

CHAPTER 3

METHOD

Introduction

This chapter describes the procedure that was followed to allow the researcher to derive a probable answer to the research question: Does a mobility programme on its own, have the same functional outcome as a programme of bed exercises and mobilisation, in patients following primary total hip arthroplasty, at discharge from hospital? The methodology utilised in this research report is based upon the methodology used by Jesudason & Stiller (2002). The ordered sequence that was used to randomise patients; the validated assessment tools that were used to collect data; the process of implementing the intervention; the data collection process; and the statistical tests used for the analysis of the results are described.

Ethical clearance was applied for, to the Human Research Ethics Committee (Medical), University of the Witwatersrand. Protocol number is M040440. (See Appendix 1).

3.2 Study Design

This study was a randomised controlled trial.

3.3 Subjects

This randomised controlled trial was carried out at the Johannesburg Hospital. All patients admitted to Johannesburg Hospital for elective primary total hip arthroplasty from November 2004 to August 2005, who gave informed written consent and who met the inclusion criteria, were considered eligible for this study.

Inclusion criteria:

- All patients admitted to Johannesburg Hospital for elective primary total hip arthroplasty from November 2004 to August 2005.
- No restriction on age, sex or race of patient as pertaining to the above sub-group of patients.
- Patients who gave informed written consent.

Exclusion criteria:

- Inability to participate in the assessment and treatment procedures, from a physical and cognitive point of view.
- Unwillingness to participate in the study.
- Specified instruction by the orthopaedic surgeon that the patient must be strictly partial weight bearing post-operatively when walking.
- Inability of the patient to walk prior to admission (with/without aid of assistive device).
- The patient did not survive the operation or passes away before day eight post operatively.

(See Appendix 2 for the patient information sheet and Appendix 3 for patient consent form.)

Sample size:

Thirty-six patients participated in the study. A two group t-test with a 0.05 one sided significance level had 90% power to detect a difference in means of 7.0, assuming the common standard deviation is 6.9 on the ILOA Scale, when the sample size is 36 (Dixon & Massey,1983). Power of sample was confirmed by Prof. P. Becker from the MRC. Patients were allocated randomly to either the control or experimental group, based on a computer generated random numbers list. A concealed random allocation was done. Opaque envelopes that were marked 1-36, were appropriately filled with slips of paper that had either “control group” or “experimental group” written on them. This was done by a third party. The researcher was blinded as to which groups the patients belonged.

3.4 Independent and Dependent variables:

The standard physiotherapy protocol consisted of daily mobilisation and a set programme of routine bed exercises. Daily mobilisation involved assisting the patient out of bed and attempting ambulation. This was done with/without the aid of an assistive device, and varying degrees of assistance by the physiotherapist.

3.4.1 Independent variable:

The independent variable was the mobility programme alone.

3.4.2 Dependent Variables:

3.4.2.1 Primary outcome measure:

Functional Status

Functional status was assessed using the Iowa Level of Assistance (ILOA) Scale, described by Shield et al (1995). (See ILOA Scale in Appendix 4). This test evaluates a patients ability to perform functional activities, most of which are also used to determine whether a patient is ready for discharge from hospital. The ILOA Scale may be considered to have two criteria. The first being the evaluation of how the patient performs specific functional activities, with regard to how much assistance is given to the patient from the physiotherapist. The amount of assistance given is rated according to a scale ranging from zero to six, where zero indicates that the patient performed the activity independently and six indicates that the task was not even attempted due to medical or safety issues. Therefore as one moves from zero to six the patient requires more assistance from the physiotherapist.

The second criterion is the assistive device used by the patient in performing the tasks. The assistive device used was also rated according to an ordinal scale ranging from zero to five. Zero indicates that no assistive device was used and five represents the most supportive assistive device, this being a walking frame.

The score allocated to the performance of each task, comprised of adding the score given for the amount of assistance given by the physiotherapist together with the score given for the assistive device used, in the performance of that task. The patients overall score was then a summation of scores given for the five functional activities assessed.

