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INFLUENCE OF GRADED AEROBIC EXERCISE ON QUALITY OF LIFE IN POST SURGICAL MITRAL VALVE DISEASE INDIVIDUAL –A PROSPECTIVE RANDOMIZED OPEN LABEL STUDY

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ABSTRACT

Background: Post surgical mitral valve disease individual focus their cardiac rehabilitation training on two major goal that is to improve cardiac output response exercises and place an important role in determining exercise tolerance and to improve quality of life. Cardiac rehabilitation programs involve prescribed exercise and education however various other method are being used to improve quality of life. But our study to find out the effectiveness of graded aerobic exercise protocol on ejection fraction and quality of life in post surgical mitral valve disease individuals.

Methods: The study design was open label studies total of 100 post surgical mitral valve disease individuals patients from the age group of 20-60 years were recruited from SVIMS hospital. They were randomly divided into two groups. Group I underwent a twelve week structured graded individually tailored exercises. The group II received only none graded (not individualized) exercise training. The ejection fraction and quality of life was measured before and after 12 weeks of exercise training for two groups.

Results: Repeated measures ANOVA was used to compare mean values of continuous variables between baseline and at the time of discharge and three months after surgery for each parameter. Comparison of means between groups was done by the unpaired student t test. Mean age of the subjects was 40.18±10.29. There was a significant increase in the ejection fraction in the group I(61.34±2.49 to 64.4±3.31) compared to with the group II (61.06±2.51. to 61.62 ±2.37.) QOL had improved in group I than group II at $p<0.05$.

Conclusion: A 12 week structured graded aerobic exercise training significantly improved ejection fraction and quality of life in post surgical mitral valve disease individuals.

Keywords: Rheumatic heart disease, ejection fraction, mitralstenosis, cardiac rehabilitation, graded exercise, and quality of life.

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INTRODUCTION

Rheumatic Heart Disease (RHD) is a permanent sequela of Rheumatic Fever [1,2] (RF) Globally, there are >15 million cases of rheumatic heart disease, with 233,000 deaths each year and 282,000 new cases per year [3]. The overall prevalence of RHD in our country is estimated to be about 1.5-2/1000 in all age groups (total population about 1.27 billion) which suggests that there are about 2-2.5 million patients of RHD in our country [4].

Rheumatic mitral valve disease (mitral stenosis or regurgitation) remains the common heart disease in developing countries. Mitral valve is involved in 99% of cases [5].

Rheumatic fever (RF) and Rheumatic heart disease (RHD) are the major causes of cardio vascular diseases in the world. Despite a documented decrease in the incidence of acute RF and a similar documented decrease in the prevalence of RHD in industrialised countries during the past five decades these non suppurative cardiovascular sequel of group A streptococcal pharyngitis is the medical and public health problem in both industrialized and industrializing countries from the beginning of the 21st century. The most devastating effects are on children and young adults in their most productive years.

Rheumatic fever (RF) and Rheumatic heart disease (RHD) are non suppurative complications of streptococcal pharyngitis because of delayed immune response. Though RF and RHD are rare in developed countries, they are still major public health problem among children and young adults in developing countries. The economic effects of the disability and premature death caused by these diseases are felt at both the individual and national levels through higher direct and indirect health care costs [6].

Rheumatic heart disease has been a major public health problem in India [7,8]. All the valves of the heart get affected in rheumatic heart disease. Mitral valve is the most common valve which gets affected in RHD [9]. It has been shown that isolated mitral stenosis is present in 25% of cases of rheumatic mitral stenosis whereas 40% cases present with mixed lesion consisting of mitral stenosis and mitral regurgitation. Rheumatic heart disease usually has multi valvular involvement with 38% affecting mitral valve causing stenosis and 35 % affecting aortic valve, 6% affecting tricuspid valve [10]. The involvement of pulmonic valve is very rare. It is estimated that 15.6-19.6 million people suffer from RHD worldwide with approximately 282,000 new cases [11]. The incidence in the United States is 1:100000 per year. In United States the prevalence rate in 2011 was less than 5 per 100000 persons. On the contrary, in the developing countries the prevalence is still high, of more than 10 cases per 1000 in India and 4-10 cases per 1000 in China, Russia, Africa, and Australia [12]. Ethiopia has highest estimated prevalence of RHD in the world [13].

