MATERIALS AND METHODS

3.1 RESEARCH DESIGN: This was a Randomized controlled trial conducted in a multi-specialty hospital after Coronary artery Bypass Graft surgery (CABG).

GROUPING: It was divided into Study Group and Control Group.

STUDY GROUP: The patients in Interventional group underwent a set of structured exercise program at out-patient physiotherapy department 3 sessions/week for a period of 12 weeks.

CONTROL GROUP: In control group, patients after discharge continued to followed conventional home based self-monitored exercise training program and were asked to record in an activity log.

3.2 SAMPLE SIZE: The sample size was determined using previous literature review including studies based on exercise based cardiac rehabilitation on the mean difference for improvement in functional capacity and quality life with a power of 80% and confidence level of 0.05. The estimated sample size was 90 patients (45 in study group and 45 in control group) by power analysis on statistical software; considering a 20% attrition rate, a total sample of 110 (55 in study and 55 in control group) was planned for study enrollment.
3.3 PROCEDURE: This study was approved by the Institutional Ethics Committee, Sri Ramachandra University (IEC-NI/O8/OCT/06/37). Patients who underwent CABG surgery were screened for study inclusion from June 2010 to Jan 2013. All the patients received the routine physiotherapy training during Phase I Cardiac Rehabilitation. The Phase I training included bronchial hygiene therapy, maintenance exercises, graded mobilization and ambulation as per tolerance of each patient; all the patients were monitored for their vitals response and observed for any event throughout the Phase I training program. The hemodynamically stable CABG patients who completed the Phase I with ejection fraction above 50% and those who consented for study participation were included for this study; Patients who had Uncontrolled arrhythmias, Cardiomegaly, Chronic lung Disease, Vital organ failure (Heart/Kidney/Liver), wound complications and Cognitive /or motor disability were excluded. The eligible patients were included after obtaining their informed consent for study participation. The randomization was done after 5th post operative day by concealed covers of ten each (using computer generated blocks of ten for randomization).

3.4 ASSESSMENT PROTOCOL: The patients were assessed for their profile, demographic variables, Physical parameters (Body Mass Index, Chest wall Tightness), Physiological parameters (Resting Heart Rate, Resting ECG changes, Systolic Blood Pressure, Rate Pressure Product, Diastolic Blood
Pressure, Left ventricular Ejection fraction, Pulmonary Function Testing (FEV1, FVC), Resting Respiratory Rate, SPO2. Blood Parameters - Blood sugar, Lipid Profile, Renal Function Test, Liver Function Test, Electrolytes, Doppler Study report for Peripheral Artery Disease. All the above were screened and analyzed for inclusion and exclusion criteria. The Functional capacity by Six Minute Walk test was assessed prior to discharge. For strength training 3 sets of repetition for at least three to four gross muscles and every two weeks it was progressed. The Physical parameters, Physiological parameters and Functional capacity were assessed before and after training.

3.5 OUTCOME TOOLS: SIX MINUTE WALK TEST:

The exercise capacity of patients was assessed with a six minute walk test (SMWT) as described and in accordance to standard protocol established by American Thoracic society (2002), (Enright and Sherrill 1998, Hamilton and Haennel 2000, Gibbons, Fruchter et al. 2001, Solway, Brooks et al. 2001, 2002). Patient’s rating of Perceived exertion (RPE) was monitored with Borg’s scale and the distance walked was noted. The pulse rate (HR) and oxygen saturation (SpO2) was monitored before, during and after the completion of test. The heart rate and Rating of Perceived Exertion (RPE) was used as basis for exercise prescription in phase II rehabilitation.

