Systematic Review

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20241561

Digital therapeutics for cardiovascular diseases in India- a low-middle income country's perspective: a systematic review

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Received: 09 April 2024 Revised: 10 May 2024 Accepted: 14 May 2024

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ABSTRACT

Cardiovascular disease acts as a predominant cause for death in India. Digital technology has shown great potential in delivering cardiac rehabilitation remotely to patients with minimal cost implications. The main aim of this study was to analyze the comprehensiveness and effectiveness of digital cardiac rehabilitation intervention for cardiovascular patients on the Indian Cardiology Continuum. A comprehensive literature search was performed in Pubmed, Springerlink, Elsevier, Embase and Google Scholar. The selected tenure for this review was 10 years (16 January 2014 to 16 January 2024). Authors separately conducted the assessment of the selected studies by using the quality assessment of diagnostic accuracy studies. Microsoft excel 2020 was used for statistical analysis and graphical designs. A total of 3 articles were included in the review. The median sample size of the included studies is 153 (30-304), mean study timeline is 7.67 months (3-17), and median follow-up period is 6 months (3-12). Digital therapeutics showed significant reduction in Systolic Blood Pressure (34.67 mmHg) and Diastolic Blood Pressure (21.97 mmHg) in stage III hypertensive patients. Medication adherence of patients using digital therapeutics was 90%, while 10% patients remained non-adherent/dropped out of the trial. Digital therapeutics builds a lucrative bridge to help cardiovascular patients cross over into improved QoL, in place of traditional face-to-face CR regimes. Further research is required to improve comprehensiveness and clinical effectiveness of the digital cardiac rehab programs on a long-term basis in India.

Keywords: Cardiac rehabilitation, Cardiovascular diseases, Digital medicine, M-health, Telemedicine

INTRODUCTION

Cardiovascular disease (CVD) acts as a predominant cause for death in India, with almost 80% of CVDs contributing to risk factors such as poor dietary regime, elevated cholesterol (elevated low-density lipoprotein- LDL, triglycerides and total cholesterol- TC) levels, decreased HDL levels (high-density cholesterol levels), sedentary lifestyle (lack of physical activity) and increased glucose levels.¹

India has also been on the top tier list for one of the highest rates of CVD patient population, with the majority of the Indian population getting affected with CVDs in their fruitful midlife years in comparison to the European ancestry.^{2,3} To overcome CVDs, a program called cardiac rehabilitation (CR) is implemented, which is defined as a physician-supervised program that furnishes physician-prescribed exercise, cardiac risk factor modification, psychosocial assessment and outcomes assessment. It is an effective modality that ensures recovery enhancement, reduction of hospital readmissions, reduced morbidity, and improvement in overall quality of life (QoL).⁴

CR is a medically supervised, multi-faceted program including patient assessment, nutritional counseling, weight management, blood pressure management, lipid management, diabetes management, tobacco cessation,

psychosocial management, physical activity counseling, and exercise training. Although concrete evidence persists itself reporting an optimistic outlook on CR outcomes, there is still a lack of evidence on CR application for CVD in India.^{5,6} A few of the challenges of CR utilization include limited coverage for health insurance, cost and time burden associated with CR participation and involvement, lack of accessibility to CR facilities due to transportation, distance or scheduling issues, and lack of facilitation/referral enrolment.^{7,8}.

One of the uplifting attempts in solving these challenges is dedicated to digital health interventions. Digital technology has shown great potential to help improve patient accessibility, deliver the concept of 'virtual care' (patient-need tailored CR programs delivered at the comfort of their own homes using technology), and hence, reduce their overall healthcare cost burden. However, even if encouraging steps are preceded towards the application of digital health interventions of CR (inclusive of remote patient monitoring, remote electrocardiograph (ECG) monitoring, and web/mobile apps), these developments find themselves in the research settings (bench) and not in the everyday clinical cardiology practice (bedside).^{7,8}

As of today, evident gaps are addressing the CR program's comprehensiveness and effectiveness in comparison to the standard of care (SoC) for CVD patients. To help cover the niche of the successful translation of CR programs into clinical practice in India, we have evaluated the technology base in the CR tailored digital health intervention (DHI), and the overall comprehensiveness of these programs as outlined by the American Heart Association (AHA) framework, from a low middle- income country's (LMIC's) perspective.⁹

Aligning with the elevating need for successful technological delivery of CR programs, this systematic review analyzes- (a) summary of current digital health interventions for CR delivery in India; (b) comprehensiveness and effective delivery of CR programs in India for CVD patients; and (c) current challenges and future perspectives for digital intervention in CR delivery for LMICs.

