

ORIGINAL ARTICLE

EFFECTS OF CARDIOVASCULAR CONDITIONING EXERCISES ON QUALITY OF LIFE IN PATIENTS WITH DILATED CARDIOMYOPATHY IN PAKISTAN

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Background: Dilated Cardiomyopathy (DCM) is the most frequently diagnosed cardiomyopathy in Pakistan and patients have significant muscles dysfunction which affects their quality of life (QOL). Available evidence have supported the role of moderate intensity exercise for improving QOL but no such studies have been conducted in Pakistan so far. **Methods:** A single blinded randomized controlled trial was conducted in two different hospitals of Rawalpindi from September 2016–February 2017. Both genders clinically stable DCM patients with ejection fraction <40% were selected through purposive non-probability sampling and randomized to Training group and Control group (n=30 each). Training group protocol included bicycling on lower limb ergometer 4days/week on alternate days for 8 weeks. Patients in control group received usual care. Patients were assessed thrice during 8-week protocol. The tools used included structured questionnaire with different standard scales like 6 Minute Walk Test, Modified Medical Research Council Scale, Modified Borg Scale and Minnesota Living with Heart Failure Questionnaire. Data was analysed on SPSS 21 software. **Results:** Prior to conditioning in training group, 6 (21%) patients reported good and 23 (79%) have poor QOL whereas in control group 14 (56%) have good and 11 (44%) have poor QOL on MLHFQ score. After 8 weeks in training group, 28 (96%) patients reported excellent QOL and in control group, 11 (44%) reported good and 14(56%) have poor QOL on MLHFQ score. Between the groups analysis depicted highly significant *p*-values for QOL and New York Heart Association (NYHA) class (*p*<0.001). **Conclusion:** Supervised cardiac conditioning program significantly improves Quality of life and NYHA functional class in dilated cardiomyopathy.

Keywords: Cardiac rehabilitation; Dilated cardiomyopathy; Exercise; Minnesota Living with Heart Failure; Quality of life; NYHA

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INTRODUCTION

Middle and low income countries contribute 85% burden of mortality due to cardiovascular diseases globally and Pakistan being ethnic group has the strongest risk factor.¹ Dilated cardiomyopathy (DCM) is one of the frequent causes of heart failure, arrhythmia and sudden cardiac death therefore it is one of the common reasons of patient's visit in emergency and cardiac care unit. Dilated cardiomyopathy is considered most common type of cardiomyopathy worldwide. The prevalence of DCM is different in different topical regions but according to the evidence available it is 1 in 2500 in adults.² DCM is the most frequently diagnosed type of cardiomyopathy after hypertrophic cardiomyopathy in both adults and paediatric group. Out of 217 cases, 144 (66%) cases of DCM were reported in Muhammadi Hospital International Medical Research Centre, Peshawar in 2013 with male to female ratio of 2:1.³ Out of 60 cardiomyopathy patients admitted in DHQ teaching hospital at Dera Ismael Khan in 2009, 54 (90%) were suffering from DCM. Ischemic cardiomyopathy is considered as commonest cause (39%) of patients with heart failure in one of the recent

study.⁴ According to the literature available, no cure for DCM has been found so far. But multiple therapies are available that reduces the severity of the disease and improve the symptoms simultaneously. Majority of DCM patients present with the symptoms of heart failure. Inotropic agents, beta-blockers, diuretics, anti-arrhythmia, anti-coagulants and afterload reducing agents are the most common medications used for treatment. Pacing therapies are also used in some DCM patients when conduction through heart rate is abnormally too slow. Contrary to this, some DCM patients developed fatal arrhythmias. Implantable cardioverter defibrillator can also be used in such patients. Treatment of choice depends on the clinical status of the patient, risk of the disease severity and the tolerance of the patient.⁵

