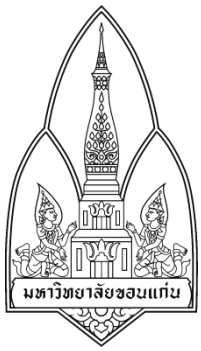


# CORRELATION BETWEEN WALKING SPEED AND FUNCTION CAPACITY AS MEASURED USING THE 6-MINUTE WALK TEST (6MinWT) IN INDEPENDENT AMBULATORY PATIENTS WITH SPINAL CORD INJURY (SCI)

**MISS SALINEE NAEWLA**

**A THESIS FOR THE DEGREE OF MASTER OF SCIENCE**

**KHON KAEN UNIVERSITY**

**2012**

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**A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT**

**FOR THE DEGREE OF MASTER OF SCIENCE**

**IN PHYSICAL THERAPY**

**GRADUATE SCHOOL KHON KAEN UNIVERSITY**

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# THESIS APPROVAL

# KHON KAEN UNIVERSITY

# FOR

# MASTER OF SCIENCE

# IN PHYSICAL THERAPY

**Thesis Title:** Correlation between walking speed and functional capacity as measured using the 6-minute walk test (6MinWT) in independent ambulatory patients with spinal cord injury (SCI)

**Author:** Miss Salinee Naewla

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สาลินี แนวหล้า. 2555. **ความสัมพันธ์ระหว่างความเร็วในการเดินและความสามารถในการทำงานที่วัดโดยการเดิน ในเวลา 6 นาที (6MinWT) ในผู้ป่วยบาดเจ็บไขสันหลังที่เดินได้เอง.** วิทยานิพนธ์ปริญญาวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด บัณฑิตวิทยาลัย มหาวิทยาลัยขอนแก่น.

**อาจารย์ที่ปรึกษาวิทยานิพนธ์:** รศ.ดร. สุกัลยา อมตฉายา, ผศ.นพ. ปรีดา อารยาวิชานนท์

## บทคัดย่อ

การทดสอบระยะทางการเดินในเวลา 6 นาที (6-minute walk test: 6MinWT) เป็นการประเมินที่ช่วยสะท้อนความสามารถในการดำเนินกิจวัตรประจำวัน ผลการทดสอบสามารถแปลงเป็นความเร็วในการเดินได้ แต่การทดสอบนี้ต้องใช้เวลานานและใช้สถานที่สำหรับการทดสอบกว้าง ในขณะที่การประเมินความเร็วในการเดินระยะทาง 10 เมตร (10-meter walk test: 10MWT) เป็นการทดสอบที่ทำได้ง่าย ใช้เวลาน้อย ผลการทดสอบช่วยสะท้อนความสามารถในกิจวัตรประจำวันและคุณภาพการเดินโดยรวม อย่างไรก็ตาม การทดสอบ 10MWT สามารถทำได้หลายแบบ ได้แก่ ความเร็วปกติ ความเร็วสูงสุด ความแตกต่างระหว่างความเร็วปกติและความเร็วสูงสุด และสัดส่วนระหว่างความเร็วปกติและความเร็วสูงสุด ดังนั้น การศึกษานี้จึงมีวัตถุประสงค์หลักเพื่อศึกษาความสัมพันธ์ระหว่างการทดสอบ 6MinWT และตัวแปรต่างๆ ที่ได้จากการทดสอบ 10MWT และมีวัตถุประสงค์รองเพื่อศึกษาความสัมพันธ์ระหว่างการทดสอบทั้งสอง ในผู้ป่วยบาดเจ็บไขสันหลังที่สามารถเดินได้เองที่มีความสามารถระดับต่างๆ อาสาสมัครจำนวน 74 ราย ได้รับการทดสอบความสามารถโดยใช้ 10MWT และ 6MinWT ผลการศึกษาพบว่าการทดสอบ 10MWT ด้วยความเร็วปกติมีความสัมพันธ์ที่ดีที่สุด ($r = 0.91$, $p<0.01$) และสามารถทำนายการทดสอบ 6MinWT ได้ดีที่สุด ($R^2 = 0.82$) อย่างไรก็ตาม เมื่อวิเคราะห์ความสัมพันธ์ตามระดับความสามารถของอาสาสมัครพบว่าการทดสอบทั้งสองมีความสัมพันธ์กันดีที่สุดในอาสาสมัครที่เดินได้ระยะทางไกลโดยไม่ต้องใช้อุปกรณ์ช่วยเดิน ผลการศึกษานี้แสดงให้เห็นว่าการทดสอบ 10MWT ด้วยความเร็วปกติ สามารถใช้แทนการทดสอบ 6MinWT ได้ ในกรณีที่มีข้อจำกัดด้านเวลาและสถานที่ในการทดสอบ อย่างไรก็ตาม ความสามารถในการทดแทนของ 10MWT จะดีที่สุด เมื่อทำการทดสอบในผู้ป่วยบาดเจ็บไขสันหลังที่มีความสามารถดี

Salinee Naewla. 2012. **Correlation between walking speed and function capacity as measured using the 6-minute walk test (6MinWT) in independent ambulatory patients with spinal cord injury (SCI).** Master of Science Thesis in Physical Therapy, Graduate School, Khon Kaen University.

**Thesis Advisor**s: Assoc. Prof. Dr. Sugalya Amatachaya,

Asst. Prof. Dr. Preeda Arayawichanon,

## ABSTRACT

The 6-minute walk test (6MinWT) reflects functional ability for daily activities. Results of the test can be converted to a walking speed but it needs considerable time and area to conduct the test. In contrast, the 10-meter walk test (10MWT) can easily be measured and requires less time to complete. The findings reflect motor function and overall quality of gait. However, the test can be reported in various forms including preferred walking speed, maximum walking speed, difference of walking speed and percentage of walking speed. Thus, this study aimed primary to evaluate the correlation between the 6MinWT and outcome derived from the 10MWT and secondary to evaluate the correlation between 2 tests in independent ambulatory patients with SCI who had different levels of walking ability. Seventy-four subjects were tested their functional abilities using the 10MWT and 6MinWT. The results demonstrated that the preferred walking speed of the 10MWT had the best correlation ($r = 0.91$, $p<0.01$) and best predictive ability for the 6MinWT ($R^2 = 0.82$). However, when analyzed the relationship in subjects with different levels of walking ability, the correlation was highest in subjects who could walk at a long distance without a walking device. The findings suggest that preferred walking speed of the 10MWT could be used as an alternative test for the 6MinWT when time and area of assessments are limited. However, alternative ability would be optimum when using in SCI patients with good walking ability.

**Goodness Portion to the Present Thesis is Dedicated**

**to my Parents and Entire Teaching Staff**

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Salinee Naewla

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# CHAPTER I

# INTRODUCTION

## 1. Rationale and background

Spinal cord injury (SCI) is one of the most devastating conditions that a person can experience (Jaeger et al., 1989). Most of patients are males, age between 16-30 years, and more than half of them have an incomplete injury (Wyndaele & Wyndaele, 2006). Approximately 80% of these patients can regain ambulatory function (Tang et al., 1994; National Spinal Cord Injury Statistical Center, 2006). However, the quality and degrees of their ambulation are affected by age, medical conditions, spasticity, muscle weakness, and coactivation of muscle groups. Thus, ambulatory capacity of the patients are likely restricted to a certain location such as within the house, at only a short distance, or with the support of assistive devices (Brotherton et al., 2007).

Presently, there is a trend that patients with SCI have shorter length of stay in hospitals (Cardenas et al., 2004). National Spinal Cord Injury Statistical Center (2008) reported that average admission time of patients with SCI reduced from 25 days in 1974 to 15 days in 2005. Van Hedel et al (2008) reported that physical ability of these patients was greatest increased within 3 months after injury; only slight improvement was demonstrated afterward. Van den Berg-Emon et al (2008) also found a similar trend of improvement. These evidences suggested that the patients cannot achieve maximum levels of functioning prior to discharge. After discharge, their functional ability is also affected by the lack of mobility aids and home adaptations (van Hedel et al., 2008). In addition, many studies indicated that the patients encountered a high risk of complications and falls that affected levels of functioning and increased rate of rehospitalization (van den Berg-Emon, 2008). In Thailand, Amatachaya et al (2011) reported that subjects with SCI demonstrated small changes of functional ability in 6 months after discharge. The study also found that 91% of the subjects experienced at least 1 medical complication (range 1–5 times/subject) and 74% of the subjects sustained at least one fall during this follow up time (1–24 times/subject). Thus, these findings emphasize the important roles of community rehabilitation and the need of a practical screening tool in order for health care professionals to effectively monitor and early detect functional alteration of the patients with SCI after discharge.

In general, clinical assessments can be done in the forms of system assessments and functional assessments using qualitative or quantitative methods. The neurological system assessments encompass the methods established by the American Spinal Injury Association (ASIA) which are standardized examinations of the motor and sensory assessments (Maynard et al., 1997). Findings of these methods indicate system disorders which provide insight into treatment plan. However, thorough system assessments take considerable time and the results may not correlate with functional ability. As a result, qualitative functional assessments are firstly applied in order to provide information for underlying systems that involve with the disorders (van Wieringen, 1996). However, these methods are rather subjective and depend largely on experience of the assessors. In addition, decisions about clinical relevant changes can be difficult when time intervals between visits are long or with changes in the assessors. Thus quantitative functional measures are more preferable because the tests are more objective and easier to be standardized. Results of the tests can also be compared among the testers and the test intervals (van Iersel et al., 2008).

In the field of SCI research, there are many functional tests have been advocated to assess ambulatory ability of the patients such as the Walking Index for Spinal Cord Injury II (WISCI II), Functional Independence Measure Locomotor (FIM-L) scores, 6-Minute Walk Test (6MinWT), and 10-Meter Walk Test (10MWT) (Jackson et al., 2008). The WISCI II and FIM-L scores categorize ambulatory ability of the patients using ordinal scales (Jackson et al., 2008; Finch et al., 2002). Thus the tests have been criticized for their sensitivity and responsiveness compared to timed walking tests (van Hedel et al., 2006; 2008)

The 6MinWT and 10MWT are timed-based assessments that can be converted into walking speed. The 6MinWT measures distance walk in 6 minutes whereas the 10MWT investigates the time required to over a walk 10 meter walkway (van Hedel et al., 2008). Both tools are valid, reliable and sensitive to address ambulatory capacity of patients with SCI (van Hedel et al., 2005). Results of the 6MinWT indicate the global and integrated responses of pulmonary, cardiovascular and muscular systems; and reflect functional status for daily activities (ATS statement, 2002). However, using the 6MinWT encounters problems of time consuming and standardization of the test due to setting and method of instruction (van Hedel et al.,

2008). The 10MWT is a quick and easy administered tool that is considered as a surrogate for the overall quality of gait and motor function (Dobkin, 2006). Thus, an evidence on correlation between the 6MinWT and 10MWT would warrant the use of the 10MWT as an alternative that to the 6MinWT. However, the 10MWT can be executed using preferred or maximum walking speed, and results of the test can be reported in various forms (Lusardi et al., 2003). Preferred or usual walking speed is valuable to inform health status and ambulatory ability of individuals (Purser et al., 2005; Cesari et al., 2005). However, van Hedel et al (2007) that preferred walking speed might only partially reflect the potential to participate in a community. The ability to voluntarily increase walking speed may better reflect the remaining capacity for a community challenge. In addition, percentages of preferred and maximum walking speed may clearly indicate and quantify how well the patients can modify their walking pattern to varying demands during daily life (van Hedel et al., 2007).

Previously, there were studies that evaluated the correlation between the 6MinWT and 10MWT (van Hedel et al., 2005). Van Hedel et al (2007) assessed the correlation using preferred and maximum walking speed of the 10MWT in 18 subjects. Thus, the results may not ensure the use of the 6MinWT. Van Hedel et al (2005) reported that preferred and maximum walking speed of the 10MWT had correlation with the 6MinWT in subjects with SCI who had good and poor walking ability. However, the study applied criteria of the WISCI II scores to classify levels of walking ability of the subjects. The WISCI II scores categorize ability of the subjects according to device use and assistance requirement over a 10-meter walkway which may not truly reflect ability in a real environment of the patient (Ditunno et al., 2005)

## 2. Objectives of the study

**Primary objectives:**

1. To quantify the relationship between the 6MinWT and outcomes derived from the 10MWT (including preferred speed, maximum speed, difference of walking speed, or percentage of walking speed) in patients with SCI.

2. To determine a predictive equation for the 6MinWT using outcomes derived from the 10MWT

**Secondary objective:**

To evaluate the correlation between the 6MinWT and outcomes derived from the 10MWT in patients with SCI who had different levels of walking ability

## 3. Research question

1. Which outcomes derived from the 10MWT had best correlation with the 6MinWT?
2. Could outcomes derived from the 10MWT use to predict data of the 6MinWT?
3. Could outcomes derived from the 10MWT be used as an alternative test to the 6MinWT in patients with SCI who had different levels of walking ability?

## 4. Hypothesis of the study

Percentage of preferred and maximum walking speed indicated relative remaining capacity. Thus the researcher hypothesized that it would have best correlation with the 6MinWT. However, outcomes derived from the 10MWT could be used as an alternative test to the 6MinWT only in patients with good walking ability.

## 5. Scope of the study

The study recruited patients with SCI who were able to walk with and without any devices for at least 6 minutes in order to be able to complete the tests in the study.

Determinant of terminologies

- FIM-L = Functional Independence Measure Locomotor scores

  FIM-L 5 refers to patients who are able to walk only short distances (a minimum of 17 m [50 ft]) independently with or without a device.

  FIM-L 6 refers to patients who are able to walks a minimum of 50 m (150 ft) with the requirement of assistive devices such as a brace (orthosis) or prosthesis, special adaptive shoes, cane, crutches, or walker.

FIM-L 7 refers to patients who can walk a minimum of 50 m (150 ft) without assistive devices (Functional Independence Measure: Guide for the Uniform Data Set for Medical Rehabilitation (Adult FIM), 1993).

- Difference of walking speed represents the difference of maximum and preferred walking speed

  [maximum walking speed - preferred walking speed (m/s)]

- Percentages of walking speed is a ratio of preferred and maximum walking speed. It can be calculated using the formula $\left(\frac{\text{Preferred walking speed}}{\text{Maximum walking speed}} \times 100\right)(\%)$

## 6. Benefits of the study

The 10MWT is an objective/practical test to document walking ability in patients with SCI. However, results of the tests can be documented using various forms. The 6MinWT indicates global endurance or functional capacity of individuals but it encounters problems of time and space consuming. Thus, results of the study would indicated the best outcome derived from the 10MWT to be used as an alternative test to the 6MinWT. Moreover, the predictive equation would help to determine outcome of the 6MinWT using data from the 10MWT when time and space limited.

## 7. Conceptual Framework

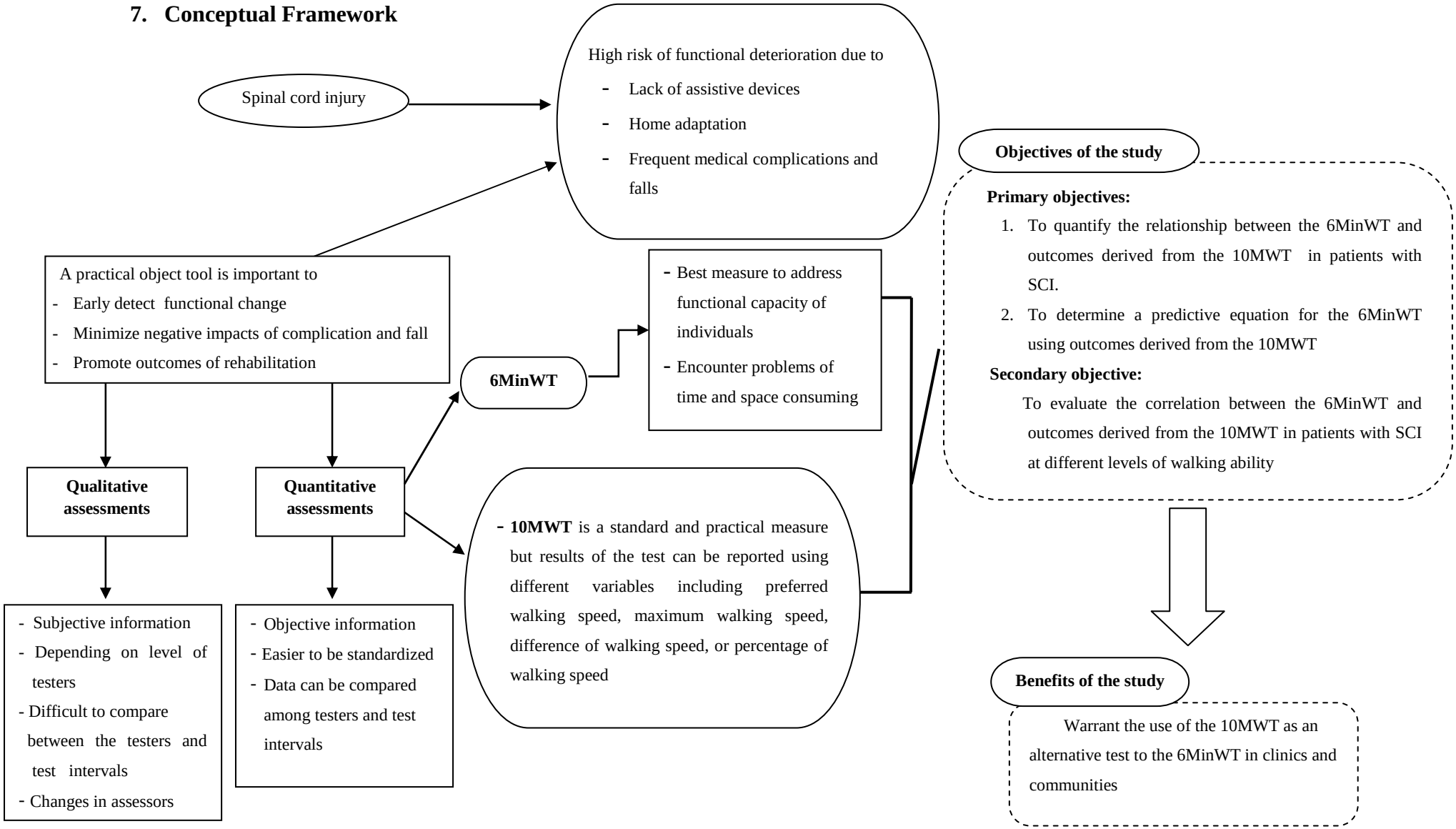



**Figure 1** Conceptual Framework of the study

# CHAPTER II
# LITERATURE REVIEW

This chapter reviews literatures relating to the study. The contents include overview of spinal cord injury (SCI), consequences of SCI, terminologies relating, severity of the lesion, factors affecting affecting ambulatory potential after SCI, and clinical ambulatory assessment in patient with SCI. Details of each topic are as follows;

## 1. Spinal cord injury (SCI)

### 1.1 Definition causes and prevalence of spinal cord injury

The term ‘spinal cord injury (SCI)’ refers to any damages or injuries to the neural elements within the spinal canal (spinal cord and cauda equina) that disrupt the ascending and/or descending nerve impulses.

