my health and amending my lifestyle."

Implementation and Maintenance: Fidelity and Attrition

A total of 851,058 (average 97 per participant) SMS text messages were sent between April 21, 2020, and April 1, 2024; 99.41% (846,009/851,058) were successfully delivered. Of the 8804 patients who participated in the HeartHealth program, 9.5% (n=840) did not complete the 6-month program, 25.0% (210/840) withdrew from the program in the first week, 52.9% (444/840) withdrew between weeks 2 and 13, and 22.1% (186/840) withdrew between weeks 14 and 26. In comparison with those patients who completed the intervention, the group of participants who did not complete the 6-month intervention was younger (mean 56.89, SD 18.7 years vs mean 58.8, SD 15.8 years; *P*=.003), more likely to be female (42.5% vs 39.2%; *P*=.09), and had a lower prevalence of cardiovascular risk factors (hypertension 38.3% vs 48.9%, *P*<.001; hypercholesterolemia 35.2% vs 44%, *P*=.002; and diabetes mellitus 17.9% vs 24.3%, *P*<.001).

Resources and Costs

The program was operationalized by 4 The University of Sydney—Westmead Applied Research Centre staff members on a part-time basis; these roles included program manager, digital product manager, health administrator, and research assistant, each with respective responsibilities as outlined in Multimedia Appendix 5. The resources and corresponding expenses required to operationalize the HeartHealth program over the 4 years were $276,728.36 (at the time of study analysis period completion [April 1, 2024], Aus $ to US $ was $0.65. Based on this, conversion to US $ is $179,873.43 [$20.43 per participant]). Since we initially provided this as an SMS text messaging–only recruitment strategy, and then later provided it as an SMS text messaging and phone call recruitment strategy, we have provided the separate estimated costs for each of these recruitment strategies in Multimedia Appendix 6. The estimated costs using the SMS text messaging–only recruitment strategy were $75,809.13 (at the time of study analysis period completion [April 1, 2024], Aus $ to US $ was $0.65. Based on this, conversion to US $ is $49,275.93 [$19.93 per participant]), and the estimated costs using the SMS text messaging and phone call recruitment strategy were $200,919.23 (at the time of study analysis period completion [April 1, 2024], Aus $ to US $ was $0.65. The cost converted to US $130,597.50 [$20.63 per participant]). A total of 2473 participants were recruited over the 18 months of the SMS text messaging–only recruitment period (137 per month), whereas a total of 6331 participants were recruited over the 30 months of the SMS text messaging and phone call period (211 per month).

Participant SMS Text Message Interaction

Participants could reply to the messages or ask questions; it was not actively encouraged to reply, but program staff did monitor SMS text messages and respond as necessary. Across a total of 8804 people enrolled between April 2020 and April 2024, a total of 8288 responses were received. In total, 73% (6050/8804) of these responses were expressing thanks or acknowledging receipt of the message sent to them. The other 27% (2238/8288) of responses were based on lifestyle behaviors or administrative content.

Barriers and Enablers to Implementing the HeartHealth Program

From a participant perspective, there were 2 main themes elicited as program enablers. First, the program content was valuable and appropriate, as it reinforced existing knowledge, improved cardiac health awareness, and improved engagement by providing relatable and actionable information. Second, the program was communicated in an effective manner, where the frequency of the messages provided steady reminders to participants and the URL hyperlinks allowed access to further information (Textbox 2). In contrast, the barriers identified by some participants were that information was not personalized enough, there were limited language options offered to participants, there was a lack of flexibility in the message delivery timing, and the content, at times, was overly simplistic (Multimedia Appendix 7).

Adaptations Made When Implementing the HeartHealth Program

From a HeartHealth staff perspective, program feedback aligned with participant survey feedback on the perceived program use, the benefit of SMS text messaging personalization, and ease of program use. In addition, staff felt empowered and effective in their ability to manage and communicate with participants if issues arose (Multimedia Appendix 8). The main barriers perceived were lack of promotion of the program by local clinical staff, leading to participants being unaware of the program and the limited digital health literacy or English literacy of some participants, thereby requiring assistance from staff or family to onboard them to the program (Multimedia Appendix 9). Recommended future program adjustments were focused around overcoming these barriers, expanding program dissemination, and improving program personalization (Multimedia Appendix 10).

Three key adaptations were made by the HeartHealth staff following program commencement. First, efforts were made to increase “site staff program awareness” through emailing senior medical staff, presenting at departmental meetings, providing additional verbal and written education to all staff, and placing posters in wards, clinics, and frequented locations. Second, HeartHealth staff members made adaptations to “improve the enrollment process”; these adaptations aimed to improve patient understanding of the program and ease of enrollment through simplifying the initial enrollment SMS text message and implementing a follow-up phone call to assist in this process where required. In total, 19.1% (1390/7281) of the follow-up phone calls resulted in patients enrolling in the program during the call and 15.3% (1114/7281) enrolling following the call. Third, the SMS text message content was continually adapted throughout the program to provide up-to-date information on COVID-19, guidelines, and cardiovascular health (Multimedia Appendix 11).

