ROLE OF CARDIAC REHABILITATION IN IMPROVING HEALTH STATUS & QUALITY OF LIFE OF HEART FAILURE PATIENTS- A RANDOMISED CONTROLLED TRIAL

Mahwish Ujala, Naila Azam*, Tariq Hussain Khattak, Syed Fawad Mashhadi, Tanzeel, Javeria Kamran, Adeela Aslam Malik

Armed Forces Institute of Cardiology/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Fauji Foundation Hospital, Rawalpindi Pakistan

ABSTRACT

Objective: To assess the role of cardiac rehabilitation in improving the health status and quality of life in heart failure patients. The main outcome measures were functional health status and health-related quality of life.

Study Design: Double blinded parallel randomized trial.

Place and Duration of Study: Outpatient department, Armed Forces Institute of Cardiology, Rawalpindi, from Jul to Dec 2018.

Methodology: A study was conducted using purposive sampling at the Armed Forces Institute of Cardiology. Screening as per eligibility criterion and informed consent was taken till sample size of 272 was achieved. Randomisation was done by computer generator on the basis of equal allocation i.e., 1:1 ratio (randomization unit were patients); outpatient usual care (control arm) or usual care plus cardiac rehabilitation (experimental arm). Interventions included education, 6-minute walk, dietary and psychosocial counselling on fortnightly basis. The main outcome measures were functional status (NYHA, Ejection fraction) and health-related quality of life measured using MLHF Questionnaire. Outcomes were assessed by cardiologist masked to the intervention.

Results: Significant improvements were found in NYHA classification, Ejection Fraction and MLHF score at baseline & after 8 weeks of intervention between both the groups (p<0.001).

Conclusion: Cardiac rehabilitation is an effective intervention in improving the health status and QoL in heart failure patients.

Keywords: Cardiac rehabilitation, Heart failure, Quality of life, Functional health status.

How to Cite This Article: *Ujala M, Azam N, Khattak TH, Mashhadi SF, Tanzeel, Kamran J, Malik AA. Role of Cardiac Rehabilitation in Improving Health Status & Quality of Life of Heart Failure Patients - A Randomized Controlled Trial. Pak Armed Forces Med J 2022; 72 (Suppl-1): S16-20.*

INTRODUCTION

Among Cardiovascular diseases, Heart failure put maximum clinical & financial burden on health resources. It affects the pumping action of one or both ventricles of the heart compromising body's needs; leading to dyspnea, edema, lethargy and poor Quality of Life.[1] Heart failure (HF) patients experience substantial deterioration in performing activities of daily living (ADL) & physical activity, decline in overall Quality of Life, consequently increased hospitalisation rates impacting both morbidity & mortality.[2] Recent researches have concluded that evidence based pharmacological and rehabilitation therapies decrease mortality, hospitalizations, and heart failure symptoms and improve quality of life. However, many patients not receiving these therapies and regimens remain burdened by dyspnea, fatigue, exercise intolerance, poor quality of life, repeated hospitalizations, and early mortality.[3-6].

Secondary prevention, early diagnosis and prompt treatment has a tremendous impact on health related quality of life in heart failure patients.[7] Treatment usually involves medications, reducing sodium in the diet and ensuring daily physical activity.

The term cardiac rehabilitation refers to "coordinated, multifaceted interventions designed to optimize a cardiac patient's physical, psychological, and social functioning, in addition to stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality".[8] CR is a multidisciplinary approach involving adjustment of medication, anti-smoking counselling & therapies, exercise administration, dietary & psychosocial counselling.[9] It helps mitigate post cardiac events, recurrent hospitalization eventually impacting health economics.[10-12]. Researches have proved that a comprehensive cardiac rehabilitation programme proved 26% reduction in cardiac death rates, over 13% decline in all cause mortality & 38% reduction in myocardial infarction.[13]

The aim of this study is to contribute in the better understanding of the significance of cardiac rehabilitation as an effective intervention in improving the health status and quality of life of heart failure patients.

METHODOLOGY

A randomized controlled trial was conducted at Cardiac Rehabilitation and Cardiac Out Department of

Correspondence: Dr Mahwish Ujala, Armed Forces Institute of Cardiology/National Institute of Heart Disease, Rawalpindi Pakistan

Armed Forces Institute of Cardiology, Rawalpindi Pakistan, from July to December 2018 using a parallel design. This study was a prospective, double-blinded, randomized controlled trial with two parallel arms; equal (1:1) randomization.

