



Effectiveness of a Nurse-Led Myocardial Infarction Follow-Up Clinic on Patient and Caregiver Outcomes: Protocol for a Randomized Controlled Trial

Article History:

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Abstract: Background: Cardiovascular disease is a leading cause of morbidity and mortality in India. Nurse-led clinics (NLCs) have emerged as effective alternatives to physician-led care in resource-constrained settings. This study aims to assess the effectiveness of a nurse-led myocardial infarction (MI) follow-up clinic on selected patient and caregiver outcome variables. Methods: The study will adopt the quantitative approach and will be conducted as a single-centre randomised controlled trial (RCT) at AIIMS, Nagpur. A total of 110 post-angioplasty MI patients will be enrolled after baseline screening based on the inclusion and exclusion criteria. They will be randomly assigned to the experimental (n=55) or control (n=55) groups. Participants will be randomised using sequentially numbered opaque sealed envelopes (SNOSE) according to a computer-generated random order. The intervention group will receive nurse-led counselling, a discharge booklet, monthly telephonic reinforcement, and scheduled follow-up in a nurse-led MI clinic, in addition to their usual cardiologist visits. The control group will receive standard cardiologist-led care. Primary outcomes include medication adherence and adherence to cardiovascular disease (CVD)-related lifestyle practices. Secondary outcomes include patient satisfaction, biophysiological and biochemical parameters, caregiver burden, and complications. Outcomes will be measured at baseline, 1st, 3rd, and 6th months post-discharge. Conclusion: The study protocol is prepared based on an extensive review of literature and previous studies, underscoring the importance of nurse-led clinics in improving patient outcomes and reducing the morbidity and mortality of patients who have had a myocardial infarction and undergone angioplasty. Verification of biophysiological and biochemical parameters strengthens the credibility of the study's findings. This study will contribute to evidence supporting the expansion of nurses' roles in cardiac care. If proven effective, the intervention could help alleviate the cardiologist's workload and improve patient outcomes in rural settings.

Trial Registration: CTRI Reg. No CTRI/2024/12/07858

Keywords:

INTRODUCTION

Cardiovascular diseases account for a significant burden of disease in India. Limited availability of specialists often results in delayed or suboptimal care. Globally, nurse-led clinics have shown considerable promise in enhancing the quality and continuity of care, especially for chronic conditions like Myocardial Infarction (MI). This study protocol outlines the design of a randomised controlled trial to evaluate the effectiveness of a nurse-led MI follow-up clinic.

Coronary artery diseases (CADs) account for 23% of total and 32% of adult fatalities, and the prevalence varies from 4-6% among rural and 9-10% in urban populations (1). According to WHO Global Health Estimates, all non-communicable diseases (NCDs) together contribute to 74% of deaths globally and ischaemic heart disease, the world's biggest killer, contributed to a mortality rate of 19.7%, i.e., 41 million deaths (2). In 2016, non-communicable diseases accounted for 63% of all deaths in India, with

cardiovascular diseases (CVDs) contributing to 27% of these deaths (3). Among individuals aged 40 to 69 years, CVDs were responsible for 45% of total mortality. Indians are hospitalised two to four times higher than other ethnic groups due to the complications of coronary artery disease, with admission rates among those under 40 years being 5 to 10 times greater (4).

The INTERHEART study identified nine modifiable risk variables-dyslipidemia, hypertension, diabetes, abdominal obesity, psychosocial factors, consumption of fruits and vegetables, regular alcohol drinking, and physical inactivity-that account for 90% of the chance of experiencing a first MI (5).

Post-MI patients require long-term management and follow-up for an indefinite period. The patients should continue to receive aspirin, a Beta-adrenoceptor blocker, ACE inhibitor, and statins. Other lifestyle changes like smoking cessation, activity recommendations, dietary changes, weight reduction, balancing lipid levels, and also controlling other comorbidities, strict medicine compliance, a clear follow-up plan, and early recognition of cardiac symptoms are necessary (6)

The morbidity and mortality after a MI is found higher in the first year, and half of the risk of the MACE were found in the first 90 days (7,8). So focusing on follow-up of the patient after MI is important in identifying the complications earlier and preventing further complications. A scoping review has revealed that transitional care interventions enhanced continuity and coordination of care while the patients were traversing through different levels of health care and further improved health outcomes and reduced hospital visits(9). Nurses in India are expected to extend and expand their scope of practice beyond general practice as per National Health Policy, 2015(10)(11)

The human health resources' density per 10000 population is less than (20.6) the minimum threshold of 22.8 recommended by WHO(12). The deficiency in trained Medical and Nursing Health Workforce has mandated the transformation of the Health care delivery system in India and nurses can contribute towards achieving Sustainable Development Goals (SDGs) through proper training which includes practical as well as theory training (12,13). This facilitates safe, cost-effective, competent and quality care accessible to the public. The growing health needs and demands of the population warrant the nurses in India to extend and expand their scope of practice beyond general practice(11).