METHODS

This systematic review was performed by following the PRISMA (preferred reporting items for systematic review and meta-analyses) guidelines.¹⁰

For this review, the definition of digital health intervention is elaborated as the digital therapeutic interventional virtual care delivered remotely to a patient via smartphone applications, integrated wearable devices, and virtual sessions conducted by experienced and credentialed healthcare professionals.

For each study, we dissected and analyzed the components of digital CR and differentiated each study as either adjunctive to conventional or standalone CR. Digital CR

was considered if the intervention was performed remotely with the first in-person visit for baseline assessments.

Study selection and search strategy

A comprehensive literature search was performed using the keywords- cardiac rehabilitation, cardiovascular diseases, digital health and medicine, m-health, and telemedicine.

This was performed on the following search engines -PubMed, Scopus (Elsevier), Springer Link, Clinical Trials Registry of India, Google Scholar, Embase

The selected tenure for this review was 10 years (16 January 2014 to 16 January 2024). Patient data was gathered from the Clinical Trials Registry of India and examined for its completion before being included in this review

Inclusion and exclusion criteria

An independent screening was performed to establish the inclusion and exclusion criteria for this review.

This was to keep the focus streamlined and avoid deviations.

Inclusion criteria

Articles with following criteria were included- (a) only English studies were included; (b) articles focusing on digital cardiac rehabilitation for CVDs in India were included; CR articles for LMICs were included as references; and (c) no bar placed on the patient's age and gender.

Exclusion criteria

Articles with following criteria were excluded- (a) all studies before 16 January 2014; (b) studies showing incompleteness or lack of evidence; and (c) case reports, case series, comments, reviews, and systematic reviews.

The outcome of the study

The main outcome of this study was to analyze the comprehensiveness and effectiveness of digital CR intervention for CVD patients on the Indian Cardiology Continuum.

Index test

The index test in this review is Digital CR intervention for CVD in India.

Risk of bias assessment

Authors separately conducted the assessment of the selected studies by using the QUADAS 2 (Quality Assessment of Diagnostic Accuracy Studies). Any

discrepancy in assessment was settled with mutual understanding. There were four main domains covered in assessing the risk of bias namely index test with time, reference standard with time, patient selection, and flow of patients. Patient selection, index test, and reference standard were assessed with applicability and all its domains. Since this was a diagnostic accuracy review, funnel plots were unreliable and hence, were excluded from this review. ¹⁰

Statistical analysis

Microsoft excel 2020 was used for the data analysis and graphical designs. Since some included studies showed heterogeneity, computational pooling of abstracts was performed by the random effect model. Studies with a high risk of bias assessment were removed using statistical analysis. P value<0.05 was considered as significant.

Continuous data was presented in the form of mean and standard deviation. The valuation was uniform (for example, if follow-up tenure was provided in years, it was converted to months for uniform analysis.

Research questions

The research questions designed were- (a) what was the study pattern employed to report the digital CR interventions in India? (b) what were the sample sizes in the included studies? (c) what type of interventional technology was implied? (d) was there a follow-up for CVD patients using these digital CR programs? If so, what was the optimum average follow-up tenure? (e) what were the outcomes of these studies? How does it align with the LMIC perspective? and (f) what were the challenges faced in the application of the CR digital interventions? Were the challenges in India similar to upper middle-income countries (UMICs)?

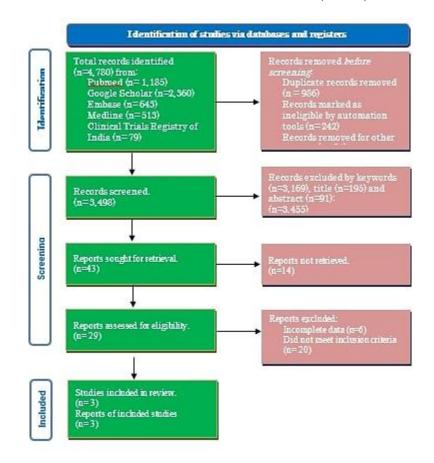


Figure 1: Flowchart of the screening, study eligibility and inclusion criteria.