In the United State, there are approximately 12,000 new cases with SCI each year (National Spinal Cord Injury Statistical Center., 2008). Barbeau et al (1999) reported that the number of patients with SCI has steadily increased from 45.9% in the 1970s to 55.3% in 2005 Most of them are males (80%), age between 16 and 30 years at the time of injury (Somers, 2001; National Spinal Cord Injury Statistical Center., 2008).

## 2. Consequences of spinal cord injury

Spinal cord injury induces the loss or impairments of voluntary movement control, sensation, and autonomic functions below the level of injury (Widerstom-Noga et al., 1999; Bloemen-Vrecken et al., 2005). SCI is mostly occurred due to a direct or indirect trauma to the vertebral column such as motor vehicle crashes (42%), falls (27.1%), acts of violence (15.3%), and sporting activities (7.4%) (figure 2) (National Spinal Cord Injury Statistical Center., 2008). In addition, SCI can be occurred as a result of nontraumatic causes such as transverse myelitis, vascular occlusion, compression by infective process or haemorrhage (New, Epi, 2005; McKinley et al., 1998). The changes are lifelong and affect every aspect of a person's

life. As a consequence, persons with SCI are at risk of developing a hypoactive lifestyle more than the able-bodied population with possible detrimental effects on physical fitness, social participation, and quality of the life of patients (Manns, Chad, 1999; van den Berg-Emons et al., 2004). The reduction of physical fitness affects functional activity (Janssen et al., 2002), functional status (Noreau et al., 1993), and community participation that increase risk of developing secondary health problems later in life (Noreau, Shephard, 1992).

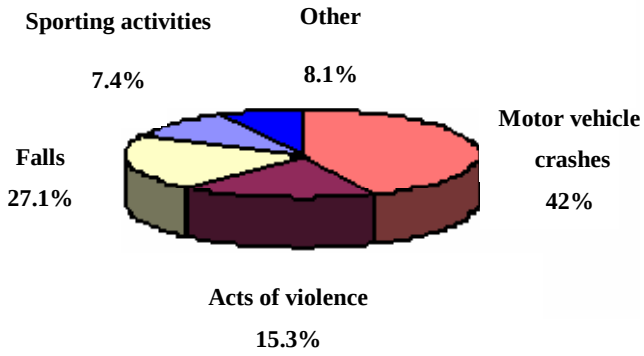



**Figure 2** Etiology of SCI since 2005
(National Spinal Cord Injury Statistical Center., 2008)

Although many studies reported that ability of patients with SCI improves after participation in a rehabilitation program (Steins et al., 2002; van den Berg-Emons et al., 2004; Heinemann et al., 1989, Middleton et al., 1998), the improvement does not continue after discharge (van den Berg-Emons et al., 2004). The decrement of functional ability after discharge due often to the lack of mobility aids and home adaptations (van den Berg-Emon et al., 2004). In addition, persons with SCI are at a greater risk of medical complications that increase rate of rehospitalization throughout their lifetime (Cardenas et al., 2004).

In Thailand, Amatachaya et al (2011) reported that 91% of persons with SCI experienced medical complications (range 1–5 times/subject) and 74% sustained at least 1 fall during 6 months after discharge (1–24 times/subject). A high incidence of complications is associated with a lower level of health-related aspects, such as physical capacity, activities and functional outcomes (Bloemen-Vrencken et al.,

2005;). Complications may disturb the start of active rehabilitation, can form a disappointing set-back during rehabilitation, frequently lead to re-hospitalization, and cause mortality following SCI (Cardenas et al., 2004; van den Bossche et al., 2005; Meyers et al., 2000; Devivo et al., 1999). Therefore, a practical monitoring measure is important, on the one hand, to early detect clinical changes of the possible positive treatment effects, and on the other hand, to minimize harmful effects of treatments or secondary complications before conditions of the patients becomes seriously affected (van Hedel et al., 2008).

**3. Terminologies relating to**

The International Standards for Neurological and Functional Classification of Spinal Cord Injury (ISNCSCI) is a widely accepted system describing the level and extent of injury based on a systematic motor and sensory examination of neurological functions (American Spinal Injury Association., 2000). The following terminologies have been developed around the classification of SCI:

**Paraplegia**

This term refers to the impairments or less of motor and/or sensory function in the thoracic, lumbar or sacral segments of the spinal cord and neural element within the spinal canal (below the T-1 spinal level). Typically these injuries result in some degrees of weakness and sensory changes in the trunk, and lower extremities. The term is also used to infer to cauda equina and conus medullaris injuries, but not to lumbosacral plexus or injury to peripheral nerves outside the neural canal (Fride, Guralnik, 1997).

**Tetraplegia**

This term refers to the impairments or less of motor and/or sensory functions in the cervical segments of the spinal cord and neural elements within the spinal canal a spinal cord injury (at or above the T-1 spinal level). Typically, tetraplegia results in weakness or sensory changes upper extremities, trunk, lower extremities and pelvic organs. It does not include brachial plexus lesions or injury to peripheral nerve outside the neural canal (Fride, Guralnik, 1997).

**Complete spinal cord injury**

This term is used when there is an absence of sensory and motor function in the lowest sacral segments (Waters et al., 1991).

**Incomplete spinal cord injury**

The incomplete SCI (iSCI) is use to describe partial preservation of sensory or motor functions below the neurological level include the lowest sacral segments. Sacral sensation includes sensation at the anal mucocutaneous junction as well as deep anal sensation. The test of motor function is the presence of voluntary contraction of the external anal sphincter upon digital examination (Maynard et al., 1997).

## 4. Severity of the Lesion

American Spinal Injury Association (ASIA) Impairment Scale (AIS) has proposed standard criteria to the neurological severity of a SCI classify using the following categories:

**A - Complete:** No sensory or motor function is preserved in the sacral segments S4-S5

**B - Incomplete:** Sensory, but not motor, function is preserved below the neurologic level and extends through the sacral segments S4-S5

**C - Incomplete:** Motor function is preserved below the neurologic level, and more than half of key muscles (Appendix D) below the neurologic level have muscle grade less than 3

**D - Incomplete:** Motor function is preserved below the neurologic level, and more than half of key muscles (Appendix D) below the neurologic level have muscle grade greater than or equal to 3

**E - Normal:** Sensory and motor functions are normal

Complete SCI constitutes the most severe form, with only 2% to 3% of such patients recovering to AIS class D at 1 year after injury (Marino et al., 1999). On the contrary, patients with iSCI have various prognosis with large differences observed

between individuals depending upon residual motor and sensory functions. These differences are particularly evident for patients with motor complete but sensory incomplete (AIS B), which represents a small but significant percentage of the total SCI population (10.3% of SCI cases a year). Such patients have some sensory preservation through the sacral segments but lack any volitional motor function below the zone of injury, thus have worse prognosis than those with some motor ability (Go et al., 1995). For persons who with a motor-incomplete injury, 28% of the injuries were classified as “motor functional” (AIS D) and 11.6% as “motor nonfunctional” (AIS C) at the time of inpatient discharge (National Spinal Cord Injury Statistical Center, 2006).

## 5. Factors affecting ambulatory potential after spinal cord injury

Literatures relating to neurological recovery after a traumatic SCI emphasized that functional recovery is mostly occurred within the first or second year post-injury (Marino et al., 1999; Water et al., 1994). The highest motor recovery occurs within the first 6 months post-injury with the greatest rate of change occurring within the first 3 months (Water et al., 1995; van Hedel et al., 2006). Tang et al (1994) indicated that approximately one-third of all SCI patients can become functional walkers within 1 year after injury (Tang et al., 1994). However, the quality and efficiency of walking capacity can be adversely affected by a many of factors such as age, body weight, spasticity, pain, motor and sensory scores, duration of rehabilitation and balance (Visintin, Barbeau., 1989; Dietz et al., 1995; Scivoletto et al., 2008). Details of each factor are follows;

### Age

Burns et al (1997) found that walking recovery in patients with SCI depends on age, where the recovery is more possible in young patients; similar results were reported by several studies (Burns et al., 1997; Penrod et al., 1990; Scivoletto et al., 2003).

### Spasticity

The spasticity could benefit in patients with a lower limb strength deficit because it might increase the supportive function. However, more recent studies have demonstrated the negative correlation between spasticity and walking ability in

patients with neurological lesions of various etiologies (e.g., stroke and cerebral palsy) (An-Lun et al., 2003; Lebiedowska et al., 2004). Elevated muscle tone impairs the smoothness of movements and, therefore impediment of walking ability. Furthermore, the inability to perform fluid movements and the need to overcome spasticity (which also tends to increase with an increase in physical work) causes an increase in effort and energy consumption during walking (Scivoletto et al., 2008).

**Motor and sensory scores**

The ratio of patients with tetraplegia to those with paraplegia is reported as 54:46 (Stover, 1986). Lesions below T10 associated with a higher residual functional levels and a greater ability of walking. Associated injuries, surgical procedure, and medical conditions also affect ambulatory potential. Even if a patient has residual motor function, and the presence of contractures, pain or uncontrolled spasticity (Subbarao, 1991).

**Balance**

The correlation between balance and walking has already been studied in healthy subjects and in patients with neurological disorder. In healthy subjects, loss of balance worsens walking features and exposes people to the risk of falls (Bogle, Newton., 1996). Leroux et al (2006) studied the postural adaptation of SCI patients during walking and concluded that this adaptation could lead to a loss of balance or a fall. The alteration of balance control restricted ambulatory ability the patients to a certain location such as within the houses, at only a short distance, and require the support of an assistive device (Brotherton et al., 2007; Lam et al., 2007).

## 6. Clinical ambulatory assessments in patients with spinal cord injury

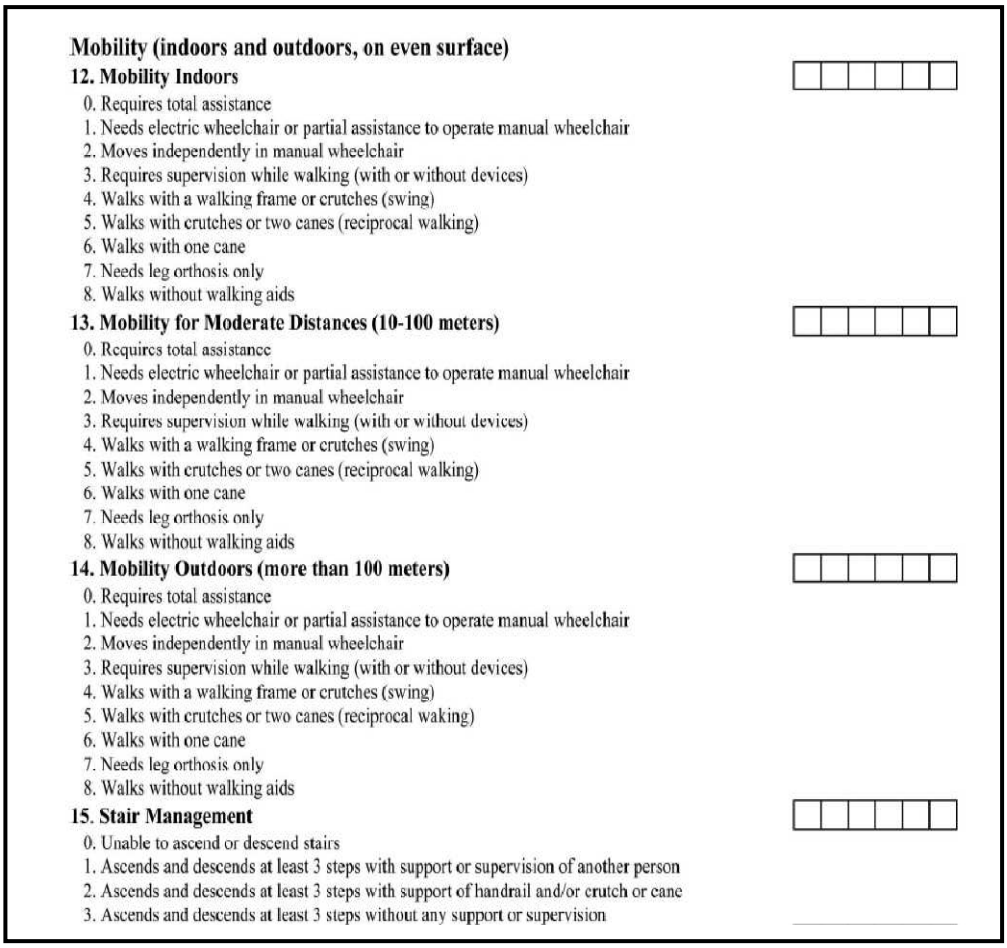
Efficient and accurate measurements of walking ability are necessary for both clinical practice and research trials. In order to evaluate change and predict outcomes (Cole, 1994). Clinical assessments can be executed using qualitative or quantitative assessments in which the quantitative measures are more preferable (van Iersel et al., 2008). The quantitative assessments can be classified into categorical and timed-base ambulatory assessments (Lam, 2008). Details of assessment are as follows:

### 6.1 Categorical ambulatory assessments

Categorical ambulatory assessments involve the use of ordinal scales to discriminate levels of walking ability. The tools offer advantage to capture both walkers and non-walkers, and the transition between ambulatory status (Lam, 2008). The categorical ambulatory assessments that are likely used in patients with SCI include the Walking Index for Spinal Cord Independence Measure (SCIM), Independence Measure-Locomotor (FIM-L), Spinal Cord Injury (WISCI), and functional details of each measurement are as follows;

#### 6.1.1 The Spinal Cord Independence Measure (SCIM)

Catz et al (1997) has developed the SCIM specifically for patients with SCI to evaluate performance in a daily life and functional ability of the patients (Catz et al., 2001). Since then, there are 3 versions of SCIM including SCIM I, SCIM II, and SCIM III (Anderson et al., 2008). The tool consists of 3 subscales, including: self care, respiration and sphincter management and mobility. The mobility subscale consists of two subscales which are ‘room and toilet’ and ‘indoors and outdoors, on even surface’ (figure 3). The scores of task is weighted according to the clinical relevance with respect to the overall activity of individuals with SCI. Patients with higher scores indicate more independence (Ackerman et al., 2010).