Formal training program improves the symptoms of moderate risk patients with symptomatic hypertrophic cardiomyopathy. Supervised exercise training program did not cause any hazard to the patients. Vast majority of the patients reported improvement in their clinical condition and New York Heart Association classification by >1 in 50% of cases.⁴

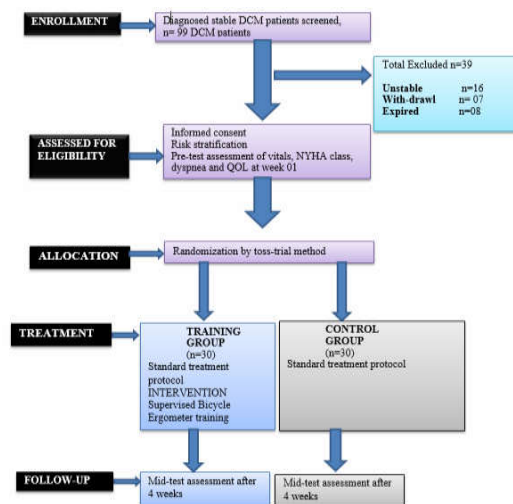
Exercise training of 8 weeks improves cardiac function in mild to moderate heart failure and along with rest and stress cardiac function. After 8 weeks of exercise training, the left ventricular end-diastolic volume was increased and left ventricular ejection fraction was improved.⁶ Evidence suggested that 3 months aerobic exercise program causes significant improvements in quality of life in patients with chronic stable heart failure.⁷ Endurance exercises causes hemodynamic stress to atria which results in atrial remodelling and will result in arrhythmias. A number of cohort and case-control studies gave evidence of increase frequency of atrial fibrillation and atrial flutter in endurance athletes. Researchers have reported a 5.3-fold more risk of atrial fibrillation due to endurance exercises in a recent meta-analysis. Ventricular arrhythmias were not so frequent with endurance exercises with only ≥ 3 ventricular premature beats in only 2.2% of athletes. Endurance exercises may increase life span but at the same time enhances the risk of arrhythmias. But the benefits of endurance exercise exceeds the risk of arrhythmias.⁸

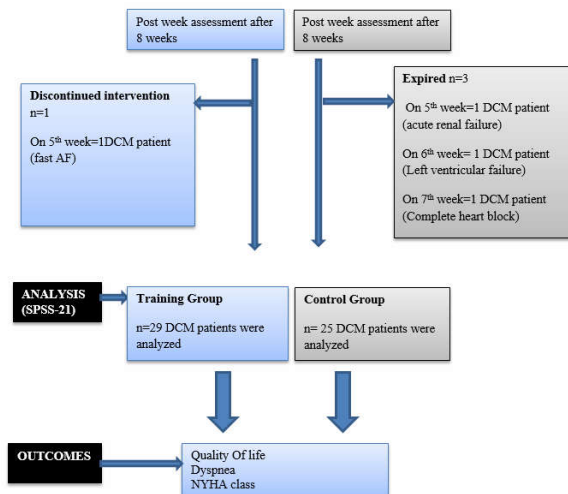
Three sessions/week for 5 months on incremental bi-cycle ergometer was performed in this study. Resistance training was added after 4 weeks of training and occurs twice per week. Patients were told to perform two home sessions per week and patients adjusted their exercise intensity as per their rate of perceived exertion. Significant improvements were recorded with respect to ejection fraction and exercise capacity in the training group and no such changes were observed in the control group. Exercise training is known to improve quality of life and exercise tolerance in patients with dilated cardiomyopathy. Twenty patients with heart failure and dilated cardiomyopathy were enrolled in study of Finland.⁹