RESULTS

A total of 4,780 citations were observed through the search engines mentioned in the results section. Post-duplication filter, 3,794 articles were screened for further analysis (Figure 1). During the second screening, 3455 articles were excluded based on keywords (3269), title (195), and abstract (91). A total of 29 articles underwent final

assessment, of which 6 studies showed incomplete data and 20 did not fit the eligibility criteria (focused on on-site cardiac rehabilitation instead of digital cardiac rehabilitation in India). A few systematic reviews are performed elaborating the efficacy of digital methods in cardiac rehabilitation (n=4) with primary focus on improvement in outcomes for CVD patients. 11-14 Although only 3 articles specifically reported digital CR programs,

many of them used the concept of 'digital therapeutics (DTx)' in management of CVD in India.

The median sample size of the included studies is 153 (30-304), mean study timeline is 7.67 months (3-17), and median follow-up period is 6 months (3-12) (Table 1). 2 of the included studies are conducted in India and 1 study is conducted in Canada, however, was included since study participants included were limited to South-Asian patients. Study by Patil et al was a single arm prospective study, study by Gharat et al was a real-world evidence study, and study by Anand et.al was a single-arm randomized control trial. 15-17

The key findings are briefly summarized in Figure 2. Diet and exercise coaching were predominant in all three studies (n=3, 100%). However, only one study was conducted on comparable basis (digital CR intervention compared to standard CR intervention), which could lead to search-satisfying bias.¹⁷

The major key outcome in all three studies was the mean change in blood pressure (SBP and DBP). Heart rate (HR) was measured only in one study. Two studies showed reduction in mean SBP from the baseline to the final visit, whereas one showed no difference in the digital CR as compared to the control CR group (mean difference of 1 mmHg SBP) (Figure 3). Sequence of 1 mmHg SBP) (Figure 3). Sequence of 1 mmHg SBP) (Figure 4).

A randomized control trial by Babu et.al ¹⁸ measured overall QoL and changed in 6-minute walk test (6 MWT), however was excluded from this review since the homebased CR program was not on a digital basis.

Unfortunately, 6MWT is not performed by any of the included studies and hence, may not be compared to the RCT study by Babu et al.¹⁵⁻¹⁸

The overall examination of the follow-up outcomes in the included studies showed mixed results. Patil et al primarily focused on stages I, II and III of primary hypertension. DTx showed significant reduction in SBP and DBP in stage III hypertensive patients (34.67 mmHg SBP and 21.97 mmHg DBP) and a total of 79.51% patients achieved SBP<140 mmHg and DBP<90 mmHg (Figure 3). Gharat et al also reported mean SBP and DBP reduction of 7.8 mmHg and 3.7 mmHg respectively, with a total of 83.3% patients showing controlled BP (120.87 mmHg SBP, 80.3 mmHg DBP). 16

However, Gharat et al (Figure 5) also elaborated medication adherence at 90% picturing the elevated efficacy of DTx in ACS post-PCI patients, while 10% patients remained non-adherent/dropped out of the study. Medication adherence was measured using the DTx application called LYFE, which sent periodic reminders and nudges to the patient's cell phone allowing patients to keep up with their respective medication regimes. However, no mean change was observed in the mean SBP of the digital health group as reported by Anand et al (127 mmHg at baseline and follow-up at 12 months) considering no patients with CAD/hypertension history were included.

The primary objective was to assess the MI score reduction to predict the risk of MI occurrence. This article was included in this review due to the digital interventional delivery of CR.

Table1: Basic description of the included studies.