Inclusin Criteria: Study participants included Out Patients of Cardiac Failure at AFIC/NIHD with the age 35-75 years, New York Heart Association (NYHA) classification Class II to IV & Left Ventricular Systolic Dysfunction (ejection fraction <40%).

Exlcusion Criteria: Patients with significant co-morbidity, terminal disease, COPD/Asthma, or who were unable to exercise, Bed bound/Oxygen dependent or who had undergone CABG in past 3 months & Patients with severe musculoskeletal disorder, unstable ischemic heart disease, advanced valvular disease, were excluded.

The sample size for the study was 272, calculated using Open Epi Sample Size.net with effect size taken to be 34% as per a similar RCT carried out on Heart Failure patients in England.[14]

The trial was both evaluated & approved by Ethical Review Board of Armed Forces Post Graduate Medical Institute, Rawalpindi & Institutional Ethical Review Board of AFIC/NIHD Rawalpindi.

Out of 3 Cardiac institutes in Rawalpindi/Islamabad, AFIC/NIHD was selected using convenience sampling. Heart failure patients visiting Cardiac OPD were screened as per eligibility criterion over a period of two months using purposive sampling. Terms/ conditions of the trial, details of the intervention in the form of Patient Information Sheet & consent form was provided to the participants. For illiterate participants, witnessed oral consent with thumb print in lieu of signatures were obtained. A trial log of patients approached for the research; consented or did not fill eligibility criterion was maintained. Enrolled participants were assessed for baseline demographics characteristics. Their functional health status was assessed through NYHA classification & Ejection fraction measurement. Quality of life (baseline) was measured with the Minnesota living with heart failure (MLHF) questionnaire.

Later, participants were randomized into one of two interventions arm on 1:1 ratio i.e., outpatient usual care (control arm) or usual care who'd receive cardiac rehabilitation (experimental arm). Simple Randomization was carried out for sample size (272) by an independent computer operator using Random computer generator software. Random assignment was carried out using Sequentially numbered, opaque, sealed envelopes (SNOwS) at the OPD to implement allocation concealment. After randomization the trial coordinator contacted each participant and intervention was assigned to them.

Control Arm

Control group (n=136) received routine care for 4-week (functional performance (NYHA), Echocardiography, laboratory evaluation) in the cardiology outpatients department by the Cardiologist.

Experimental Arm

Experimental arm (n=136) received medical treatment by the cardiologist like the control arm alongwith out patient cardiac rehabilitation including education on a patient care like medication compliance, smoking cessation, dietary counseling (salt and fluid restriction), exercise management and psychological counseling. This intervention was provided by members of the multidisciplinary team at out patient/CR department; comprising of dietitian, psychologist, rehabilitation staff, medical officer, cardiologist and a pharmacist. Participants were called on fortnightly basis to attend classes for almost 25-30 minutes duration under supervision of a medical officer to ensure treatment adherence and address clinical concerns.

The whole intervention was carried out on experimental group on fortnightly basis for two-months. The impact of the intervention was measured by NYHA Class assessment/ EF/QoL at baseline and at 8 weeks. No adverse reactions and serious adverse events (SAEs) were reported by the participant or by the investigators or other staff members throughout the trial.

Blinding

The Cardiologist and statistician were blinded of the intervention and control group. NYHA classification and Ejection fraction on echocardiography were assessed by the cardiologist.

Statistical comparisons of both the study groups was done using 2-tailed with p-value <0.05 on an Intention-To-Treat principle on Statistical Package for Social Sciences (SPSS) version 22.

RESULTS

Out of 489 patients screened for the trial, 156 (32%) were excluded as they did not fulfill eligibility criterion, 56 (17%) of the eligible participant declined to give consent. The Mean (n) and frequencies (%) were calculated for the baseline assessment and clinical

details of the participants. The demographic profile revealed no significant difference in the baseline parameters of both the usual care and the experimental arm.