**Mobility (indoors and outdoors, on even surface)**

**12. Mobility Indoors**

0. Requires total assistance
1. Needs electric wheelchair or partial assistance to operate manual wheelchair
2. Moves independently in manual wheelchair
3. Requires supervision while walking (with or without devices)
4. Walks with a walking frame or crutches (swing)
5. Walks with crutches or two canes (reciprocal walking)
6. Walks with one cane
7. Needs leg orthosis only
8. Walks without walking aids

**13. Mobility for Moderate Distances (10-100 meters)**

0. Requires total assistance
1. Needs electric wheelchair or partial assistance to operate manual wheelchair
2. Moves independently in manual wheelchair
3. Requires supervision while walking (with or without devices)
4. Walks with a walking frame or crutches (swing)
5. Walks with crutches or two canes (reciprocal walking)
6. Walks with one cane
7. Needs leg orthosis only
8. Walks without walking aids

**14. Mobility Outdoors (more than 100 meters)**

0. Requires total assistance
1. Needs electric wheelchair or partial assistance to operate manual wheelchair
2. Moves independently in manual wheelchair
3. Requires supervision while walking (with or without devices)
4. Walks with a walking frame or crutches (swing)
5. Walks with crutches or two canes (reciprocal waking)
6. Walks with one cane
7. Needs leg orthosis only
8. Walks without walking aids

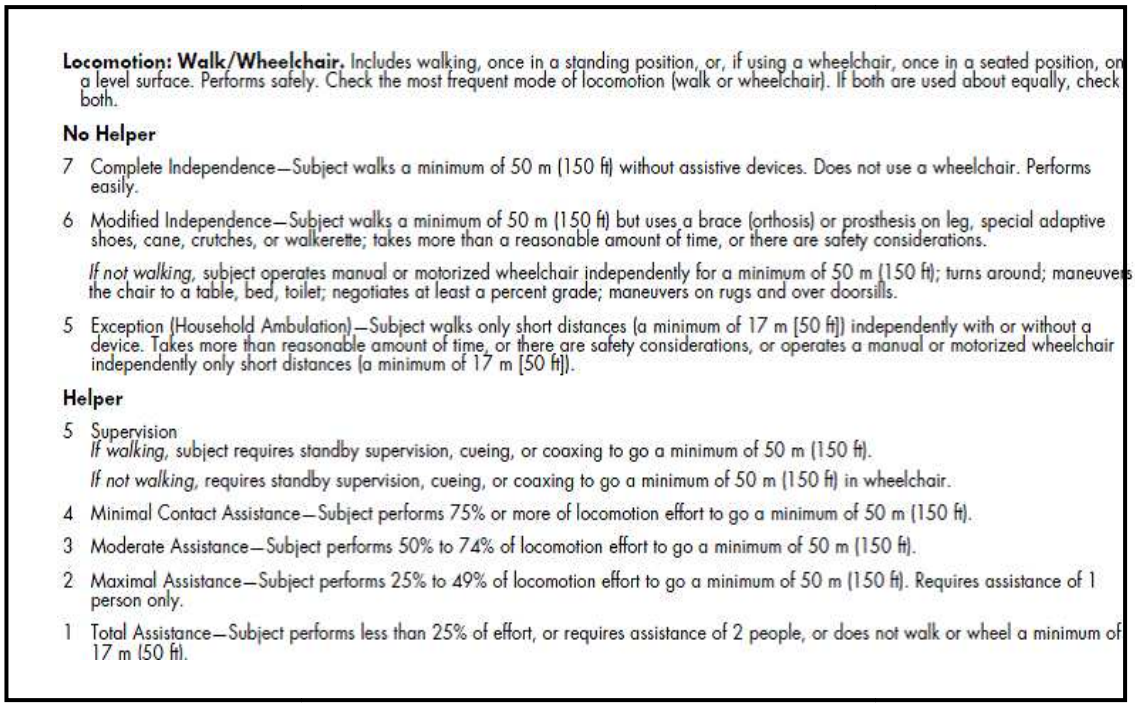
**15. Stair Management**

0. Unable to ascend or descend stairs
1. Ascends and descends at least 3 steps with support or supervision of another person
2. Ascends and descends at least 3 steps with support of handrail and/or crutch or cane
3. Ascends and descends at least 3 steps without any support or supervision

**Figure 3** The Spinal Cord Independence Measure III (SCIM-III) (Itzkovic et al., 2007)

### 6.1.2 The Functional Independence Measure-Locomotor (FIM-L)

The FIM locomotor item (FIM-L) has been used in stroke and SCI populations (Dokin et al., 2006; Yagura et al., 2006; Behrman, Harkema., 2000). The test has two distinct subscales, which allow individuals with widely varying ability to be included in one. Scoring is dependent on walking aids or assistance used to cover a distance over level ground up to 150 feet. A score is assigned on a 7-point scale depending on the assistance used to ambulate: 1 is equal to total assistance, 2 maximum assistance with 1 person, 3 is moderate assistance, 4 minimal assistance with hands on contact, 5 supervision, 6 modified independence (with equipment), and 7 independent without equipment (figure 4) (Jackson et al., 2006). Results of the test has been correlated with the WISCI-II ($\rho$ = 0.89 - 0.92 and 6MWT ($\rho$ = 0.62 - 0.78) (Ditunno, 2007).



**Locomotion: Walk/Wheelchair.** Includes walking, once in a standing position, or, if using a wheelchair, once in a seated position, on a level surface. Performs safely. Check the most frequent mode of locomotion (walk or wheelchair). If both are used about equally, check both.

**No Helper**

7 Complete Independence—Subject walks a minimum of 50 m (150 ft) without assistive devices. Does not use a wheelchair. Performs easily.

6 Modified Independence—Subject walks a minimum of 50 m (150 ft) but uses a brace (orthosis) or prosthesis on leg, special adaptive shoes, cane, crutches, or walkerette; takes more than a reasonable amount of time, or there are safety considerations.

*If not walking,* subject operates manual or motorized wheelchair independently for a minimum of 50 m (150 ft); turns around; maneuvers the chair to a table, bed, toilet; negotiates at least a percent grade; maneuvers on rugs and over doorsills.

5 Exception (Household Ambulation)—Subject walks only short distances (a minimum of 17 m [50 ft]) independently with or without a device. Takes more than reasonable amount of time, or there are safety considerations, or operates a manual or motorized wheelchair independently only short distances (a minimum of 17 m [50 ft]).

**Helper**

5 Supervision
*If walking,* subject requires standby supervision, cueing, or coaxing to go a minimum of 50 m (150 ft).

*If not walking,* requires standby supervision, cueing, or coaxing to go a minimum of 50 m (150 ft) in wheelchair.

4 Minimal Contact Assistance—Subject performs 75% or more of locomotion effort to go a minimum of 50 m (150 ft).

3 Moderate Assistance—Subject performs 50% to 74% of locomotion effort to go a minimum of 50 m (150 ft).

2 Maximal Assistance—Subject performs 25% to 49% of locomotion effort to go a minimum of 50 m (150 ft). Requires assistance of 1 person only.

1 Total Assistance—Subject performs less than 25% of effort, or requires assistance of 2 people, or does not walk or wheel a minimum of 17 m (50 ft).

**Figure 4** The Functional Independence Measure-Locomotor (FIM-L) (Functional Independence Measure: Guide for the Uniform Data Set for Medical Rehabilitation (Adult FIM), 1993)

### 6.1.3 The Waking Index for Spinal Cord Injury (WISCI)

The WISCI was proposed by Ditunno et al (2000) to measure walking in patients with SCI. The ranking scores are ordered along the dimension of impairments from the level of the most severe impairment (0) to the least severe impairment (20) where the lower the number indicates the higher impairment (figure 5). The scores are dependent on the requirement of devices, braces, and physical assistance used to complete the 10-meter walking distance (Ditunno et al., 2001). The simple construct, minimal equipment use, minor time requirements, and ease of understanding of the WISCI II make the test being a promising outcome measure (Ditunno et al., 2000). Results of the test showed good correlations with other walking tests such as the 6MinWT (Spearman's correlation coefficient $\rho = 0.60$), the 10MWT ($\rho = -0.68$) and the TUGT ($\rho = -0.76$) (van Hedel et al., 2005). However, the WISCI II does not account for gait quality and has less sensitivity to the changes of gait in chronic subjects than that of the 10MWT, 6MinWT, and TUGT (Wirz et al., 2005). In addition, the WISCI levels are based on a 10 m distance (33ft), which is closer to

household ambulation (50ft) than to community ambulation, which is 150 ft (Morganti et al., 2005). The scale does not take into account the two additional extremely important parameters which are walking speed and energy consumption.

**Table 2.** Walking Index for Spinal Cord Injury, Version II

Name_____ Date_____

Check descriptors that apply to current walking performance, then assign the highest level of walking performance. (In scoring a level, one should choose the level at which the patient is safe as judged by the therapist. If devices other than stated in the standard definitions are used, they should be documented as descriptors. If there is a discrepancy between two observers, the higher level should be chosen.)

**Descriptors:** (circle or check)

Gait: reciprocal _____; swing through _____

| Devices | Braces | Assistance |
|---|---|---|
| //bars < 10 meters | Long Leg Braces—Uses 2___ Uses 1___ | Max Assist x 2 people |
| //bars 10 meters | Short Leg Braces—Uses 2___ Uses 1___ | Min/Mod assist x 2 people |
| Walker— | Locked at knee ____ | Min/mod assist x 1 person |
| Standard | Unlocked at knee ____ | |
| Rolling | | |
| Platform | | |
| Crutches— | Other: _____ | |
| Uses 2 | | |
| Uses 1 | | |
| Canes—Quad | | |
| Uses 2 | | |
| Uses 1 | | |
| No devices | No braces | No assistance |

**WISCI Levels**

| Level | Devices | Braces | Assistance | Distance |
|---|---|---|---|---|
| 0 | | | | Unable |
| 1 | Parallel bars | Braces | 2 persons | Less than 10 meters |
| 2 | Parallel bars | Braces | 2 persons | 10 meters |
| 3 | Parallel bars | Braces | 1 person | 10 meters |
| 4 | Parallel bars | No braces | 1 person | 10 meters |
| 5 | Parallel bars | Braces | No assistance | 10 meters |
| 6 | Walker | Braces | 1 person | 10 meters |
| 7 | Two crutches | Braces | 1 person | 10 meters |
| 8 | Walker | No braces | 1 person | 10 meters |
| 9 | Walker | Braces | No assistance | 10 meters |
| 10 | One cane/crutch | Braces | 1 person | 10 meters |
| 11 | Two crutches | No braces | 1 person | 10 meters |
| 12 | Two crutches | Braces | No assistance | 10 meters |
| 13 | Walker | No braces | No assistance | 10 meters |
| 14 | One cane/crutch | No braces | 1 person | 10 meters |
| 15 | One cane/crutch | Braces | No assistance | 10 meters |
| 16 | Two crutches | No braces | No assistance | 10 meters |
| 17 | No devices | No braces | 1 person | 10 meters |
| 18 | No devices | Braces | No assistance | 10 meters |
| 19 | One cane/crutch | No braces | No assistance | 10 meters |
| 20 | No devices | No braces | No assistance | 10 meters |

Level assigned_____ Revised 3/19/2002

Reprinted from Ditunno PL. Walking Index for Spinal Cord Injury (WISCI II): scale revision. *Spinal Cord.* 2001;39:654–656. Copyright © 2001.

**Figure 5** The Walking Index for Spinal Cord Injury II (Ditunno et al., 2001)

### 6.2 Timed base ambulatory assessments

Since categorical ambulatory assessments have been criticized for their sensitivity and responsiveness, the time-based assessment are encouraged to measure ability of patients. Such tools include Timed Up and Go Test (TUGT), 6-Minute Walk

Test (6MinWT), 10-Meter walk test (10MWT). Details of each test are as follows;

### 6.2.1 The Timed Up and Go Test (TUGT)

The TUGT is mainly applied to evaluate balance ability and functional mobility in community-dwelling and frail older adults (aged 70–84 years). It contains basic activities required in a daily life such as standing up from a chair, walking forward, turning around, walking back to the chair, and sitting down (figure 6) (Podsiadlo, Richardson., 1991). Thus, the advantage of the TUGT is that it embraces a more complex task rather than 'just' walking, which may better reflect daily activities (van Hedel et al., 2008). The total time taken to complete the TUGT is normally used to predict the risk of falling (Whitney et al., 2004).

In patients with SCI, the TUGT has an excellent intra- and interrater reliability ($r > 0.97$). The test also shows strong correlation with the WISCI II, 6MinWT and 10MWT which warrant concurrent validity of the tool ($\rho = -0.76$ for WISCI II, $\rho = -0.88$ for 6MinWT, and $r = 0.89$ for 10MWT) (van Hedel et al., 2005). In patients with a WISCI II score of 0 to 10, the correlation coefficients of the TUGT and the 10MWT was 0.92 and the 6MinWT was 0.70. These values were 0.79 and 0.78 respectively in patients with the WISCI II scores of 11 to 20 (van Hedel et al., 2005).

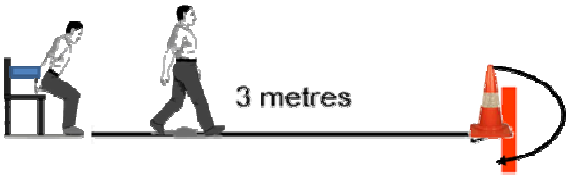



**Figure 6** The Timed Up and Go Test (TUGT)

### 6.2.2 The 6-minute walk test (6MinWT)

The test was firstly developed by Balke in the 1960s (figure 7) and initially tested the distance walk in 12 minutes of patients with respiratory impairments (Olsson et al., 2005). Later, Lipkin et al (1986) introduce the 6MinWT as a functional exercise test that is generally well tolerated by patients. The results highly correlated with those of the 12MinWT (Butland et al., 1982). Several studies confirmed that the 6MinWT is a submaximal exercise test that mimics daily activities

(Sparrow et al., 1994; Eng et al., 2002). Nowadays, the 6MinWT has been widely used to objectively indicate functional capacity and exercise intolerance of individuals. Results of the test related to the maximal symptom-limited oxygen consumption, and overall response of the systems involved, such as the cardiopulmonary, musculoskeletal, sensory, and neurologic systems (Zugck et al., 2000; Hamilton, Haennel, 2000; Opasisch et al., 2001; ATS statement, 2002; Woo et al., 1995; Smidt 1990). It reflects exercise tolerance required for the performance of daily activities, and predicts ability to walk in the community (van Loo et al., 2004). In the clinical setting, the 6MinWT could be useful for rehabilitation practitioners as an integrated measure of mobility function. However, the test has been criticized for its application in terms of time consuming and standardization of the test due to setting of the test and method of instruction (van Hedel et al., 2008). Several studies suggested factors of affecting the 6MinWT including;

- Learning effects

Wu et al (2003) report learning effects on outcomes of the 6MinWT. The study was designed to determine whether the learning effect persist after 2 months in fifty healthy subject who were unfamiliar with the 6MinWT. Subjects completed 3 tests at baseline (walks 1-3) and 3 tests at 2 months follow-up (walks 4-6). The results demonstrated that the distance walked significantly increased between walks 1 and 3, 4 and 6. However, there no differences in distance walked between walks 3 and 4, which were conducted 2 months apart. The results confirmed carry-over effects of repeated the 6MinWT tests.

- Encouragement

Guyatt et al (1984) reported that encouragement significantly increased the distance walked of the 6MinWT. Thus, authors suggested that the test should be conducted using standardized phrases such as You’re doing well’ or ‘keep up the good work’, ‘you are doing well, you have only 1 minute to go’.

When applied in patients with SCI, the 6MinWT demonstrated good validity and reliability (Gibbon et al., 2001). It has high correlation coefficients for inter-rater ($r > 0.97$) and intra-rater reliability ($r > 0.98$), and correlated well with the 10MWT and TUGT ($r > 0.88$) (van Hedel et al., 2005) and has good responsiveness in patients with SCI (van Hedel et al., 2008).

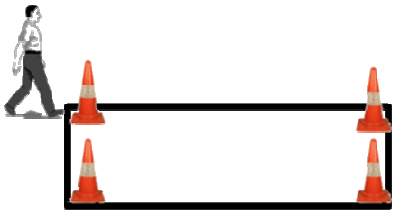


**Figure 7** The 6-minute walk test (6MinWT)

### 6.2.3 The 10-Meter Walk Test (10MWT)

The 10MWT is a quick, inexpensive and easy measurement when using in clinical settings (Guralink et al., 2000; Hardy et al., 2008). The test is normally performed on a flat, smooth, non slippery surface without any disturbing factors (van Hedel et al., 2008). Subjects walk along a straight line in 10 meters with a ‘‘flying start’’ to minimize acceleration and deceleration effects. The speed was mostly recorded during 10, 6 and 4 m distances, and reported in 37, 20 and 11 studies respectively (Graham et al., 2008). Commonly, acceleration and deceleration periods of up to 3 meters is provided and subjects are permitted to use their preferred assistive devices (figure 8) (Finch et al., 2002). The measurement requires 2 to 3 minutes to complete in the outpatient clinical setting (Studenski et al., 2003). Result of the test represent walking speed of individuals that is a surrogate for the overall quality of gait and motor function (Jackson et al., 2008). Results of the test correlate with other parameters such as balance control, use of walking aids and number of fall, and reflect activities of daily living and future health status (Kollen et al., 2006)

It has been used for gait assessment in stroke, Parkinson’s disease, and other neurological movement disorders. More recently the test has been successfully utilized in the SCI population (Jackson et al., 2008). In patients with SCI, the 10MWT is likely used to assess at a preferred walking speed (Kollen et al., 2006; van Hedel et al., 2005; 2006). However, preferred walking speed may partially reflect the potential to participate in the community. The ability to increase walking speed toward the maximum capacity may give better insight into ability to response to the community challenges (Kollen et al., 2006; van Hedel et al, 2007). This ability can be measured in terms of percentage of preferred divided by maximum walking speed

or the differences of maximum and preferred walking speed (van Hedel et al., 2007). Van Hedel et al (2007) suggested that the percentage of preferred divided by maximum walking speed indicates the remaining capacity that the patient has to increase toward the maximum walking speed. This measure may imply and quantify how well the walking pattern can adapt to varying demands during daily life.