S. no	Study, year	Study design	Population	Intervention design	Target outcomes
1.	Patil et al, 2023 ¹⁵	12 week, prospective single-arm, interventional trial	125 patients with primary hypertension (SBP>140, DBP>90) between age 30-65 years	Smart phone-based program providing diet management, physical activity tracking, self-monitoring and health-education by health coaches and nutritionists	Assessment of effectiveness of digital health intervention in controlling primary hypertension and endpoint assessments including SBP, DBP, HR and lipid profile
2.	Gharat et al, 2023. ¹⁶	Real-world evidence, pilot, single centered trial	30 patients with ACS post-PCI between October 2022 to November 2022	Software-driven digital therapeutic intervention with self-monitoring, behavioral management, personalized coaching, emergency response, tele-consultation with cardiologist and caretaker	Mean changes in SBP, DBP, HR, medication adherence, major adverse cardiovascular events (MACE) incidence, hospital admissions and lifestyle adherence
3.	Anand et al, 2016. ¹⁷	Community- based, single- blind, randomized control trial	304 Indian patients in Canada free from CAD to assess the MI score by counting the 9p-21 risk alleles	Emails and text-messages tailored to individual patient needs to improve diet and physical activity	Change in MI score; change in components of MI score (waist-hip ratio, SBP/DBP, ratio of apolipoprotein B to A and hemoglobin A _{1c})

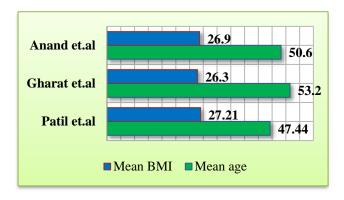


Figure 2: Mean age and mean BMI of the included studies.

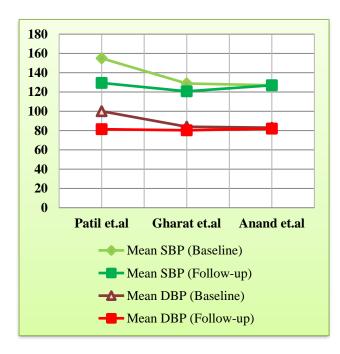


Figure 3: Mean SBP/DBP at baseline and follow-up in the included studies.

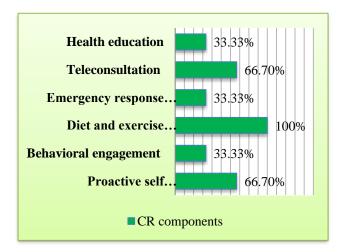


Figure 4: Digital CR components applied in the included studies.

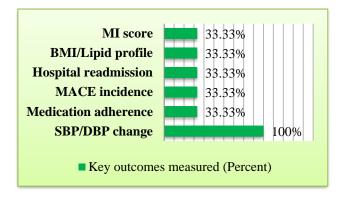


Figure 5: Key outcomes measured in the included studies.

DISCUSSION

Potential of digital CR in the coming future

This study elaborates the application of digital interventions to help improve accessibility of CR for the cardiology continuum. This review follows systematic outline primarily focusing on the digital CR interventions in India; multiple systematic reviews are published in the previous few years; however, no specific focus was given on the LMIC perspective from an Indian consensus standpoint. This review focuses on digital CR interventions like wearable devices, smart-phone based applications and tele-health services for the management of CAD in Indian population in the past 10 years, except for article by Anand et al, which was performed to predict the risk of MI in CAD-free South Asian patients in Canada.¹⁷

Key outcomes measured in the included studies

Several studies reported positive outcomes of CAD management in Indian patients using traditional or alternative CR methods. 18-22 Our systematic review shows similar outcomes using the digital and home-based CR digital intervention reporting similar efficacy in SBP/DBP reduction and overall improvement in QoL to the traditional CR intervention. 15-17 This can also be confirmed by the official scientific statement by the AHA, AACVPR and ACC elaborating the effectiveness of facility-based and home-based CR intervention.²³ However, analyzing the current evidence in India regarding digital intervention, it is perspicuous that in-person sessions are still needed to achieve optimal efficacy on the digital CR front. In-person sessions support patients in diverse aspects including individualized treatment plans, baseline to follow-up progress and helping patients (especially older patients) cope with technological aspects of digital CR.^{24,25}

Limitations

One of the major limitations of this review is the heterogeneity ceasing the possibility of a meta-analysis.

