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Impact of nurse-led cardiac rehabilitation on patient's behavioral and physiological parameters after a coronary intervention: A pilot randomized controlled trial

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Abstract:

BACKGROUND: Coronary artery disease, one of the leading causes of mortality and morbidity globally, is a major burden on healthcare resources. Cardiovascular rehabilitation is highly recommended for the early recovery of patients with Ischemic heart disease by improving the functional capacity and decreasing disease progression. A randomized controlled trial was conducted to assess the effect of nurse-led cardiac rehabilitation (CR) on behavioural parameters.

MATERIALS AND METHODS: Sixty-two adult patients who underwent percutaneous coronary intervention (PCI) were randomised to two groups to assess the effect of nurse-led cardiac rehabilitation (CR) on behavioural parameters, including adherence to drugs, cardiac diet, lifestyle changes, and selected physiological parameters. The intervention group had nurse-led individualized discharge counseling and clinical follow-up by telephone, whereas the control group received usual care. The comparisons between the control and intervention groups were made using independent Student's *t*-test or Mann–Whitney U test as appropriate. Pre-test and post-test scores were compared using paired *t*-test; all tests performed at 5% significance level.

RESULTS: Participants in the intervention group presented with moderate to good smoking cessation, improved adherence to drugs ($P < 0.0001$), physically active lifestyle in 90.3 versus 45.2% ($P < 0.0001$), adherence to dietary changes, and improved healthcare satisfaction ($P < 0.0001$). There was also a significant reduction in triglycerides level in the intervention group at 62.51 versus 20.12 mg/dl in the control arm with ($P < 0.05$), and better controlled physiological indices, including a reduction in systolic blood pressure of 1.54 vs-7.12 mmHg ($P = 0.003$), bodyweight reduction of 2.48 kg versus-0.09 kg ($P < 0.0001$) and body mass index of 0.9 versus-0.05 ($P < 0.0001$).

CONCLUSION: Personalised, nurse-led CR significantly improved the participants adherence to healthy lifestyle behaviors and decreased the cardiac risk factors in patients with coronary artery disease.

Keywords:

Cardiac rehabilitation, coronary artery disease, coronary heart disease, coronary intervention, myocardial infarction, nurse-led rehabilitation

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Introduction

Coronary artery disease (CAD), the most common type of heart disease, has assumed epidemic proportions worldwide, and the burden of CAD is significant for

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patients as well as healthcare delivery systems. In India, a tenfold increase in the prevalence of coronary heart disease has been seen in urban populations and less than 1% to 4%–6% has been observed in rural populations.^[1,2] In spite of evidence-based interventions, CAD remains a leading cause of global mortality.^[3,4] Rehabilitation programs with a focus on counseling and health education are vital components of the holistic approach in the treatment of CAD as studies signify that there is a dependent association between behavioral and physiological risk factors in the incidence and progression of CAD.^[5,6]

Secondary prevention strategies are vital to the care of the patient with cardiovascular disease (CVD). The term cardiac rehabilitation (CR) denotes coordinated, comprehensive interventions planned to improve a cardiac patient's physical, social and psychological functioning, in addition to slowing or reversing any further development of the underlying atherosclerotic processes, thereby decreasing morbidity and mortality.^[7] A supervised CR program can affect the health-related behavior and modify the cardiovascular risk factor profile leading to better clinical outcomes. However, the rather diverse parameters make secondary prevention after a coronary intervention a formidable task,^[5,6] a unique challenge for the treating physician.^[8]

Published evidence claims that 18% of acute myocardial infarction (AMI) patients are affected with a second CVD event in the 1st year, and approximately half of these readmissions happen after discharge from hospital following an acute coronary syndrome (ACS).^[5] Although CR programs reduce morbidity and mortality rates in adults with ischemic heart disease, heart failure, or cardiac surgery, they are not well utilised, since only a few eligible patients participate in them.^[9,10] Novel strategies in CR delivery are urgently needed to improve participation. One potential strategy is nurse-led CR to enhance and encourage patients to meet the goals of improved physical activity, good adherence to antiplatelets and other prescribed medications, improved dietary habits, smoking cessation, and optimal psychosocial well-being, and thereby help to reduce their risk of future CVD events. Various studies have shown that nurse-led CR strategies have reduced secondary events and improved the participants' therapeutic lifestyle modification following an AMI.^[7,11,12]