The concurrent validity of the 10MWT has been tested with the 6MinWT ($\rho = 0.95$), TUGT ($\rho = 0.89$) and WISCI II ($\rho = - 0.68$). Compared to the TUGT and 6MinWT, the 10MWT showed better inter- and intra-rater reliability in SCI (van Hedel et al., 2005). The correlation coefficient for inter-rater reliability were $r = 0 .974$, $p < 0.001$ and $r = 0.983$, $p < 0.001$ for intra-rater reliability (van Hedel et al., 2005).

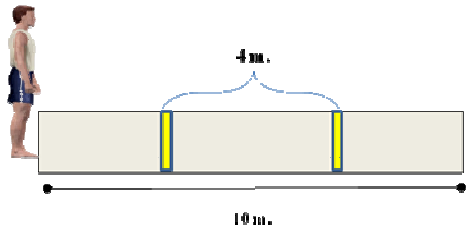



**Figure 8** The 10-Meter Walk Test (10MWT) (Finch et al., 2002)

The 6MinWT is a robust test for functional capacity but it encounters problems of time and area consuming. The 10MWT is a practical tool but can be reported using different forms. Therefore, an investigation on the correlation between the 6MinWT and 10MWT would direct an effective/ alternative method to address functional changes in clinics or communities.

# CHAPTER III
# METHODOLOGY

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

## 1. Study Design and Setting

This study was cross-sectional by conducted in independent ambulatory patients with SCI from hospitals and communities in the Northeast areas of Thailand.

## 2. Sample sizes

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

$$n = \left[\frac{Z_\alpha + Z_\beta}{Z_{(r)}}\right]^2 + 3$$

n = sample size

α, β = α error and β errror

r = level of correlation

$$Z_{(r)} = \frac{1}{2}\ln\left[\frac{1+r}{1-r}\right]$$

The study used r = 0.8 that referred to excellent correlation. The study set levels of significant level at 0.05 and power of test at 0.90; thus

$$Z_{(r)} = \frac{1}{2}\ln\left[\frac{1+0.8}{1-0.8}\right]$$

$$Z_{(r)} = 1.0986$$

$$n = \left[\frac{1.96+1.28}{1.0986}\right]^2 + 3$$

$$= 11.70 \text{ or } 12 \text{ subjects}$$

However, patients with SCI are likely to have heterogeneous individual characteristics. Thus, 12 subjects were too small to warrant findings of the study. In order to minimize the effects, the study considered number of sample size from hospital record that would be possible to recruit in a year that was 70 subjects.

## 3. Subjects

The study recruited ambulatory patient with SCI from either traumatic or non-traumatic causes [ASIA impairment scale (AIS) C or D]. The eligible subjects needed to have at least 18 years of age, and were able to walk with or without any walking devices (FIM-L scores = 5 – 7). Patients were excluded from the study if they presented signs and symptoms that might affect participation in the study such as pain in the muscles or joints of the extremities with a pain scale more than 5 out of 10 on a visual analog scale, deformity of the spine and lower extremities, or medical complications that limited mobility. Subjects provided a written inform consent approved by the Khon Kaen University Ethics Committee for Human Research prior to participation in the study.

## 4. Experimental protocol

Subjects were interviewed and assessed their baseline demographics, SCI characteristics including causes, levels of injury, severity of SCI (AIS classes) and post-injury time, and baseline walking ability (FIM-L scores). Then, subjects were assessed their functional ability using the 10MWT and 6MinWT in a random order. Details of the tests are as follows;

### 4.1 The 10-meter Walk Test (10MWT)

The test measured walking speed both preferred and maximum walking speed of the subjects along a 10-meter walkway. The time required during the middle 4-meter of the walkway was recorded in order to minimize acceleration and deceleration effects (Graham et al., 2008; Finch et al., 2002). Prior to the test, the assessor explained the aim of the test to the subjects that ‘the goal of this test is to assess the time you need to walk 4 meters, please walk in a straight line without any break to the end point’ (van Hedel et al., 2008). Then, the subjects were instructed to walk at ‘a preferred or comfortable speed’ for the test of preferred walking speed and ‘as fast and safely as you can, but do not run’ for a maximum walking speed. Subjects needed to perform 3 trials for each speed; then the average time required for each speed was recorded.

**4.2 The 6-minute walk test (6MinWT)**

The test represents functional capacity of the subjects using the longest distance walk in 6 minutes (ATS Statement., 2002). The test was performed along a rectangular walkway in order to minimize effects of turning that attributed significant impact on distance walk after 6 minutes (Brooks et al., 2003; Enright, 2003). Prior to the test, the assessor explained objectives of the test to the subject that 'the goal of this test is to assess the distance you can cover during 6 minutes. I will inform you every minute about the time you have left. If you feel uncomfortable, you can stop at any time. If you want to take a rest, you can stop for a while and continue walking as soon as you feel better' (van Hedel et al., 2008). Every minute during the test, the assessor informed the time left and encouraged the subjects to continue in a good manner by using words 'You're doing well' or 'keep up the good work'. After 5 minutes, subjects were informed 'you are doing well, you have only 1 minute to go'. After 6 minutes, the total distance covered was recorded in meters. (van Hedel et al., 2008; ATS Statement., 2002).

**5. Outcome measures**

Outcomes of the study included;

5.1 The 6MinWT: Distance walk in 6 minutes (m)

5.2 Outcomes derived from the 10MWT including

- Preferred walking speed (m/s)
- Maximum walking speed (m/s)
- Difference of walking speed (Maximum walking speed-Preferred walking speed) (m/s)
- Percentage of walking speed $\left(\frac{\text{Preferred walking speed}}{\text{Maximum walking speed}} \times 100\right)$ (%)

**6. Instrumentations**

6.1 Stopwatch

6.2 Color tapes

6.3 A chair for subjects to take a rest during the tests

6.4 Four small cones to mark the turning points

## 7. Statistical analyses

Data analyses were executed using the SPSS for window program (version 17.0). Descriptive statistics were applied to explain baseline demographics, SCI characteristics and findings of the study. Findings in subjects with FIM-L 5, 6 and 7 were compared using the One-way Analysis of Variance (ANOVA). Then, the data of every pairwise were analyzed using the post-hoc (Sheffe) test. Correlation between the 2 tests was analyzed using Pearson product-moment correlation coefficient. Then, the simple linear regression analysis was applied to formulate a predictive equation for the 6MinWT using outcomes derived from the 10MWT ($y = ax + b$), where x is an independent variable (10MWT), y is a dependent variable (6MinWT), a represent slope of the graph, and b infers intercepting point with the y-axis (Chatburn et al., 2004). If the 6MinWT speed could be perfectly deduced from the 10MWT, a should be equal to 1 and $b = 0$. Then the linear regression equation ($y = ax + b$) would be 6MinWT speed = 10MWT speed (van Hede et al., 2007). Levels of significant differences were set at $p<0.01$.

# CHAPTER IV
# RESULTS

## 1. Subject characteristics

Seventy-four independent ambulatory patients with SCI participated in the study. Most subjects had a chronic stage of injury (64 subjects) and non-traumatic lesions (42 subjects). Their demographics and baseline characteristic are presented in table 1.

**Table 1:** Demographics and SCI characteristics of subjects

| **Variables** | **Findings (N = 74)** |
|---|---|
| Age (years)* | 49.24±12.06 (25-47) |
| Post-injury time (months)* | 42.19±36.99 (2-180) |
| Genders: males/females (n) | 55/19 |
| AIS classes: C/D (n) | 29/45 |
| Levels of injury: Tetraplegia /Paraplegia (n) | 25/49 |

* Data were presented using Mean±SD (range)

AIS: American Spinal Injury Association (ASIA) Impairment Scales

## 2. Functional ability and correlation between the 6MinWT and outcomes derived from the 10MWT

Table 2 presents data of the 6MinWT and outcomes derived from the 10MWT were demonstrated in table 2. The 6MinWT had excellent correlation with the preferred and maximum walking speed, but fair to poor correlation with the difference and percentages of walking speed (figure 9). Thus, the study formulated predictive equations for the 6MinWT only from the preferred and maximum walking speed, the results are as follows;

Preferred walking speed:

$$6MinWT\ speed = 0.70 \times 10MWT\ speed + 0.04;\ (R^2 = 0.82)$$

Maximum walking speed:

$$6MinWT\ speed = 0.57 \times 10MWT\ speed + 0.02;\ (R^2 = 0.78)$$

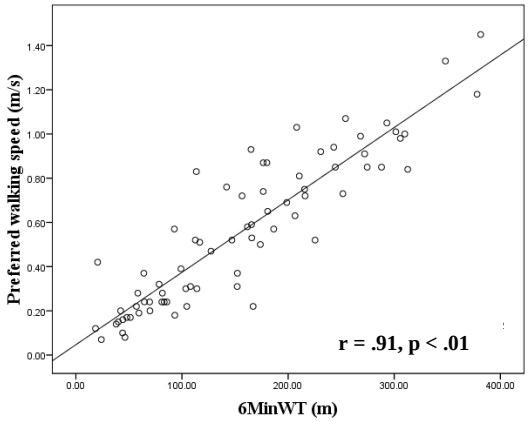
**Table 2:** Walking ability of the subjects (N = 74)

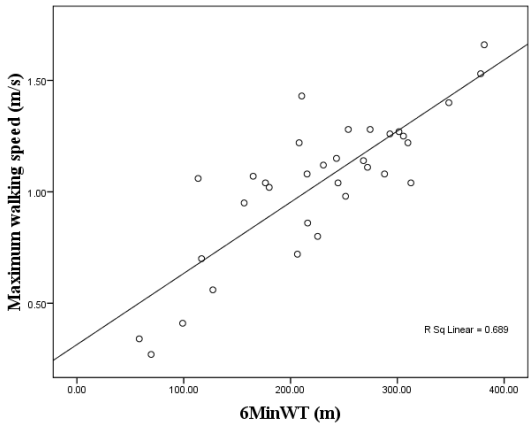
| Variables | Mean±SD | Range |
|---|---|---|
| Outcomes derived from the 10MWT | | |
| - Preferred walking speed (m/s) | 0.58 ± 0.34 | 0.70 - 1.45 |
| - Maximum walking speed (m/s) | 0.72 ± 0.41 | 0.90 - 1.66 |
| - Difference of walking speed (m/s) | 0.16 ± 0.13 | 0.01 - 0.69 |
| - Percentages of walking speed (%) | 77.46 ± 12.60 | 24.18 - 95.12 |
| 6MinWT (m) | 155.96 ± 93.65 | 18.50 - 381.39 |

**Note:** Difference of walking speed

= Maximum walking speed - preferred walking speed (m/s)

$$\text{Percentages of walking speed} = \left( \frac{\text{Preferred walking speed}}{\text{Maximum walking speed}} \times 100 \right) (\%)$$

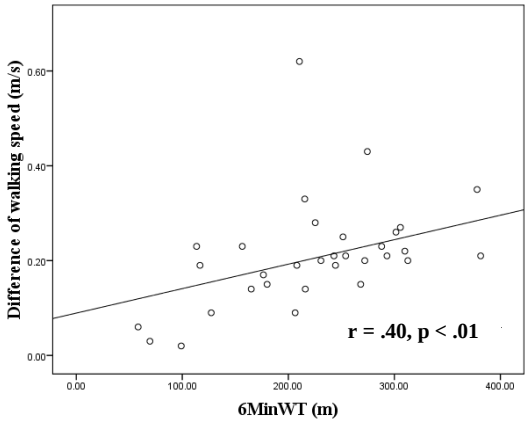

Preferred walking speed (m/s)
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
r = .91, p < .01
0.00
100.00
200.00
300.00
400.00
6MinWT (m)


Maximum walking speed (m/s)
1.50
1.00
0.50
R Sq Linear = 0.689
0.00
100.00
200.00
300.00
400.00
6MinWT (m)

(a)

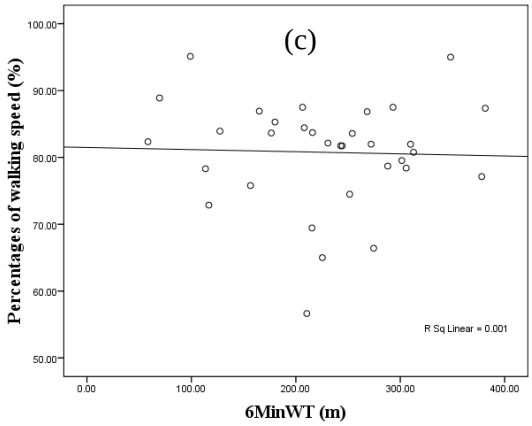
**r = .89, p < .01**

(b)




r = .19, p < .05

(c)




(d)

**Figure 9** Correlation between the 6MinWT and outcomes derived from the 10MWT

(a) Preferred walking speed

(b) Maximum walking speed

(c) Difference of walking speed

(d) Percentages of walking speed

### 3. Walking ability of subjects with different levels of ability

In order to clearly quantify the correlation between the 6MinWT and outcomes derived from the 6MinWT, the study further analyzed the data according to levels of functional independence in environment using the FIM-L scores. There were 10 subjects with FIM-L 5, 31 subjects with FIM-L 6, and 33 subjects with FIM-L 7. There were no significant differences of age, BMI and post-injury time among the 3 groups ($p>0.05$). The detail of baseline demographics and SCI characteristics were given in table 5 (Appendix E).

Figures 10 and 11 present data of outcomes derived from the 10MWT and 6MinWT in subjects with FIM-L 5-7. The data illustrated that subjects with FIM-L 5 walked at the slowest speed with the least differences between preferred and maximum walking speed (figure10). The differences of walking speed in subject with FIM-L 5, 6, 7 were 0.05, 0.15 and 0.21 m/s respectively. The subjects also achieved shortest distance walk in 6 minutes (figure 11). On the contrary, subjects with FIM-L 7 walked at the highest speed with the greatest differences between preferred and maximum speed. The subjects also obtained longest distance walk in 6 minutes (figure 11). The findings of subjects with FIM-L 7 were significant difference from those of subjects with FIM-L 5 and 6 ($p<0.001$).

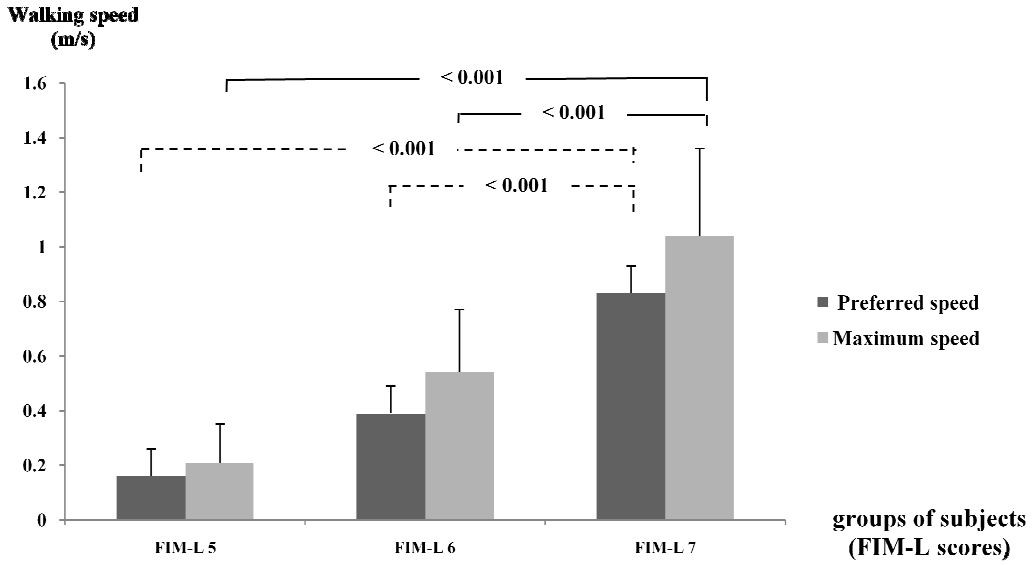



**Figure10** Preferred and maximum walking speed of subjects with FIM-L scores 5-7

- The dashed lines (- - -) represent statistical analyses for preferred walking speed
- The solid lines (—) demonstrate statistical analyses maximum walking speed

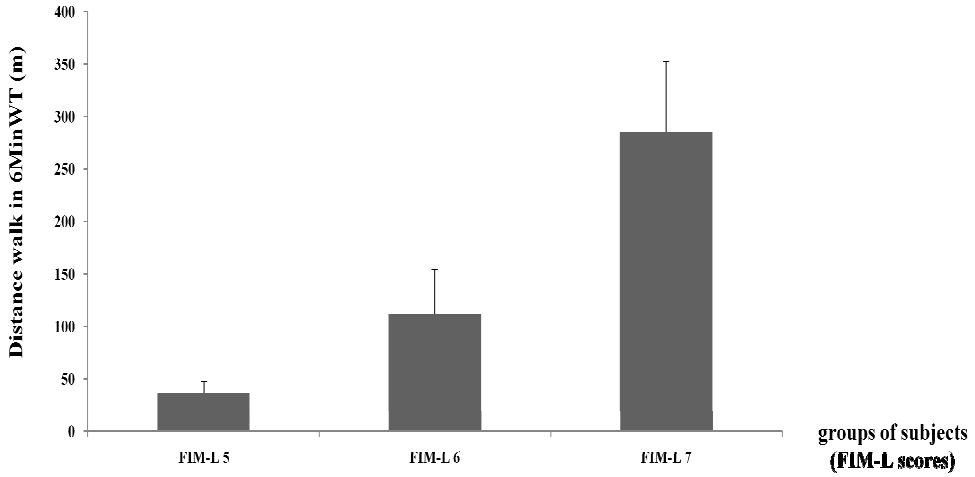



**Figure 11** Distance walk in 6 minutes (6MinWT) in subjects with FIM-L scores 5-7

**4. Correlation between data of the 6MinWT and outcomes derived from the 10MWT in subjects with different levels of walking ability**

The data were analyzed only in variables with significant correlation when analyzed in all subjects (figure 9). Similarly, the data indicated that preferred walking speed had best correlation with the findings of the 6MinWT, followed by the maximum walking speed and the difference of walking speed. However, levels of correlation were highest in subjects with FIM-L 7 but lowest in those with FIM-L 5. Significant correlation was demonstrated in subjects with FIM-L 6 and 7 ($p<0.001$) but not in subjects with FIM-L 5. The data in subjects with FIM-L 5 also showed inversed correlation (table 3). The study further analyzed predictive equations for the 6MinWT according to walking ability of subjects (table 4.)