Cardiovascular disease (CVD)is prevalent more in India especially in the north, where cardiac

rehabilitation is more in need (14)(15). Research indicated that there are shortages in availability of cardiac rehabilitation centers, approximately one center available for every 360 IHD patients annually. This means that millions of additional CR spaces are needed annually, indicating a significant discrepancy between the demand and supply(16).

The healthcare delivery system including multispecialty and super-specialty hospitals are primarily distributed in urban areas and the rural areas lack proper access to health care systems. Focusing on primary health care helps us to achieve Universal Health Coverage to achieve the Sustainable Development Goals (17). The population seems forced to travel great distances to urban areas to access even the most basic medical treatments (18). There are 9354 vacant posts of doctors in the PHCs as of 9 December 2024((19)).

As per WHO reports of 2017, India has 1.34 doctors serving 1,000 people, while it is 2.6 per 1000 population in developed countries according to estimates from the World Health Organization(20). As per the Rural Health Statistics report by the Ministry of Health and Family Welfare, around 80% of the country's doctors are serving in urban areas, leaving a significant portion of rural India with less access to health care (20). Many developing nations likewise have shockingly low levels of qualified medical workers. The National Health Protection Scheme, also known as Pradhan Mantri Jan Arogya Yojana or PM-JAY, and the Health and Wellness Center (HWC) are the two main components of the Ayushman Bharat Scheme, which was introduced by the Government of India (GOI) to provide comprehensive need-based health care rather than a segmented and sectoral approach to (21). While the goal of health for all is anticipated to be achieved through the program's modernization of the health system, there is no indication that there is a large enough pool of competent health workers to enable successful implementation. Considering the importance level, a qualified health workforce should be at the apex of the health care delivery system. India has less than 4,000 cardiologists and 1,200 cardiac surgeons for a population of 1.2 billion. This emphasizes the need for nurse practitioners in today's scenario. In situations when there are service gaps brought in by excessive demand and/or a lack of doctors, nurse-led clinics are a recommended type of care. Due to their ability to provide prompt access to specialised services, nurse-led clinics are growing.

Nurse-led clinics (NLCs) vary in their organizational structure, but they share some common characteristics. They are frequently managed by highly skilled and knowledgeable nurses who can work independently. Nurses in most clinics see

patients at designated timeslots and handle their caseload. Nurses perform thorough physiological assessments, organize patients' care, administer treatments, make referrals and stay updated on the patient's health condition.

NLCs in developed countries provide quality service, improved patient satisfaction and reduced patients' costs of health care(22). Though in India, the doctor-patient ratio varies a lot, as per the data collected at AIIMS, one cardiologist has to consult at least around 30 to 50 patients in AIIMS, Nagpur. This indicates the existing work burden of cardiologists.

The nurse health workforce can be utilised optimally with proper training, thus reducing the demand-supply ratio(18). Previous studies have revealed that the nurse-led telephonic interventions and the nurse-led clinics resulted in lower complications and healthy lifestyle among the patients with different conditions and thus this study is proposed to evaluate the effectiveness of Nurse Led clinics on the outcomes of patients who had Myocardial Infarction. To bring out reliable results the biophysiological and biochemical parameters will also be studied in the project. By keeping all these points in mind, this study aims to assess the effectiveness of Nurse led Myocardial Infarction follow-up clinic on selected outcome variables of patients and caregivers of patients with Myocardial Infarction.

Objectives

1. To assess and compare the patient outcomes (patient satisfaction, medication adherence, adherence to CVD-related lifestyle practices, biophysiological measures and biochemical measures) at baseline, 1 month, 3 months and 6 months between the experimental group (attending the Nurse-Led MI follow-up clinic) and the control group (receiving standard care):
2. To evaluate and compare the level of caregiver burden between the caregivers of patients in the experimental group and the control group at the 6-month follow-up.
3. To compare the incidence of MI-related complications between the experimental group and the control group over the 6-month study period.