Public hospitals with a limited number of specialists attend to a large number of patients, which makes the maintenance of proper controls of the quality of healthcare a challenge. Assent to secondary prevention strategies as vital to treatment after ACSs is unanimous. The core components are well defined, and current guidelines recommend a multidisciplinary approach to a total

CVD risk reduction.^[13,14] An individual, patient-tailored risk reduction program is supported, and studies have indicated that it is more efficient and cost-effective.^[15-17] Hence, we planned to study the effect of nurse-led specific CR programs on patients with CAD who have had elective percutaneous coronary interventions (PCIs), in comparison with routine care, on patients' Behavioural and Bio physiological parameters at 12-week intervals.

Materials and Methods

A nonblinded randomized control trial was designed to assess the effect of a nurse-led CR program on behavioural, physiological and biochemical parameters control at 12 weeks intervals of the patients with CAD who had undergone elective coronary angioplasty at a tertiary care centre in South India. Ethical approval was obtained from the Institutional Review Board vide Letter No. JIP/IEC/SC/2016/29/925 dated 15/07/2016 and informed written consent was taken from all participants. The trial was registered in the Clinical Trial Registry of India (CTRI) Reg. No: CTRI/2017/03/008022. The sample size was calculated by comparing the mean difference of total cholesterol (TC) between the Intervention group and control group as -0.50 (0.47) versus -0.17 (0.47) at 3-months' intervals of the group who had nurse-led CR and routine care, with the power of the study as 80% and at 5% level of significance. The sample for this study consisted of 62 participants with CAD who had undergone elective PCI, 31 of whom belonged to the experimental group and 31 in the control group.^[3]

Patients aged more than 18 years with CAD who had undergone elective PCI for chronic stable angina or ACS with left ventricular ejection fraction (EF)^[3] 50% and above were eligible for enrolment. We excluded patients with cardiac failure or other debilitating illnesses such as chronic kidney disease, chronic liver disease, and physical disabilities that prevented them from adhering to prespecified rehabilitation protocol, i.e., those who could not perform physical activities, patients with significant visual or hearing impairment, and those with depression or other major psychiatric disorders and any who had earlier participated in any kind of CR program. In this study, a smoker refers to someone who smokes any tobacco product, either daily or occasionally. Alcoholism refers to a person who has the desire or physical need to consume alcohol.

The consecutive sampling technique was used to select the study participants and a simple randomization technique using a computer-generated random number table was employed for random allocation of participants to the control and intervention groups. The random allocation sequence was prepared by a statistician who was not involved in the study. The study participants

were randomized to intervention and control groups after obtaining informed consent. The investigator obtained a socio-demographic and lifestyle history from the enrolled patients when they were stable after the PCI procedure. Information on clinical parameters including body weight, body mass index (BMI) blood pressure (BP) was measured on the day of discharge. Fasting lipid profile blood sample was collected on the day of the coronary intervention procedure. In this study, the following operational definitions were used, i.e., nonvegetarian refers to someone who consumes meat. Lifestyle changes or behavioral parameters refer to adherence to prescribed treatment regime, adherence to a physically active lifestyle (minimum of 30 min of walk/day), following cardiac healthy diet advice, cessation of smoking and alcoholism. Physiological parameters include changes in BMI and BP in both groups, biochemical parameters refer to changes in lipid profile values following intervention. Family history of CAD refers to the presence of myocardial infarction, angina, or coronary revascularization in any first-degree relatives of the family.

