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A Comparative Study on the Effects of Comprehensive Rehabilitation in Uncomplicated Coronary Artery Bypass Grafting Patients from Rural and Urban India

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Abstract

Objectives: This study intended to compare the effect of comprehensive rehabilitation in uncomplicated coronary artery bypass grafting (CABG) patients from rural and urban India using a low-cost, home-based rehabilitation programme. The outcome measures were MET Scores measured by Treadmill Test, 6-Minute Walking Distances (6-MWD) and Quality of Life Indices measured by the WHOQoL-BREF Questionnaire.

Methods : **Patients fulfilling the inclusion and exclusion criteria were enrolled from amongst those scheduled to undergo CABG. A baseline evaluation, laboratory examination and pre-operative counselling were done. Following CABG, a graded rehabilitation programme consisting of drugs, prescribed exercise, diet, therapeutic lifestyle changes, and sexual rehabilitation was implemented and continued for 4 months after discharge, with periodic monitoring and follow-up.**

Results : **52 patients participated in the study, 43 of whom went on to complete it. There were significant improvements in the MET Scores, 6-MWDs and all domains of quality of life in both the groups ($p < 0.001$), compared to baseline values, but no statistical difference between the groups.**

Conclusion: **This study demonstrated that comprehensive rehabilitation following CABG using even a low-cost, home-based programme caused significant improvement in the work capacity and quality of life of both rural and urban Indian population.**

Key Words: **CABG, Home –based Rehabilitation, Indian population**

Introduction

At the beginning of the 20th century, Coronary Artery Disease (CAD) accounted for less than 10% of the deaths worldwide, but now it accounts for nearly half of all the deaths in the developed world and 25% in the developing countries [1]. The most common cause of CAD is atherosclerosis of the coronary arteries leading to diminished blood flow, ischaemia and myocardial infarctions. Advanced disease not adequately responding to medical measures necessitates coronary reperfusion. Though minimally invasive techniques like Percutaneous Transluminal Coronary Angioplasty (PTCA) have been

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employed for the same, Coronary Artery Bypass Grafting (CABG) remains the procedure of choice, especially for 3 - vessel atherosclerosis, significant left main coronary artery stenosis, 2 or 3 vessel disease with proximal stenosis in the left anterior descending artery [2], and is associated with a lower incidence of re-admissions and repeat procedures than is PTCA [3].

However, the duration of hospital stay and the immediate post - operative morbidity after a CABG procedure is longer than PTCA. Thus, there is a need to help the patient resume his or her normal activities as soon as possible after CABG, in order for him or her to once again lead a socially and economically productive life. Furthermore, it is essential to prevent recurrence. Out of all these necessities was born the science of rehabilitation for post-CABG patients, in order to reduce cardiovascular mortality, improve functional capacity, attenuate myocardial ischaemia, retard the progression, foster the reversal of coronary atherosclerosis, and reduce the risk of further coronary events.

50 years ago, patients who suffered myocardial infarction were confined to bed for two months or longer and then were urged to limit their physical activity indefinitely [4]. The avoidance of physical activity was likewise advocated for those with angina [4]. Dramatic success in medical rehabilitation achieved during the course of World War II helped clinicians question the benefits of extended immobility [4]. Early Cardiac Rehabilitation programmes focused almost exclusively on exercise [4]. Although exercise remains the central part of modern cardiac rehabilitation, it has, in addition to risk factor management, the goals of secondary prevention to reduce both symptoms and risk of premature death and improvement in quality of life, including sexual rehabilitation[4]. Strategies to improve adherence to all medical therapies and lifestyle changes are employed. An additional goal is to provide information to the patient's family members and others [4]. A cost-effectiveness analysis suggests that cardiac rehabilitation improves life expectancy and is more effective than many other post-myocardial infarction treatment interventions [4].

The World Health Organization therefore has defined modern cardiac rehabilitation as "the sum of activity required to ensure cardiac patients the best possible physical, mental, and social conditions so that they may, by their own efforts, regain as normal as possible a place in the community and lead an active life " [5].