4. To determine the association between socio-demographic and clinical variables of the patients and their level of satisfaction with the Nurse-Led MI follow-up clinic.
5. To explore the relationship between patient satisfaction and other key outcome variables, including medication adherence, CVD-related lifestyle practices, biophysiological parameters, biochemical parameters, and the incidence of complications among patients in the experimental group.

Hypothesis

H1: Patients with Myocardial Infarction who attend the Nurse-Led MI follow-up clinic (experimental group) will show a statistically significant improvement in patient satisfaction, medication adherence, CVD-related lifestyle practices, biophysiological parameters, and biochemical parameters at 1 month, 3months and 6 months compared to those receiving standard care (control group).

H2: Caregivers of patients who attend the Nurse-Led MI follow-up clinic will experience a statistically significant reduction in caregiver burden at 6 months compared to the caregivers of patients receiving standard care.

H3: There will be a statistically significant lower incidence of MI-related complications over the 6-month study period among patients in the experimental group compared to the control group.

H4: There will be a statistically significant relation between patient satisfaction and medication adherence, CVD-related lifestyle practices, biophysiological and biochemical parameters, caregiver burden, and complications of patients with Myocardial Infarction at 6 months among the interventional group at 0.05 level of significance.

Approach and Design: The study will adopt a quantitative approach and the design will be a prospective randomized controlled trial with time series design. The study design will be guided by the CONSORT statement (Figure 1).

	Enrolment	Allocation	Post Allocation					
TIME POINT			O1 (Before discharge)	Telephone calls (Reinforcement of intervention)		O2	O3	O4
				1month after	2month after	1month follow-up	3month follow	6month follow

							-up	w-up
ENROLMENT:								
Eligibility Screen	x							
Informed Consent	x							
Allocation		x						
INTERVENTIONS:								
Intervention A								
Structured Counselling (Lifestyle management, CVD Care, Medication adherence, Physical activity, Smoking cessation, Healthy Diet)			x			x	x	x
MI Nurse Discharge Booklet			x					
Telephonic Reinforcement of the intervention (2 nd month and 3 rd month)				x	x			
Telephonic Follow-up reminders -1 st month, 3 rd month and 6 th month end)						x	x	x
Reinforcement of Caregiver			x			x	x	x
Cardiologist follow-up			x			x	x	x
Intervention B								
Standard routine Care • Cardiologist follow- up • Assessment of patients' variables - clinical variables, complications, documentation)			x			x	x	x
ASSESSMENTS:								
Subject Data Sheet			x					
CVD Related Lifestyle Practices Assessment Questionnaire • BLOOD PRESSURE, BMI • Heart Rate, Ejection Fraction • Lipid profile, RFT • HbA1C, FBS			x			x	x	x
MI Complications Assessment Questionnaire			x			x	x	x
Patient Satisfaction Scale			x			x	x	x
ARMS			x			x	x	x
Modified Caregiver Strain Questionnaire			x			x	x	x



Setting: Cardiology OPD, AIIMS Nagpur. The All India Institute of Medical Sciences (AIIMS), Nagpur, is one of the apex healthcare institutions established by the Ministry of Health and Family Welfare, Government of India, under the Pradhan Mantri Swasthya Suraksha Yojana (PMSSY). The institute is committed to delivering high-quality medical education, cutting-edge research, and comprehensive patient care. It serves as a center of excellence for advanced tertiary healthcare services and is equipped with state-of-the-art diagnostic and therapeutic facilities. The hospital functions through a multidisciplinary team of healthcare professionals, offering services across a wide range of specialties and super-specialties. Catering to a large population from Maharashtra and adjacent states, AIIMS Nagpur prioritizes affordable, accessible, and equitable healthcare. In addition, the institute plays a significant academic role, emphasizing competency-based, patient-centered medical and nursing education integrated with research and innovation.

Participants: Patients diagnosed with MI who had undergone angioplasty in a selected hospital in Nagpur and meet the inclusion criteria will be included in the study.

Inclusion Criteria: The patients diagnosed with MI and undergone angioplasty who have:

1. Residency in Nagpur
2. Having access to a phone,
3. Clinically and hemodynamically stable
4. Not suffering from any severe and life-threatening diseases,
5. Able to perform daily routine activities and categorised as NYHA Class I or II.

Exclusion Criteria:

1. Patients who have undergone CABG
2. Symptoms of NYHA Class III/IV
3. Having any psychiatric illness, or severe systemic disease
4. History of sustained VT/VF
5. Patients who are not capable of self-monitoring will be excluded from the study.