MATERIAL AND METHODS

A randomized controlled trial was conducted in in-patient and outpatient departments of Rawalpindi Institute of Cardiology (RIC) and Pakistan Railway General Hospital (PRGH), Rawalpindi, Pakistan from June 2016 till January 2017. Purposive non-probability sampling technique was used and 99 patients were screened, out of which 60 DCM patients were meeting the inclusion criteria and were enrolled in the study. Both genders diagnosed stable DCM patients with ejection fraction $\leq 40\%$ on echocardiography were enrolled. Individuals with severe depression, chronic medical illness, neurological disease requiring medications, systemic illness limiting exercise, severe uncontrolled hypertension, angina, excess variability ($>10\%$) at baseline cardiopulmonary exercise test were excluded from the study. Patients were randomly allocated into training and control groups by toss trial method. (Training group $n=30$, control group $n=30$). Informed consent was taken from the patients and the protocol

followed was also approved by Ethical Review Board of Riphah International University, governing body of RIC and PRGH respectively. Data was collected through structured questionnaire with different standard scales like 6-minute walk test (6MWT), Modified Borg Scale, Modified Medical Research Council Scale (MMRC) and Minnesota living with Heart Failure Questionnaire (MLHFQ). Higher scores of MLHFQ represents poor quality of life (QOL) and vice versa. Standard treatment protocol was given to both groups with addition of cardiovascular conditioning exercises in training group only subjects were asked not to perform any additional exercises during the 8-week study project. Pre-assessment of vitals, dyspnoea and quality of life was done by the therapist. Risk stratification was also done to rule out need for medical supervision. The cardiac conditioning protocol involved warm up of 5–10 minutes via deep breathing and 5 repetitions of large muscles activity. In sitting, arms raised by 90 degrees and forward bending and quadriceps activity. In standing static walk was used for warm-up. Bicycle ergometer was used for cardiac conditioning. Start with short bouts of activity 5–10 minutes pedalling on ergometer. Intensity was kept according to Target Heart Rate (40–50% initially) and rate of perceived exertion (RPE) on Borg’s scale, work phase 30 seconds and recovery phase of 60 seconds. Total 10–12 phases of work for 5–10 minutes. Cool down 10–15 minutes via deep breathing and 5 repetitions of large muscles activity. The duration was progressed by 5–10 minutes/week depending on patient tolerance. The protocol was followed 4 times/week on alternate days for 8 weeks. Patients were assessed thrice during 8 weeks protocol (pre-test, mid-test and post-test). Drop outs of 6 patients among the groups (1 from Training Group and 5 from Control Group). Data was collected through questionnaires and analysed on IBM SPSS 21 software. Test of choice was non-parametric due to abnormally skewed data distribution and sample size <30 .





RESULTS

The demographics and clinical characteristics of patients were reported in table-1. Analysis of data showed that in training group, 6 (21%) DCM patients reported good QOL and 23(79%) with poor QOL on MLHFQ score. In control group, 14(56%) DCM patients were having good QOL and 11(44%) with poor QOL on MLHFQ score on week 01. After 4 weeks of training in training group, 1 (4%) DCM patient reported excellent QOL, 28 (96%) reported good QOL and none reported poor QOL on MLHFQ score. Comparatively, in control group, 15 (60%) reported good QOL, 10 (40%) reported poor QOL and none reported excellent QOL on MLHFQ score. After 8 weeks of training in training group, 28 (96%) DCM patients reported excellent QOL, only 1 (4%) reported good QOL and none reported poor QOL on MLHFQ score. Comparatively, in control group, 11 (44%) reported good QOL, 14 (56%) reported poor QOL and none reported excellent QOL on MLHFQ score. ($p < 0.001$).