The Indian Scenario: One - sixth of the world's population lives in India and approximately 75 % of our people reside in rural settings [1]. Although a study in the South Indian setting [6] in a top-grade private hospital was done evaluating the effectiveness of a rehabilitation programme after CABG, there has been no study so far evaluating the impact of the same on the rural population, as compared to their urban counterparts. In this background, our study was done which intended to compare the effect of comprehensive rehabilitation in uncomplicated coronary artery bypass grafting (CABG) patients from rural and urban India using a low-cost, home-based rehabilitation programme, to see whether the benefits of rehabilitation following CABG can be extended beyond the urban boundaries to the rural masses.

Materials and Methods

This exploratory study was conducted in the Department of Physical Medicine and Rehabilitation in collaboration with the cardio-thoracic and vascular surgery (CTVS) unit of the Institute of Cardio-Vascular Sciences, at the Institute of Post Graduate Medical Education and Research (IPGMER) & SSKM Hospitals, Kolkata, from 1st of July , 2005 to 30th of June , 2006 . The screening was done at the CTVS outdoor (OPD), after the decision to perform CABG had been taken by the Visiting Surgeon based on the clinical profile, Coronary Angiography (CAG) and other reports. All the eligible patients were then explained about the study and invited to participate in the same.

The outcome measures recorded were the Metabolic Equivalent (MET) Scores recorded by a Treadmill Test using the Bruce Protocol, 6 – minute walking distances (6MWD) and the various domains (Physical, Psychological, Social Relationships and Environment) of the WHOQoL – Bref Questionnaire. These were measured at baseline, 6-weeks after operation and at the end of the study period (4 months from the date of operation. Statistical Analysis was done employing the Wilcoxon's Signed Rank Sum Test for intra-group comparison and the Mann-Whitney U and Chi-Square Tests for inter-group comparison, employing the SPSS for Windows, Version 11.5 software.

- **Inclusion Criteria:** Patients of both sexes having undergone a CABG procedure in the institute of our study and without any of the exclusion criteria as specified.
- **Exclusion Criteria:**
  - i. Unstable angina or acute myocardial infarction.
  - ii. Cardiac arrythmias (life-threatening)
  - iii. Uncompensated CCF.
  - iv. Advanced A-V block.
  - v. Acute myocarditis , pericarditis or active endocarditis .
  - vi. Critical Aortic Stenosis .
  - vii. Severe hypertrophic obstructive cardiomyopathy.
  - viii. Uncontrolled hypertension .
  - ix. Acute pulmonary embolism or pulmonary infarction .
  - x. Acute systemic illness.

Table 1: Acute post-CABG Rehabilitation Programme

Post Operative Day	Breathing	Activities	Walking	Other (supervised) Exercises	Counseling
0 (Day of Operation)	Weaning from ventilator - huffing and assisted coughing	Encouraged to sit up	X	P - AA-Active Foot-ankle exercises (target HR upto 30 bpm above baseline)	X
1	Huffing and assisted couging	Situ up in chair	X	1-2 METs. Range of Motion Exercises	Re-orientation of the programme
2	-do-	Read newspaper in chair, self feeding, bedside commode	Walk short distances	1-3 METs. Range of motion exercises.	Visit by dietitcian
3	-do-	Partial self-bath in bed+ above	Walk in the hall upto thrice daily	2-4 METs. Range of motion exercises	Cessation of smoking
4	Breathing Exercises	As above + out of bed for 3-4 hours	Walk ad lib. (Target 300')	2-4 METs. Range of motion exercises	Risk-factor reduction, specific limits to exercises
5	-do-	-do- (with increasing duration)	Stair climbing. Increase distance of walking	3-5 METs. Range of motion exercises	RPE scale. ADL training. Relaxation Training.
6	-do-	-do-	-do- (increase extent and frequency of stari-climbing)	4-5 METs exercises. Trunk exercises, active range of motion exercises of all four limbs	Participation in peer-support groups + discharge planning
7	-do-	-do-	-do-	5-6 METs exercises + above	Discussion of post-discharge issues, follow-up visits, smoking cessation

At the OPD itself, the particulars of the patient, baseline clinical examination, the results of the laboratory investigations relevant to the study as well as the baseline response to the WHO-QoL BREF questionnaire, which is an index for the quality of life, were noted in the study proforma. If any particular investigation was lacking, the patients were asked to get them done prior to admission for CABG.