Textbox 2. Participant-reported enablers for implementing the HeartHealth program.

Theme 1: Appropriate and valuable content was delivered

SMS text messaging content reinforced existing knowledge

- "Most of the information I knew but liked getting the messages to reinforce my knowledge."
- "All the texts were very helpful and from memory, some were repeated which was fantastic as it kept reinforcing the message if I had not taken on board what the message was telling me."

SMS text messaging content provided awareness of their cardiac condition

- "Messages were a reminder that despite feeling well I still have a chronic heart disease and need to take care about that."
- **"**The message content wasn''t the most important to me as was the reminder that I did need to consider my cardio health overall."
- "The messages provided additional reminder/reinforcement of the need to pay regular attention to aspects of lifestyle that affect health and wellbeing particularly in the context of my medical conditions."
- "For a brief moment every day I was reminded to do all I could for my health. My heart is of great concern to me and I have learnt a bit with the resources you have recommended."

Engaged with relatable information

- "My favourite messages that explain a little about the science of heart conditions and how the text advice could assist with that."
- "My favourite message was the one that described what happens to the body as a result of exercise in video format."
- "Symptoms of a heart attack or related heart disease the viewer could have & what to do.
- "More points on how smoking alcohol and eating the wrong foods can damage your heart and body."

Engaged with actionable advice

- "I liked the ideas, suggestions and reminders to get me thinking about what I could do more than the more-prescriptive messages."
- "Diet messages about nuts and salad to avoid sugar and reduce cholesterol are very encouraging."
- "They were all good, some better than others. I liked the ones with actionable [information]."

Theme 2: Information was communicated in an effective manner

Frequency of SMS text messages serving as consistent reminders

- "I have been to Weight Watchers many times and know what I should do to keep healthy but unless you are getting somebody or a text message every day , you go backwards. The daily reinforcement is the key to my success. I want to thank you all for allowing me to be a participant as you have certainly made a difference in keeping me healthy and happy."
- "Extremely important educational information...However, the frequent texts reminders help to be mindful on following the diet, medication and exercise plan. Many thanks."
- "The actual message was less important than the fact that they reminded me to be careful of diet and to exercise regularly."

Hyperlinks facilitated expanding knowledge

- "My favourite messages were 'healthy type of facts' or ideas with hyperlinks. [This allowed] the recipient the option to investigate further."
- "I was interested in the messages that provided links to more detailed and comprehensive advice, particularly about salt intake."
- "In general the comments where helpful, however, some of the messages might have links for further help. E.g., There was a message which suggested using herbs to add flavour to reduce salt. Finding the relevant information was very hard to find. Actual suggestions or a link would have been a lot more helpful."

Discussion

Principal Results

This paper describes the initial implementation and a detailed appraisal of an algorithm-driven personalized digital education and support program "HeartHealth" for patients with heart conditions. Key learnings of this study were that (1) the program was able to be implemented with high fidelity with relatively low-resource usage; (2) the majority of participants completed the 6-month program; however, program noncompletion was more commonly seen in patients of a younger age, female sex, and a lower prevalence of CVD risk factors; (3) most participants who completed the postintervention survey reported improved health and behavioral risk factors; (4) content analysis of feedback questionnaires indicated that program benefits were driven by improved self-efficacy, feeling psychologically supported, and initiating healthy lifestyle behaviors; and (5) further personalization and further engagement with local stakeholders could improve engagement and impact of the program.

The program had a high reach of the target population who were offered enrollment within a 4-year time frame. The high rates of enrollment were likely facilitated by the simple method of enrollment and that patients may have been motivated to address their heart health because of their recent hospitalization or clinic visit. It was notable that participants, compared with nonenrollee patients, were younger and, consistent with this, had fewer comorbidities. Recent studies that followed a similar program structure by automatically obtaining eligible patient contact details were also able to reach a large number of their targeted patients [21,22]. Opt-out models in cardiovascular rehabilitation programs have also shown significant increases in patients referred to the program compared with opt-in models [23,24]. Future adaptations to the HeartHealth program are required to optimize enrollment rates; using an opt-out model may be an effective option. Telephone detailing could increase enrollment and may be particularly helpful for older participants with more comorbidities. Our previous analyses have indicated that the HeartHealth program may be more effective in reducing hospitalization in older participants and could justify the additional resources for telephone detailing [19].