The functional activities assessed are:

Task 1: Moving from supine to sitting over the edge of the bed.

Task 2: Getting from sitting over the edge of the bed to standing.

Task 3: Walking 4.57 metres. Distance was reproducible by using a 4.57m, pre-measured tape, which was appropriately placed to assess whether the required distance was walked.

Task 4: Climbing up and down 3 steps.

Task 5: Walking speed over a 13.4m distance is recorded and ranked using an ordinal scale.

Task 1 was graded only according to level of assistance given to the patient by the physiotherapist. Tasks 2- 4 were graded according to the level of assistance and the assistive device used. Task 5 had its own point allocation depending on the time taken to walk the set distance of 13.4m. The scale used for this task ranges from zero to six. Zero representing 0 to ≤ 20 seconds. Six representing > 70 seconds. Task 5 was also assessed with regard to the assistive device used.

To allow the patient's true level of function to be assessed, the researcher tried to provide the least amount of assistance possible, while still maintaining the safety of the patient. The best overall score that a patient may achieve with this scale is zero indicating complete independence with performing the tasks. The worst overall score is 50.

3.4.2.2 Secondary outcome measures:

Severity of pain

A horizontal 10cm visual analogue scale (VAS) was used to rate the patient's resting level of pain. The left hand end of the line indicated no pain and the right end of the scale represented excruciating pain. No further demarcations were made on the line. This was verbally expressed to the patient by the researcher. The patient was then requested to indicate the level of pain they were experiencing by marking on the line where his/her pain level lay. This was then measured by the researcher for data collection purposes. The VAS is

viewed as a reliable and valid tool of assessing pain levels (Myles & Urquhart, 2005).

Range of hip flexion and abduction

The active (unassisted) range of the patient's hip flexion and abduction was measured to the nearest degree using a goniometer. This was done with the patient in a supine position. To standardise goniometric measurements, anatomical reference points were marked on patients according to the guidelines described by the American Academy of Orthopaedic Surgeons (1965).

3.5 Procedure:

Before the patient was randomly allocated to the control or experimental group, the researcher, who was blinded as to which group the patient was allocated to, collected relevant data from the patient's file pre-operatively. This data allowed for the patients to be profiled.

The researcher recorded the following patient details:

- Gender
- Age
- Pre-existing medical conditions (as this could influence the rehabilitative process and outcome).
- Operative procedure – whether a lateral or posterior approach was used.
- Major post-operative complications – this could affect the length of stay in hospital. Possible complications were deep vein thrombosis, cardiac events, wound dehiscence etc. Post-operative complications influence how vigorous the physiotherapist is with the rehabilitation of the patient.

The patient was also questioned specifically on the following:

- History of previous lower limb pain/injury on the involved side.
- Previous general joint problems and whether medication was taken for it.
- Pre-admission level of mobility.

(See Appendix 5 for pre-operative data collection sheet and Appendix 6 for postoperative patient data collection sheet.)

3.5.1 Experimental Group:

Patients in the experimental group did not receive any bed exercises. They were mobilised, according to the standard mobility protocol used at the Johannesburg Hospital, following total hip arthroplasty. The protocol used is the same as that utilised by Jesudason & Stiller (2002). This protocol consists of:

Day one post-operatively:

- Sitting over the edge of the bed.
- Attempted standing and walking using appropriate walking aid, with the assistance of one/two physiotherapists as required.

Day two post-operatively and onwards:

- Mobilisation was progressed in regards to distance walked, speed of walking, degree of assistance given by physiotherapist/s, and required mobility aid.
- This was done according to the individual patient's capabilities, and deemed appropriate by the treating physiotherapist. If the patient required more than one physiotherapist to assist in the mobilisation, a second physiotherapist/physiotherapy assistant was called in to help.
- The patient was mobilised once per day by the physiotherapist. But the patient also mobilised independently, or with the assistance of nursing

staff, for toileting purposes, as and when, the patient was confident to do so.