**Table 3:** Correlation between the 6MinWT and outcomes derived from the 10MWT in subjects with different levels of walking ability (FIM-L scores)

| **Variables derived from the 10MWT** | | **FIM-L 5** (N=10) | **FIM-L 6** (N=31) | **FIM-L 7** (N=33) |
|---|---|---|---|---|
| Preferred walking speed | r | -0.33 | 0.74 | 0.83 |
| | p-value* | 0.36 | <0.001** | <0.001** |
| Maximum walking speed | r | -0.29 | 0.58 | 0.83 |
| | p-value* | 0.42 | <0.001** | <0.001** |
| Difference of walking speed | r | -0.16 | -0.22 | 0.37 |
| | p-value* | 0.65 | 0.91 | <0.05 |

*p-value from Pearson product-moment correlation coefficient

**Indicated significant difference

**Table 4:** Predictive equations for the 6MinWT in subjects with different levels of walking ability (FIM-L scores)

| | **Equations** |
|---|---|
| FIM-L 5 (N=10) | Preferred walking speed: 6MinWT speed = -0.10× 10MWT speed + 0.12; ($R^2$ = 0.10) Maximum walking speed: 6MinWT speed = 0.59 ×10MWT speed + 0.12; ($R^2$ = 0.07) |
| FIM-L 6 (N=31) | Preferred walking speed: 6MinWT speed = 0.51 ×10MWT speed + 0.13; ($R^2$ = 0.55) Maximum walking speed: 6MinWT speed = -0.32× 10MWT speed + 0.16; ($R^2$ = 0.34) |
| FIM-L 7 (N=33) | Preferred walking speed: 6MinWT speed = 0.70× 10MWT speed + 0.04; ($R^2$ = 1.00) Maximum walking speed: 6MinWT speed = 0.55 ×10MWT speed + 0.50; ($R^2$ = 0.89) |

# CHAPTER V
# DISCUSSION

This study investigated the correlation between the 6MinWT and outcomes derived from the 10MWT in independent ambulatory patients with SCI (AIS C or D). The preferred walking speed had significant correlation with the 6MinWT followed by the maximum walking speed and difference of walking speed, whereas percentages of walking speed had inverse, no significant correlation with the 6MinWT. Data of preferred and maximum walking speed of the 10MWT had excellent ability to predict distance walk in 6 minutes ($R^2$ = 0.82 and 0.78 for the preferred and maximum speed, respectively). However, when analyzed data according to ability of walking, the high correlation was demonstrated only in subjects with good walking ability (FIM-L 7, table 3).

The results offered different findings from those reported previously (van Hedel et al., 2005, 2007). Van Hedel et al (2007) reported that the 10MWT had excellent correlation with the 6MinWT both when tested using preferred and maximum walking speed (regression coefficients did not differ from 1). In addition, the findings suggested that their subjects achieved 109% of the predicted distance of the 10MWT. In this study, regression coefficients were slightly lower (r = 0.91 and 0.89 for preferred and maximum speed, respectively), and the linear regression equation suggested that subjects achieved only 74% of the predicted distance of the 10MWT. The different findings may relate to characteristics of subjects and methods of test. Van Hedel et al (2007) recruited subjects with good walking ability (median WISCI II scores = 17.5) and at a subacute stage of injury (average post-injury time =1.5 months). In contrast, most of subjects in this study were at a chronic stage of injury (average post-injury time = 42.19 months) and more than half of them required a walking device (n = 43). Being at a chronic stage and walking with a device posed negative impacts onto functional endurance. Bateni and Maki, (2005) indicated that using a walking device promoted levels of independence of the patients. However, manners of walking put a considerable demand onto upper extremities and energy expenditure (Subbarao, 1991, Melis et al., 1999). These may have significant impact

on the total distance covered in 6 minutes. In addition, van Hedel et al (2007) assess the 6MinWT using a hallway that the walking path contained as few turn as possible in order to avoid the influence of turn on walking speed. In this study, however, the tests were performed in a rehabilitation ward and subjects' houses. Thus, the 6MinWT was executed using a 19-meter square walkway in order to offer similar testing area among subjects. Using a square walkway might help to minimize effects of total turning that occurred when testing using up and down walkway. However, small area of test might increase the number of turns that had impact on overall distance walk after 6 minutes. Therefore, findings of this study suggested that data of the short distance walk (10MWT) overestimated those of long distance walk (6MinWT). The findings were associated with those of Dean et al (2001) who found that stroke subjects could actually achieve 84% of the predictive distance of the 10MWT. The study recruited subjects at a chronic stage who had poor walking ability. Although, the study tested the 6MinWT using up and down walkway around traffic cones, the total distance per round was rather long (50 meters). Thus the findings were coherent with those in this study.

Van Hedel et al (2005) reported that the 10MWT had high correlation with the 6MinWT in patients with SCI who had good and poor walking ability ($r = -0.93$ to $-0.96$ for subjects with good and poor walking ability, respectively). However, the study applied WISCI II scores as standard criteria of subject classification The WISCI II scores rank orders of walking ability at least 10 meters along the dimension of impairments based on the use of assistive devices, braces and physical assistance of person(s) (Jackson et al., 2008). The result indicates ability of walking in a standard environment, thus it may not truly reflect ability of subjects in their environment (Ditunno et al., 2005; Dobkin, 2006). In contrast, the FIM-L has been indicated as a disability scale which by definition to assess functions of subjects in different environments (the ranking scores are dependent on walking aids or assistance used to cover a distance over level ground up to 150 feet), that the data truly represents burden of care (Ditunno et al., 2005). FIM-L 5 refers to individuals who can walk at least 17 meters with or without a walking device. FIM-L 6 are those who can walk at least 50 meters with a walking device, and FIM-L 7 are those who are able to walk at least 50 meters without a walking device (Functional Independence Measure: Guide

for the Uniform Data Set for Medical Rehabilitation (Adult FIM), 1993). Thus, using the FIM-L scores may better classify levels of functioning of subjects than the WISCI II scores.

Finding of this study indicated that the correlation between the 6MinWT and 10MWT was highest in subjects with FIM-L 7, followed by those with FIM-L 6 and FIM-L 5, respectively. Melis et al., (1999) reported that walking with a walking device puts a considerable demand onto upper extremities and energy expenditure. This may attribute higher impact onto a more challenge task of 6MinWT than a less demand task of the 10MWT. As a result, the correlation between the 6MinWT and 10MWT was lower in subjects with FIM-L 6 than those with FIM-L 7 (table 3)

FIM-L 5 inferred that the subjects could walk at only a short distance. The results also showed that these subjects had lowest walking ability (walked at the lowest speed with the least differences between preferred and maximum walking speed) (figure 10). Ability of walking at a short distance implied that the subjects had minimal functional endurance due to severity of the lesion or just start of walking. Minimal difference of walking speed also inferred that the subjects retained meager remaining capacity to modify movement patterns according to the task demands in a daily life (Dobkin, 2006). This may pose higher impact on a more challenge task of the 6MinWT than the 10MWT. Thus, the correlation between the 2 tests was lowest in these subjects (table 3). The inverse correlation also implied that the subjects who walked at a higher speed could achieve shorter distance walk in 6 minutes and vice versa. These results are consistent with those in van Hedel et al (2005). The study found that, in subjects with poor walking ability (WISCI II <10), the WISCI II scores had positive correlation with the TUGT and negative correlation with the 6MinWT. The data implied that, in subjects with poor walking ability, improved walking ability was associated with increased time to complete the TUGT and decreased distances walked in 6 minutes. However, this study recruited a small number of subjects with FIM-L 5, thus an investigation in a larger number of subjects would warrant this assumption

# CHAPTER VI
# CONCLUSION

## 1. Conclusion

This study evaluated levels of correlation between the 6MinWT and outcomes derived from the 10MWT in 74 subjects with SCI (FIM-L scores = 5-7). The excellent correlation was demonstrated when tested the 10MWT using preferred and maximum walking speed. Findings of the 10MWT could predict data of the 6MinWT using equation: 6MinWT speed = 0.70× 10MWT speed + 0.04 (for a preferred walking speed, $R^2$ = 0.82) and equation: 6MinWT speed = 0.57 ×10MWT speed + 0.02 (for a maximum walking speed, $R^2$ = 0.78). However, when analyzed the data according to walking ability, the excellent correlation was demonstrated only in subjects with good walking ability (FIM-L 7). Findings of this study suggest that, when space and time are limited, preferred walking speed of the 10MWT can be used as an alternative test to the 6MinWT. The tool may help health care professionals to early detect change of functional capacity and administer an appropriate program for the patients. This will enhance effectiveness of rehabilitation strategies and reduce the rate of rehospitalization of patients with SCI

## 2. Limitation of the study and suggestion for further study

There was small number of subjects with FIM-L 5 participating in the study because of the demanding of the 6MinWT. Further study with more number of subjects with FIM-L 5 is necessary to confirm results of the study.

# REFERENCES


Amatachaya S, Wannapakhe J, Arrayawichanon P, Siritarathiwat W, Wattanapun P. Functional abilities, incidences of complications and falls of patients with spinal cord injury 6 months after discharge. **Spinal Cord** 2011; 49: 520-4.

American Spinal Injury Association. International Standards for Neurological Classifications of Spinal Cord Injury. revised ed. Chicago, Ill: **American Spinal Injury Association** 2000; 1-23.

An-Lun H, Pei-Fang T, Mei-Hwa J. Analysis of impairments influencing gait velocity and symmetry of hemiplegic patients after mild to moderate stroke. **Arch Phys Med Rehabil** 2003; 84: 1185-93.

ATS statement: guidelines for the six-minute walk test. **Am J Respir Crit Care Med** 2002; 166: 111-7.

Balke B. A Simple Field Test for the Assessment of Physical Fitness. **Rep Civ Aeromed Res Inst US** 1963; 1-8.

Barbeau H, Ladouceur M, Norman KE, Pepin A, Leroux A. Walking after spinal cord injury: evaluation, treatment, and functional recovery. **Arch Phys Med Rehabil** 1999; 80: 225-35.

Bateni H, Maki BE. Assistive devices for balance and mobility: benefits, demands, and adverse consequences. **Arch Phys Med Rehabil** 2005; 86: 134-45.

Behrman A, Harkema S. Locomotor training after human spinal cord injury: a series of case studies. **Phys Ther** 2000; 80: 688–700.

Bloemen-Vrencken JH, Post MW, Hendriks JM, De Reus EC, De Witte LP. Health problems of persons with spinal cord injury living in the Netherlands. **Disabil Rehabil** 2005; 27: 1381-9.

Bogle TLD, Newton RA. Use of the Berg Balance Test to predict falls in elderly persons. **Phys Ther** 1996; 76: 576-83.

Brooks D, Solway S,Gibbons WJ. ATS statement on six-minute walk test. **Am J Respir Crit Care Med** 2003; 167: 1287.

Brotherton SS, Krause JS, Nietert PJ. A pilot study of factors associated with falls in individuals with incomplete spinal cord injury. **J Spinal Cord Med** 2007; 30: 243-50.

Burns SP, Golding DG, Rolle Jr WA, Graziani V, Ditunno Jr JF. Recovery of ambulation in motor-incomplete tetraplegia. **Arch Phys Med Rehabil** 1997; 78: 1169–72.

Butland RJ, Pang J, Gross ER, Woodcock AA, Geddes DM. Two-, six-, and 12-minute walking tests in respiratory disease. **Br Med J (Clin Res Ed)** 1982; 284: 1607-8.

Cardenas DD, Hoffman JM, Kirshblum S, McKinley W. Etiology and incidence of rehospitalization after traumatic spinal cord injury: a multicenter analysis. **Arch Phys Med Rehabil** 2004; 85: 1757-63.

Catz A, Itzkovich M, Steinberg F, Ring H, Ronen J, Spasser R, et al. The Catz-Itzkovich SCIM: a revised version of the Spinal Cord Independence Measure. **Disabil Rehabil** 2001; 23: 263 – 8.

Cesari M, Kritchevsky SB, Penninx BW, Nicklas BJ, Simonsick EM, Newman AB, et al., Prognostic value of usual gait speed in well-functioning older people--results from the Health, aging and body composition study. **J Am Geriatr Soc** 2005; 53: 1675-80.

Cole B, Finch E, Gowland C, Mayo N. **Physical Rehabilitation Outcome Measures**. Toronto: Canadian Physiotherapy Association; 1994.

Chatburn Robert L. **Handbook for health care research**. 1st ed. Cleveland: Mandu Press Ltd; 2003.

Delahaye N, Cohen-Solal A, Faraggi M, Czitrom D, Foult JM, Daou D, et al. Comparison of left ventricular responses to the six-minute walk test, stair climbing,mand maximal upright bicycle exercise in patients with congestivemheart failure due to idiopathic dilated cardiomyopathy. **Am JmCardiol** 1997; 80: 65-70.

DeVivo MJ, Krause JS, Lammertse DP. Recent trends in mortality and causes of death among persons with spinal cord injury. **Arch Phys Med Rehabil** 1999 ; 80: 1411-9.

Dietz V, Colombo G, Jensen L, Baumgartner L. Locomotor capacity of spinal cord in paraplegic patients. **Ann Neurol** 1995; 37: 574-82.

Ditunno JF, Ditunno PL, Graziani V, Scivoletto G, Bernardi M, Castellano V, et al. Walking index for spinal cord injury (WISCI): an international multicenter validity and reliability study. **Spinal Cord** 2000; 38: 234-43.

_____, Dittunno PL. Walking index for spinal cord injury (WISCI II): scale revision. **Spinal Cord** 2001; 39, 654-6

_____, Barbeau H, Dobkin BH, Elashoff R, Harkema S, Marino RJ et al. Validity of the Walking Scale for Spinal Cord Injury and Other Domains of Function in aMuliticenter Clinical Trial. **Neurorehabil Neural Repair** 2007; 21:539-50.

_____, Burns AS, Marino RJ. Neurological and functional capacity outcome measures: essential to spinal cord injury clinical trials. **J Rehabil Res** 2005; 42: 35-41.

Dobkin BH. Short-distance walking speed and timed walking distance: Redunda measures for clinical trials?. **Neurology** 2006; 66: 584–6.

Eng J, Chu K, Dawson A, Kim C, Hepburn K. Functional walk tests in individuals with stroke: relation to perceived exertion and myocardial exertion. **Stroke** 2002; 33: 756–61.

Enright PL, McBurnie MA, Bittner V, Tracy RP, McNamara R, Newman AB. The Cardiovascular Health Study. The six minute walk test: a quick measure of functional status in elderly adults. **Chest** 2003; 123: 387-98.

Fried LP, Guralnik JM. Disability in older adults: evidence regarding significance, etiology, and risk. **J Am Geriatr Soc** 1997; 45: 92–100.

Finch E, Brooks D, Stratford P, Mayo N. **Physical Rehabilitation Outcome Measures: A guide to enhanced clinical decision making**. 2sded. Hamilton: BC Decker Inc; 2002.

Functional Independence Measure: Guide for the Uniform Data Set for Medical Rehabilitation (Adult FIM). New York: State University of New York at Buffalo; 1993.

Go B K, DeVivo M J, Richards J S. The epidemiology of spinal cord injury. In Stover S, DeLisa J, Whiteneck G, eds Spinal Cord Injury. Clinical Outcomes from the Model Systems Maryland: **Aspen Publishers** 1995: 21–55.

Graham JE, Ostir GV, Fisher SR, Ottenbacher KJ. Assessing walking speed in clinical research: a systematic review. **J Eval Clin Pract** 2008; 14: 552-62.