The content analysis of participants provides multiple insights into the reasons for improved health effects from the program. These factors included a combination of direct and indirect factors, such as the psychological or emotional support, continued light-touch connectivity, and increased self-efficacy that improved patient experiences and also encouraged positive behavior changes. These reasons align with prominent psychobehavioral theories such as the theory of planned behavior [25], social cognitive theory [26], and the self-determination theory [27], which should be further used when planning future program adaptations and dissemination. It is well recognized that providing emotional support is essential for patient-centered care [28,29] and when combined effectively with clinical care, it positively increases the patient experience [30-32]. Through the HeartHealth program providing an avenue of continual support via the SMS text messaging platform, participants were highly engaged with the program. Importantly, many replies were a general comment or to say “thanks,” rather than using the program as a modality to report health concerns requiring a reply from the health counselor, which is consistent with previous research [33]. This form of engagement provides patients with an increased sense of care and support without being resource-intensive and demanding on staff workload. To continue delivering an effective program, it is vital to consider both the education content and the emotional support provided by the program when considering program adaptations.

The HeartHealth program was implemented with high fidelity and low participant attrition rates. An important factor for the successful implementation was due to the simplicity of participation and wide acceptance of the program. The acceptance and usability of SMS text messaging programs have previously been demonstrated in other cohorts with CVD [11], as well as cohorts with mental health [34,35] and renal diseases [36] and diabetes [37]. Furthermore, HeartHealth staff reported that the successful implementation was partly enabled through an appropriate, easy-to-use program design, personalized patient contact upon program invitation, and skilled, adaptive staff members. For example, an adaptation initiated by staff members was to contact patients via a phone call to assist with enrollment if they had not responded to the SMS text messaging invitation, resulting in a large increase in enrollment. Previous studies have found self-enrollment to be a barrier for some patients, thereby highlighting the importance of providing assistance with enrollment or offering alternative enrollment modalities [38,39]. It is important to note that despite the HeartHealth program being implemented as a hospital service, the majority of the staff involved were from The University of Sydney. Lower engagement of local clinicians was identified as a barrier. This is consistent with previous observational studies of the implementation of new clinical services, finding that insufficient clinician time [40], lack of clinician motivation [41,42], high staff turnover [43], lack of continuing education [40,42], and an unsupportive organizational culture [40,41] were all barriers to implementation.

Participants identified that a lack of personalization of both message content and delivery was a main program barrier. A common theme from participants was that “one size does not fit all,” with the information not always being relevant and the message timing and modality not suiting all participants. The need for content personalization has been described previously in mHealth interventions among populations with CVD [44,45], and studies comparing personalized with nonpersonalized content on clinical outcomes in cardiovascular populations are lacking [46]; however, benefits have been shown in smoking populations [47]. Advances in machine learning and artificial intelligence will enable the development of personalization of content and responses to patient questions [48]; future research into the design and implementation evaluation of such programs is required.

To enable program sustainability and ongoing improvements, adaptations are required. HeartHealth staff and participants highlighted that the program could be further supported by incorporating a communication channel with health care members to provide information and support when required. It has been shown that patients may feel overwhelmed and unguided on where to find trusted information with the rising tide of health misinformation [49]. Patients with CVD have previously reported that they want their doctor or nurse to recommend information sources [50]. Future research should assess the feasibility and impact on clinical outcomes of an interactive SMS text messaging program before incorporating it into the HeartHealth program.

An important consideration with wider dissemination is the required cost and resources to implement the program. While a comprehensive cost-effectiveness analysis of the HeartHealth program is required, previous community SMS text messaging trials, using the TextCare platform, were found to be cost-saving and health improving in cohorts with CVD [51] and diabetes [52]. Other SMS text messaging programs have demonstrated program cost-effectiveness in patients with renal disease [53] and in smoking cessation campaigns [54]. The cost of the HeartHealth program was significantly less than that of traditional cardiac rehabilitation programs, which has previously been reported to cost between US $631 and US $1457 per participant, depending on the program setting (hospital, home,

or remote) [55-57]. While the HeartHealth program is not designed as a replacement for traditional cardiac rehabilitation programs, it may serve as an effective adjunct. Overall, the HeartHealth program is likely to be appealing to other departments, given the frugal nature of the program, participant benefits, and low-resource requirements needed to implement the program.