3.5.2 Control Group:

Patients in the control group received a set programme of bed exercises in addition to being mobilised by the physiotherapist. These bed exercises were aimed at increasing the range of movement and the muscle strength of the hip, knee and ankle. The exercises were taught to the patient by the physiotherapist on the first day after the operation. The patient was instructed to carry out these exercises two/three times per day, with the physiotherapist supervising the exercise programme once per day, until the patient was discharged. The exercises utilised in this study were duplicated from the study conducted by Jesudason & Stiller (2002).

The bed exercises were performed by the operated limb in supine, and comprised the following:

- Hip and knee flexion and extension to neutral: The patient slides the heel, which is supported on the bed, gradually toward his/her buttocks. The patient then gradually slides the heel down to the original position.
- Hip abduction and adduction to neutral: The patient slides the lower limb which is supported on the bed, out to the side to $\pm 45^\circ$ of abduction. The patient then brings the limb from the abducted position to neutral.
- Ankle dorsiflexion and plantarflexion: The patient performs this exercise by pointing the feet down and then up as much and as fast as possible. Taking care to move from the ankles and not just the toes.
- Static quadriceps contraction: The patient dorsiflexes the ankle, and then pushes the knee down into the bed, to tighten the quadriceps

muscle. This contraction is held for five seconds. The patient then relaxes and repeats the exercise.

- Inner range quadriceps exercises: A rolled up towel is placed under the patient's knee to allow for $\pm 15^\circ$ of knee flexion. The patient then lifts the heel of the bed, to extend at the knee thus contracting the quadriceps. The patient then lowers the leg to the original position.

Patients were instructed to do each exercise five times initially, building up to ten repetitions. These patients were also given handouts explaining how the exercises should be done and the frequency with which they should be done. The reasons why the exercises should be done were also explained in the handout. (See Appendix 7 for Handout given to patients).

In order to prevent “pollution” between the control and experimental group, the patients from the two groups, were kept in separate cubicles. The physiotherapists at the Johannesburg Hospital rotate from one unit to the next every four months. It was therefore out of the control of the researcher, to have only one physiotherapist treating the THA patients, from Monday to Friday, throughout the course of the study, that being November 2004 to August 2005. At the end of the time period it took to collect the required number of patients (ten months), three physiotherapists had been responsible for treating the patients. Weekend patient treatments were carried out by the physiotherapist working that particular weekend.

Each physiotherapist rotating into the orthopaedic unit was briefed comprehensively by the researcher regarding the treatment protocols for each group. The physiotherapists working over the weekends were also thoroughly briefed by the researcher, on the Thursday or Friday prior to the commencement of weekend duty, in regards to the treatment protocols for each group. The physiotherapists were also given these guidelines in the form of a written handout. The purpose of this was to try and minimise differences in treatment interventions, from one physiotherapist to the next.

(See Appendix 8 for the instructional handout given to physiotherapists.)

3.6 Statistical Considerations

In a randomised controlled study, the effect of bed exercises added to a mobility programme for total hip arthroplasty patients was assessed, with regards to function, pain and range of movement, measured using the ILOA Scale, VAS and goniometric readings respectively.

Sample size

Of primary interest was the function and this was therefore considered in determining sample size with the help of nquery Advisor V6.0. The sample size indicated was 36 subjects. From the literature the standard deviation for a group of hip arthroplasty patients with mobility programme only was found to be 6.9 and a clinically important change on the ILOA Scale was suggested as 7 (Jesudason & Stiller, 2002).

Statistical analysis

Data analysed was ROM and VAS measurements (parametric data) and ILOA Scale functional scores (non-parametric data). For all the parameters (functional ability scores, ROM of operated hip, resting levels of pain) groups were compared at days three/four and at days seven/eight as well as for the changes from days three/four up to days seven/eight, using Student's independent two-sided t-test. The conclusions of the latter were also confirmed using the Welch t-test and the nonparametric Wilcoxon rank sum test.