Guralnik JM, Ferrucci L, Pieper CF, Leveille SG, Markides KS, Ostir GV, et al. Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. **J Gerontol A Biol Sci Med Sci** 2000; 55: 221-31.

Guyatt GH, Pugsley SO, Sullivan MJ, Thompson PJ, Berman LB, Jones NL, et al. Effect of encouragement on walking test performance. **Thorax** 1984; 39: 818–22.

Hamilton DM ,Haennel RG. Validity and reliability of the 6-minute walk test in a cardiac rehabilitation population. **J Cardiopulm Rehabil** 2000; 20: 156-64.

Hardy SE, Gill TM. Recovery from disability among community-dwelling older person s. **JAMA** 2004; 291:1596-602.

Heinemann AW, Yarkony GM, Roth EJ, Lovell L, Hamilton B, Ginsburg K, et al. Functional outcome following spinal cord injury. A comparison of specialized spinal cord injury center vs general hospital short-term care. **Arch Neurol** 1989; 46: 1098-102.

Jackson AB, Carnel CT, Ditunno JF, Read MS, Boninger ML, Schmeler MR, et al. Outcome measures for gait and ambulation in the spinal cord injury population. **J Spinal Cord Med** 2008; 31: 487-99.

Jaeger RJ, Yarkony GM, Roth EJ. Rehabilitation technology for standing and walking after spinal cord injury. **Am J Phys Med Rehabil** 1989; 68: 128-33.

Janssen TW, Dallmeijer AJ, Veeger DJ, van der Woude LH. Normative values and determinants of physical capacity in individuals with spinal cord injury. **J Rehabil Res Dev** 2002; 39: 29-39.

Kollen B, Kwakkel G, Lindeman E. Hemiplegic gait after stroke: is measurement of maximum speed required? **Arch Phys Med Rehabil** 2006; 87: 358-63.

Lam T, Eng JJ, Wolfe DL, Hsieh JTC, Whittaker M. A systematic review of the efficacy of gait rehabilitation strategies for spinal cord injury. **Top Spinal Cord Inj Rehabil** 2007; 13: 32–57.

Lam T, Noonan V, Eng J, SCIRE Team. A systematic review of functional ambulation

outcome measures in spinal cord injury. **Spinal Cord** 2008; 46: 246-54.

Lebiedowska MK, Gaebler-Spira D, Burns RS, Fisk JR. Biomechanic characteristics of patients with spastic and dystonic hypertonia in cerebral palsy. **Arch Phys Med Rehabil** 2004; 85: 875-80.

Leroux A, Fung J, Barbeau H. Postural adaptation to walking on inclined surfaces: II. Strategies following spinal cord injury. **Clin Neurophysiol** 2006; 117: 1273-82.

Lipkin DP, Scriven AJ, Crake T, Poole-Wilson PA. Six minute walking test for assessing exercise capacity in chronic heart failure. **Br Med J (Clin Res Ed)** 1986; 292: 653-5.

Lusardi MM, Pellecchia GL, Schulman M. Functional performance in community living older adults. **J Geriatr Phys Ther** 2003; 26: 14-22.

Manns PJ, Chad KE. Determining the relation between quality of life, handicap, fitness, and physical activity for persons with spinal cord injury. **Arch Phys Med Rehabil** 1999 ; 80: 1566-71.

Marino RJ, Ditunno J, Donovan WH, Maynard F. Neurologic recovery after traumatic spinal cord injury: data from the Model Spinal Cord Injury Systems. **Arch Phys Med Rehabil** 1999; 80: 1391-6.

Maynard FM, Bracken MB, Creasey G, Ditunno JF, Donovan WH, Ducker TB, et al. International Standards for Neurological and Functional Classification of Spinal Cord Injury. American Spinal Injury Association. **Spinal Cord** 1997; 35: 266-74.

McKinley WO, Jackson AB, Cardenas DD, DeVivo MJ. Long-term medical complications after traumatic spinal cord injury: a regional model systems analysis. **Arch Phys Med Rehabil** 1999; 80: 1402-10.

Middleton JW, Truman G, Geraghty TJ. Neurological level effect on the discharge functional status of spinal cord injured persons after rehabilitation. **Arch Phys Med Rehabil** 1998; 79: 1428-32.

Melis EH, Torres-Moreno R, Barbeau H, Lemaire ED. Analysis of assisted-gait characteristics in persons with incomplete spinal cord injury. **Spinal Cord** 1999; 37: 430-9.

Morganti B, Scivoletto G, Ditunno P, Ditunno JF, Molinari M. Walking index for spinal cord injury (WISCI): criterion validation. **Spinal Cord** 2005; 43: 27-33.

National Spinal Cord Injury Statistical Center. **Annual statistical report for the Model SCI Care System**. Birmingham: University of Alabama at Birmingham; 2006.

_____. Spinal cord injury facts and figures at a glance. **J Spinal Cord Med** 2008; 31: 357-8.

New PW, Epi MC. Functional outcomes and disability after nontraumatic spinal cord injury rehabilitation: Results from a retrospective study. **Arch Phys Med Rehabil** 2005; 86: 250-61.

Noreau L ,Shephard RJ. Return to work after spinal cord injury: the potential contribution of physical fitness. **Paraplegia** 1992; 30: 563-72.

Olsson LG, Swedberg K, Clark AL, Witte KK, Cleland JG. Six minute corridor walk test as an outcome measure for the assessment of treatment in randomized, blinded intervention trials of chronic heart failure: a systematic review. **Eur Heart J** 2005; 26: 778-93.

Opasich C, Pinna GD, Mazza A, Febo O, Riccardi R, Riccardi PG, et al. Six-minute walking performance in patients with moderate-to-severe heart failure; is it a useful indicator in clinical practice? **Eur Heart J** 2001; 22: 488-96.

Penrod LE, Hedge SK, Ditunno JF. Age effects on prognosis for functional recovery in acute, traumatic central cord syndrome. **Arch Phys Med Rehabil** 1990; 71: 963–8.

Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. **J Am Geriatr Soc** 1991; 39:142-8.

Purser JL, Weinberger M, Cohen HJ, Pieper CF, Morey MC, Li T, et al,. Walking speed predicts health status and hospital costs for frail elderly male veterans. **J Rehabil Res 2**005; 42: 535-46.

Scivoletto G, Morganti B, Ditunno P, Ditunno JF, Molinari M. Effects on age on spinal cord lesion patients' rehabilitation. **Spinal Cord** 2003; 41: 457-64.

_____, Romanelli A, Mariotti A, Marinucci D, Tamburella F, Mammone A, et al. Clinical factors that affect walking level and performance in chronic spinal cord lesion patients. **Spine** 2008; 33: 259-64.

Sparrow J, Parameshwar J, Poole-Wilson PA. Assessment of functional capacity in chronic heart failure: time-limited exercise on a self-powered treadmill. **Br Heart J** 1994; 71: 391-4.

Steins SA, Kirshblum SC, Groah SL, McKinley WO, Gittler MS. Spinal cord injury medicine. 4. Optimal participation in life after spinal cord injury: physical, psychosocial, and economic reintegration into the environment. Arch Phys Med Rehabil 2002; 83: 72-81.

Stover S, Fine P. Spinal Cord Injury: The fact and Figures. The University of Alabama at Birmingham, Birmigham 1986.

Studenski S. Landefeld CS, Palmer R, Johnson MA. **Current Geriatric Diagnosis and Treatment**. New York: McGraw-Hill; 2004; 436–46.

Subbarao JV. Walking after spinal cord injury. Goal or wish? **West J Med** 1991; 154: 612-4.

Tang SF, Tuel SM, McKay WB, Dimitrijevic MR. Correlation of motor control in the supine position and assistive device used for ambulation in chronic incomplete spinal cord-injured persons. **Am J Phys Med Rehabil** 1994;73: 268-74.

van den Berg-Emons HJG, Bussmann JBJ, Sluis TAR, Bergen MP, Van der Woude LHV, Stam HJ. Restoration of the level of everyday physical activity during spinal cord injury rehabilitation: preliminary results. **J Rehabil Res Develop** 2004; 41.

van den Berg-Emons RJ, Bussmann JB, Haisma JA, Sluis TA, van der Woude LH, Bergen MP, et al. A prospective study on physical activity levels after spinal cord injury during inpatient rehabilitation and the year after discharge. **Arch Phys Med Rehabil** 2008;89: 2094-101.

van Hedel HJ, Wirz M, Dietz V. Assessing walking ability in subjects with spinal cord injury: validity and reliability of 3 walking tests. **Arch Phys Med Rehabil** 2005; 86: 190-6.

_____, Wirz M, Curt A. Improving walking assessment in subjects with an incomplete spinal cord injury: responsiveness. **Spinal Cord** 2006; 44: 352-6.

_____, Dietz V, Curt A. Assessment of walking speed and distance in subjects with an incomplete spinal cord injury. **Neurorehabil Neural Repair** 2007; 21: 295-301.

van Hedel HJ, Wirth B, Kometer B, Dietz V, Curt A. Changes in activity after a complete spinal cord injury as measured by the Spinal Cord Independence Measure II (SCIM II). **Neurorehabil Neural Repair** 2008; 22: 145-53.

_____, Wirz M, Dietz V. Standardized assessment of walking capacity after spinal cord injury: the European network approach. **Neurol Res** 2008; 30: 61-73.

van Iersel MB, Munneke M, Esselink RA, Benraad CE, Olde Rikkert MG. Gait velocity and the Timed-Up-and-Go test were sensitive to changes in mobility in frail elderly patients. **J Clin Epidemiol 2008**; 6:186-91.

van Loo MA, Moseley AM, Bosman JM, de Bie RA,Hassett L. Test-re-test reliability of walking speed, step length and step width measurement after traumatic brain injury: a pilot study. **Brain Inj** 2004; 18: 1041-8.

van Wieringen PCW. Ecological and dynamical approaches to rehabilitation: an epilogue. **Hum Mov Sci** 1996; 15: 315-23.

Visintin M ,Barbeau H. The effects of body weight support on the locomotor pattern of spastic paretic patients. **Can J Neurol Sci** 1989; 16: 315-25.

Waters RL, Adkins RH, Yakura JS, Sie I. Motor and sensory recovery following incomplete tetraplegia. **Arch Phys Med Rehabil** 1994; 75: 306-11.

_____, Sie I, Adkins RH,Yakura JS. Injury pattern effect on motor recovery after traumatic spinal cord injury. **Arch Phys Med Rehabil** 1995; 76: 440-3.

Whitney SL, Marchetti GF, Schade A, Wrisley DM. The sensitivity and specificity of the Timed "Up & Go" and the Dynamic Gait Index for self-reported falls in persons with vestibular disorders. **J Vestib Res** 2004; 14: 397-409.

Widerstrom-Noga EG, Felipe-Cuervo E, Broton JG, Duncan RC,Yezierski RP. Perceived difficulty in dealing with consequences of spinal cord injury. **Arch Phys Med Rehabil** 1999; 80: 580-6.

Wu G, Sanderson B, Bittner V. The 6-minute walk test: how important is the learning effect? **Am heat J** 2003; 146: 129-3.

Wyndaele M, Wyndaele JJ. Incidence, prevalence and epidemiology of spinal cord injury: what learns a worldwide literature survey?. **Spinal Cord**. 2006; 44: 523-9.

Yagura H, Hatakenaka M, Miyai I. Does therapeutic facilitation add to locomotor outcome of body weight–supported treadmill training in nonambulatory patients with stroke? A randomized controlled trial. **Arch Phys Med Rehabil** 2006; 87: 529–35.

Zugck C, Krüger C, Dürr S, Gerber SH, Haunstetter A, Hornig K, et al. Is the 6-minute walk test a reliable substitute for peak oxygen uptake in patients with dilated cardiomyopathy?. **Eur Heart J** 2000; 21:540-9.

# APPENDICES

# APPENDIX A

## Certificate of Ethical Approval of the Khon Kaen University Ethics Committee for Human Research


**มหาวิทยาลัยขอนแก่น**

**หนังสือฉบับนี้ให้ไว้เพื่อแสดงว่า**

**โครงการวิจัยเรื่อง:** ความสัมพันธ์ของความเร็วในการเดินและการเปลี่ยนแปลงความสามารถในการทำงานที่วัดโดยการเดินในเวลา 6 นาที (6MinWT)

Correlation of walking speed and the changes of functional capacity as measured by the 6 minute-walk test (6MinWT)

**ผู้วิจัย:**

1. นางสาวสาลินี แนวหล้า
   คณะเทคนิคการแพทย์ มหาวิทยาลัยขอนแก่น
2. ผู้ช่วยศาสตราจารย์ ดร.สุกัลยา อมตฉายา
   คณะเทคนิคการแพทย์ มหาวิทยาลัยขอนแก่น
3. ผู้ช่วยศาสตราจารย์นายแพทย์ปรีดา อารยาวิชชานนท์
   ภาควิชาเวชศาสตร์ฟื้นฟู คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น

**สำหรับเอกสาร:**

1. แบบเสนอเพื่อขอรับการพิจารณาด้านจริยธรรมของการวิจัยในมนุษย์ เวอร์ชั่น 1.1 ฉบับวันที่ 10 พฤษภาคม พ.ศ. 2554
2. เอกสารคำชี้แจงสำหรับอาสาสมัคร เวอร์ชั่น 1.1 ฉบับวันที่ 10 พฤษภาคม พ.ศ. 2554
3. แบบฟอร์มใบยินยอม จำนวน เวอร์ชั่น 1.1 ฉบับวันที่ 10 พฤษภาคม พ.ศ. 2554
4. โครงการวิจัยฉบับสมบูรณ์พร้อมประวัติและความรู้ความชำนาญของนักวิจัย เวอร์ชั่น 1.0 ฉบับวันที่ 29 มีนาคม พ.ศ. 2554
5. แบบบันทึกข้อมูลหรือแบบสอบถามการวิจัย เวอร์ชั่น 1.1 ฉบับวันที่ 10 พฤษภาคม พ.ศ. 2554

**ลำดับที่ :** 4.2.01 : 10/2554

**เลขที่ :** HE541064 วันหมดอายุ : 19 เมษายน พ.ศ. 2555

**คณะกรรมการจริยธรรมการวิจัยในมนุษย์มหาวิทยาลัยขอนแก่น** **Institutional Review Board Number; IRB00001189**

**สำนักงาน: อาคารสมเด็จพระศรีนครินทราบรมราชชนนี อนุสรณ์ 1 (ชั้น 17)** **Federal Wide Assurance; FWA00003418**

โทร. (043) 366616, (043) 366617 โทรสาร (043) 366617

**ได้ผ่านการรับรองจากคณะกรรมการจริยธรรมการวิจัยในมนุษย์มหาวิทยาลัยขอนแก่น โดยยึดหลักเกณฑ์ตามคำประกาศเฮลซิงกิ (Declaration of Helsinki) และแนวทางการปฏิบัติการวิจัยทางคลินิกที่ดี (ICH GCP)**

ให้ไว้ ณ วันที่ 18 พฤษภาคม พ.ศ. 2554

(นายแพทย์เกรียงศักดิ์ เวทีวุฒาจารย์)
รักษาราชการแทนประธานคณะกรรมการจริยธรรมการวิจัยในมนุษย์
มหาวิทยาลัยขอนแก่น

**ลำดับที่ :** 4.2.01 : 10/2554
**เลขที่ :** HE541064
วันหมดอายุ : 19 เมษายน พ.ศ. 2555

**คณะกรรมการจริยธรรมการวิจัยในมนุษย์มหาวิทยาลัยขอนแก่น**
**สำนักงาน: อาคารสมเด็จพระศรีนครินทราบรมราชชนนี อนุสรณ์ 1 (ชั้น 17)**
โทร. (043) 366616, (043) 366617 โทรสาร (043) 366617

**Institutional Review Board Number; IRB00001189**
**Federal Wide Assurance; FWA00003418**

# APPENDIX B

## Information Sheet for Subjects

## (Thai version)

**แบบคำชี้แจงเพื่ออธิบายแก่อาสาสมัครสำหรับโครงการวิจัยทางคลินิก**

**<u>แบบคำชี้แจงอาสาสมัคร</u>**

**<u>ชื่อโครงการวิจัย</u>** ความสัมพันธ์ของความเร็วในการเดินและความสามารถในการทำงานที่วัด โดยการเดินในเวลา 6 นาที ในผู้ป่วยบาดเจ็บไขสันหลังที่เดินได้เอง

**<u>หัวหน้าโครงการวิจัย</u>:** นางสาวสาลินี แนวหล้า นักศึกษาวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด คณะเทคนิคการแพทย์ มหาวิทยาลัยขอนแก่น