Prior to training in training group, 5 DCM patients were with NYHA class II and 24 with NYHA class III whereas in control group, 2 patients were with NYHA class II and 23 with NYHA class III respectively. After 8 weeks of training, 13 DCM patients have NYHA class I, 11 were NYHA class II and only 5 have NYHA class III. Comparatively in control group, 2 DCM patients have NYHA class II, 14 were NYHA class III and 9 worsen to NYHA class IV. Comparison between the groups on NYHA class by applying Mann Whitney showed that pre-ex NYHA median (IQ) was 3 (0) in both training and control groups. Their z value was -0.999 and p-value was 0.31 which is non-significant. Post-ex median (IQ) of training group was 2 (1) and control group was 3 (1) respectively. Their z value was -5.531. p-value was 0.000 which was highly significant. (Table-2)

Table-1: Demographics and clinical characteristics of DCM patients in both Training and Control groups

	Training Group	Control Group
Age in years (Mean±SD)	53.14±14.41	61.04±13.39
Gender		
Male	17 (58.6%)	16 (64%)
Female	12 (41.4%)	9 (36%)
Risk stratification		
Moderate	2 (6.9%)	1 (4%)
High	27 (93.1%)	24 (96%)
BMI (Kg/m²)		
Underweight	2 (6.9%)	-
Normal	12 (41.4%)	10 (40%)
Overweight	13 (44.8%)	11 (44%)
Obese	2 (6.9%)	4 (16%)
Medications**		
Group 1	1 (3.4%)	5 (20%)
Group 2	6 (20.7%)	6 (24%)
Group 3	5 (17.2%)	4 (16%)
Group 4	4 (13.8%)	8 (32%)
Group 5	12 (41.4%)	1 (4%)
Group 6	1 (3.4%)	1 (4%)
6 MWT*		
Distance Covered in Week 01 (Median±IQ)	88±22.5	78±13
Distance Covered in Week 04 (Median±IQ)	103±66	72±9.5
Distance Covered in Week 08 (Median±IQ)	147±91.5	67±15
Follow-up	29	25
Deaths	-	5

*6MWT=6 Minute Walk Test. **Group 1 (Beta-blockers, anti-coagulants, diuretics), Group 2 (Group 1 + anti-hypertensives), Group 3 (Group 2+anti-anginal), Group 4 (Group 3 + hypoglycaemic), Group 5 (Group 4 + antacids), Group 6 (others)

Table-2: Comparison of cardiac conditioning exercise variables between Training and Control groups

	Training Group (Median±IQ)	Control Group (Median±IQ)	p-value
W1 MLHFQ score	82±24	67±18	0.389
W4 MLHFQ score	50±9	67±17	0.025
W8 MLHFQ score	13±13	68±23	0.005**
Pre-NYHA	3±0	3±0	0.313
Post NYHA	2±1	3±1	0.000***
W1 BORG	6±3	5±2	0.227
W4 BORG	3±3	5±2	0.021
W8 BORG	1±1.5	5±2	0.000***
W1 MMRC	3±1	2±1	0.001
W4 MMRC	2±1	2±1	0.003
W8 MMRC	1±1	3±1	0.000***

DISCUSSION

The main aim of this study was to assess the quality of life in dilated cardiomyopathy. Our study reported that 79% of DCM patients in training group and 44% in control group have poor QOL on MLHFQ score. Four weeks of training resulted in improvement in their QOL and 96% patients in training group reported good QOL. After 8 weeks of supervised cardiac conditioning program, 96% patients in training group reported excellent QOL and 4%

reported good QOL on MLHFQ score. Statistical analysis of MLHFQ indicated the marked difference between the groups. MLHFQ scores were highly significant in training group ($p=0.000$). Contrary to this, control group shows non-significant MLHFQ scores ($p=0.091$).

Evidence reported the reduction of MLHFQ scores in training group by 66% ($p=0.003$) which means that QOL was improved in training group only. QOL improved with high intensity training program even in DCM patients with ICD and those who are in worst NYHA class. Most famous intervention study on large-sample ($n=2331$ patients) is the HF-ACTION (Heart-failure-a-controlled trial investigating outcomes of exercise training). Training group of HF-ACTION reported 11% decrease risk of hospitalization, 15% reduced risk of CVS morbidity and better scores of QOL.¹⁰

Another study supported the results of current study. According to that study, these patients are severely impaired in their daily activities as compared to normal individuals. Hospital-based training program can effectively improve their physical functioning, role limitation and competence in social activities. Weilenga *et al* also reported moderate improvement in exercise capacity with the aerobic training program.⁷

Eight weeks of supervised cardiac conditioning program resulted in marked improvement in NYHA functional class and 13 DCM patients have NYHA class I after cardiac training. Conversely in control group, functional class of 9 patients deteriorated to NYHA class IV.