Sample Size: Purposive sampling technique will be adopted for the study. Eligible post angioplasty patients will be sequentially recruited to the study. A sample size of 110 (55 in each group) was estimated with the help of the Openepi software with 80% power and 5% significance level to achieve the maximum effect at 80% and considering 20% attrition rate.

Randomization and Blinding: Computer-generated sequence and SNOSE method for allocation will be used. Outcome assessors and data analysts will be

blinded.

Nurse-led Intervention:

The nurse-led intervention includes:

- Discharge counselling by a qualified nurse
- Discharge booklet
- Monthly telephonic reinforcement for 3 months
- Nurse-led follow-up at 1st, 3rd, and 6 months

Date Collection Procedure:

- The Nurse researcher (certified by the Head of the Cardiology Department of the hospital) with expertise in assessing, diagnosing, interpreting the investigation results, planning treatment for the patient, follow-up care of Myocardial Infarction patients, lifestyle management, risk factor management, and medication adherence will be implementing the intervention.
- Patients listed for Percutaneous coronary angioplasty (PTCA) getting admitted to the ward will be scrutinised based on the inclusion and exclusion criteria by the Senior Nursing officer (SNO) incharge, and the selected subjects will be **randomised** to experimental and control groups.
- **Informed consent** will be obtained from the subjects after explaining the research process, its benefits, and risks.
- The SNO will be there for generating sequence, enrollment and allocation. **SNOSE (Sequentially numbered Opaque Sealed Envelope) technique** will be used for allocation concealment by the Senior Nurse. This concealed randomisation ensures that neither the researcher nor the participants are aware of whether the next eligible participant will be allocated to the control or intervention arms. This will be masked until the time when participants are ready to receive the intervention. Intervention will be administered by the researcher himself.
- The experimental group will receive **discharge counselling and a discharge booklet** (to address gaps in knowledge and to make it easier for the patient to remember important and relevant points) in the ward in a specified room where there will be a one-to-one interaction with the patient and caregiver, to avoid contamination. The Nurse researcher will follow-up the patient till discharge and will give reinforcement of expected behaviours.
- The 2 research assistants will collect the baseline data (1st observation) while the subjects in both the groups will be admitted in the ward.

- Patients of the intervention group will also receive telephonic reinforcement once a month (to identify the strengths and limitations, set goals in consensus with the subject, assess their readiness for change, reinforce the positive behaviour and encourage them to adopt healthy lifestyle practices, evoke internal motivation to follow the set goals) till 3 months and reminded to come for follow-up with the blood investigations report (2 days before the appointment) in OPD in the hospital at 1 month, 3 month and 6 months by the Nurse researcher.
- On the upcoming OPD visits, the research associate will send the Experimental group patient to the Nurse-led MI follow-up clinic and then to the Cardiologist's clinic, while the control group subject will be sent to the Cardiologist's clinic only.
- The Experimental group subject then visits the Nurse-led MI follow-up clinic and then the Cardiologist's clinic, while the control group subject visits only the Cardiologist's clinic during the OPD visits. On each follow up visit, the outcomes (O2, O3 and O4) will be assessed by the research assistants.
- The experimental group patients will be able to contact the researcher anytime for any queries or clarifications.
- The intervention fidelity will be achieved by carefully designing the nurse-led intervention package based on the patient's condition and after a thorough literature review.
- All the components will be given due importance during the data collection with proper planning, and the structured intervention will be provided to the subjects by the same researcher
- Training, educating and orienting the caregivers regarding the care of Myocardial Infarction patients at home will also be given due importance.
- All the relevant information will be given in written form to the caregiver, for reference at home and the checklist is encouraged to be filled out to avoid loss of information due to memory loss during long-term follow-up.

INTERVENTION:

Nurse-led clinic activities

The patients assigned to the experimental group will first be assessed and subsequently provided with structured counselling on the lifestyle management. Tailored instructions based on the individual condition are also given to the patient. During each

telephonic interaction, the advices are reinforced and their doubts are cleared. The patients' motivation to bring the lifestyle changes is checked, and reinforcement is given during the follow-up calls and further OPD visits at 1 month, 3 months and 6 months follow up.

Control Group: The patients assigned to the control group will receive standard cardiologist-led care, which includes a routine discharge summary with general instructions. Follow-up assessments will be scheduled at one month, three months, and six months post-discharge.

