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Long Term Effect of Cardiac Rehabilitation Program on Patients with Percutaneous Coronary Intervention

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Subjects and Methods: Sixty patients of both sexes (41 men and 19 women) had been recruited from National Heart Institute, Cairo. All patients underwent PCI. They were randomly assigned to two equal groups in number. Study group was 30 patients (21 men and 9 women, mean age was 52.6 ± 5 years) that had been received aerobic mild to moderate intensity exercise training on bicycle ergometer for 50 minutes, 3 times/week, for 6 months and educational program of secondary prevention, and was followed up after one year, while control group was 30 patients (20 men and 10 women, mean age was 53.8 ± 5 years) that had been received instructions about risk factors after PCI once and followed up after one year. Functional capacity was evaluated by 6-minutes walking test (6MWT), quality of life (QoL) was assessed by 36-Item Short- Form Health Survey (SF-36) and different risk factors e.g. smoking status, body mass index(BMI), fasting blood glucose, blood pressure, blood lipid levels, were assessed before and after the CR for both groups.

Results: After CR, a significant increase was observed in 6 MWT (P < 0.05), significant improve in cardiovascular risk factors(smoking status, body mass index, fasting blood glucose, blood pressure, blood lipid levels) and QoL were increased in the study group (P < 0.05) compared to control group.

Conclusion: Cardiac rehabilitation significantly improves functional capacity and cardiovascular risk factors and QoL after percutaneous coronary intervention. It is recommended not to miss referral to rehabilitation units.

Keywords: percutaneous coronary intervention, cardiac rehabilitation, functional capacity, cardiovascular risk factors, quality of life.

I. Introduction

oronary artery disease (CAD) is the main cause of death worldwide. (1) It is potentially fatal disease with high lifetime prevalence. In terms of mortality it represents the most important disease in the group of all CVD, which, in turn, are responsible for most of the deaths in developing and in industrialized countries. (2) In Egypt, and Similar to other Arab countries, ischemic heart disease and stroke are the second and fourth common cause of death in 1990 but in 2010 they shifted to be the first and second cause respectively. CAD mortality accounts for 46% of total deaths, all ages and both sexes, according to WHO (2014). Trends in CAD mortality in the last few years show a minor reduction due to preventive efforts especially against smoking, an operational action plan to reduce the burden of tobacco use. (3)The development of CAD is multicausal and is related to a variety of risk factors, many of them strongly influenced by individual behavior, such as smoking, exercise, diet, diabetes mellitus, hypertension and hypercholesterolemia. (4) It has been suggested that modification of these modifiable risk factors could reduce the burden of CAD by approximately 90%. These risk factors, however, also strongly influence the prognosis of patients with established CAD. In addition to the well established pharmacological management of patients with CAD, behavioral changes to modify these lifestyle factors in affected individuals are therefore recommended to form the basis of all secondary prevention strategies of CAD.

Cardiac rehabilitation programs have become an integral part of the standard of care in modern cardiology. Their scope has shifted from the emphasis on exercise therapy to comprehensive secondary prevention strategies managing risk factors, nutritional, psychological, behavioral and social factors that can affect patient outcomes. While the importance of primary prevention measures aimed at delaying or preventing the onset of cardiovascular disease is obvious and cannot be emphasized enough, CR is mainly involved with secondary prevention which relies on early detection of the disease process and application of

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interventions to prevent the progression of disease. These interventions include education, counseling and behavioral strategies to promote lifestyle change and modify risk factors. Clinical trials have proven that strategies for the detection and the modification of risk factors can slow, stabilize or even modestly reverse the progression of atherosclerosis and reduce cardiovascular events. In most current guidelines of cardiovascular societies worldwide, CR is a class I recommendation. (5)

The American Heart Association (AHA) defined CR as a "medically supervised program to help heart patients recover quickly and improve their overall physical and mental functioning". (6) Goals for CR include improving aerobic endurance and muscular strength, and modifying cardiovascular risk factors, including losing weight, lowering cholesterol, improving blood glucose, controlling blood pressure, and smoking cessation. (7) Recent research has shown that people who have experienced cardiac events can handle more frequent and intense exercise than originally thought. (8)

Quality of life reflects the functional effect of an illness and its therapy from the patient's point of view. Poor QoL has been associated with poorer outcomes, such as lower survival rates, increases in the number of hospitalizations, decreased capacity to perform activities of daily living, and decreased compliance with treatments in other populations like cardiac patients. (10) This study was conducted to find out the long term effect of CR on patients with PCI, and the potential effect CR to improve functional status, cardiovascular risk factors presented with these patients, and its effect to improve their QoL.

