Chapter 4

Methodology

This chapter details the methodology used in the study - which was conducted in conjunction with the cardiac rehabilitation programme with those patients who fitted the criteria and agreed to take part in the study.

All the tests were carried out by the author and/or the technical instructor of the Cardiac Rehabilitation programme to avoid inconsistency in results.

4.1 Referrals

All subjects were recruited on a voluntary basis. Subjects were those referred to the cardiac rehabilitation programmes, who were not excluded (see below) and fulfilled the criteria. There was no selection process. All patients were considered who would be able to complete the eight week exercise programme within the study timescale. The study was discussed with each patient that fulfilled the criteria to see if they wanted to take part.

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>PCI</th>
<th>MI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>9</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>3</td>
<td>1</td>
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</tbody>
</table>

Table 4.1 Illustration of patient numbers/diagnosis who took part in the study

Their informed permission to use the data collected was sought. The patients were given the patient information sheet (appendix 1) when they received
their appointment to attend the assessment for the cardiac rehabilitation programme. At the assessment the patient consent form was completed (appendix 2). The number of patients that attend the exercise component of cardiac rehabilitation at Southport & Ormskirk NHS Trust is on average 180 per year. The number of patients involved in this study was 33 patients; 7 were female, 26 were male (mean age 57.3 years, range 49 -73). Patients referred for CR were recruited between January 2\textsuperscript{nd} 2007 and June 4\textsuperscript{th} 2007. 41 of 45 eligible patients assessed during this period consented to take part in this study. 8 were unable to complete the necessary assessments and were excluded from the study. This study was approved by the local research ethics committee (appendix 3) and written consent was obtained from all patients.

4.2 Exclusion criteria

1. Musculoskeletal problems affecting mobility
2. Heart failure
3. Patients suffering from intermittent claudication
4. Poor balance
5. Unable to take part in the ISWT or CST for any other reason
6. Did not want to take part

During the period of the study eight subjects were withdrawn from the study due to the fact they either did not complete the programme, there was an alteration in medication which changed the heart rate, or they were unable to complete the tests on the appropriate days.
4.3 Inclusion criteria

1. Referred to the cardiac rehabilitation post MI, PCI, CABG
2. Able to complete the assessment and 8 week cardiac rehabilitation programme

4.4 Test Design

Each subject was to complete two different functional capacity tests (ISWT and CST) on three separate occasions. The first time the subjects completed the two tests allowed them to become familiar with both tests and was done at the initial patient assessment to attend the cardiac rehabilitation programme. The participants were screened against the inclusion/exclusion criteria and completed the tests as follows. The patients completed the two different tests (ISWT and CST) on the same day. There was a rest period of at least 20 minutes between the first and second test to allow the heart rate to return to resting level. Half the patients completed the CST first and the ISWT second. The others did the opposite; this allowed the possibility of checking if the order of tests had any effect on the outcome. The order of the tests was allocated as follows: the first patient did the ISWT first and the CST second and the second patient did vice versa. On the first day of their formal rehabilitation programme they completed the two tests as described above, within one week of the assessment tests. The results were then compared to a) the results from the tests performed at the practice session b) those collected at the final session. The first two tests
were looked at to see if there is any difference and whether a practice test changed the results.

The patients then completed the eight-week programme, as described in section 3 above.

At the last session they were asked which test they preferred and this was recorded as CST, ISWT or no preference.

Patient referrals ↓
Initial eligibility ↓
Enrolled and gave consent ↓
ISWT and CST ↓
1 week later ISWT and CST ↓
Exercise programme 8 weeks ↓
Repeated ISWT and CST

Figure 4.1 Study outline

There was no difference in content and structure of the cardiac rehabilitation programme for those taking part in the study compared to those who were not.

4.5 Equipment and design

Heart rate, monitored via a wireless radio telemetry chest strap and wristwatch system (Polar Electro, Kempele, Finland) and Rating of Perceived
exertion (RPE) using Borg’s 6-20 scale (Borg 1998), were recorded as per the instructions in both the CST and ISWT. The patients were encouraged to openly report their RPE at any time to ensure patients comfort.

Using RPE (Appendix 4)

Standard instructions were given before each test (Borg 1998, Noble 1996)

- Clarification that the patients understood the definition of RPE
- Anchoring the top and bottom ratings to previous experienced sensations of no exertion at all and extremely hard/maximal effort
- Make sure they are aware of giving an all over integrated rating which incorporates both physical, muscular and central cardio respiratory sensations
- Focusing on verbal descriptors as well as numerical values
- No right or wrong answers
- Scales in full view at all times

Prior to and after the test the patients’ blood pressure (BP) was taken in sitting; this was done by an automated sphygmanometer and recorded on the patients’ records. It was taken on the left arm unless the patient had had surgery on that arm or there was some other reason the left arm cannot be used. This ensured that no one had a blood pressure that would exclude them from taking part.
4.6 ISWT description

The shuttle walk test was performed three times, on three separate occasions. The patient received full instructions prior to the tests, which were as follows: the patient was required to walk a 10m course at a speed dictated by signals from an audio CD. The walking speed increased by a small increment at 1-minute intervals. During the test a Polar heart rate monitor was used to monitor heart rate and at the end of each level on the triple bleep the patient was asked what their heart rate was on the wrist monitor. The patient was also asked to report at what level they feel they were working on the Borg RPE. The test ended when the subject’s heart rate reached 80% of their maximum heart rate, when the RPE got to 15 or the subject reached the final test level. Ideally maximum heart rate for the equation should be calculated by means of a maximal stress test but this is not indicated in exercise prescription due to the risk of adverse events so the estimation of 220 – age is used. The recommendation for those taking beta blockers is to subtract 30 beats when making the calculation as advocated by BACR. The distance in meters covered was recorded.