The participants in the intervention group were counselled one-on-one by a nurse trained in cardiology nursing. The research nurse was trained on CR with American Heart Association (AHA) guidelines by the faculty from medical and nursing discipline. Personalized discharge counseling was given to all patients in the Intervention Group at a minimum of two to three sessions per patient, with standard audio-visual aids on CR aspects as per AHA guidelines including the importance of adherence to antiplatelets and other drugs, regular physical activity, quitting smoking, and adherence to a cardiac diet. This was given when patient was stabilized following the procedure and before the discharge and all their questions were answered. After the hospital discharge, weekly telephone interviews were made and an assessment of compliance to a healthy lifestyle and medication adherence done with a checklist. Patients were advised to maintain a diary of the physical activity, medication adherence, 24 h food recall, which was checked by the investigator during the monthly follow-ups for 3 months. Personal follow-up and follow-up counseling sessions were conducted in the cardiac outpatient department (OPD) at the end of every month to reassure the patient. Outcome measurement including physiological parameters (BP), biochemical parameters (lipid profile), and behavioral outcome (smoking cessation, drug adherence, cardiac diet adherence, and adherence to physical activity) were taken at the end of 3 months for all patients, their satisfaction with the personalized counseling were assessed and the outcome assessment by the research nurse done. No blinding was used in this study for outcome assessment.

The control group was given a standard discharge procedure, (with discharge summary including treatment plans), that was followed in the department where the decision to discharge was made by the treating physician. The unit nurses discharged the patient based on discharge summary guidelines given by the physician. Patients in both groups were treated equally apart from the issue of comorbidity-specific drugs. Both group patients were advised to come to the cardiology OPD for clinical follow-up and for medication refill.

The participants were administered a questionnaire to assess their baseline compliance to prescribed medications, physical activity, dietary adherence, and smoking cessation. Compliance with medications (drug adherence) was assessed by 8 points on Morisky's scale. This self-report Morisky scale contains 7 items with yes or no answers and 1 item with a 5-point Likert scale. The scores range from 0 to 8. A score below 6 specifies low adherence, a score between 6 < 8 medium adherence and a score of 8 indicates high adherence with content validity score of Cronbach alpha as 0.83 and reliability as 0.8. Exercise pattern was assessed by Dijon's activity scale with a total of 27 scores where <17 was considered as sedentary lifestyle and a score of >17 considered as active lifestyle.^[18,19] Cardiac diet adherence, smoking cessation, and patient satisfaction were assessed by using a self-developed structured questionnaire, and content validity established with Cronbach alpha of 0.87, and reliability as $r = 0.9$ by test and re-test method.

All data were analyzed using IBM SPSS version 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Continuous data were summarized using the mean and standard deviation or median and interquartile range, as appropriate. Categorical data were summarized using frequency and percentage. Chi-square or Fisher's exact test was applied for the comparison of categorical data. A comparison of the impact of counseling between control and intervention groups was done using independent Student's *t*-test or the alternative nonparametric tests like Mann-Whitney U test. A comparison between the pretest and posttest scores was made using paired *t*-test or the alternative nonparametric tests. Independent student *t*-test, analysis of variance, and difference in difference (DiD) were used to evaluate the effectiveness of counseling on CR. All the tests were carried out at a 5% level of significance.

Results

The study consisted of 62 patients with 31 in each group. The majority of the study participants were aged between 50 and 65 years, with a male preponderance. Smokers constituted 67.7% in the control group as against

48% in the intervention group; 71% versus 48% of the participants had a history of alcoholism and almost all in both groups were nonvegetarian. The participants in the intervention and control groups were homogenous at baseline as regards the reason for percutaneous transluminal coronary angioplasty (PTCA), BMI, and family history of CAD [Table 1].

The baseline mean values of lipoprotein fractions, i.e., low-density lipoprotein (LDL), triglycerides (TG), and

Table 1: Demographic characteristics and baseline behavioral characteristics of patients

