Influence of Physiotherapy Follow-up Programs on Quality of Life and Heart Rate Variability among Patients after MI and Angioplasty in Pakistan

Ahmed,1 Ahmed J. Buksh,2 Ahmed S.3

Abstract

Background: Heart rate variability (HRV) and decreased Quality of Life (QOL) are among the major risk factors for deaths due to cardiac complication in Pakistan after angioplasty. In the past, various studies have been conducted on animals to investigate the influence of exercise programs. Plenty of evidences have been available which suggest the importance of such physical training programs to increase HRV and reduced mortality after catherizations in human populations as well. In our recent studies, we have appraised the change in exercise capacity, quality of life and HRV in cardiac rehabilitation patients by randomising them between either conventional or intensive physiotherapy follow up programs in Pakistan. In our current prospective study design, stratified randomization was adopted and pre-specific subgroup analysis was also performed.

Methods: We used exercise tolerance test and Adopted Quality of Life Questionnaire at baseline, 4 and 12 months after myocardial infarction (MI) or Angioplasty. Sixty two patients including 43 with MI and 19 with Angioplasty were randomised with double blind randomization. Study subjects were randomly allocated to either twice weekly (N) or six times weekly (I) physiotherapy follow up programs at a physiotherapy outpatient department.

Results: Exercise capacity, Global HRV measurements and quality of life were improved significantly in group (I) after 3 months physiotherapy follow up and these results were consistently better than group (N) even after one year. A momentous HRV response was seen in angioplasty patients as compared to MI patients when a subgroup analysis was performed at 3 months after intensive physiotherapy follow up.

Conclusion: Intensive physiotherapy follow up programs in cardiac rehabilitation increases exercise capacity, quality of life and global HRV measurements thus reducing the number of deaths due to cardiac complications. These results could have important prognostic significance among cardiac patients in Pakistan.

Author Keywords: Cardiac rehabilitation; Myocardial Infarction; Angioplasty; Heart rate variability, Physiotherapy follow up, Exercise training.
**Introduction**

Sudden cardiac deaths after myocardial infarction (MI) are generally associated with various imperative risk factors and reduced heart rate variability (HRV) is considered among one of the major factors. Alterations in cardiac autonomous balance and vagal withdrawal reflects the crucial changes in HRV. However, Low fervency variability due to unknown origin in HRV is believed to have strongest correlations with mortalities due to cardiac complications after angioplasty. Using β-blockade and ACE-inhibitors are among the few available risk reducing strategies after MI however later is believed to be the best choice for patients with reduced ejection fraction. ACE-inhibitors have also been shown to increase both total variability and vagal indices. Another significant risk – reducing approach is physiotherapy follow up programs emphasizing exercise training which has been evidenced to reduce mortality rate. Significant shielding effects of physical training and exercises have been studied by various researchers in animals. Conflicting results have been published in various clinical trials which could be due to the variations in the duration and intensity of physiotherapy follow up programs. Therefore, we decided to study the changes in quality of life, mortality rate and HRV in patients attending various physiotherapy follow up programs after MI and angioplasty. For the sake of evaluation, we have randomised the patients in two different physiotherapy follow up programs after they have experienced MI and have been treated with both pharmacological and Interventional strategies including angioplasty.

**Methods**

Study participants were selected from the patient register at both outpatient department at Faisalabad Institute of Cardiology (FIC) and Faisal Hospital Faisalabad between 2010 and 2011. These patients were then randomly referred for the proposed study into two different physiotherapy follow up programs at Executive Physiotherapy clinic, Faisal Hospital Faisalabad. Patients with age between 50 and 60 years who had episodes of MI or had undergone angioplasty in last 12 months were included in this double blinded study. An exclusion criterion was designed and those patients were excluded from the study that had episodes of unstable angina, congenital cardiac anomalies or non-cardiac diseases which could influence HRV like hyper or hypothyreosis. All patients were then screened by qualified physiotherapist to rule out any functional disabilities or potential hazards during intensive exercise program.

Informed consents were gained from all the patients, but both the patients and clinicians involved in the study were kept unaware of the fact that which patient is being considered for data evaluation, or who is being referred for intensive physiotherapy follow-up.

**Medication**

Apart from drugs which have possible interaction with metabolism, all drugs were allowed. During the initial 3 months physiotherapy follow up, patients were given constant dosage of β-blocker. Patients were advised to take medications in the morning on the day when they were asked to attend the exercise program. These instructions were designed to minimise the risks of withdrawal effects on HRV measurements.