Significant improvement was seen during statistical analysis between the groups in which NYHA was non-significant on week 01 ($p=0.31$) and becomes highly significant on week 08 ($p=0.000$).

Complementary to the results of our study, another study did not observe the statistically significant results of NYHA class with the training program. Weak co-relations exist between patient's perception of QOL and physician's NYHA classification previously.⁷

Available study reported that only 29% females were included in the study. Out of total 54 patients, only 49% completed the study. The patients selected have mild to moderate heart dysfunction.¹¹ Another study reported a 3 months exercise program for improvement of quality of life in patients with severe and chronic heart failure. Out of total 27 patients, only 25 completed the study duration. Aerobic exercises were performed in training group and only ADLS were performed in the control group. Quality of life was assessed by MOS SF-36 (Medical Outcome Study Short Form-36)⁷ a randomized controlled trial of 100 patients were also conducted

with NYHA class III and IV patients. For QOL assessment, translated version of MLHFQ was utilized.¹⁰ Contrary to this, training group has 12 (41.4%) female and control group has 9 (36%) female DCM patients in the current study and out of 60 patients, 54 DCM patients completed the study. The patients enrolled in this study have moderate to severe heart dysfunction. 93.1% DCM patients in training group and 96% DCM patients in control group are high risk cardiac patients falling in NYHA class III. Quality of life was assessed by MLHFQ in the current study project.

Compliance of the DCM patients to the training protocol was 97% in training group and 83% in control group in our study. Another study reported the compliance of patients to training protocol in both groups was excellent (91%).¹²

The results of this study correspond well with the previous studies showing that effective cardiac conditioning program improves QOL in DCM. Moreover, NYHA functional class is also improved along with the clinical sign and symptoms of the patients.

CONCLUSION

Cardiovascular conditioning exercises are safe and advantageous for DCM even for patients with NYHA class III. This study also concluded that DCM patients have average QOL which can be significantly improved by supervised cardiac conditioning program. Training group depicted marked improvements in their MLHFQ scores and no expiry reported. Supervised cardiac conditioning exercise program also improves NYHA functional class along with clinical improvement in symptoms.

Limitations & Recommendations: Sample size was small and out of total enrolled patients in this study, only 13% were from NYHA class II. This study was conducted in only two rehabilitation centres in Rawalpindi. Therefore, the results of this study cannot be generalized to whole DCM population in Rawalpindi and specifically DCM with class II. MLHFQ used in this study covers just two dimensions (physical & emotional) of QOL. More comprehensive approach is required for future studies.

Results of this study recommend the addition of supervised cardiac rehabilitation program along with the pharmaceutical therapy for DCM patients for the provision of cost-effective treatment. Similar study should be conducted on NYHA class II and III DCM patients with large sample size. Future researches with combination of aerobic program with high-intensity interval program should be conducted to gain beneficial hemodynamic effects and clinical

improvements in DCM especially QOL to carry out daily activities comfortably. Future researches should be conducted on effects of different components of rehabilitation on QOL in dilated cardiomyopathy. Moreover, researchers should explore the combinations of other exercise regime for DCM as it is very common cardiomyopathy in Pakistan.

AUTHORS' CONTRIBUTION

SB: Study design, questionnaire design, data collection, drafting, analysis and interpretation. FAS: Study concept, drafting, analysis and interpretation. Also assisted in recruitment of patients and designing questionnaire. MIT: Data collection, patients counselling and motivation, data entry, analysis. Helped in patient enrolment. MWB: Data collection, analysis, data interpretation.

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