II. Patients and Methods

This study was conducted in physiotherapy department of National Heart Institute (NHI). 60 Patients of both sexes, their age was 40-60 years old, within the first year after PCI, their mean BMI was ≤ 35Kg/m², were selected and assigned to two equal groups in number. The study group (30 patients, 21 men and 9 women) that had been received aerobic mild to moderate exercise training and educational program of secondary prevention, while the control group (30 patients, 20 men and 10 women) that had been received instructions about risk factors after PCI once and were followed up after one year.

Exclusion criteria were patients with renal failure, chronic liver disease, Patients with arrhythmia, Chest disease, and patient who could not fulfill the questionnaire or cooperate through the performed procedures.

Before starting the study, a meeting was done for all patients to record demographic data and risk factors (smoking status, BMI, fasting blood glucose,

systolic and diastolic blood pressure, and blood lipid levels) presented with each patient. In that stage a face to face instructions and administration of SF- 36 questionnaire to all participants was given. 6-MWT was introduced to each patient along the 20 m straight corridor of the physiotherapy department of NHI. All patients were taking their medications normally. Participants in the CR program were requested to attend their exercise program three times/week for a period of six months.

Mild to moderate intensity exercise prescribed based on Borg's rating of perceived exertion (RPE) scale. The scale is comprised of 15 points where a rating of 6 means no exertion and a rating of 20 means maximal exertion. Patients were encouraged to achieve a rating between 11 (fairly light) and 14 (hard), as many cardiac patients may use beta blockers in their treatment medications, that work to reduce resting and maximal heart rate. (11) For participants in the CR program involved in this study, each exercise session is comprised of a 5 - 10 minute warming up, 5-10 minutes cooling down, and approximately 30 minutes of aerobic exercise. Aerobic exercise was the dominant mode of exercise which implemented using bicycle ergometer in the CR program 3 times/week for 6 month. Patients were given an idea about risk factors control and secondary prevention according to AHA guidelines for secondary prevention 2011. (12) After one year, risk factors were measured, and also SF- 36 and 6 MWT were measured again.

Data were analyzed with SPSS software version 17. Parametric data was analyzed using the student ttest. Non parametric data was analyzed using McNemar test for the same group, and Mann-whitney test to compare between both groups. The level of significance was set at P < 0.05. Paired t-test was applied for each group to compare pre and post values within the same group. Unpaired t-test was applied to compare pre and post values between both groups of the study.

III. RESULTS

Base line measurements had shown no statistical significant differences between both groups (P>0.05). The baseline and final values of each group (Table 1) had shown highly significant differences in 6MWT, smoking cessation rate, BMI, TC, HDL and LDL (P<0.001), FBG and TG had improved significantly (P<0.05), SBP and DBP did not improve significantly in the study group (P>0.05). The control group had shown significant improves in 6MWT and BMI, other parameters did not change significantly (P>0.05).

All risk factors were improved significantly in the study group when compared with the control group after the program (P<0.05). The increase in 6MWT was highly significant (P<0.001).

As shown in (table 2) the 8 domains of SF-36 of the study group had increased highly significantly (P<0.001). The control group had shown highly significant increase in PF and GH (P<0.001), and significant increase in E/F (P<0.05), other parameters did not increase significantly (P>0.05).

ΑII domains of SF-36 were improved significantly in the study group when compared with the control group after the program (P<0.05), and EW increased highly significantly (P<0.001).

Table (1): Changes of risk factors from baseline to the end of the program within each group and between groups