Characteristics	Control group (n=31) N (%)	Intervention group (n=31) N (%)	P-value*
Age in years			
25-50	12 (38.7)	9 (29.0)	0.595
50-65	14 (45.1)	18 (58.0)	
>65	5 (16.1)	4 (12.9)	
Gender			0.053
Male	30 (96.8)	22 (70.9)	
Female	1 (3.2)	9 (29.0)	
Education			0.680
Illiterate	4 (12.9)	7 (22.6)	
Primary	21 (67.7)	20 (64.5)	
Higher secondary	4 (12.9)	2 (6.5)	
Graduate	2 (6.5)	2 (6.5)	
Body weight (kg)	65.9±11.1	66.03±11.5	0.964
BMI [#]	23.9±3.6	24.5±3.6	0.533 [#]
BP [#]			
SBP	122.3±18.0	129.5±18.8	0.130 [#]
DBP	75.8±12.3	80.5±13.9	0.165 [#]
Reason for PTCA			0.72
Chronic stable angina	6 (19.3)	5 (16.1)	
Unstable angina	6 (19.3)	7 (22.5)	
STEMI	12 (38.7)	13 (41.9)	
NSTEMI	79 (22.5)	6 (19.3)	
History of smoking	21 (67.7)	15 (48.4)	0.123
History of alcoholism	22 (71)	15 (48.4)	0.070
Dietary pattern			0.554
Nonvegetarian	30 (96.8)	29 (93.5)	
Family history of CAD			0.393
Present	10 (32.3)	7 (22.6)	

*Pearson Chi-square, [#]Student's *t*-test, PTCA: Percutaneous transluminal coronary angioplasty, STEMI: ST elevated myocardial infarction, NSTEMI: Non-STEMI, BP: Blood pressure, SBP: Systolic BP, DBP: Diastolic BP, BMI: Body mass index, CAD: Coronary artery disease

very-low-density lipoprotein (VLDL) ($P < 0.031, 0.004, 0.001$ respectively) was not homogenous at baseline, hence the difference in DiD was calculated for further interpretation. The difference in serum TC levels was significant at the end of 3 months in the intervention group ($P = 0.014$). Although the LDL levels were reduced significantly for both groups, the increased reduction was more evident in the intervention group ($P < 0.051$). The TG and VLDL values were not different ($P = 0.48$ and 0.14 respectively). The DiD analysis revealed an increased reduction in the levels of TG and VLDL cholesterol ($P = 0.04$ and 0.01 respectively) by the 3rd month of follow-up in the intervention group [Tables 2 and 3]. The systolic BP, body weight, and BMI showed a change in the intervention arm at 3 months on Pearson Chi-square analysis of DiD ($P = 0.03, <0.0001, <0.0001$ respectively). The DiD analysis is shown in table [Table 4].

The participants in the intervention group were more adherent to medications than those in the control group with a $P < 0.0001$ [Table 5]. The participants in the intervention groups had an active lifestyle and adhered more strictly to the healthy dietary pattern ($P \leq 0.0001$) [Table 4]. Moderate-to-good smoking cessation was noted in the intervention group. Twenty-nine (93.5%) patients were very satisfied with the CR program.

Discussion

We obtained very interesting and encouraging results from this randomized trial of the effect of rehabilitation following PCI. Developing economies like India and middle-income South East Asian countries are facing an epidemic of CAD.^[2,4] Public hospitals often have to deal with the burden of a large number of patients with CAD.^[1] This raises the issue of the importance of sub-optimal care delivery. Behavioral education for better lifestyle practices and proper drug counseling, which are integral to secondary prevention of CVD are never given the necessary significance.^[8] Furthermore, ensuring drug compliance is a major challenge as many patients do not understand the significance of secondary prevention drugs after myocardial infarction. There is very little data on the impact of CR programs in India,

Table 2: Lipid profile values at baseline and at 3 months after intervention (n=62)

Name of the variables	At baseline		P-value	After 3 months		P-value*
	Control group (n=31)	Intervention group (n=31)		Control group (n=31)	Intervention group (n=31)	
	Mean±SD	Mean±SD		Mean±SD	Mean±SD	
TC	150.3±31.8	148.5±30.4	0.823	152.4±40.1	137.5±39.8	0.014*
HDL	33.8±8.1	34.2±8.5	0.843	39.8±8.4	35.7±6.4	0.039*
LDL	89.5±31.0	73.7±24.9	0.031*	88.6±35.3	72.8±26.5	0.051*
TG	140±69.7	195.2±77.1	0.004*	119.8±71.4	132.7±71.0	0.481
VLDL	27.1±12.5	38.5±13.8	0.001**	21.4±7.5	25.1±11.5	0.144