India contributes to nearly 25% to 50% of the global burden of RHD [14]. In 2003,45% of cardiac admission in tertiary care teaching hospital in Orissa were due to RHD [15]. Agarwal et al. in his population survey which was done in 2000 in North India reported a high prevalence of RHD i.e., 6.4/1000 [16]. The prevalence of RHD was 0.5/1000 in children belonging to age group of 5-15 years [17] Reports from Indian Council of Medical Research (ICMR) New Delhi, India between 2002 to 2005 have shown a decline in the prevalence of RHD (0.43-1.47/1000) [18]. A recent Indian Council of Medical Research (ICMR) study between (2000 and 2010) in 10 different mostly urban, found the prevalence to range from 0.2 to 1.1/1000 for RHD. Bed rest after surgery significantly decreases the cardiovascular tolerance for exercise in normal subjects and contributes to physical disability.

Mitral stenosis has been associated with decrease in the exercise intolerance which results in impaired activities daily of living and functional activities which ultimately leads to impaired Quality of life.(QOL). Many studies were done on post MI, post CABG, congenital heart disease and heart failure. very few studies done on influence on physical training on post surgical mitral valve disease individual. The studies done by goldsmith revealed that there is changes in quality of life in post operative mitral valve repair and replacement individuals. A few studies were done on graded protocol for post operative MVR. Hence there was a need of study to find out the influence of graded aerobic exercise on ejection fraction and quality of life in post surgical mitral valve disease individual.

The aim of study is to find out the influence of Graded aerobic exercise protocol on post Surgical Mitral valve disease individuals and objectives of the study is to find out the effectiveness of Graded aerobic exercise protocol on post Surgical mitral valve disease individuals who have undergone surgical correction on physiological variation measured by Ejection fraction(EF) and also to study the effectiveness of Graded aerobic exercise protocol on post Surgical mitral valve disease individuals who have undergone surgical correction on functional variation as measured by quality of life (QOL).

PATIENTS AND METHOD

Study design

The study procedure was designed in accordance with Helsinki declaration this was open label study randomised control trail in which they effectiveness of graded aerobic exercise individually tailored exercise training on ejection fraction, QOL was studied eligible patients who gave a written inform consent were allocated into group I and group II by means of lottery method.

STUDY SUBJECTS

Mitral valve disease patients those who were clinically diagnosed and admitted in cardiothoracic ward at a tertiary care centre, Sri Venkateswara Institute of Medical Sciences University, Tirupathi, Andhra Pradesh, and the patient underwent mitral valve surgery were taken up for the study based on inclusion and exclusion criteria given below.

INCLUSION CRITERIA

Study subjects included patients under went mitral valve

replacement fulfilling the following criteria : Mitral stenosis with LVEF >45% before surgery, mitral stenosis with moderate to trivial mitral regurgitation, mitral stenosis with atrial fibrillation, mitral stenosis with or without trivial to moderate MR with mild aortic valve disease, calcific mitral valve, mitral restenosis, post PTMC, post CMV or post OMV, mitral stenosis with tricuspid regurgitation, Age range : 20 – 60 age group and Both sex.

EXCLUSION CRITERIA

Isolated severe mitral regurgitation, mitral stenosis with severe mitral regurgitation, Ischemic mitral regurgitation, mitral valve replacement with coronary artery bypass grafting, double valve replacement, congenital mitral valve disease, Patients more than 60 years less than 20 years, chronic obstructive pulmonary diseases, atrial septal defect with mitral stenosis, mitral valve disease with severe aortic regurgitation, mitral stenosis with cardiomyopathy, mitral stenosis with left ventricular dysfunction.