WHO- QOL BREF: It is a shorter version of the widely used World Health Organization (WHO QOL) Quality of Life assessment instrument. WHO-QOL BREF is cross culturally validated tool assessing patient’s QOL on four
domains namely Physical health, Psychological, social and environmental, that comprises 26 items in the domains of physical health, psychological health, social relationships, and the environment. The quality of life was assessed using WHO BREF Questionnaire. The WHO QOL-BREF was self-administered by respondents but exceptionally, an experienced interviewer assisted administration by reading items aloud where self-completion was not possible, usually for reasons of literacy. Standard instructions, socio-demographic details and an item on current health status were completed before answering the 26 items of the WHO-QOL BREF. The procedure followed was as described by standard guidelines. (Ref: Annexure). The assessment was done only after 12 weeks at the end of Phase II CR and not during Phase I discharge time, as recovering patients from CABG had limitations in many domains and their activity was restricted only activities of daily living.
3.6 INTERVENTION PROTOCOL:

STUDY GROUP:

EXERCISE PROTOCOL: The patients in Interventional group underwent a set of structured exercise program at out-patient Physiotherapy department 3 sessions/week for a period of 12 weeks. The training session included Warm up and cool down (5 minutes each), Brisk walking on plain surface, Strength training with a load of minimal load and General maintenance exercises, which included breathing exercises, scar mobilization, trunk mobility training were done. Progression done at interval of 2 weeks.

EXERCISE TRAINING INTENSITY: All sessions had adequate warm up and warm down for about 10-25 minutes. The total duration of exercise lasted up to 30-40 minutes. The exercise was supervised and the Pulse rate, Blood Pressure, SpO₂, Respiratory rate and Rating of Perceived Exertion (RPE) were monitored during training session. The intensity progression was based on Target Heart Rate (THR) during supervised training program. The exercise prescription for the patients was moderate intensity with 55%-75% of achieved maximal heart rate (ACSM 2007, AACVPR, 2004). The exercises were started with moderate intensity level i.e.55% of heart rate reserve; over and above the resting heart rate was considered as the intensity of training during phase II rehabilitation.
Table 3.1. Exercise intensity progression

<table>
<thead>
<tr>
<th>Parameters</th>
<th>1-4WEEKS</th>
<th>4-8 WEEKS</th>
<th>8-12 WEEKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rise of heart beat during Training (ACSM)</td>
<td>20 - 25</td>
<td>25- 30</td>
<td>30- 35</td>
</tr>
<tr>
<td>Target heart rate (220-Age-30)</td>
<td>55-60%</td>
<td>60-70%</td>
<td>70-75%</td>
</tr>
<tr>
<td>RPE</td>
<td>11-14</td>
<td>11-14</td>
<td>11-14</td>
</tr>
<tr>
<td>Training duration</td>
<td>10-20 mins</td>
<td>20-30 mins</td>
<td>30-40 mins</td>
</tr>
</tbody>
</table>

The RPE level of mild to moderate exertion (11-14) was used in this study. The patients were trained with Borg’s RPE (Ref: Annexure) method for maintaining the intensity monitoring in Phase II.
**Control Group:** The patient’s in in control group continued to follow exercise trained at time of discharge advice at home and at home the patients were asked to record in an activity log. The patients in Control group continued the self-paced unsupervised exercise as per their tolerance. After the end of 12 weeks, patients of both the groups were evaluated for the changes in Physical parameter (BMI), Physiological parameters (Resting Heart Rate, Resting ECG changes, Systolic Blood Pressure, Rate Pressure Product, Rating of Perceived Exertion, Left ventricular Ejection fraction), Quality of Life and Functional capacity (SMWD). As some patients were unable to maintain regular follow up for outpatient therapy even though they all showed interest in exercise counseling, the barriers to Phase II program participation was also noted down for further analysis.
3.7 PLATES

Plate: 1 Phase One Care-Breathing Exercises

Plate: 2-Incentive Spirometer Training
Plate: 5 General Maintenance Exercise Training
Plate: 6 Breathing Exercise and Resistance Training

Walking training (Aerobic)
Plate: 7. Six Minute Walk Test
3.8 STATISTICAL DATA ANALYSIS

The collected data was analysed with SPSS 16.0 version. (SPSS Inc., Chicago, IL, USA) To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and for continuous variables the mean and S.D were used. To find the significance difference between the bivariate samples in paired groups Paired sample t-test was used & for independent groups Independent t-test was used. To assess the relationship between the variables Pearson's Correlation was used. To find the significance in categorical data Chi-Square test was used. In all the above statistical tools the probability value .05 is considered as significant level.

