CHAPTER III
METHODOLOGY

This chapter explains methodology of the study. The contents are divided into study design and setting, sample size, subjects, research protocol, outcome measures, instrumentation and statistical analyses. Details of each topic are as follows;

1. Study design and setting

This study was cross-sectionally conducted in independent ambulatory patients with SCI who were recruited mainly from the Srinagarind hospital, Khon Kaen province, Thailand.

2. Sample size

The sample size of the study was calculated using the formula;

$$n = \frac{n_0 \times 100}{Rate\ of\ disease}$$

$$n_0 = \frac{Z^2_{\alpha/2} P^{(1-p)}}{e^2}$$

Set

N = sample size

n_0 = number of disease people

P = sensitivity value = 0.90

α = α error = 0.05

e = precision of estimation value = 0.10

$$n_0 = \frac{1.96^2 \times 0.90(1-0.90)}{0.10^2}$$

$$n_0 = 34.57$$

$$n = \frac{34.57 \times 100}{58.33}$$

$$= 59.26$$

Thus the appropriate number of subjects in this study was 60.

3. Subjects

Subjects of this study were patients with SCI from both non-traumatic and traumatic causes, aged 18 to 60 years old. The eligible subjects needed to be able to stand up from a chair or bed independently, and independently walking with or without a walking device at least 50 meters continuously [FIM_L scores 6 – 7]. Patients with SCI were excluded if they had brain function disorders, visual deficits, pain in the musculoskeletal system with the visual analog scale (VAS) more than 5, deformity in the spine or joints, and other medical conditions that might affect participation in the study.

4. Research protocol

Every subject participated in the study for 2 consecutive days. On the first day, subjects were interviewed and assessed their baseline demographics and SCI characteristics including causes, severity and level of injury, post-injury time, and baseline walking ability (ability to walk at least 50 meters continuously with or without a walking device). Then, subjects were arranged into 2 groups according to the requirements of a walking device (FIM_L scores). Subjects with FIM_L 6 were those who could walk at least 50 meters with the use of a walking device, and FIM_L 7 referred to those who were able to walk at least 50 meters without using any assistive devices. The study employed the criteria of FIM_L scores to classify walking ability of subjects because it documented functional ability of individuals in different environments, thus truly indicated burden of care that they needed (Jackson et al., 2008).On the second day, subjects were tested their ability using the FTSST, TUGT, and 10MWT in a random order to minimize carrying-over effects due to sequences of

the tests that might occur such as fatigue and learning effects. Details of the tests are as follows;

4.1 The five times sit to stand test (FTSST)

The test required a stop watch and an armless chair. The backrest of the chair was closed to the wall in order to ensure safety of the subjects and accuracy of the test. Subjects sat on the chair with their back upright 90 degrees against the backrest. Their feet placed flat on the floor at 10 cm behind the knees, while their arms were on their sides (Janssen et al., 2002; Lipsitz et al., 1991; Whitney et al., 2005). Then subjects were instructed to stand up with the hips and knees in full extension and sit down 5 times as quickly as they could without using the arms. The test recorded the time in seconds from the command “Go” until the subject’s back touching the backrest of the chair on the fifth repetition (Whitney et al., 2005).

4.2 The timed up and go test (TUGT)

The test required a stop watch, a standard armchair, and a traffic cone. The chair was positioned close to the wall in order to ensure subjects’ safety and accuracy of the test. Subjects sat on the chair with their back upright 90 degrees against the chair and placing their feet flat on the floor at 10cm posterior to the knees. Then the examiner instructed the subjects to stand up, walk around the traffic cone that was located 3m away from the chair, and returned to sit on the chair at a maximum and safe speed with or without a walking device. The test recorded the time taken in seconds from the word “Go” until and the subject’s back against the backrest of the chair again (Podsiadlo and Richardson, 1991; Read et al., 2008; Shumway-Cook et al., 2000; Lusardi et al., 2003).

4.3 The assessment of walking speed using the 10-meter walk test (10MWT)

The test required a stop watch and a 10m walkway. The subject stood at the starting point with their feet behind the line. Then they were instructed to walk with or without a walking device at a preferred or comfortable speed along a straight line without any break to the end point. In order to minimize acceleration and deceleration effects, the test measured the time required during the middle 4 meters of the walkway with the use of greater trochanter as a landmark for time recording (Graham et al., 2008; Finch, 2002 Cesari et al., 2005; Jackson et al., 2008; van Hedel

et al., 2008). Then the walking speed was calculated using the formula $V = \frac{S}{T}$, where V was velocity (m/s), S was distance (meter), and T was time (second).

Each test was performed 3 trials; then the average performance of the 3 trials was recorded. In order to warrant safety for the subjects, they had to wear a safety belt around their waist with a physiotherapist being aside of the subject throughout the tests. During the tests, subjects were able to take a period of rest as needed until their heart rates returned to a baseline level.

Reliability test

The study investigated inter-tester reliability of the tools in 20 subjects with iSCI using 3 physiotherapists. Each therapist measured ability of the subjects 3 times/test. The average performance of the 3 times was used for data analyses.

5. Outcome measures

Outcomes of this study were

- The five times sit to stand test (FTSST)
- The timed up and go test (TUGT)
- The 10 meter walk test (10MWT)

6. Instrumentation

6.1 Tape measure

6.2 Color tapes

6.3 Traffic cone

6.4 Chair with and without armrest

6.5 Stopwatch

7. Statistical analyses

The data analyses were executed using the SPSS program (version 1 7 .0). Descriptive statistics (mean ± SD and 95%CI) were applied to explain baseline demographics, SCI characteristics, and findings of the study. Intraclass correlation coefficients (ICCs) were applied to determine the inter-tester reliability of the functional tests. Findings in subjects with FIM_L6 and FIM_L7 were compared using

the independent samples t-test. Then the optimal cut-off scores, sensitivity and specificity of the tests were determined using the receiver-operating characteristic (ROC) curves. The sensitivity is a true positive rate or the probability of a positive test result in subjects with the condition. On the contrary, specificity is the true negative rate or the probability of a negative test result in subjects without the condition. The closer the area under the ROC curve approaches the 1 value, the better the predictive ability (van Hedel, 2009). The level of significance was set at $p < 0.05$.