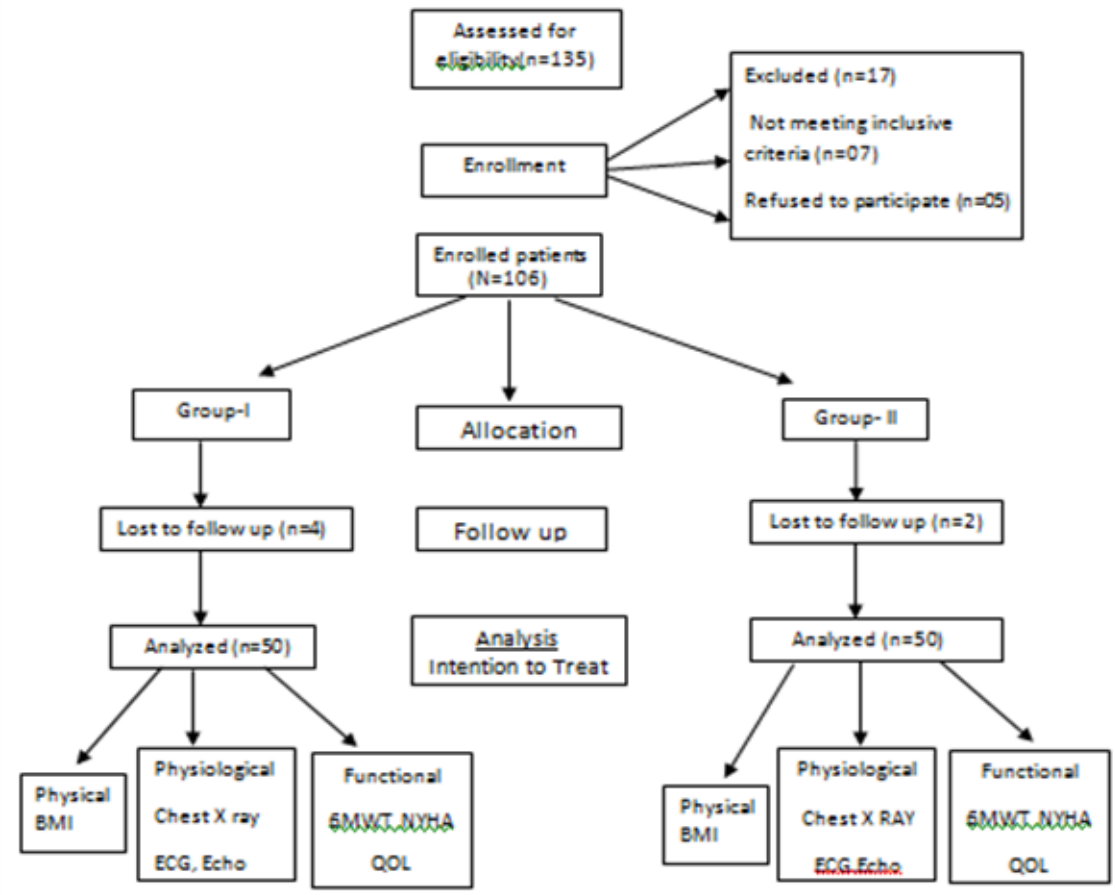
METHODOLOGY

Graded aerobic exercise protocol for group I:

During their hospital stay, subjects in the group I received a physical therapist supervised phase I stabilization protocol (Table I). After discharge they received a structured aerobic exercise training (Phase II) lasting for 12 weeks (TableII)

During phase I, the patients were exercised in hospital under supervision and monitoring. The various steps mentioned in table I served as a guide for the patients to follow. The exercise prescription was individualized for each patient's tolerance. If patients was able to perform a particular step without any discomfort a faster progression through the steps was made. On the contrary, if a patients was unable to perform a particular step, the progression was not made until the patient was comfortable at that level.

Chart 1: Study flow chart



STUDY PERIOD: Exercise protocol was administered for 12 weeks post surgically. The sampling and data record was done from 2010 to 2014.

RANDOMIZATION PROCEDURE**:** Patients were randomly allocated to either a group I or group II through concealed allocation using lottery method.

Ethical Aspects: The study was cleared by the Institutional Ethical Committee and written Informed consent was obtained from each participant.