* $P < 0.05$, ** $P < 0.001$, [#]Student's *t*-test. TC: Total cholesterol, HDL: High density lipoprotein, LDL: Low density lipoprotein, TG: Triglyceride, VLDL: Very LDL

Table 3: Changes in biochemical parameters following nurse-led cardiac rehabilitation

Name of the variables	Control group (n=31)		Mean difference	Intervention group (n=31)		Mean difference	P-value
	Pre-intervention Mean±SD	Post-intervention Mean±SD		Pre-intervention Mean±SD	Post-intervention Mean±SD		
TC	150.3±31.8	152.4±40.1	-2.09	148.5±30.4	137.5±39.8	11.0	0.143
HDL	33.8±8.1	39.8±8.4	-5.96	34.2±8.5	35.7±6.4	-1.5	0.042*
LDL	89.5±31.0	88.6±35.3	0.90	73.7±24.9	72.8±26.5	0.9	0.997
TG	140±69.7	119.8±71.4	20.1	195.2±77.1	132.7±71.0	62.5	0.056*
VLDL	27.1±12.5	21.4±7.5	5.7	38.5±13.8	25.1±11.5	13.4	0.015*

*P<0.05-ANOVA. TC: Total cholesterol, HDL: High-density lipoprotein, LDL: Low density lipoproteins, TG: Triglyceride, VLDL: Very LDL, SD: Standard deviation

Table 4: Changes in physiological indices following nurse-led cardiac rehabilitation

Name of the variables	Control group		Mean difference	Intervention group		Mean difference	P-value
	At baseline Mean±SD	After 3 months Mean±SD		At baseline Mean±SD	After 3 months Mean±SD		
SBP	122.3±18.0	129.5±13.5	-7.1	129.5±18.8	128±0.10.6	1.5	0.003*
DBP	75.8±12.3	79.8±6.9	-3.9	80.54±13.9	79.6±6.7	0.9	0.064
BMI	23.97±3.6	24±3.5	-0.05	24.55±3.6	23.6±3.3	0.9	<0.0001*
Weight	65.90±11.14	66±10.7	-0.09	66.03±11.5	63.5±11.1	2.4	<0.0001*

*Student t-test. SBP=Systolic blood pressure, DBP=Diastolic blood pressure, BMI=Body mass index, SD: Standard deviation

Table 5: Effect of nurse-led cardiac rehabilitation on drug adherence and other behavioral parameters (n=62)

Name of the variables	Control group (n=31) N (%)	Intervention group (n=31) N (%)	P-value
Drug adherence			
Low adherence (<6)	24 (77.4)	7 (22.6)	<0.0001*
Moderately adherent (6-7)	5 (16.1)	19 (61.3)	
Highly adherent (8)	2 (6.4)	5 (16.1)	
Physical activity score			
Active (score >17)	14 (45.2)	28 (90.3)	<0.0001
Sedentary (score <17)	17 (54.8)	3 (9.7)	
Dietary pattern adherence score:			
Highly adherent (5-6)	4 (12.9)	12 (61.3)	<0.0001
Moderately adherent (of 3-4)	21 (67.7)	19 (38.7)	
Low adherence (score of 0-2)	6 (19.4)	0	
Smoking cessation (n=15 in intervention group and n=21 in control group)			
Low (score of "0")	6 (28.5)	2 (13.3)	<0.01*
Moderate (1-2)	12 (57.1)	8 (53.3)	
Good (score of 3)	3 (14.2)	5 (33.3)	
Patient's satisfaction with cardiac rehabilitation			
Yes	-	29 (93.5)	

*Pearson Chi-square

especially after elective coronary intervention. This study reveals the strength of the impact of specific counseling focused rehabilitation program on lifestyle, behavioral changes and drug compliance.