**<u>หัวหน้าโครงการวิจัยร่วม</u>:** ผศ.ดร.สุกัลยา อมตฉายา

**<u>บทนำ</u>**

การบาดเจ็บของไขสันหลังก่อให้เกิดผลกระทบที่สำคัญต่อตัวผู้ป่วย โดยเฉพาะอย่างยิ่งเมื่อการบาดเจ็บของไขสันหลังที่มักเกิดกับผู้ป่วยที่มีอายุน้อยกว่า 30 ปี มีรายงานว่าประมาณ 1 ใน 3 ของผู้ป่วยบาดเจ็บไขสันหลังสามารถเดินได้อีกครั้งภายใน 1 ปี อย่างไรก็ตาม ปัจจุบันมีแนวโน้มที่ผู้ป่วยจะสามารถอยู่รักษาตัวในโรงพยาบาลได้เป็นเวลาสั้นลง ทำให้ผู้ป่วยยังไม่ได้รับการพัฒนาความสามารถไปสู่ระดับสูงสุดของแต่ละคน ทำให้ผู้ป่วยต้องพึ่งพาบุคคลอื่นในการทำกิจวัตรประจำวัน นอกจากนี้ เมื่อกลับไปอยู่ที่บ้าน ผู้ป่วยยังมีความเสี่ยงสูงที่จะเกิดภาวะแทรกซ้อนที่ส่งผลต่อการคงหรือการพัฒนาความสามารถของผู้ป่วย ดังนั้น การตรวจประเมินที่มีประสิทธิภาพที่สามารถใช้ได้จริงและระบุการเปลี่ยนแปลงความสามารถของผู้ป่วย ในชุมชนต่างๆได้จึงมีความสำคัญในการติดตามการเปลี่ยนแปลงความสามารถของผู้ป่วยในชุมชนตั้งแต่ระยะแรกๆ เพื่อให้การพัฒนาความสามารถของผู้ป่วยกลุ่มนี้มีประสิทธิภาพมากยิ่งขึ้น การทดสอบโดยใช้ความเร็วในการเดิน (10MWT) เป็นการทดสอบความเร็วในการเดินที่ทดสอบทั้งความเร็วปกติ (preferred walking speed) และความเร็วสูงสุด (maximum walking speed) โดยผลการทดสอบช่วยสะท้อนความสามารถในการทำงาน และคุณภาพการเดินโดยรวม และการทดสอบโดยการเดินในเวลา 6 นาที เป็นการประเมินที่ดีที่สุดในการสะท้อนความสามารถในการทำงาน (functional capacity) แต่การทดสอบนี้มีข้อจำกัดในการนำไปใช้งานในชุมชนต่างๆ เนื่องจากต้องใช้เวลานานในขณะที่การประเมินความเร็วในการเดินได้แต่ เป็นการประเมินที่สามารถทำได้ง่าย และสะท้อนความสามารถด้านต่างๆ ที่เกี่ยวข้องกับการทำงานและการเดิน การรายงานผลการประเมินความเร็วในการเดิน

สามารถทำได้หลายวิธี ซึ่งปัจจุบันยังไม่พบรายงานว่าข้อมูลใดของความเร็วในที่สามารถใช้แทนการทดสอบการเดินในเวลา 6 นาทีได้ดีที่สุด

**<u>วัตถุประสงค์ของการวิจัย</u>**

เพื่อศึกษาความสัมพันธ์ระหว่างผลการทดสอบระยะทางเดินในเวลา 6 นาที (6MinWT) และความเร็วในการเดิน (10MWT) ที่รายงานโดยค่าต่างๆ ในผู้ป่วยบาดเจ็บของไขสันหลัง

**<u>การเข้าร่วมโครงการวิจัยของท่านเป็นไปด้วยความสมัครใจ</u>**

การเข้าร่วมโครงการนี้เป็นไปได้โดยความสมัครใจ หากท่านไม่ยินดีเข้าร่วมการศึกษา หรือต้องการยุติการเข้าร่วมการศึกษา ท่านสามารถขอยุติการเก็บข้อมูลหรือถอนตัวจากโครงการวิจัยนี้ได้ตามต้องการ โดยไม่มีผลกระทบใดๆ ต่อการรักษาและการดำรงชีวิตประจำวันตามปกติของท่าน ทั้งในปัจจุบันและอนาคต

**<u>ขั้นตอนการปฏิบัติตัวหากท่านเข้าร่วมโครงการวิจัย</u>**

เมื่อท่านตัดสินใจเข้าร่วมในการวิจัยและได้ลงนามเป็นหลักฐานในแบบยินยอมเข้าร่วมการวิจัยแล้ว ผู้วิจัยขอความร่วมมือจากท่านในการให้ข้อมูลและการประเมินความสามารถทางการเคลื่อนไหวของท่าน และขั้นตอนการปฏิบัติ ดังนี้

1. หลังจากผู้วิจัยได้อธิบายความสำคัญและวัตถุประสงค์ให้ท่านได้ทราบแล้ว จะทำการสัมภาษณ์ข้อมูลทั่วไปและความผิดปกติเนื่องจากภาวะไขสันหลังบาดเจ็บของท่าน เพื่อเป็นข้อมูลพื้นฐาน (การทดสอบกำลังของกล้ามเนื้อและการรับความรู้สึก ได้รับการตรวจประเมินจากแพทย์เพื่อยืนยันผลของการทดสอบ)
2. ผู้วิจัยจะทำการทดสอบความเร็วในการเดินทั้งเดินปกติและเดินเร็วที่สุด โดยใช้ระยะทาง 10 เมตรและทดสอบระยะทางเดินในเวลา 6 นาที
3. ผู้วิจัยจะสรุปข้อมูลความสามารถของท่านให้ทราบ

**<u>ความเสี่ยงและ/หรือความไม่สบายที่อาจเกิดขึ้น</u>**

ในการทดสอบการเดินอาสาสมัครอาจรู้สึกเหนื่อยล้า หรือมีความเสี่ยงในการล้มได้ ดังนั้น เพื่อความปลอดภัยในขณะที่ทำการทดสอบ ผู้วิจัยจะให้ทุกท่านใส่เข็มขัดนิรภัยและเดินตามด้านข้างของอาสาสมัคร

ตลอดเวลาในการทดสอบ เพื่อคอยดูแลและให้ความช่วยเหลือตามความจำเป็นระหว่างการทดสอบแต่ละอย่าง อาสาสมัครสามารถพักได้จนหายเหนื่อยหรือพร้อมที่จะประเมินต่อไป

**ประโยชน์ที่อาสาสมัครจะได้รับ**

ท่านได้ทราบถึงการเปลี่ยนแปลงความสามารถในการทำงานในเวลา 6 เดือน รวมถึงและวิธีการติดตามการเปลี่ยนแปลงความสามารถด้วยตัวท่านเอง ซึ่งจะเป็นประโยชน์ในการติดตามและพัฒนาความสามารถของตนเองได้อย่างต่อเนื่อง

**ค่าใช้จ่ายในการวิจัย/ค่าชดเชยเดินทาง/ค่าเสียเวลา**

ในการเข้าร่วมในการวิจัยนี้ท่านจะได้รับค่าชดเชยเดินทางหรือค่าเสียเวลาครั้งละ 100 บาท

**การรักษาความลับ**

คณะผู้วิจัยจะใช้รหัสของอาสาสมัครในแบบบันทึกข้อมูล การสืบค้นข้อมูล และรหัสประจำตัวของอาสาสมัครโดยจะมีเพียงผู้วิจัยนี้เท่านั้นที่ทราบข้อมูล หากผู้วิจัยได้มีการตีพิมพ์ผลการศึกษาในวารสารทางการแพทย์ ผู้วิจัยจะไม่มีการระบุชื่อของอาสาสมัครไม่ว่ากรณีใดๆ ความสมัครใจเข้า/ไม่เข้าร่วมการวิจัยไม่ได้มีผลต่อการดำรงชีวิตในประจำวันและการได้รับการฟื้นฟูความสามารถของท่านแต่อย่างใด

**ชื่อ/ที่อยู่/โทรศัพท์ของผู้รับผิดชอบโครงการวิจัยที่ติดต่อได้สะดวก**

นางสาวสาลินี แนวหล้า นักศึกษาวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด คณะเทคนิคการแพทย์ มหาวิทยาลัยขอนแก่น หมายเลขโทรศัพท์ 085-490-5073

ผศ.ดร.สุกัลยา อมตฉายา สายวิชากายภาพบำบัด คณะเทคนิคการแพทย์ มหาวิทยาลัยขอนแก่น โทรศัพท์ 081-346-6036

**แหล่งให้ข้อมูลหากมีข้อสงสัยเกี่ยวกับสิทธิอาสาสมัคร**

**สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์มหาวิทยาลัยขอนแก่น ชั้น 17 อาคารสมเด็จ พระศรีนครินทราบรมราชชนนี คณะแพทยศาสตร์ โทร. 043-366616, 366617 เบอร์ภายใน 66616, 66617 โทรสาร 043-36617**

# APPENDIX C

## Inform Consent of Subjects

## (Thai version)

แบบยินยอมอาสาสมัครสำหรับโครงการวิจัยทางคลินิก

แบบยินยอมอาสาสมัคร

ข้าพเจ้า (นาย, นาง, นางสาว)…….....……..นามสกุล…….....อายุ……..…ปี อยู่บ้านเลขที่……..…..หมู่ที่…….ตำบล…….อำเภอ……จังหวัด……...…… ได้รับฟังคำอธิบายจาก.....…… (ชื่อผู้ให้ข้อมูล) เกี่ยวกับการเป็นอาสาสมัครในโครงการวิจัย ***ความสัมพันธ์ของความเร็วในการเดินและการเปลี่ยนแปลงความสามารถในการทำงานที่วัดโดยการเดินในเวลา 6 นาที*** ได้รับทราบถึงรายละเอียดของโครงการวิจัยเกี่ยวกับ

- วัตถุประสงค์และระยะเวลาที่ทำการวิจัย
- ขั้นตอนและวิธีการปฏิบัติตัวที่ข้าพเจ้าต้องปฏิบัติ
- ผลประโยชน์ที่ข้าพเจ้าจะได้รับ
- ผลข้างเคียงหรืออันตรายที่อาจเกิดขึ้นจากการเข้าร่วมโครงการ (ระบุตามความเหมาะสมให้สอดคล้องกับลักษณะโครงการ)

ข้าพเจ้าสามารถถอนตัวจากการศึกษานี้เมื่อใดก็ได้ถ้าข้าพเจ้าปรารถนา โดยไม่เสียสิทธิ์ใดๆ ในการรับการรักษาพยาบาลที่จะเกิดขึ้นตามมาในโอกาสต่อไปทั้งในปัจจุบันและอนาคต ณ สถานพยาบาลแห่งนี้หรือสถานพยาบาลอื่น และหากเกิดมีอาการข้างเคียงขึ้น ข้าพเจ้าจะรายงานให้คณะผู้วิจัยที่กำลังปฏิบัติงานอยู่ในขณะนั้นทราบทันที

ข้าพเจ้าได้อ่านและเข้าใจคำอธิบายข้างต้นแล้ว จึงได้ลงนามยินยอมเป็นอาสาสมัครของโครงการวิจัยดังกล่าว

ลายมือชื่ออาสาสมัคร…….……..…….

(…….....……..……)

ลายมือชื่อผู้ให้ข้อมูล…….……...…….

(……...……..…)

พยาน…… (ไม่ใช่ผู้อธิบาย)

(……...…….)

วันที่…….....…เดือน……..…..…พ.ศ……..……

**หมายเหตุ:** (1) ในกรณีที่อาสาสมัครเป็นเด็กโตแต่อายุไม่ถึง 18 ปี สามารถตัดสินใจเองได้ ให้ลงลายมือชื่อ ทั้งอาสาสมัคร (เด็ก) และผู้ปกครองด้วย

(2) พยานต้องไม่ใช่แพทย์หรือผู้วิจัย

(3) ผู้ให้ข้อมูล/คำอธิบายชัดเจนต้อง<u>ไม่เป็นแพทย์ผู้วิจัยเพื่อป้องกันการเข้าร่วมโครงการด้วยความเกรงใจ</u>

(4) ในกรณีที่อาสาสมัครไม่สามารถ อ่านหนังสือ/ลงลายมือชื่อ ได้ ให้ใช้การประทับลายมือแทนดังนี้:

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในแบบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดี ข้าพเจ้าจึงประทับตราลายนิ้วมือขวาของข้าพเจ้าในแบบยินยอมนี้ด้วยความเต็มใจ

ลายมือชื่อผู้อธิบาย……..……..

(…….……..)

พยาน……..……...(ไม่ใช่ผู้อธิบาย)

(  )

# APPENDIX D

## Questionnaire to Interview and Assess Baseline Demographics of Subjects (Thai version)

**ID** | | | | |

วันที่สัมภาษณ์...../...../2554

**<u>แบบสัมภาษณ์และบันทึกข้อมูลเพื่อการวิจัย</u>**
**<u>เรื่อง ความสัมพันธ์ของความเร็วในการเดินและการเปลี่ยนแปลงความสามารถ</u>**
**<u>ในการทำงานที่วัดโดยการเดินในเวลา 6 นาที</u>**

แบบสัมภาษณ์และบันทึกชุดนี้เป็นเครื่องมือสำหรับการวิจัยเรื่อง *ความสัมพันธ์ของความเร็วในการเดินและการเปลี่ยนแปลงความสามารถในการทำงานที่วัดโดยการเดินในเวลา 6 นาที* ที่มีวัตถุประสงค์เพื่อศึกษาความสัมพันธ์ระหว่างการเปลี่ยนแปลงของผลการทดสอบระยะทางในการเดิน 6 นาที (6-Minute Walk Test (6MinWT)) และความเร็วในการเดิน (10-Meter Walk Test (10MWT)) ที่รายงานโดยค่าต่างๆ ในผู้ป่วยบาดเจ็บของไขสันหลังที่สามารถเดินได้เอง ข้อมูลที่ได้จะช่วยให้ได้วิธีการประเมินที่สามารถใช้ติดตามการเปลี่ยนแปลงความสามารถของผู้ป่วยในชุมชนต่างๆตั้งแต่ระยะแรกๆ เพื่อให้การพัฒนาความสามารถของผู้ป่วยมีประสิทธิภาพมากยิ่งขึ้น และเพื่อช่วยให้บุคลากรทางการแพทย์จะได้วางแผนการตรวจประเมินเชิงลึกต่อไป ข้อมูลที่ได้จากการศึกษาจะนำเสนอเป็นภาพรวม โดยไม่ก่อให้เกิดผลกระทบต่อผู้ให้ข้อมูลแต่อย่างใด จึงใคร่ขอความร่วมมือในการให้ข้อมูลอย่างครบถ้วนและตรงกับความเป็นจริงมากที่สุด เพื่อให้ผู้วิจัยสามารถนำผลการศึกษาไปวิเคราะห์และสามารถตอบคำถามของการวิจัยได้ดีมากที่สุด

**<u>คำชี้แจง</u>** แบบสัมภาษณ์ชุดนี้ แบ่งเป็น 3 ส่วน ดังนี้
ส่วนที่ 1 แบบสัมภาษณ์และบันทึกข้อมูลพื้นฐานส่วนบุคคล
ส่วนที่ 2 แบบบันทึกข้อมูลพื้นฐานเกี่ยวกับการบาดเจ็บของไขสันหลัง และความสามารถในการเคลื่อนไหว
ส่วนที่ 3 ตารางบันทึกผลการทดสอบความสามารถของอาสาสมัคร

**ส่วนที่ 1 แบบสัมภาษณ์และบันทึกข้อมูลพื้นฐานส่วนบุคคล**

**<u>คำชี้แจงการบันทึกข้อมูล</u>** ผู้วิจัยเป็นผู้สัมภาษณ์/สังเกตโดยใช้คำถามที่เป็นตัวเลือก และจดบันทึกข้อมูลที่ได้จากการสัมภาษณ์/สังเกตอาสาสมัครโดยให้กาเครื่องหมายถูก ( / ) ในช่อง ( ) หน้าตัวเลือกที่ตรงกับข้อมูลมากที่สุดเพียงข้อเดียว

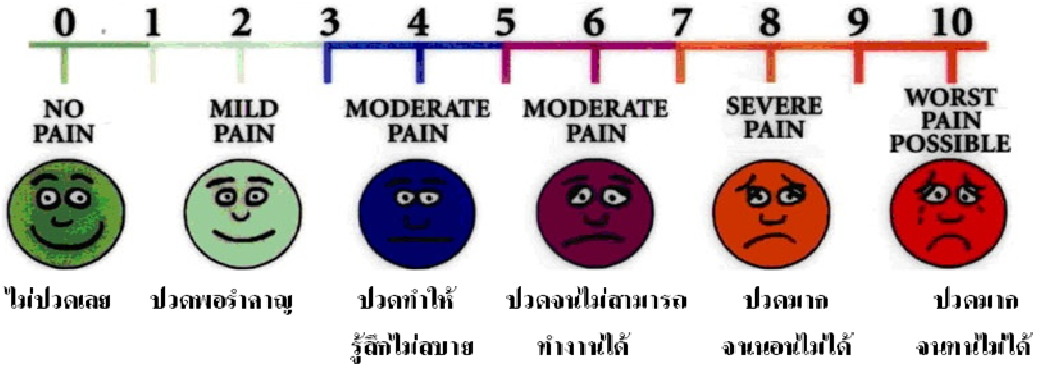
1. เพศ ( ) 1. ชาย ( ) 2. หญิง
2. อายุ.....ปี
3. น้ำหนัก.....กก. ส่วนสูง.....ซม. BMI = .....
4. ท่านมีอาการเหล่านี้หรือไม่

( ) 4.1 มีอาการปวดที่ส่งผลกระทบต่อความสามารถด้านการเดิน ระบุ

.....