The arithmetic mean

The arithmetic mean, often simply called the mean, of a set of values is calculated by adding up all the values and dividing this sum by the number of values in the set.

\[ \bar{x} = \frac{\sum x}{n} \]

The standard deviation

The standard deviation is the square root of the variance. In a sample of n observations, it is:

\[ s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}} \]
The paired t-test

Assumptions

In the population of interest, the individual differences are normally distributed with a given (usually unknown) variance.

If the two sets of measurements were the same, then we would expect the mean of the differences between each pair of measurements to be zero in the population of interest. Which follows the t-distribution with \((n - 1)\) degrees of freedom

\[
t = \frac{\bar{d} - 0}{SE(\bar{d})} = \frac{\bar{d}}{s_d/\sqrt{n}}
\]

The unpaired (two-sample) t-test

Assumptions

In the population, the variable is normally distributed and the variances of the two groups are the same. In addition, we have reasonable sample sizes so that we can check the assumptions of Normality and equal variances.

We consider the difference in the means of the two groups. Under the null hypothesis that the population means in the two groups are the same, this difference will equal zero. Therefore, we use a test statistic that is based on the difference in the two sample means, and on the value of the difference in population means under the null hypothesis (i.e. zero). This test statistic, often referred to as \(t\), follows the t-distribution.
Notation

Our two samples are of size $n_1$ and $n_2$, which follows the $t$-distribution with $(n_1 + n_2 - 2)$ degrees of freedom

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - 0}{SE(\bar{x}_1 - \bar{x}_2)} = \frac{\bar{x}_1 - \bar{x}_2}{s \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

Pearson correlation coefficient

We say that we have a linear relationship between $x$ and $y$ if a straight line drawn through the midst of the points provides the most appropriate approximation to the observed relationship. We measure how close the observations are to the straight line that best describes their linear relationship by calculating the Pearson product moment correlation coefficient, usually simply called the correlation coefficient.

Its true value in the population, $\rho$ (the Greek letter, rho), is estimated in the sample by $r$, where

$$r = \frac{\sum (x - \bar{x})(y - \bar{y})}{\sqrt{\sum (x - \bar{x})^2 \sum (y - \bar{y})^2}}$$

Properties $r$ lies between -1 and +1. Its sign indicates whether one variable increases as the other variable increases (positive $r$) or whether one variable decreases as the other increases (negative $r$).

CHI-SQUARE TEST
The chi-square (I) test is used to determine whether there is a significant difference between the expected frequencies and the observed frequencies in one or more categories. Do the numbers of individuals or objects that fall in each category differ significantly from the number you would expect? Is this difference between the expected and observed due to sampling error, or is it a real difference?

**Chi-Square Test Requirements**

1. Quantitative data.
2. One or more categories.
3. Independent observations.
4. Adequate sample size (at least 10).
5. Simple random sample.
6. Data in frequency form.
7. All observations must be used.

**Formula**

\[ \chi^2 = \frac{(O - E)^2}{E} \] (O is observed frequency, E is expected frequency)

**The steps in using the chi-square test may be summarized as follows:**

1. Write the observed frequencies in \( O \)
2. Figure the expected frequencies in \( E \).
3. Use the formula to find the chi-square value:
4. Find the \( df \). (\( N-1 \))
5. Find the table value (consult the Chi Square Table.)

6. If our chi-square value is equal to or greater than the table value, reject the null hypothesis: differences in your data are not due to chance alone.