**Randomisation Procedure**

The study evaluated the outcome measurements of patients after they were randomly referred to one of the two physiotherapy follow up programs i.e., normal intensity (N) or high intensity (I) training. During normal intensity training, patients were given the usual set of advises and conventional exercises which are usually considered after angioplasty in various cardiac centres across Pakistan. The patients were stratified for MI versus angioplasty while sub-group analyses of these patient groups were pre-specified in the study protocol.

**Physiotherapy Follow-up**

MI patients were asked to attend an exercise tolerance test before discharge while angioplasty patients did not. Subsequently, routine therapy sessions were conducted for an initial period of one month under the supervision of qualified physiotherapists with the frequency of 1 hour twice weekly. After study phase – 1 (initial one month), patients were randomly selected to be allocated among either normal training program (N) or intensive training (I) program for the next three months. Patients in group (N) continued therapy sessions for 1 hour twice weekly with rehabilitation assistants, while patients in group (I) were asked to attend exercise sessions for 1 hour three times a week. Addi-
tionally, intensive training (I) group patients were advised to practice additional exercise session three times weekly at home including brisk walking and light jogging. The home exercise program was designed to last for 30 minutes with 3 periods of 5 minutes each when they were required to practice light jogging to perform 75% of maximal workload. A qualified physiotherapist was involved throughout to individualise and increase the maximal workload every month based on the patient’s performance in these additional exercise sessions. If intensive training (I) patients were sometimes not attending the exercise sessions with routine training (N) patients under supervision, they were encouraged to increase the frequency of home exercise sessions to maintain the level of six training sessions a week.

**Exercise Tolerance Test**

Study participants in both groups were assessed with exercise tolerance tests at baseline, after one month but before randomisation, after 3 months and also after 1 year. The exercise tolerance test started at level 2 for women and level 3 for men, while maximal workload was increased gradually after every 5 minutes until patients reported being exhausted. These tests were conducted under strict supervision of cardiologist before the start of their scheduled exercise sessions of that day. Maximal achieved workload, heard rate and blood pressure readings were recorded during each test. Furthermore, comparison was made between the recorded readings of above mentioned parameters between the patients of group (N) and group (I) at baseline, after 1 month, 3 months and after 1 year.

**Adapted Quality of Life (QOL) Questionnaire**

The original Quality of Life Questionnaire (QOL) designed by David Evans and World Health Organisation Quality of Life (WHOQOL) were both studied and critically evaluated by the qualified physiotherapist for the proposed study. In order to customise these outcome measures for people living in Pakistan, an Adapted Quality of Life Questionnaire (AQOL) was designed jointly by Neuro-Musculoskeletal and Cardiac Rehabilitation Physiotherapists. This AQOL questionnaire was designed to evaluate the affiliation between the patient’s quality of life and other behaviours including physical and psychological health, family and social support and medical history. This AQOL questionnaire consisted of same five major domains and a social desirability scale which the original QOL questionnaire has, while 15 content scales were removed to customise it for people living in Pakistan. The five major domains were: general wellbeing, Interpersonal relationships, Organisational activity, Occupational activity, leisure and recreational activity.

A qualified physiotherapist explained to all the patients how to complete the designed questionnaire in a discussion session during the baseline assessment period. Later on, patients were advised to complete the questionnaire within 30 minutes at baseline, after one month, at four months, and after 12 months of the exercise programs. These questionnaires were evaluated by an external physiotherapist who was not directly involved in the data collection process to ensure the double blind nature of the study. The external physiotherapist was not given information about the individual patient, interventional group or their past medical history.

**Evaluation**

Analysis and evaluations were performed in three pre-specific end points; primary endpoint after one month at the time of randomisation, secondary endpoint after 3 months of randomisation and after 12 months of randomisation.

**Statistics**

Data analyses were calculated in Microsoft Office Excel 2007 and SPSS for Windows version 5 ‘Vista’ edition. Normally distributed data were analysed by Students t-test for independent comparison, presented as mean (S.E.). Data not normally distributed were analysed by Mann – Whitney U test. Categorical data were analysed by the Chi-square test with Yates correction. Spearman rank test was used for the calculation of the correlations. A P-value of less than 0.05 was considered as significant.

**Results**

Seventy – six patients were initially included in the study of which 11 did not completed initial 3 months training period due to family and work commitments, eight patients from the (I) group and three from the (N) group. 3 patients were advised to drop out the study due to medical complications not related to the parameters of current study. These 3 were diagnosed
with Dengue Virus thus were admitted to Allied Hospital Faisalabad for treatment.