Variations are observed from the included studies in terms of study design, objectives, endpoints, and digital CR interventions applied in each aspect. Patil et al focused on the digital CR for hypertension, whereas Gharat et al attempted digital CR application in vital parameter control and medication and lifestyle adherence. Another major limitation is the number of articles included in this review; this can lead to publication bias due to variation and lack of quantitative analysis for hypothesis testing. However, collectively, this research was performed to address a niche in the area of digital health intervention for CR in CAD management in India. Fewer studies in this domain clearly suggest that more research needs to be performed in this domain to establish its credibility further. Also, evidence suggests digital health is the upcoming frontier for CAD management, helping patients not only improve their overall QoL, but also reduce the healthcare cost burden by decreasing their frequency to visit clinical setting physically. Third limitation is that even though this study used AHA, AACVPR and ACC statement, it may not be fully applicable to the Indian context in digital CR intervention due to societal and community differences, causing a reporting bias in comparison to western counterparts. Included studies also reported limited digital CR components delivered, producing vague outline of efficacy encircling the CAD management in India. Although the technological outline was elaborated, one study (Anand et al) failed to intricate the strategy of sending text messages regarding patient-specific diet and physical activity; in comparison to tele-consultation and/or emergency services. Furthermore, study by Patil et al focused primarily on hypertension control using digital CR; this creates an extensive scientific gap reporting the efficacy of digital CR in other cardiac events like arrhythmia and syncope.

CONCLUSION

Digital therapeutics builds a lucrative bridge to help CVD patients cross over into improved QoL, in comparison to the traditional face-to-face CR regimes. DTx can be effectively used to deliver remote care for patients across the cardiology continuum focusing on monitoring adherence and awareness. In LMICs, it is more essential than ever that any CVD patient gets access to digital CR which could not only help cover all CR treatment regime corners but also reduce their overall healthcare cost burden and provide them with better clinical outcomes and improved QoL. This review elaborates the optimistic outlook of DTx in CVD management from an Indian perspective, especially in terms of medication adherence. lifestyle modifications, reduced hospital admissions and improved QoL. However, the intricacies established by the accreditations for these CR components are currently out of scope for this review, majorly due to a lack of studies focusing on digital CR in India. Further research is required to elaborateon the comprehensiveness and clinical effectiveness of the digital CR programs for CVD patients in India on a long-term basis and help establish a concrete basis for the optimum assessment, design, and delivery of digital CR programs in India.

Recommendation

However, a few potential future directions were gained from this review. Paucity was observed in the number of studies focusing on digital CR intervention in predicting the risk factors leading to CVD. Risk factors such as sedentary lifestyles and psychosocial stress stimulators are still unaddressed in digital CR programs in India. Anand et al performed an MI score risk factor assessment using digital CR, however, the other two studies failed to address any risk factors relating to ACS post-PCI and stage III hypertension. In addition to this, digital CR also needs to be further evaluated on a long-term effectiveness basis. If the technology works, may not essentially imply it is efficient a few years down the line. Also, a larger sample size is required to safely concretize the hypothesis; only 3 studies with a total sample size of 459 patients using digital CR intervention, among which only two studies reported (n=155) digital CR in CAD patients. More research needs to be undertaken considering the MACE post-digital intervention; Gharat et al (n=30) reported MACE including major bleeding events, cardiac stroke, and cardiovascular death, however, the other two studies failed to report any MACE events during the course of the intervention. 16 Furthermore, adverse events need to be further evaluated on the following basis (a) other cardiac events- arrhythmia, dsypnea, syncope etc; (b) non-cardiac events- pneumonia, asthma, any potential factors contributing to the interventional disparateness; and (c) cardiac etiology- cardiac issue present from birth, cerebral ischemia etc. This review was also handed over to a few experts in the interventional cardiology field to doublecheck and confirm whether any articles were left out from the initial search. This strategy was deemed unimpeachable since the keywords 'telehealth' and 'telemedicine' remain in emergent phase. Hence, literature may include a few studies using varied internet search methods which may not be captured. CR can be prescribed to CAD/non-CAD patients on varied levels of regimes which could be missed. This also highlights the essentiality of concrete terminology encircling the digital CR intervention.

Funding: No funding sources

Conflict of interest: Chetan Gharat is the Medical Affairs Lead at Lupin Digital Health which intends to further research the digital therapeutics platform for heart failure and acute coronary syndrome patients. This review was conducted by Ashwin Prabhughate and reviewed by CG to ensure bias elimination in the review process

Ethical approval: Not required

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Cite this article as: Prabhughate A, Gharat C. Digital therapeutics for cardiovascular diseases in India- a low-middle income country's perspective: a systematic review. Int J Res Med Sci 2024;12:2071-8.