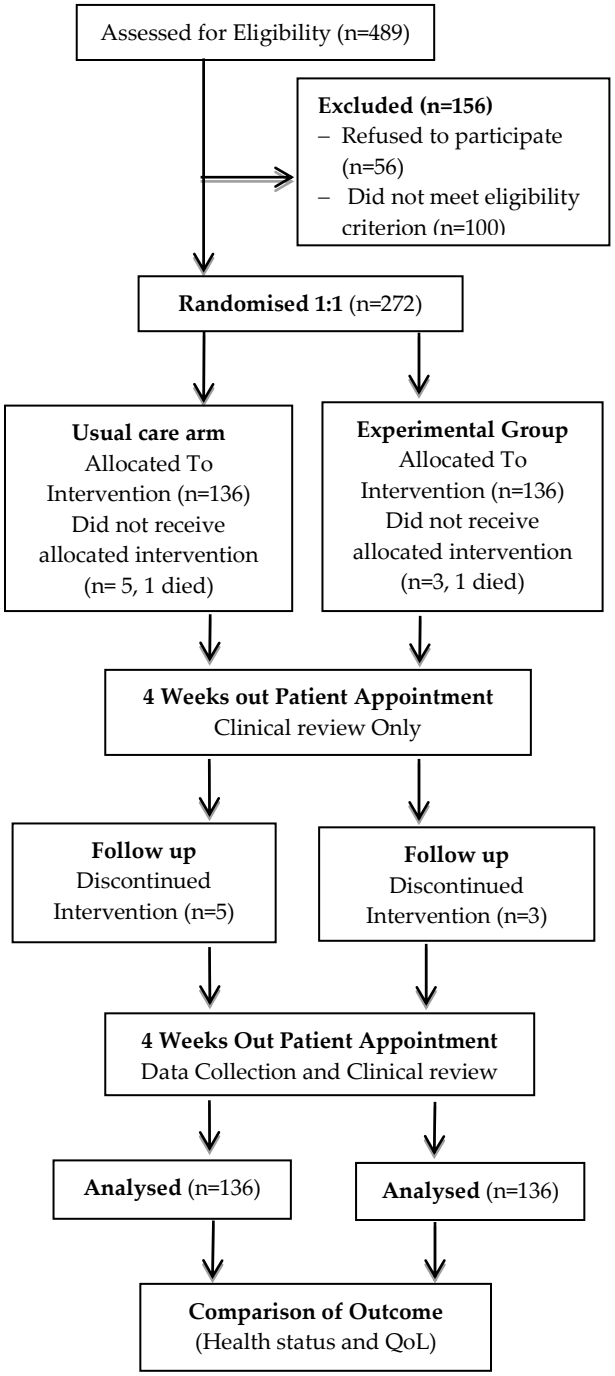

Figure: Flow chat of methodology.

Baseline Mean scores of NYHA Class of both usual care and experimental arm were compared with mean NYHA scores at 8 weeks respectively (Table-II). Paired Sample t-test was applied. No significant difference was found in the mean score of the usual care arm. However, there was highly significant difference in the mean score of the experimental group at baseline & after 8 weeks.

Health status was assessed using Ejection fraction. The means EF scores of usual care and experimental arm were calculated (Table-II). Paired sample t-test was applied for each arm. No significant difference was found in the means EF score of usual care arm. However, there was a significant difference in the mean scores of Ejection fraction in the experimental arm.

Table-I: Baseline clinical characteristics of both the usual care or experimental group.

Variable	Usual Care % (n)	Experimental % (n)
Mean (SD) Age (years)	62.3 (10.5)	60.6 (9.3)
Male	80 (108)	74 (101)
Primary Aetiology		
CAD	99 (134)	98 (133)
MI	77 (104)	50 (66)
PCI	23 (31)	31 (42)
CVA	10 (14)	20 (28)
Dyslipidemia	80 (48)	89 (121)
Co-Morbids		
DM	42 (56)	27 (36)
HTN	54 (72)	73 (98)
Smoking	41 (55)	57 (77)
Mean (SD) BMI	25.2 (4.06)	24.8 (3.91)
Degree of Left Ventricular Diastolic Function		
Mild (EF<40 -35.5%)	50	40
Moderate (EF >31-35%)	26	25
Severe (EF <30%)	60	70
Functional Status, NYHA Class		
II	70	60
III	66	76

Table-II: Change in patients NYHA functional classification & Mean scores of EF from baseline and at 8 weeks.