| | Study group | | | Control group | | | P value |
|-------------|-------------|--------------|--------|---------------|--------------|-------|-----------------|
| Variables | Pre program | Post program | Р | Pre program | Post program | Р | for both groups |
| | Mean ±SD | Mean ±SD | Value | Mean ±SD | Mean ±SD | Value | after program |
| 6MWT (m) | 414.8±57.4 | ↑489±54.8 | 0.000* | 419±50.2 | ↑430.5±47.3 | 0.01* | 0.000* |
| Smoking | 67% | ↓17% | 0.000* | 63.3% | ↓50% | 0.13 | 0.007* |
| BMI (Kg/m²) | 30.8±1.9 | ↓28.2±2.6 | 0.000* | 30.2±1.7 | ↓29.6±2.1 | 0.03* | 0.03* |
| FBG (mg/dl) | 131.7±47.3 | ↓106.8±36.5 | 0.01* | 128.5±54.5 | ↓127±38.3 | 0.86 | 0.04* |
| SBP (mm/Hg) | 129.2±18.7 | ↓123.8±13.5 | 0.22 | 128.5±16.6 | ↑131.2±14.6 | 0.47 | 0.05* |
| DBP (mm/Hg) | 81.3±8.8 | ↓79.2±7.8 | 0.31 | 82.8±9.2 | ↑84.6±8.2 | 0.38 | 0.01* |
| TC (mg/dl) | 199.1±48.9 | ↓176.3±42.1 | 0.000* | 198.8±41.7 | ↓197.3±39.4 | 0.71 | 0.05* |
| TG (mg/dl) | 148.2±34.2 | ↓132.1±28.8 | 0.01* | 151.1±32.5 | ↓149.8±35.1 | 0.65 | 0.04* |
| HDL (mg/dl) | 35.6±8.5 | ↑37.5±8.8 | 0.001* | 33.3±7.8 | ↓32.1±7.4 | 0.72 | 0.01* |
| LDL (mg/dl) | 134±49.1 | ↓112.1±44.6 | 0.000* | 135.2±45.3 | ↑136±41.5 | 0.88 | 0.04* |

SD=Standard Deviation, 6MWT= 6 minutes walking test, BMI=Body mass index, FBG=Fasting blood glucose, SBP= Systolic blood pressure, DBP= Diastolic blood pressure, TC=Total cholesterol, TG=triglyceride, HDL=High density lipoprotein, LDL=Low density lipoprotein, Significant level: P<0.05*.

Table (2): Changes of 8 domains of SF-36 from baseline to the end of the program within each group and between aroups

| groupe | | | | | | | | | | |
|-----------|-------------|--------------|------------|---------------|--------------|------------|----------------------------------|--|--|--|
| Variables | Study group | | | Control group | | | P value | | | |
| | Pre program | Post program | P Value | Pre program | Post program | P Value | for both groups after program | | | |
| | Mean ±SD | Mean ±SD | | Mean ±SD | Mean ±SD | | | | | |
| PF | 64.3±7.1 | ↑83.5±6.5 | 0.000* | 63.2±6.9 | ↑76.7±10.6 | 0.000* | 0.01* | | | |
| RLPH | 35±24.2 | ↑62.5±23.4 | 0.000* | 40.8±23.2 | ↑50.8±20.2 | 0.11 | 0.04* | | | |
| RLEP | 34.1±23.7 | ↑61.1±21.6 | 0.000* | 41.8±21.1 | ↑49.9±19.1 | 0.09 | 0.04* | | | |
| E/F | 51.7±7.8 | ↑66±11.1 | 0.000* | 51.3±7.9 | ↑57.7±11.7 | 0.01* | 0.01* | | | |
| EW | 61.3±6.2 | ↑69.5±2.6 | 0.000* | 59.1±6.1 | ↑61.5±7.5 | 0.18 | 0.000* | | | |
| SF | 50.9±10.5 | ↑67.5±19 | 0.000* | 51.7±10.9 | ↑56.3±16.3 | 0.23 | 0.02* | | | |
| Р | 65.2±9.7 | ↑79.6±18.4 | 0.000* | 62.7±10.2 | ↑67.9±15.9 | 0.07 | 0.01* | | | |
| GH | 28.2±5 | ↑43±7.9 | 0.000* | 27.3±4.8 | ↑38.5±8.8 | 0.000* | 0.04* | | | |

SD=Standard Deviation, PF=Physical functioning, RLPH=Role limitations due to physical health, RLEP=Role limitations due to emotional problems, E/F=Energy/ fatigue, EW=Emotional wellbeing, SF=Social functioning, P=Pain, GH=General health. Significant level: P<0.05*.

IV. Discussion

The benefits of exercise-based CR on cardiovascular risk factors, QoL, exercise tolerance, cardiac morbidity and mortality have been widely established in CAD patients. (1) The aim of this study was to determine the long term effect of CR on patients with PCI, and its potential effect on risk factors control and the subsequent improvement in their QoL. The results of the current study showed significant improvement of functional status, risk factors of CVD and QoL in the study group. The following is a detailed discussion of the different variables of the study.