However, though CR should be part of the normal care for patients with cardiovascular disease, few continue in the modified lifestyle strategy following an acute event. The literature advocates that instead of the traditional advice-giving, programs which are patient-centred may have better outcomes by improving the reduction of the risk factors. Nurse-led rehabilitation clinics have been established to provide patients and families with knowledge and skills for symptom management and

support, adjust medication and provide the patients with referral for investigations.^[9,12-14] Previous studies have shown the effects of the nurse-led rehabilitation clinic on the reduction of hospital readmission, and its positive effects on clinical endpoints such as the improved control of the patients' BP and drug adherence. Our results are similar to the accumulated evidence of the efficacy of nurse-led clinics on clinical outcomes.^[19,20]

There was a significant change in the lipid profile parameters as serum TC, TG, and VLDL were found to be significantly reduced in the intervention group at 3 months' follow-up. HDL in this study was increased in

both groups after 3 months and increased significantly in the control group. The lipids level reduction in this study might be credited basically to the medication effect raised by medication adherence as well as cardiac diet adherence of rehabilitation participants.^[21] This argument is supported by the demonstration of significantly better adherence to a healthy diet and medication in the intervention group. Similar results were noted in previous studies which showed a successful reduction in TG, TC, and LDL at 3 months ($P < 0.01$) and 6 months ($P < 0.05$).^[21,22] In another study also, it was noticed that Median total and LDL cholesterol levels were decreased in the intervention arm, and the relative change in LDL cholesterol levels at 6 months was significant in the intervention arm than in the standard care arm (-36% reduction vs. -26% reduction, $p 0.025$).^[23,24]

The majority of coronary patients have unhealthy lifestyles in terms of sedentary behavior, smoking, and diet, which adversely affects their clinical outcome.^[25] Studies that evaluated the effectiveness of nonpharmacological CAD prevention strategies have shown that individual counseling (IC) had a significant impact on the control of BP ($P < 0.05$).^[10-13] Similarly, in the present study, by analyzing the difference of the mean scores between the groups, the systolic BP was better controlled (-7.1 mmHg vs. 1.5 mm Hg) in the intervention arm than the control arm ($P < 0.05$). This we believe is the result of the combined effect of counseling on lifestyle changes and improved drug adherence as shown previously.^[26,27]

The study also revealed a positive effect of the intervention on the BMI. This is contradictory to the previous studies that showed the effect of counseling on body weight as neutral.^[28,29] At 3 months, the rehabilitation group participants had gained 0.06 kg. But by 6 months, the intervention group participants had demonstrated a 0.16 kg weight loss compared to a 0.39 kg weight gain in the control participants ($P < 0.05$), the BMI was slightly lower in the intervention group ($P = 0.05$).

Similar to the previously published studies on CR programs, the cardiac risk factors were considerably modified proving the importance of improved drug adherence, smoking cessation, and adherence to the modified dietary and exercise pattern in the intervention arm for cardiovascular secondary prevention.^[28,30-33] We found superior drug compliance in the rehabilitation group. This is crucial, as drug default, especially premature stoppage of antiplatelet drugs is an important cause of sub-acute and late stent thrombosis. We consider this novel concept as successful in most of the parameters we analyzed since it showed the positive impact of the intervention. We plan to do a larger study involving more participants.

The study limitations include single-centre data. Small sample size but the positive impact has made us follow the specified intervention on all of our patients in a similar manner. Only specific predefined parameters were assessed for the effect of an intervention. The major limitation is the rather brief 3-month follow-up. A longer duration would have been of greater value as the intervention effects shown could be transitory.

Conclusion

The study results show a strong favorable impact of a specific CR program on the risk parameters studied. There was an improvement in drug adherence, lifestyle changes such as diet, physical activity, and smoking cessation in addition to improved patient satisfaction on the delivery of care after the rehabilitation program. Biochemical risk factors like blood lipoprotein fractions showed an improving trend with the improved adherence to drugs and the possible effect of adoption of healthy dietary habits. We propose that a dedicated rehabilitation program involving patient-centric counseling and periodic reassurance may prove useful if integrated into secondary prevention programs after elective coronary interventions.

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Conflicts of interest

There are no conflicts of interest.

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