Outcomes:

The primary outcomes will be medication adherence and adherence to CVD-related lifestyle practices (assessed using CVD Risk Assessment Questionnaire), while the secondary outcomes will be patient satisfaction (assessed using patient satisfaction scale), medication adherence (assessed using ARMS or Adherence to Refills and Medications Scale, changes in biophysiological (ECG, Blood pressure, Ejection fraction and heart rate) and biochemical parameters (Lipid profile, RFT, FBS and HbA1C), burden of the caregivers of the patients (assessed using Modified Caregiver Strain Questionnaire), and the presence of complications (MI complications assessment Questionnaire). The outcomes will be assessed at baseline (before discharge), after 1 month, 3 months and 6 months after discharge. Criterion validity will be assessed by computing the Pearson's correlation coefficient. A correlation coefficient of ≥ 0.70 will be considered evidence of good criterion validity.

Participant timeline

The participants will be enrolled to the study while being admitted and the baseline observation will be taken before discharge and the patient has to come for follow-up after 1 month, 3 months and 6 months after discharge. This is standard timeline of visits for all patients who undergo PTCA.

Ethical considerations/clearance

Institutional ethical committee approval has been taken (letter no. IEC/Pharmac/2024/1076 dated 5.12.24). A study information sheet will be given to participants and the researcher will further explain the study protocol and prerequisites in a simple language that patient can readily understand. Participation in the study will be purely on voluntary basis and will inform that they can withdraw at any time as they wish. A written informed consent shall be obtained from the participants before enrolling them into the trial. Confidentiality of the data would be maintained throughout the study.

Plan for data analysis

Descriptive and inferential statistics including chi-

square, t-tests, ANOVA, regression, and correlation tests will be applied as appropriate after the data collection.

DISCUSSION

Mostly nurse-led clinics are managed autonomously by nurses, supported by a multidisciplinary team with advanced training and expertise. In these clinics, nurses conduct comprehensive physiological assessments, plan and coordinate patient care, administer therapies and medications, monitor patients' conditions, provide health education, and, when necessary, refer patients to other healthcare professionals.

Nurse led HF clinics have shown to improve the self-care skills, quality of life of patients, reduced the readmission rates and has significantly improved the professional value and social dignity of nurses. Many clinics have focused on discharge planning, home visits, telephonic follow-ups and Heart Failure clinics.(23, 24, 25) This study too emphasises discharge planning, giving telephonic reminders about the follow up visits, individualised health education, evoking motivation and visiting Nurse led MI clinic.

Self-motivated and empowered patients are the cornerstone of effective chronic disease management. While specialist physicians prescribe medications, nurses play a critical role in promoting adherence to drug regimens and facilitating necessary lifestyle and dietary modifications. Through their counseling skills, trained nurses can significantly influence patients' motivation and behavior, leading to better health outcomes. The nurse researcher in this study too will be focusing on improving the health care behaviour of the patients by employing an individualised approach. Nurse led clinics improve the access to healthcare to all categories of people. They help in reducing needless emergency visits and reduce the waiting time to access healthcare. Nurse led clinics help in improving interdisciplinary coordination for better health care. The patient tailored approach helps in raising the patient satisfaction towards the healthcare and engagement in healthcare processes. Nurse led clinics serves as a collaborative model that guarantees patients thorough and seamless care approach.

This protocol outlines a structured, nurse-led intervention designed to enhance medication adherence, patient satisfaction, and clinical outcomes among post-myocardial infarction patients following angioplasty. The inclusion of biophysiological and biochemical parameters measured over time adds rigor and validity to the study findings. Continuous access to healthcare personnel enables patients to seek clarification and make informed decisions promptly, without having to wait for follow-up appointments.

Positive outcomes from this trial may provide valuable insights for healthcare policy, particularly in advocating for an expanded role of nurses in cardiology care. Furthermore, it highlights the potential to utilize postgraduate nurses more effectively within the healthcare system through specialized training. This trial aspires to contribute meaningfully to the domains of nursing education, clinical practice, and research.

CONCLUSION

This study has been initiated to evaluate whether nurse-led clinics can improve patient outcomes and reduce complications and caregiver burden among myocardial infarction patients who have undergone angioplasty. This theory-driven intervention and rigorously designed trial aim to generate robust evidence to address the research question and potentially offer a sustainable solution for enhancing post-angioplasty care.

Dissemination Plan: Results will be published in peer-reviewed journals and presented at national/international conferences.

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Conflicts of Interest: None declared.

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