Of the remaining 62 patients whose exercise period was evaluable, 33 were in the low intensity group and 29 in the high intensity group. Non-spectral HRV was evaluable in 50 patients, spectral HRV in 43. Clinical baseline data are presented in Table 1. There were no significant differences between the groups, although there was a trend towards more anterior infarctions in group (I) and more inferior infarctions in group (N). The β-blockade dosage was unchanged during the training period but reduced in 35% of the patients between the 3 months and the 1–year visit.

There were no difference between the two training groups, and no cardiac events occurred during the 3 months of exercise training, one acute myocardial infarction occurred during the 1 year follow up and this patient, from the (I) group, was excluded from the 1 year analysis. Interestingly, this patient differed markedly from all other patients in the (I) group as all his HRV indices were considerably reduced during the 3 months of training.

There were no significant differences between the (N) and (I) training groups at baseline but notably there was a significantly difference in the Quality of Life of patients with angioplasty after 3 months of

Table 1: Clinical baseline data.

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Low Intensity Group (N)</th>
<th>High Intensity Group (I)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>33</td>
<td>29</td>
</tr>
<tr>
<td>Inclusion Criteria MI / CABG no of patients</td>
<td>24 / 9</td>
<td>19 / 10</td>
</tr>
<tr>
<td>Age (years, mean, S.D.)</td>
<td>56.5 (7.7)</td>
<td>57.5 (8.4)</td>
</tr>
<tr>
<td>Male / Female (%)</td>
<td>82 / 18</td>
<td>76 / 24</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>59.2 (13.7)</td>
<td>58.6 (12.1)</td>
</tr>
<tr>
<td>Previous history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary artery bypass grafting (%)</td>
<td>36</td>
<td>41</td>
</tr>
<tr>
<td>Coronary angioplasty (%)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Myocardial infarction (%) 0 / 1 / more than 1</td>
<td>15 / 73 / 12</td>
<td>21 / 72 / 7</td>
</tr>
<tr>
<td>Location of MI (%), ant / inf / Int / unknown</td>
<td>29 / 37 / 17 / 17</td>
<td>58 / 16 / 16 / 10</td>
</tr>
<tr>
<td>Arterial hypertension (treated) (%)</td>
<td>27</td>
<td>38</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Smokers / ex</td>
<td>18 / 42 / 40</td>
<td>14 / 41 / 45</td>
</tr>
<tr>
<td>Smokers / non-smokers (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacological treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>β-blockers (%)</td>
<td>85</td>
<td>93</td>
</tr>
<tr>
<td>Calcium antagonists (%)</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>Long acting nitrates (%)</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Diuretics (%)</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>Angiotensine converting</td>
<td>27</td>
<td>21</td>
</tr>
<tr>
<td>Enzyme inhibitors (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombolysis (%)</td>
<td>54</td>
<td>58</td>
</tr>
<tr>
<td>Change of β-blockade treatment from 3 months to 1 year: decreases / unchanged / increased (%)</td>
<td>36 / 64 / 0</td>
<td>35 / 58 / 7</td>
</tr>
</tbody>
</table>
INFLUENCE OF PHYSIOTHERAPY FOLLOW-UP PROGRAMS ON QUALITY OF LIFE AND HEART RATE VARIABILITY

exercise training. The maximal workload capacity increased significantly during the training period of 3 months and the exercise capacity persisted 1 year later. The exercise tolerance capacity and quality of life appeared to be increased significantly after 3 months of training in the (I) group.

This was evident in both the post MI and angioplasty patients although there was a trend towards higher improvement in the angioplasty group. There was also a significant increase of maximum heart rate at exercise after 3 months in group (I) compared to group (N), but the maximal workload at comparable heart rate still differed significantly. One year later the exercise capacity remained at the same level in the (I) group and there was only an insignificant trend towards increased maximal workload in the (N) group. Hence the difference between the two groups remained significant throughout the study period and even after 12 months.

Significant improvements was seen in the scores for general wellbeing, organisational and occupational activities in patients of intensive training (I) group after 3 months and these results were consistent even after 12 months on training. Scores for leisure and recreational activities were similar for both (N) and (I) groups at 3 months after randomisation while significant improvement was also seen in (I) group after 12 months of training. Interpersonal relationship scores could not be compared for analysis for 30 patients out of 62, due to being left over. 13 patients from intensive training (I) group and 17 from normal training (N) choose not to complete this section of AQOL questionnaire. When these individuals were asked the reasons for this left over, no significantly important reasons were presented by them. 32 patients from both groups who completed interpersonal relationship section of AQOL provided significant evidence that intensive training had negative effect on the interpersonal relationship of patients evaluated by AQOL questionnaire. This might be linked with the personal choices and individual life styles of different families of people living in Pakistan.