The patient's relatives were also encouraged to be a part of the rehabilitation program and were educated on the importance of exercise. The patients and the relatives were taught to identify signs and symptoms of complication of exercise so that it could be terminated.

After discharge from the hospital, Group I patients were expected to attend supervised exercise sessions two times per week for three months in physiotherapy outpatient department. Exercises included 10 to 15 minutes of warm up followed by upper limb mobility and lower limb mobili-

ty exercises. The total exercise time was approximately 40 minutes. This was followed by a cool down period of 10 -15 minutes. Exercise intensity was initially prescribed at 50-70% functional capacity. The exercises were as given below.

Phase I (0-8 days) cardiac rehabilitation physiotherapy protocol-stabilization phase.

Table 1: Wenger's protocol [19]

Step I	1-2 days	Stabilization phase	Incentive spirometry in the form deep breathing exercises, active assistive to active range of motion. Postural awareness and care with monitoring.
Step II	3-5 days		In Sitting-Repeat exercises from step1 and increase repetitions to5-10 Mobilization of Upper limb, monitored Ambulation of 100 feet as tolerated.
Step III	6- 8 days		In standing-step1+2 Active upper limb, Trunk exercises, ankle exercise 5-10 repetions twice daily Out of intensive care unit, pre discharge plan, monitored ambulation 200 feet twice daily or as tolerated.

- Cardiac rehabilitation physiotherapy protocol,
- Phase II (Training phase)

Table 2: Graded aerobic exercise programme (Exercise protocol)

	Warm up Walk slowly	Target zone Walk briskly	Cool- down Walk slowly
Week 1	5 minutes	5 minutes	5 minutes
Week 2	5 minutes	7 minutes	5 minutes
Week 3	5 minutes	9 minutes	5 minutes
Week 4	5 minutes	11 minutes	5 minutes
Week 5	5 minutes	13 minutes	5 minutes
Week 6	5 minutes	15 minutes	5 minutes
Week 7	5 minutes	18 minutes	5 minutes
Week 8	5 minutes	20 minutes	5 minutes
Week 9	5 minutes	23 minutes	5 minutes
Week 10	5 minutes	26 minutes	5 minutes
Week 11	5 minutes	28 minutes	5 minutes
Week 12	5 minutes	30 minutes	5 minutes

Along with the above protocol, breathing exercise should be carried out for 2 to 5 minutes. Body exercises for 5 to 10 minutes and slow walking for 5 minutes. Complete the protocol with breathing exercise and relaxation positions.

Group II-Non graded Exercises

The patients allocated to this group were provided post operative care and treated as per the standard protocol of the hospital till the time of their discharge. They were advised to carry on the home program of aerobic exercises (non graded) as advised at the time of discharge and to continue the medication, day to day activities and visit the doctor when required for symptom management. The exercises were not monitored, nor individualized according to exercise tolerance. Exercises prescribed for group II included breathing exercises, upper limb and lower limb exercises, and walking within the limit of tolerance during the in-patient phase with further advice to carry out the above exercises progressively along with ADL & other functional activities for 12 weeks from the date of surgery. Patients were asked to record day in and day out activities and limitations faced by them in a log book. The researcher reviewed the logbook after 12 weeks period when patient visited the Cardio thoracic outpatient for follow up.

RESULTS

The Continuous variables like Ejection Fraction and SF-36 -(QOL) questionnaire score were expressed as the mean±SD. Repeated measures ANOVA was used to compare mean values of continuous variables between baseline and at the time of discharge and 3months after surgery for each parameter. Comparison of means between groups was done by the unpaired student's t test. Data was analysed taking p value <0.05 as significant.