Patient education is an important aspect of cardiac rehabilitation[7,8] both to raise their consciousness level and also to remove the fear and anxiety of the impending open-heart surgery. For this purpose, a slide show presentation on the computer in simple language was prepared regarding the pathophysiology of coronary artery disease, the risk-factors involved, essential details about the bypass surgery procedure, photographs of the operating room and recovery room, the "tubes and drains" that would be attached to the patients body immediately following surgery (along with their importance), and the immediate post – operative

rehabilitation programme, stressing on early mobilization. Special emphasis regarding compliance to the programme and regular follow–ups , as well as the importance of quitting smoking to prevent recurrence . Lots of illustrations and sketches were used instead of lengthy texts, to make it comprehensible to even the illiterate patients. After admission, on a fixed day of the week, the patients with their family members sat with members of the rehabilitation team, and after introductions, the presentation was made. All the individual queries of the patients and their family members were answered in plain language, avoiding technical terms to the maximum possible extent, and their fears and concerns were addressed to. The family members were also asked to quit smoking and adopt the lifestyle changes that would be subsequently prescribed to the patient, to ensure full support from the family once the patient was discharged.

A schedule for acute rehabilitation in the recovery room was made (Table 1), and after the patients had been stabililized following the surgery, it was rigidly implemented to ensure the shortest possible stay in the recovery room (ICU). In the step-down unit, the patients were asked to gradually increase their activities, and perform exercises under supervision and relevant activities of daily living, so that discharge could be planned at the earliest.

Prior to discharge, a complete physical examination was done and the patient's response to the WHO-QoL BREF questionnaire was again noted. The drug regimen, lifestyle changes, graded exercise programme, diet schedule, smoking cessation and the dates of follow – up visits were discussed with the patient, and any doubts were clarified. The insulin or oral hypoglycaemic agent (OHA) prescription, in case of diabetic patients, was however done by consultants from the Department of Endocrinology of our institute.

After discharge, the patients were asked to follow-up weekly at the OPD for the first 2 visits, thereafter fortnightly twice, then at 3-weekly intervals for the next 2 visits, and then once after another 4 weeks, which would be the end-point of the study.

At each of the follow-up visits, the patients underwent a physical examination including recording of the vital parameters. Six weeks after CABG, they were asked to undergo a treadmill test, perform a 6-minute walking distance test, and respond to the WHOQoL-Bref questionnaire, and the results were noted. A similar exercise was carried out at the end of the study, approximately sixteen weeks after the CABG.

Drugs: In general, a long-acting nitrate, aspirin, a statin, a beta-blocker and/or another anti-hypertensive drug and a laxative were routinely prescribed to the patients following surgery. Additionally, Insulin/OHA (as described above), a course of antibiotics, sedative/anxiolytics were prescribed where applicable.

Exercises: The initial supervised exercise programme gave way to an unsupervised exercise programme with the proper precautions, which the patients were to follow at home. The patients were taught to take their pulse, and at each visit a target heart rate, based on Karvonen's formula, was set — the patients told to stop if that was exceeded, or if they felt chest pain or constriction or shortness of breath. The exercise intensity was fixed at a rating of perceived exertion of "somewhat hard" to "hard", that is between 13 to 15 on the Borg scale of perceived exertion[7,8] . Gradually, resistive exercises like leg presses were included into the programme. Resistive exercises for the upper extremities were incorporated not before 6-weeks from the date of surgery, after making certain that there was no evidence of sternal dehiscence. Counseling was done at each visit, and the need to stop smoking was reiterated.

Diet: Despite an extensive search of literature, there was no mention of any specific diet after CABG. So, after discussions with the chief dietitian of our hospital, it was decided to adopt the recommended diet set by the National Institute of Nutrition, Hyderabad for sedentary patients adding supplemental protein for the first six weeks, the time expected to take for the wounds to heal properly.

After that, the patients were put on the diet for the Indian reference man or woman, according to his or her activity. At each follow-up visit, monitoring in the form of recording the body-weight, body mass index (BMI) and body-fat percentage was done and the diet modified, if required, to ensure that the above parameters remained within normal range.

Sexual Rehabilitation: The patients were encouraged to frankly discuss about their concerns regarding the resumption of sexual relationship if it was applicable. An effort was made to remedy the misconceptions and apprehensions of the patient and the spouse, and options for a successful resumption of sexual activities were presented to the patient. Where possible, any offending medication was attempted to be withdrawn.