NYHA	Usual Care Arm		Experimental Arm	
	Baseline (n=136)	8 weeks (n=131)	Baseline (n=136)	8 weeks (n=135)
Mean (SD.)	2.25 (0.451)	2.38 (0.547)	2.82 (0.55)	2.21 (0.58)
95% CI	2.17-2.32	2.28-2.47	2.75-2.92	2.10-2.29
p-value	0.062		0.001	
Ejection Fraction	**Usual Care Arm**		**Experimental Arm**	
	Baseline (n=136)	8 weeks (n=132)	Baseline (n=136)	8 weeks (n=135)
Mean (S.D.)	32.85 (7.702)	32.56 (8.408)	31.65 (7.579)	35.99 (8.899)
95% CI	-33.15 to -30.53	-31.99 to -29.11	-31.94 to -29.36	-35.50 to - 32.48
p-value	0.068		0.001 (-32.17 to -30.24)	

The QoL was measured by using MLHF Questionnaire. Scores were obtained for three domains i.e., physical, emotional and total scores for QoL at baseline & 8 weeks (Table-III). At the end of the trial, baseline means score were compared with mean score at 8 weeks for each domain using paired t test. QoL was considered to be improving if the mean scores dropped at 8th week and vice versa. The mean score of the experimental arm dropped down in all the three domains, showing significant improvement in the physical, emotional domain and overall QoL.

Table-III: Quality of life scores in usual care and experimental arm.

	Usual Care			Experimental Care		
	Mean	**95% CI**	***p*-value**	**Mean**	**95% CI**	***p*-value**
MLHF Scores (Physical)						
Baseline	12.57	-4.9 to -2.0	0.01	17.03	8.53 to 11.12	0.0001
8 weeks	16.06			7.20		
Emotional						
Baseline	4.20	-2.83 to -2.07	0.06	5.28	-2.83 to -1.07	0.001
8 weeks	4.78			3.33		
Total						
Baseline	20.77	-10.26 to (-4.71)	0.01	31.44	15.62 to 20.64	0.0001
8 weeks	28.26			13.31		

DISCUSSION

This trial demonstrated the significance of Cardiac Rehabilitation in improving the Health status and Quality of life in Heart Failure patients.

Cardiac-rehabilitation programs were first developed from the 1960s,[15-17] but despite being class 1 indication remain less prioritized in healthcare settings. The impact of CR on Health status is generally assessed through measurement of NYHA classification and Ejection fraction. Significant improvements were found in both the NYHA classification/Ejection fraction in the experimental arm. This improvement has also been demonstrated in a study conducted in Iran, showing significant impact of CR on functional capacity/health status of CVD patients.[18] Similarly, a study by Sales *et al*, showed improvement in the experimental group in all components of functional capacity when compared to the control group (p<0.001).[19] Another study by Wilcox *et al* also demonstrated that among 3,994 patients who received CR, highly significant improvement in the overall mean LVEF was witnessed, demonstrating an increase in LVEF from 25.8% at baseline to 32.3% (+6.4%) at the end of the trial over a period of 24 months.[20]

Quality of life is one of the imperative determinant which is targetted by various CR Programmes. Our trial exhibited significant improvement in the physical domain & total score of QoL. An Iranian study reported significantly improved mean score of Quality of Life in HF patients after rehabilitation 256. Long term impact of a 6-weeks CR Programme was studied on HF patients through comparison of the overall QoL, phycological health & general physical activity in the control & experimental groups. Patients were reassessed for their outcome measures after 12 months upon the completion of the CR Program. Substantial improvements were observed in overall mood, pychosocial well-being, Activities of Daily Living & Functional parameters (Yohannes *et al*).[21]

A systematic review, Cardiac rehabilitation and Quality of Life conducted by Shepherd *et al*.[22,16] RCTs conducted in nine countries were reported. Four themes emerged from the papers after the thematic analysis: physical well-being; psychological well-being; social well-being; and functional status. Physical domain outcomes suggest that cardiac rehabilitation may improve physical well-being and thereby improved levels of physical fitness.

CONCLUSION

In this trial it has been concluded that CR played significant role in improving health status and general physical, emotional, overall QoL and Activities of Daily Living. CR programs need to be part of every healthcare system as these are declared as Class I indication for Cardiac patients. Hence, advocacy to reinforce the importance of outpatient CR at higher level is imperative and crucial, not only at healthcare systems but also among the family members, public and community.

ACKNOWLEDGEMENTS

We thank the physicians and nurses working in AFIC/NIHD for allowing us to study their patients. Our sincere gratitude to the cardiac rehabilitation team, pharmacy, Research & Development office for their consistent valuable support.

Conflict of Interest: None.

Author's Contribution

MU: Primary resarcher, NA: Supervision, THK: Technical supervisor, SFM: Statistical analysis, T: Clinical assessment, JK: Research writing, AAM: Intellectual.

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