For full protocol see appendix 5

4.7 CST description

The CST was performed three times with the ISWT as recorded above. The test was conducted using a pre-recorded audio CD with instructions and timed metronome rhythms and a 15cm step. The patient received full instructions prior to the test as follows: The patient stood in front of the 15cm step and
listened to the instructions, when the CD started the subject started to step on and off the bench in time with an audio metronome signal which starts at 15 steps per minute for 2 minutes. At the end of each 2-minute level (maximum 5) the subject’s steady state heart rate was noted. The heart rate was recorded by the use of a Polar heart rate monitor and the patient was asked to call out the heart rate. The patient was also asked to report their RPE at the end of each CST level. The test ended when the subject’s heart rate reached 80% of their maximum heart rate, when the RPE got to 15 or if the subject reached the end of the final stage, Level 5 in which case the test was repeated with a 20cm step. Then the plotted estimated VO$_{2\text{max}}$ was used (as recommended in the instructions for use of the CST), using the graphical datasheets.

For full protocol see appendix 6

The exercise tests were stopped if patients reported:

- Chest pain
- Patient requests that they stop e.g. leg/hip pain
- Excessive shortness of breath where patient is unable to speak
- Unable keep up with beeps as per ISWT test protocol
- Unable to keep up with the CST audio signal rate
- Reached pre-determined heart rate if patient likely to experience silent angina
- Reached Borg scale 15 on the 6-20 scale
4.8 Parameters

Data collected from the ISWT included heart rate, RPE, and meters walked.

The CST data collected included Heart rate, RPE, and estimated VO$_2$ max. For both tests from the data Mets reached, VO$_2$ and Oxygen pulse were calculated.

O$_2$ pulse is an indirect index of combined cardiopulmonary oxygen transport. The method of calculation is to divide oxygen uptake by heart rate. Circulatory adjustments that occur during exercise which include widening a-VO$_2$ difference increased cardiac output and redistribution of blood flow to the working muscle will increase O$_2$ pulse. Maximal O$_2$ pulse is higher in fitter or healthier individuals (Froelicher & Myers 2000).

4.9 Further Exclusions

Any subject not attending at least thirteen of the sixteen cardiac rehabilitation sessions were excluded from the study. However previous internal audits indicated that compliance is generally high and therefore a large proportion of the subjects that started would successfully complete the programme.

4.10 Safety

All the tests took place in the gymnasium at Southport and Ormskirk hospitals. The tests were carried out with a minimum of two people trained in at least basic life support, a full resuscitation trolley including defibrillator and oxygen was available. Patients who have been prescribed a GTN spray/tablets were
asked to bring them. There was cover from the hospital emergency team and a phone was to hand to contact them.

4.11 Encouragement

Due to the risk of the tester altering the outcome of the test encouragement was standardised.

With the ISWT the tester said ‘you are doing well’ at the end of each level.
With the CST the tester said ‘you are doing well’ at the end of each level.
Other than that the tester did not offer any other encouragement.

4.12 Ethical Considerations

Exercise tests are by their very nature a potential health risk as are the exercise classes themselves. The tests and classes were held within the physiotherapy department, cardiac rehabilitation department and gymnasium. There were always a minimum of two qualified staff members with resuscitation qualifications present, access to the hospital crash team, crash trolley, defibrillator and a telephone. Full consent was obtained from the patients.

Patient information sheet (appendix 1) and written informed consent from the patients (appendix 2), before the tests the patients were screened to check their suitability to perform the tests.
4.13 Ethical Approval

Ethical approval was granted by University of Chester Ethics Committee, St Helens and Knowsley Research Ethics committee (appendix 3) and the Southport and Ormskirk NHS Trust local ethics committee.

4.14 Statistical analysis

Summary data are expressed as mean (SD) unless otherwise stated, and a 5% level of significance was adopted throughout. Relationships between variables were examined using the Paired sample T test.

All analyses were performed using Statistical Package for Social Sciences software program (SPSS) 14 for windows (SPSS Inc, Chicago, IL, USA).

The subjects were a group of 33 participants who had been referred for cardiac rehabilitation programme. They completed both the ISWT and CST tests on three separate occasions.

As the total number of values was less than 50 the Shapiro-Wilk test can be used to determine normality of distribution. This indicates significance values >0.05 for both groups, indicating normality of distribution.

Under these circumstances parametric testing is appropriate and the parametric test used to compare two separate groups is the paired sample t-test.

The conventional way to analyse data to quantify the test – retest reliability of many performance and physiological measurements is by the use of Pearson’s correlation (Lamb et al 1998). This is incorrect and not sensitive enough. Limits of Agreement (LoA) analysis is a more complete appraisal of
reliability than Pearson’s correlation co-efficient as it allows repeatability to be expressed in the unit of measurement (Bland & Altman 1986). The distance achieved on the first and practice tests were compared using the Bland Altman limits of agreement method and were considered to agree if 95% of the points on the Bland Altman plots lay between the mean difference ± 2 standard deviations. The reliability of the ISWT assessments were assessed using an intraclass correlation using between and within subjects means squares produced from an analysis of variance (Rankin, Stokes 1998). Differences between the practice and second walk were compared using the paired t-test.

95% LoA agreement is the preferred choice of analysing the reliability in most of today’s clinical researches (Lamb 1998).