Others: The medications were reviewed at the follow-up visits, and barring the nitrate preparation, the anti-platelet agent (Aspirin) and the statins, an attempt was made to wean off all the un-necessary drugs gradually. Adjustment of the anti-diabetic medication regime was however, outside the scope of this study, and this was left to consultants from the Department of Endocrinology of our hospital.

At the end of the study, the patients were asked to follow the lifestyle, diet, medications and exercise as advised, and to come for regular follow-up visits as directed by

the visiting cardiothoracic surgeon. They were also asked to attend PMR OPD every 3 months, or sooner if necessary. Their family members were directed to adopt similar lifestyles in order to prevent this disease from occurring in their families.

Results

A total of 54 patients met the eligibility criteria, but 2 patients who lived in another state expressed their inability to come for regular follow–up visits and did not participate in the study. The remaining 52 patients gave informed consent to participate in the study. 5 patients dropped out during the course of study, and 4 patients died in the early post-operative period. The remaining 43 patients went on to complete the study.

All 4 deaths occurred in the rural group, 2 of these patients died on the day of operation itself, one from cardiac arrest, and another, who had a history of diabetes mellitus, from hypoglycemia. A similar incident occurred on the first post-operative day in another diabetic patient, while the fourth patient died from multiple-organ failure.

The dropout rate (13.79 %) was more in the urban group than in the rural group (4.35 %). Amongst the patients who dropped out, one got transferred to another state, while another patient moved with his family and couldn't come for follow-up. 3 other patients could not be traced, so their reason for dropping out could not be ascertained.

The study results have been summarized in Table 2. Of the initial 52 patients, 44.23 % (23 out of 52) came from rural areas, while 55.77 % (29 out of 52) were from urban background. Males constituted 91.30 % of the rural patients and 96.55 % of the urban patients.

78.26 % of the rural population and 86.21 % of the urban population were active smokers. None of the 3 women were smokers, although 1 such patient was exposed to passive smoking from her husband.

There were no significant differences between the Rural and urban groups at the baseline, 6 weeks after surgery or at the end of study (p-values denoted by p_0, p_6 and p_{end} respectively), in the MET Scores ($p_0 = 0.525$, $p_{6=} 0.688$, $p_{end=} 0.579$), 6MWD ($p_0 = 0.847$, $p_{6=} 0.487$, $p_{end=} 0.247$) and Physical ($p_0 = 0.175$, $p_{6=} 0.718$, $p_{end} = 0.939$), Psychological ($p_0 = 0.331$, $p_6 = 0.098$, $p_{end=} 0.184$), Social Relationships ($p_0 = 0.162$, $p_{6=} 0.526$, $p_{end=} 0.920$) and Environment ($p_0 = 0.063$, $p_{6=} 0.162$, $p_{end=} 0.300$) Domains of the WHOQoL-Bref questionnaire, as measured by the Mann-Whitney U Test.

However, intra-group analysis done by Wilcoxon's Signed Rank Test, at the end of the study period when compared to the baseline in both the groups (p-values denoted by p_{rural} and p_{urban} respectively), revealed a highly significant difference in the MET Scores ($p_{rural} < 0.001$, $p_{urban} < 0.001$), 6MWD ($p_{rural} < 0.001$, $p_{urban} < 0.001$) and Physical ($p_{rural} < 0.001$, $p_{urban} < 0.001$), Psychological ($p_{rural} < 0.001$, $p_{urban} < 0.001$), Social Relationships ($p_{rural} < 0.001$, $p_{urban} < 0.001$) and Environment ($p_{rural} < 0.001$, $p_{urban} < 0.001$) domains of the WHOQoL-Bref questionnaire.

Upon comparison of the change in the above parameters

Fig. 1 : SEX DISTRIBUTION OF THE STUDY POPULATION

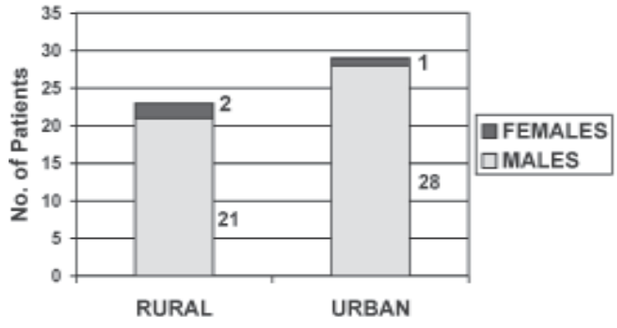


Fig. 2 : SMOKING STATUS OF THE STUDY POPULATION.