About smoking, percent of reduction were 75% ↓ and 21% ↓ in the study and control groups respectively. Reduction in the study group was statistically significant and also, comparison between both groups after CR. The results were supported by Wood et al. The proportions of patients with CHD who quit smoking at 1 year were significantly higher in the study group than in usual-care group. In the intervention group, 58% of the volunteers were not smokers at 1 year compared with 47% in the usual-care group. (13) Along with the same results Redfern et al. had reported significant reductions in smoking behaviors in the study group compared to the control group. (14) Although Judith et al. had reported a non significant difference between intervention and control groups at one year about smoking cessation, he reported a significant improvement results at two and three years. (15)

In current study the patients of study group revealed highly significant increase in their functional capacity, and control group increased significantly, Percent of change was (18% ↑ and 3% ↑) respectively, when measured by 6-MWT, that was reflected in improvement of the physical functioning score section of SF-36 for both groups (Percent of change was 29.8% ↑and 21.4% ↑) respectively. Changes in control group reflected the positive effects of PCI on physical function of the patients. Comparison of both groups revealed highly significant increase in the study group at the end of the program, which, in turn reflect the more beneficial effect of CR on patient when added to PCI effect. Supporting the study results Fatimah et al. revealed an increase in functional capacity after the CR program measured by 6-MWT and no significant differences were seen in their control group and mean distance walked was increased 19.3% in the study group. (16) Raymond et al. had shown significant improvement in exercise capacity after CR including low risk individual, exercise capacity parameters such as 6MWT and treadmill exercise test were statistically significant after the program. (17) In a study by Viviane et al. both aerobic interval training and continuous training equally improved aerobic exercise capacity in patients with CAD and self perceived QoL increased significantly (P<0.05) and to a similar extent after both types of training. (1)

Consequently, the results was coincided with results achieved by Yu et al. who showed significant improvement in the frequency, duration of physical activities and total score of self efficacy scale in the experimental group, which can effectively improve the patients exercise compliance, promote the willingness of physical exercise and help the patients establish healthy behaviors. (18) As a result, promoting the recovery of cardiac function. Consistent with the results, Judith et al. who reported significant improvements in the study

group compared to the control group in maximal workload. (15)

In current study, following CR program, study group achieved positive reduction in weight and BMI. BMI was decreased highly significantly in the study group, also control group decreased significantly. Comparing two groups showed four times reduction in study group more than control group, Percent of reduction was (8.4 % 1 and 2% 1) for study and control groups respectively. Masoumeh et al. showed that obese patients in the study group had greater improvement in weight reduction and subsequent BMI that was statistically significant when compared with control group. (19) Another study by Manzoni et al. showed the positive effects of short term CR program on weight reduction and functional capacity in obese patients with CAD. (20) In contrast, results of Kiat et al. suggested CR program didn't had effect on weight reduction, while it is useful in increasing levels of functional capacity. (21) Pantaleo et al. estimated that at baseline, there was no significant difference in BMI between the study and usual care groups, at 6months, it increased by 0.7% in the study group and 0.9% in the usual care group, there was a 0.2% lower increase in BMI in the study group. At the end of his study, BMI increased by 1.7% and 2.1% in the study and usual care groups, respectively, a difference that was statistically significant. (22)

Fasting blood glucose was highly significantly reduced in the study group after the program, without significant change in the control group. Percent of reduction was (18.8 % ↓ and 1.2% ↓) for study and control groups respectively; comparison of both groups had showed significant decrease in the study group after program.

Both SBP and DBP changed to levels that were statistically significant when comparing both groups after the program, although changes in both groups separately were not significant. Percent of change in SBP was $(4.2 \% \downarrow \text{ and } 2.1\% \uparrow)$ and DBP was $(2.6\% \downarrow)$ and 2.3% ↑) for study and control groups respectively. Improvement of study group and deterioration of control group showed the positive effect of CR program. Diabetes mellitus is a chronic condition with devastating cardiovascular complications, the prevalence of diabetes was reported as 13.5% in Egypt and it is closely associated with a concomitant rise in obesity rates. (23) (24) Going with the same effects of CR on FBG and blood pressure control Bestehorn et al. mentioned that at discharge FBG values decreased to 104 mg/dl (108 mg/dl at entry), mean SBP and DBP decreased also to 122/73 mmHg (131/77 mmHg at entry) which were statistically significant. (25) Again Redfern et al. had concluded significant difference in SBP among study group compared to control group patients at three months and 12 months. (14) Fatemeh et al. results showed that CR to have significant effects on hemodynamic responses such as resting and maximum systolic and diastolic blood pressure. (16) In a systemic review by Judith et al. significant improvements in SBP and DBP in study group patients compared to control groups, at one, two, and three years were seen. (15)