Subgroup analysis revealed an increase in maximal workload capacity in the (N) group in angioplasty patients whereas there was a remaining reduced exercise capacity in the post MI patients after 1 year.

After 3 months analysis of the subgroups, the post angioplasty patients had a significantly better augmentation in the (I) group than the (N) group. The same trend was evident in the post MI patients but this change did not reach statistical significance. When comparing HRV differences between baseline and 3 months in patients with \( n = 42 \) and without \( n = 7 \) β-blockade, there was an insignificant trend towards increased vagal tone in the patients without β-blockade.

During a mean follow-up period of 2 years, there were four patients from both groups who had an acute MI or angioplasty performed. One patients from the (I) group died with Dengue Virus and one in the road traffic accident, both non-cardiac deaths.

Discussion

Results of this study not only signifies the value of physiotherapy follow up programs after MI and angioplasty, but also proves that intensive exercise sessions could be arranged as community physiotherapy visit after cardiovascular diseases without inducing complications.

High intensity physiotherapy follow up produced marked improvements in exercise tolerance and Quality of life of patients post MI and post angioplasty. Interestingly the difference in workload capacity remained 1 year after cessation of the formal training program. The primary endpoint changes in HRV revealed several interesting findings, some of them less expected. The increase of HRV over time is consistent with earlier findings, although subgroup analysis indicated a difference between the MI and angioplasty patients. In addition there was a significantly higher increase in the intensively trained group, in contrast to some earlier trials, but consistent with findings in a later non-randomised study and a study after MI followed by PTCA. Subgroup analysis indicated less improvement in the post MI patients compared to the post angioplasty group in our study. The differences in the magnitude of change in HRV between the angioplasty and post MI groups could indicate a relative impairment of autonomic response in the post MI group. In contrast, HRV impairment, demonstrated in an earlier study in patients up to 6 weeks after angioplasty, seems to be reversible when exercising. Another explanation for the different response in the two groups could be the significantly higher baseline HRV in the post MI patients with lesser potential for improvement than for the angioplasty group.

Fascinatingly, the changes in HRV persisted 1 year after ending the exercise program. In contrast to earlier findings our patients did not increase significantly in parasympathetic HRV indices over time and there was no significant difference between the two
exercise groups, there were, however, significantly increased parasympathetic indices after 3 months in the post angioplasty group but not in post MI patients. Previously differences in exercise time and intensity have been proposed as a possible explanation for the results observed in our study.29,30

It would be tempting to assume that the prognostic benefits from physiotherapy follow up, as indicated by meta analysis studies22,23 could be assessed from the augmentation of AQOL questionnaire. Nonetheless, there are several pitfalls when using surrogate endpoints for mortality, probably best demonstrated in the CAST study.38

Limitations of the Study
Patients with history of unstable angina, or suspected functional disability were excluded due to the fact that the study was planned in Pakistan. Currently, the benefits from physiotherapy follow up in patients with CHF are less well established in Pakistan. Baseline HRV was not low, especially not in the post MI group and therefore this was a low risk group of patients. This could also explain the lesser increase of HRV in the post MI group.

Current study participants only included 18% female population due to male dominating society in Pakistan. Female patients’ seams to have less access to physiotherapy follow up programs in Pakistan or It might be the socio-economical life style in Pakistan which does not allow them to participate in such rehabilitation programs. Results could be gender biased due to less number of female patients in the study, and could be explored reliably by the equal representation of both genders in the study.

Lack of specialised cardiac rehabilitation centres in Pakistan and less number of cardiac rehab physiotherapist hindered us to design further studies to explore about the long term effects of physiotherapy follow up after various cardiac complications including CABG, Angina etc. More emphasis is required to investigate the effects of physiotherapy on patients with age from 40 onwards, due to life expectancies of less than 70 years in cardiac patients across Pakistan. A unified, well organised cardiac rehabilitation program is needed to propose the guidelines specific to culture & life style of Pakistani population which bests suits them considering the imperative aspects of financial burden and community based rehabilitation programs.

Conclusion
Intensive physiotherapy follow up in post MI and post angioplasty patients increases the exercise capacity, global HRV and quality of life of patients, and this could be of prognostic significance specially in the people living in socio-economical setup of Pakistan.

Acknowledgements
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References