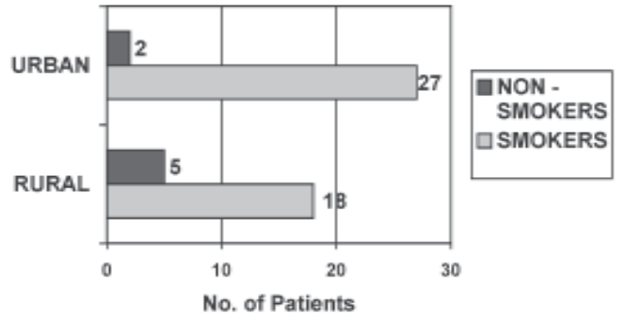


Fig. 3 : Average MET Scores of the Study Population.

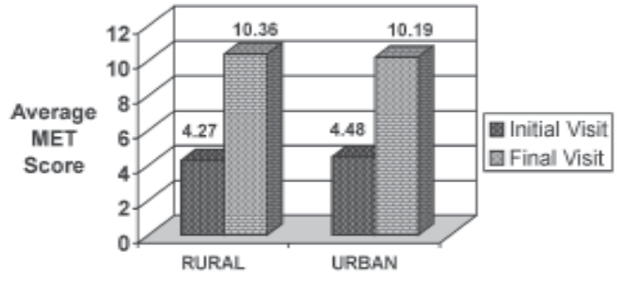


Fig. 4 : Average 6 - Minute Walking Distances of the Study Population.

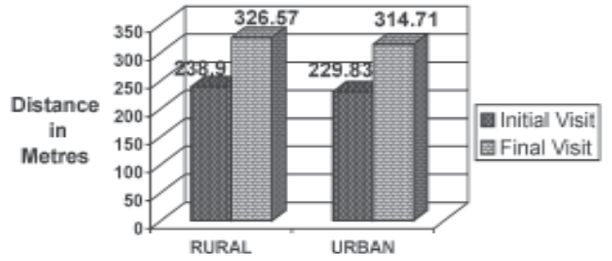


Fig. 5 : PHYSICAL Domain of WHOQoL - BREF.

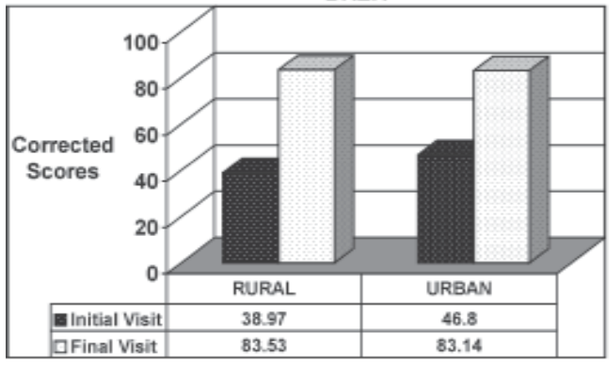


Fig. 6 : PSYCHOLOGICAL Domain of WHOQoL - BREF.

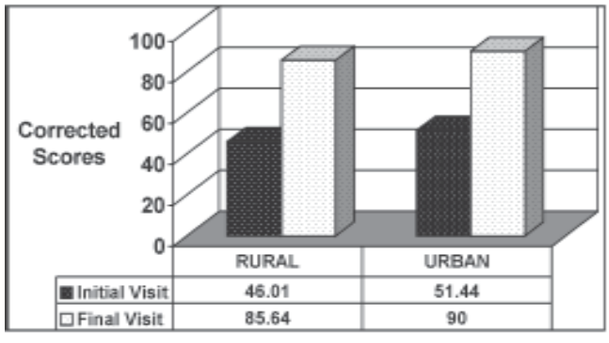


Fig. 7 : SOCIAL RELATIONSHIPS Domain of WHOQoL - BREF.