Limitations

There were limitations to this study. First, the postintervention survey had a moderate response rate (3533/7964, 44.4%); therefore, feedback may not be representative of all participants. This response rate is in keeping with previous online surveys and may be attributable to survey fatigue during and after the COVID-19 pandemic [58,59]. Second, we did not capture information from those participants who declined the initial SMS text messaging invitation, nor those who opted out of the program after enrollment; therefore, limiting our interpretation of the program's reach and translational ability. Given the program having high participant acceptability and low-resource requirement to implement the program, evaluating long-term program maintenance, awareness, and funding sources will be pertinent for wider dissemination. Third, program effectiveness was assessed using patient-reported outcomes obtained only from a self-selected subgroup of program completers; therefore, the effectiveness results may overstate the true impact of the program due to this inherent bias. However, our previous research underpinning the HeartHealth program conducted using a randomized controlled design demonstrated improved lifestyle behaviors and cardiovascular risk factor profiles [11,16]. To assess program effectiveness more robustly, it would be beneficial to conduct a randomized controlled trial assessing the impact of the program on health care service usage. Fourth, as this was an evaluation of a program implemented into real-world clinical practice, we were limited in data collection and approval to extract linked medical record data. We were able to provide comorbidity data for HeartHealth participants and nonenrollee patients only for the period between April 2020 and April 2022. This limits the ability to describe and characterize those patients who opted in to the program and identify barriers to wider program adoption. Finally, the comorbidity data were drawn from both patient-reported information ("Fidelity and Attrition" section of the "Results" section) and linked medical record data diagnoses (Multimedia Appendix 4), with the latter potentially underrecording conditions such as hypercholesterolemia, hypertension, and diabetes mellitus, as these are typically diagnosed and managed in primary care settings. These differing data sources likely explain the lower prevalence discrepancy of hypercholesterolemia, hypertension, and diabetes mellitus in the "Results" section and in Multimedia Appendix 4.

Implications

The adoption of mobile health technologies has significantly risen over recent years, which can largely be attributed to the COVID-19 pandemic, a heightened focus on telehealth, and the increasing burden on health care services [60]. SMS text messaging programs within cardiovascular populations have been shown to be an effective modality to improve cardiovascular health; however, to date, there have been few that have proceeded to large-scale implementation and a formal scientific evaluation. This study demonstrates the feasibility and use of implementing personalized postdischarge support at low cost. It also identifies important enablers and barriers to implementation. Future scale-up should consider further customization of programs to individuals and broadening availability through personalized language and health literacy.

Conclusions

This thorough implementation evaluation highlights the successful implementation of the HeartHealth program. Participant attrition and perceived lifestyle benefits demonstrate the program effectiveness; additionally, staff and participant feedback has highlighted key program barriers and enablers. These insights provide key learnings for future scale-up and improvement of HeartHealth postdischarge digital support.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

BS contributed to conceptualization, data curation, formal analysis, methodology, and writing—original draft. LL and RT participated in data curation, formal analysis, and writing—review and editing. TS contributed to conceptualization, methodology, and writing—review and editing. GS, JC, AT, SZ, and PQ participated in data curation and writing—review and editing. ABI

participated in data curation, project administration, and writing—review and editing. CKC participated in conceptualization, data curation, methodology, supervision, and writing—original draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Examples of text messages used in the HeartHealth program.
[DOCX File, 15 KB - cardio_v10i1e68896_app1.docx]

Multimedia Appendix 2
HeartHealth postintervention participant survey.
[DOCX File, 36 KB - cardio_v10i1e68896_app2.docx]

Multimedia Appendix 3
HeartHealth staff focus group discussion topics.
[DOCX File, 21 KB - cardio_v10i1e68896_app3.docx]

Multimedia Appendix 4
HeartHealth participant and nonenrollee participant cardiovascular comorbidities and English as preferred language data between April 2020 and April 2022 (adapted with permission from Sheahen et al [19]).
[DOCX File, 16 KB - cardio_v10i1e68896_app4.docx]

Multimedia Appendix 5
Roles and duties of HeartHealth staff.
[DOCX File, 16 KB - cardio_v10i1e68896_app5.docx]

Multimedia Appendix 6
Costs associated with the HeartHealth program over the 4-year analysis period, with breakdown of costs during the initial text messaging–only recruitment period during the first 18 months of the program (April 2020 to October 2021) and the subsequent text messaging and phone call recruitment period used during the following 30 months (October 2021 to April 2024).
[DOCX File, 17 KB - cardio_v10i1e68896_app6.docx]

Multimedia Appendix 7
Participant barriers for implementing the HeartHealth program.
[DOCX File, 16 KB - cardio_v10i1e68896_app7.docx]

Multimedia Appendix 8
HeartHealth staff enablers for implementing the HeartHealth program.
[DOCX File, 16 KB - cardio_v10i1e68896_app8.docx]

Multimedia Appendix 9
HeartHealth staff barriers for implementing the HeartHealth program.
[DOCX File, 16 KB - cardio_v10i1e68896_app9.docx]

Multimedia Appendix 10
HeartHealth staff recommended future adaptations for implementing the HeartHealth program.
[DOCX File, 17 KB - cardio_v10i1e68896_app10.docx]

Multimedia Appendix 11
Organization adaptations made to implementing the Heart Health program.
[DOCX File, 16 KB - cardio_v10i1e68896_app11.docx]

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Abbreviations

CVD: cardiovascular disease
REDCap: Research Electronic Data Capture

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