Table 3: Demographic characteristics (age and gender) of subjects in the group II and group I

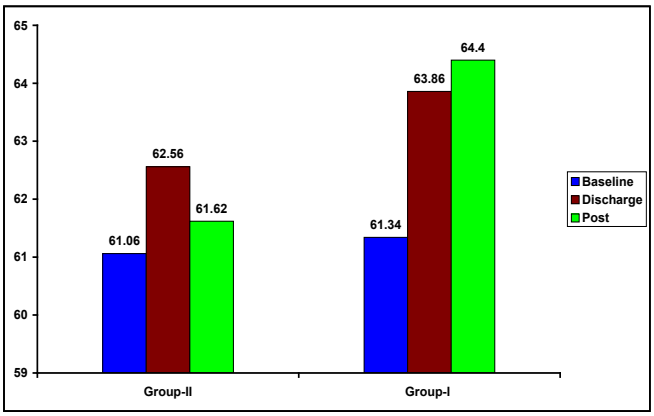
Group	N	Age	Gender	
			Male	Female
Group-II	50	40.18± 10.29	24 (48.00%)	26 (52.00%)
Group-I	50	39.86 ± 9.22	20 (40.00%)	30 (60.00%)

Interpretation of results Table reveals that gender wise percentage distribution of subject in each group in group 1 males are of 40% and females are of 60% out of 50 samples. Whereas in group II males are of 48% and females are of 52% out of 50 samples

Table 4: Mean of EF in the Group II and Group I

PARA METER		GROUP I MEAN±SD	GROUP II MEAN±SD	P VALUE GROUP I & II
EF	BASE LINE	61.34± 2.49	61.06±2.51	0.577
	AT DISCHARGE	63.86± 2.81	62.56±2.14	0.015
	POST	64.4± 3.31	61.62±2.37	0.000

Two groups were equally matched at baseline but 12 weeks of exercise programme the ejection fraction in group I improved from 3% from base line where as group I remains more are less same together at the end of study period.



Graph 1: Comparison of mean values of EF between in Group II and Group- I

Comparison between the two groups for each component of the SF-36 score at each point of time (baseline, discharge, post) has been given below in table.

The two groups of Physical component summary (PCS) were matched at base line.

However, by the time of discharge and also at 12 weeks after surgery patients in group I (graded exercise) fared better than patients in group II (non graded exercise) at ($p<0.001$)

Table 5: SF-36 score

Components of SF-36 questionnaire	Time of assessment	Group I score	Group II score	P value
1. Physical functioning (3,4,5,6,7,8, 9,10,11, 12) 10 items	Base line	14.0±9.53	15.2±7.95	0.496
	Discharge	32.70±7.64	16.90±5.88	0.000
	Post	45.10±7.11	18.30±3.44	0.000
2. Role limitations due to physical health (13,14,15,16) 4 items	Baseline	15.0±12.37	16.0±12.12	0.684
	Discharge	34.50±12.26	23.50±13.75	0.000
	Post	55.50±11.62	28.00±12.00	0.000
3. Role limitations due to emotional health (17,18,19) 3items	Baseline	16.65±16.82	15.98±16.81	0.843
	Discharge	39.98±13.50	21.98±15.94	0.000
	Post	62.01±20.23	27.32±19.85	0.000
4. Energy/fatigue (23,27,29,31) 4 items	Baseline	25.40±4.15	24.00±4.29	0.1
	Discharge	41.90±7.06	24.50±4.20	0.000
	Post	66.20±11.41	26.80±2.99	0.000
5. Emotional well being (24,25,26,28,30) 5 items	Baseline	9.68±7.41	9.60±6.10	0.148
	Discharge	30.48±9.52	12.72±6.89	0.000
	Post	56.72±13.94	16.80±5.04	0.000
6. Social functioning (20,32) 2 items	Baseline	16.00±12.12	18.00±11.34	0.396
	Discharge	31.50±11.08	21.00±12.74	0.000
	Post	57.50±11.34	24.00±14.25	0.000
7. Pain (21,22) 2 items	Baseline	12.30±8.33	11.02±6.11	0.453
	Discharge	37.14±11.50	14.25±7.41	0.000
	Post	54.30±9.57	17.35±7.70	0.000
8. General health (1,33,34,35,36) 5 items	Baseline	27.50±3.07	28.30±4.36	0.291
	Discharge	44.30±5.15	29.70±5.09	0.000
	Post	63.70±7.48	32.50±5.37	0.000