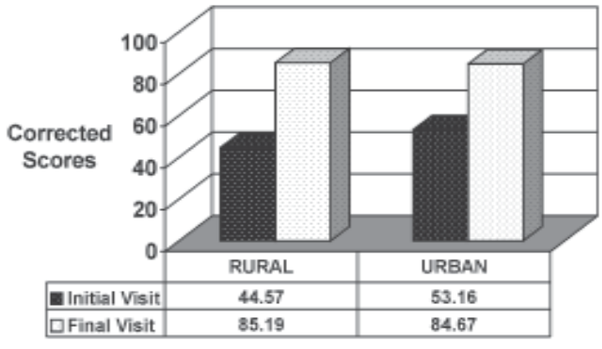
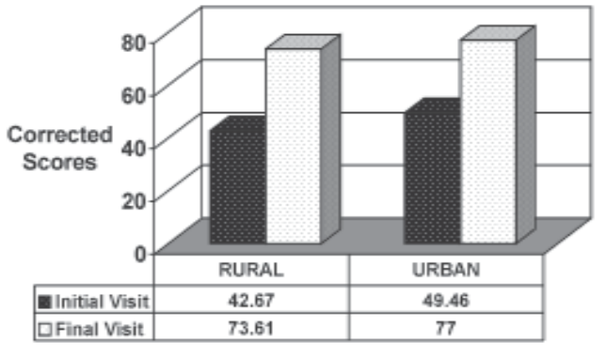


Fig. 8 : ENVIRONMENT Domain of WHOQoL - BREF.



from baseline to the end of study, employing the Chi-Square test, , we could find no difference between the two groups (p_{met} = 0.91, p_{6mwd} = 0.37, $p_{physical}$ = 0.25, $p_{psychological}$ = 0.37, $p_{social\ relationships}$ = 0.24, $p_{environment}$ = 0.30).

Discussion

From the study, it is seen that the maximum incidence of cardiovascular disease in the study population occurred males (Fig.1). This is in accordance with *Park*[10] and *Kumar et al* [9] that male sex is a major risk factor for cardiovascular disease. The meager number of females in the study population (5.77 %) also may corroborate with the observation that women are less likely to be referred for cardiac rehabilitation than their male counterparts [7].

The literature has said that the majority of the cardiovascular diseases occured in urban areas [1,10], and our study pointed to a similar trend (Table – 2) with 29 of the 52 cases (55.77 %) from urban regions. The apparently large proportion of cases from the rural areas (44.23 %) may be attributed to 2 causes–

a. Since this study evaluated only the established cases, it is not representative of the population. As much as 75% of India's population lives in rural areas [1], so the absolute number of cases from those regions is expected to be high.

b. The institution of study is a premier referral institution where patients from whole of Eastern and North-Eastern India as well as from neighbouring countries are sent for treatment – so what we are seeing in the OPD may not be a true reflection of disease prevalence at the community level.

Just as has been mentioned in the literature, smoking[1,10] was associated with an overwhelming majority (Fig.2) in the study population (44 out of 52 cases, or 84.62 %). smoking and other tobacco-related addictions, can therefore be said to be a major risk factor for cardiovascular disease.

There was a highly significant improvement in the Metabolic Equivalents (MET) Scores from the baseline for both the rural and urban arms of the study (Fig.3), as measured by ETT. This points to the success of comprehensive cardiac rehabilitation in enabling patients to increase their peak work capacity. Comprehensive cardiac rehabilitation therefore, can be said to have a positive impact in the functional work capacity of the people undergoing CABG, and therefore should routinely be a part of the postoperative care, at least in all the uncomplicated cases.

There was a highly significant increase in the 6-minute

walking distance following CABG (Fig.4). This corroborates with the increased exercise capacity as measured by the MET scores discussed above. Again, the statistically significant improvement in the MET scores from 6 weeks till the end of study points to the success of the rehabilitation programme.

There was also a highly significant improvement in all the domains (Physical, Psychological, Social Relationships and Environment) of the WHOQoL-Bref questionnaire for determining improvement in the Quality of Life in both the rural and urban populations (Figs.5 to 8), proving that along with work capacity, benefits are also seen in the quality of life of all sections of the Indian population following a comprehensive rehabilitation programme after CABG.

Conclusions

The very fact that comprehensive cardiac rehabilitation in uncomplicated post-CABG patients using a low cost, home-based programme results in significant benefits in the work capacity and quality of life equally in both the rural and urban population indicates its necessity routinely after CABG in any setting.

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