The results of this study indicated that exercise and educating patients of PCI during CR program could improve lipid profile levels. The patients of the study group had achieved significant reductions in TC, TG and LDL levels and significant increase in HDL levels, no significant changes were seen in control group. Significant improvements were seen in the study group when compared to the control group after the program. Percents of changes were (11.5% ↓ and 0.75% ↓ for TC, 10.9% ↓ and 0.86% ↓ for TG, 5.3% ↑ and 3.6% ↓ for HDL, and 16.3% ↓ and 0.44% ↑ for LDL) for study and control groups respectively. Both groups were taking lipid lowering drug therapy as prescribed by the physicians, which explains the effect of exercise training and awareness program on lipid profile for the study group. The greater effect of exercise and education on the study group suggests a possible additional effect on adherence to physical activity, prescribed medications and healthy life style. Masoumeh et al. presented significant improvements in all lipid profiles in non obese patients, and in obese patients, this positive improvement was only perceived in TC. (19) Results of the current study were more supported by Viviane et al. that found that both aerobic interval training and continuous training improved HDL levels significantly in both groups. (1)

Bassem et al. mentioned affection in the QoL in patients with CAD in the form of presence of symptoms limiting their activity, such as chest pain due to angina attacks, shortness of breath, palpitation. Also, the daily activities may be limited in usual daily activities as moderate activities. Lifting or carrying groceries, climbing several flights of stairs, climbing one flight of stairs, bending, kneeling, stooping, walking for a bus station distance, bathing or dressing himself, and sexual dysfunction, and recurrent sick leaves due to his or her heart condition. (26)

The results obtained in the present study revealed statistical significant increases in SF-36 variables. Percent of changes were (29.8% †and 21.4% ↑for PF, 78.6% ↑ and 24.5% ↑for RLPH, 79.2% ↑and 19.4% †for RLEP, and 27.9% †and 12.5% †for E/F, 13.4% \(\gamma\) and 4.1% \(\gamma\) for EW, 32.6% \(\gamma\) and 8.9% \(\gamma\) for SF, 22.1% †and 8.3% †for P, and 52.5% †and 41% †for GH) for study and control groups respectively. CR has large effects on improving different domains of SF-36 as presented in results of study group, although some domains like PF, E/F and GH had increased significantly in the control group reflecting the positive effect of PCI, they were not as large as improvements of study group. Supporting current results, Marzieh et al. had shown that

scores of all physical domains of the SF-36 were significantly improved in all patients compared to the baseline. Patients with age < 65 years had greater improvements in mental health and social function than patients with age 65 years. Women had greater improvement in PF, vitality and mental health compared to men. Furthermore he concluded from his results that CR can improve QoL in cardiac patients especially in women. Elderly patients get benefit the same as other patients in physical domains. On the other hand, increasing exercise capacity improves patients' ability for daily living activities, work and leisure activities, which in turn results in improving QoL. (27) A systematic review article Taylor et al. indicated that home based CR and center based CR both improve QoL. CR can decrease psychological stress of cardiovascular diseases and improve QoL in cardiac patients. (28) Marzieh et al. pointed out that 12 months CR improves physical index and QoL of cardiac patients. (27)

Roberto et al. published the results of a study designed to compare the effect on QoL of CR programs shorter than 6 months, longer than 6 months, or no CR. Nine months after completion of the different programs, QoL was significantly higher among patients who had undergone CR, regardless of duration, and there were no significantly different effects between CR programs of more than or less than 6 months, also he note that the increased patient compliance observed in the shorter programs. (29) Yohannes et al. results demonstrated the benefits of CR in improving QoL and physical activity, and in reducing anxiety and depression. Furthermore, these benefits were maintained at 12 month follow up. (30)

There is a significant and positive relationship between changes in secondary prevention and changes in QoL. Patients started the study with low level of QoL scores and had shown significant increases in QoL scores following the CR programme. Also, the ability of patients to exercise had increased significantly. As the physical abilities of patients increased, they reported feeling less pain, more energy and better emotional state. Increased physical ability was associated with a brighter outlook on current and expected future health status.

V. Conclusion

It was concluded that long term CR program and secondary prevention according to the guidelines of AHA has a positive effects in improving risk factors in patients who presented with uncontrolled cardiovascular risk factors, also QoL was improved, further more CR is a good method that improve adherence to healthy life style, orientation and ability of the patient to cope with the disease.

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