โดยมีระดับความเจ็บปวด.....

**หมายเหตุ**: รูปแสดงอาการเจ็บปวด




( ) 4.2 มีแผลกดทับที่ต้องจำกัดการเคลื่อนไหว

( ) 4.3 มีความผิดปกติของแขนหรือขาที่ส่งผลต่อความสามารถด้านการเดิน เช่น ความยาวของขาไม่เท่ากันทั้ง 2 ข้างที่ไม่สามารถแก้ไขได้โดยการใส่รองเท้าเสริมส้น กระดูกสันหลังผิดรูป เช่น กระดูกสันหลังคด (scoliosis) ที่ทำให้เหนื่อยง่าย อื่นๆ ระบุ

.....

**ส่วนที่ 2 แบบบันทึกข้อมูลเกี่ยวกับการบาดเจ็บของไขสันหลัง และความสามารถในการเคลื่อนไหว**

**<u>คำชี้แจงการบันทึกข้อมูล</u>** ข้อมูลในข้อ 5-9 เป็นข้อมูลที่ได้การตรวจประเมินของผู้วิจัย แล้วบันทึกข้อมูลที่ได้ โดยการกาเครื่องหมายถูก (/) ในช่อง ( ) หน้าตัวเลือกที่ตรงกับข้อมูลที่ได้มากที่สุด เพียงข้อเดียว และ/หรือเขียนตอบด้วยตัวบรรจง

5. สาเหตุของการบาดเจ็บของไขสันหลัง

   ( ) 1. Traumatic SCI ระบุสาเหตุ.....

   ( ) 2. Non-traumatic SCI ระบุสาเหตุ.....

      ( ) 1. Progressive diseased ( ) 2. Non progressive diseased

6. ระดับการบาดเจ็บของไขสันหลัง (levels of SCI)

   ( ) 1. Quadriplegia ( ) 2. Paraplegia ระบุระดับ.....

6. ความรุนแรงของการบาดเจ็บของไขสันหลัง (AIS class)

   ( ) 1. AIS C ( ) 2. AIS D

7. ระยะการบาดเจ็บของไขสันหลัง (stages of SCI)

   ( ) 1. Subacute ระยะเวลา.....เดือน

   ( ) 2. Chronic ระยะเวลา……..ปี.....เดือน

8. ระยะทางที่สามารถเดินได้ (FIM locomotor scores)

   ( ) 1. FIM-L = 5 (เดินได้อย่างน้อย 17 เมตร แต่น้อยกว่า 50 เมตร) โดย

      ( ) ไม่ใช้อุปกรณ์ช่วยเดิน ( ) ใช้อุปกรณ์ช่วยเดินระบุ.....

   ( ) 2. FIM-L = 6 (เดินได้อย่างน้อย 50 เมตร โดยใช้อุปกรณ์ช่วย)

      ระบุอุปกรณ์ช่วยเดิน.....

   ( ) 3. FIM-L = 7 (เดินได้อย่างน้อย 50 เมตร โดยไม่ใช้อุปกรณ์ช่วย)

**ส่วนที่ 3 ตารางบันทึกผลการทดสอบความสามารถของอาสาสมัคร**

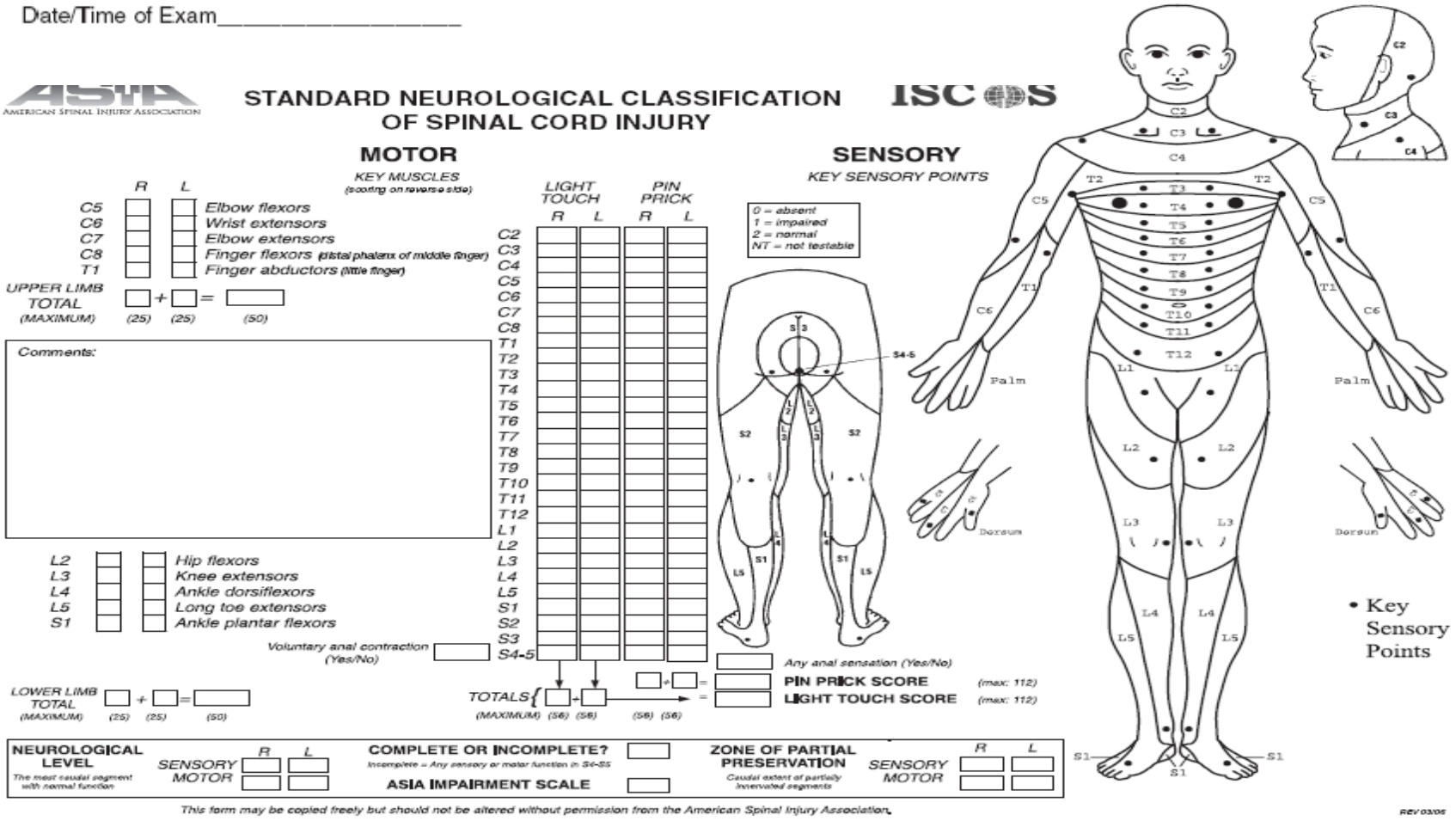
**<u>คำชี้แจงการบันทึกข้อมูล</u>** ข้อมูลส่วนนี้ได้จากการทดสอบความเร็วในการเดิน โดยบันทึกความเร็วปกติ ความเร็วสูงสุดอย่าง ละ 3 ครั้ง และระยะทางในการเดิน 6 นาที และการตรวจร่างกายทางกายภาพบำบัด

**ตารางบันทึกผลความสามารถในการเดิน**

| | | **เดินด้วยความเร็วปกติ (Preferred speed)** | | **เดินด้วยความเร็วสูงสุด (Maximum speed)** | |
|---|---|---|---|---|---|
| | | เวลา (วินาที) | ความเร็ว (เมตร/วินาที) | เวลา (วินาที) | ความเร็ว (เมตร/วินาที) |
| **10 MWT** | ครั้งที่ 1 | | | | |
| | ครั้งที่ 2 | | | | |
| | ครั้งที่ 3 | | | | |
| | **ค่าเฉลี่ย** | | | | |
| **6 MinWT** | | | | | |

หมายเหตุ……

**ผลการทดสอบกำลังของกล้ามเนื้อและการรับความรู้สึก**



# APPENDIX E

## Additional Data of the Study

**Table 5:** Baseline demographics and SCI characteristics of subjects with FIM-L scores 5-7

| **Parameters** (N = 74) | **FIM-L 5** (N = 10) | **FIM-L 6** (N = 31) | **FIM-L 7** (N = 33) | **p-value*** |
|---|---|---|---|---|
| Age [Mean±SD] (years) | 41±11.82 | 51.97±13.23 | 49.18±10.00 | 0.42 |
| Post-injury time [Mean±SD] (months) | 53.80±35.66 | 44.26±43.18 | 36.72±30.63 | 0.41 |
| Gender [males/females] (n) | 8/2 | 25/6 | 23/10 | - |
| Causes [Non-traumatic/Traumatic] (n) | 7/3 | 11/20 | 16/17 | - |
| Levels of injury [Tetraplegia/Paraplegia] (n) | 4/6 | 5/26 | 16/17 | - |
| AIS classes [C/D] (n) | 9/1 | 18/13 | 30/3 | - |

*p-values from one-way analysis of variance (one-way ANOVA)

FIM-L: Functional Independence Measure Locomotor scores

AIS: American Spinal Injury Association (ASIA) impairment scales

**Table 6:** The 6MinWT and outcomes derived from the 10MWT in subjects with different levels of walking ability

| **Parameters** | **FIM-L 5 (N=10)** | **FIM-L 6 (N=31)** | **FIM-L7 (N=33)** | **p-value*** |
|---|---|---|---|---|
| Outcomes derived from the 10MWT | | | | |
| - Preferred speed (m/s) | 0.16±0.10 (0.1-0.23) | 0.39±0.18 (0.23-0.30) | 0.83±0.27 (0.81-1.12) | 0.001** |
| - Maximum speed (m/s) | 0.21±0.14 (0.11-0.31) | 0.54±0.23 (0.30-0.56) | 1.04±0.32 (1.07-1.40) | 0.001** |
| - Difference of walking speed (m/s) | 0.05 ± 0.4 (0.02-0.08) | 0.15± 0.15 (0.10-0.20) | 0.21±0.12 (0.17-0.25) | 0.005** |
| - Percentages of walking speed (%) | 76.71 ± 8.73 (57.14 – 88.24) | 74.18±16.47 (68.14-80.22) | 81.95±112.99 (17.94-85.95) | 0.07 |
| 6MinWT (m) | 36.56±11.19 (28.56-44.57) | 112.23±41.80 (82.34-142.13) | 284.68±67.48 (235.82-332.38) | 0.001** |

Data were presented using mean±SD (95%CI)

FIM-L: Functional Independence Measure Locomotor scores

*p-value from one-way analysis of variance (one-way ANOVA)

** Indicated differeces significant

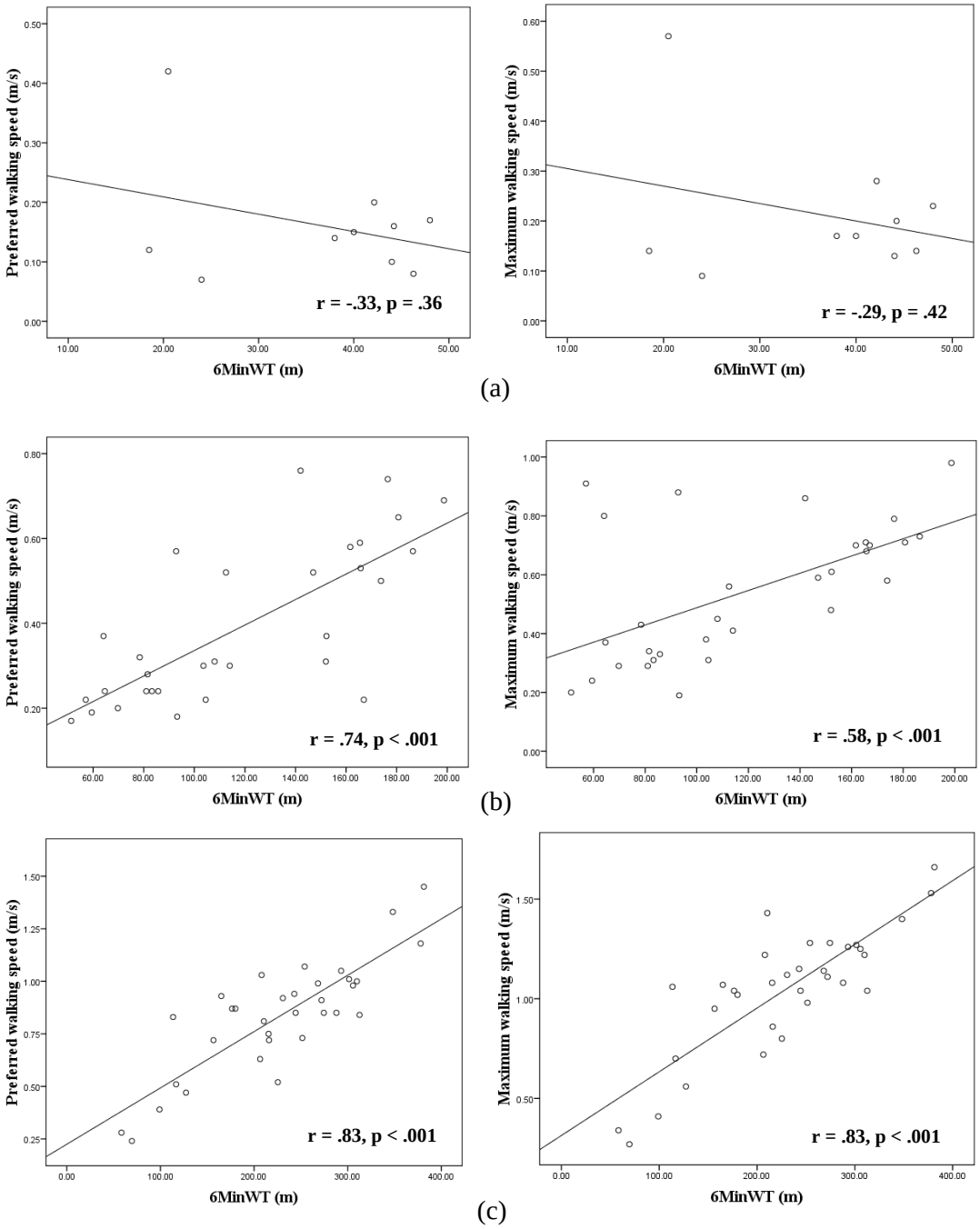



**Figure 12** Correlation between the 6MinWT and outcomes derived from the 10MWT in subjects with different levels of walking ability: x-axis refers to 6MinWT (m), y-axis demonstrate outcomes derived from the 10MWT

(a) Correlation subjects with FIM-L 5

(b) Correlation subjects with FIM-L 6

(c) Correlation subjects with FIM-L 7

# RESEARCH PUBLICATIONS

สาลินี แนวหล้า, ปรีดา อารยาวิชานนท์, วัณทนา ศิริธราธิวัตร, สุกัลยา อมตฉายา. ความสัมพันธ์และความสามารถของการทดสอบการเดินระยะทาง 10 เมตร ในการทำนายผลการทดสอบการเดินในเวลา 6 นาที ในผู้ป่วยบาดเจ็บไขสันหลังที่สามารถเดินได้เอง. **วารสารเทคนิคการแพทย์และกายภาพบำบัด** (inpress).

**Salinee Naewla**, Preeda Arayawichanon, Wantana Siritaratiwat, Worrawan Kumruecha, Sugalya Amatachaya, Correlation between walking speed and function capacity as measured using the 6-minute walk test (6MinWT) in independent ambulatory patients with spinal cord injury (SCI). Spinal cord (in review).

**Presentation**

**International presentation**

**S Naewla**, S Amatachaya, W Siritaratiwat, P Arayawichanon. Correlation of the 10-meter walk test (10MWT) and 6-minute walk test (6MinWT) in patients with spinal cord injury (SCI). **The XIIX World Congress on Parkinson's Disease and Related Disorders.** Shanghai, China (December 11-14, 2011) (Poster presentation)

**S Naewla**, S Amatachaya, W Siritaratiwat, P Arayawichanon. Correlation of 10-meter walk test (10MWT) and 6-minute walk test (6MinWT ) in independent ambulatory iSCI patients who walked with walking devices. **1st Singapore Rehabilitation Conference**. Singapore (February 10-11, 2012) (Poster presentation)

**National presentation**

สาลินี แนวหล้า, สุกัลยา อมตฉายา, ปรีดา อารยาวิชานนท์, วัณทนา ศิริธราธิวัตร. ความสัมพันธ์ของทดสอบการเดินระยะทาง 10 เมตรและการเดินในเวลา 6 นาที ในผู้ป่วยบาดเจ็บไขสันหลัง. ๒๕๕๕...สามทศวรรษกายภาพบาบัด ม.ขอนแก่น: ก้าวย่างเพื่อพัฒนาสุขภาพประชาชนไทย. ขอนแก่น (19-22 มีนาคม 2555) (นำเสนอทางวาจา) (ได้รับรางวัลชมเชย)