The two groups of mental component summary (MCS) were not significant at base line. However, by the time of discharge and also at 12 weeks after surgery patients in (graded exercise) there was significant difference found in both groups (non graded exercise) at ($p<0.001$)

For physical functioning, social functioning, limitation of physical functioning, emotional functioning, pain, energy and general health , the two groups were matched at baseline. However by the time of discharge and also at 12 weeks after surgery patients in group I (graded exercise) fared better than patients in group II (non graded exercise) ($p<0.001$)

DISCUSSION

BASELINE, DISCHARGE AND POST INTERVENTION VALUES OF EF BETWEEN GROUP II AND GROUP I

We found that 12 weeks of aerobic training significantly improved ejection fraction and quality of life. Our findings are in consistent with a recently published zakai SB et al (2010) found that there was significant improvement in ejection fraction in the mitral valve replacement at $p\leq 0.01$ which support our study [20]. Aerobically, there is linear relationship between heart rate and oxygen consumption. The cardiac muscle responds to exercise by increasing rate and force of contraction, which in turn increase stroke volume. The normal ejection fraction is 60-75%, which further increases with exercise. The heart rate and stroke volume increases when an individual is exercising at 40-50% the maximum capacity [21].

Mitral valve replacement individual were benefited from cardiac rehabilitation program due to increase in oxygen uptake, increase in aerobic capacity of the peripheral muscles, which is accompanied by increased cardiac output. Very few studies of cardiac rehabilitation had used ejection fraction to measure the cardiac output. The cardiac rehabilitation programs in various types of cardiovascular disease have shown positive influence on the EF. The increase of EF is associated with increase in exercise capacity. The structured aerobic exercise increases ejection fraction, this in turn increases exercise capacity in post surgical mitral valve disease individual.

BASELINE, DISCHARGE AND POST INTERVENTION VALUES OF QOL BETWEEN GROUP II AND GROUP I

We found that global improvement in the components of QOL are physical health, mental health and social well being. Group I graded aerobic exercise which has improved QOL have been observed because of exercise training adaptation. With exercise, there is decrease in catecholamine secretion and increase in β endorphins which induces relaxation indicates physical and mental health well being. However, our findings showed are similar to reports by Babu et al[22]. They studied QOL pre operative and post operatively and found changes in the SF-36 scores. Statistically significant difference with rehabilitation was observed in physical component and mental component and also changes in general, health, vitality, social functioning, role emotional, and mental health. Our findings are also in consistence with overall of other reports. Ueshima et al. also found similar improvement in QOL and exercise tolerance in post open heart surgery individuals [23].

Karapolat et al. reported a better quality of life outcome in supervised exercise training compared to home-based training program in heart transplant subjects [24]. Vojtech et al. concluded that there was significant improvement in all eight health domains of the SF-36 Questionnaire at $p\leq 0.01$ which supports statistical data of our study [25]. From this study, it is clear that an early rehabilitation program begun once the patient is medically stable is of great importance in improving components on the SF-36. These benefits can be sustained if accompanied by a graded aerobic exercise. Significant improvements in QOL were seen during this period in both the groups. However, the changes were more in the Group I than the Group II.

CONCLUSION

We conclude that rejecting null hypothesis and accepting alternate hypothesis in post surgical mitral valve disease individuals. Therefore, we strongly concluded that the graded aerobic exercise has been effective as compared to non graded exercise in the following parameters.

QOL-SF-36 physical and mental component and Physiological parameters like EF.

LIMITATION

1. High risk subjective was not included.
2. Long term, follow up after 12 weeks was not planned.

SCOPE OF FEATURE RESEARCH

1. There is need to study in different phases of cardiac rehabilitation.
2. Cardiac rehabilitation needs to be tested on high risk subjects.

RECOMMENDATION

On the basis of this study following recommendations can be made.

1. Physical therapy should be routinely prescribed to postoperative mitral valve patients both to increase their exercise capacity and their quality of life.
2. Physical therapy should be delivered in a graded format by individualizing the exercise prescription based on the level of exercise tolerance and also by supervising the exercise training in order to ensure better QOL.

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