EFFECT OF SPASTICITY ON QUALITY OF LIFE IN PATIENTS WITH SPINAL CORD INJURY

A Thesis Presented to the
Faculty of the Department of Health and Human Performance
University of Houston

In Partial Fulfillment
of the Requirements for the Degree
Master of Science

by
Amruta A. Dongre

December 2013

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ABSTRACT

The basic goal of any rehabilitation program is to restore function and to improve quality of life. In patients with spinal cord injury, spasticity is one of the major complications which affects quality of life. The use of an Intrathecal Baclofen (ITB) pump to treat spasticity has recently increased. Even though ITB treats spasticity, it results in various complications and is very expensive. It is important to examine the long term benefits of ITB in improving quality of life along with spasticity in patients with spinal cord injury.

In this study, we have compared the Quality of Life (QoL) and patient reported impact of spasticity in first time ITB pump users and those who have had it re-implanted. We have examined the relationship between patient reported impact of spasticity and QoL. We have also compared the physician's evaluation of spasticity with patient's perception of spasticity. 36 patients with tetraplegia having an ITB pump implant (14 patients who were on their first pump as well 22 patients who have it re-implanted) were selected from TIRR Memorial Hermann's ITB pump clinic in Houston, TX. Clinical assessment for spasticity was performed by a clinician or nurse, and the clinical scales including World Health Organization Quality of Life- BREF (WHOQOL-BREF), Patient Reported Impact of Spasticity Measure (PRISM), and the Pump Complications Questionnaire were administered by the Principal Investigator via telephone. Independent *t*-tests were performed to compare the group differences (first time pump users versus individuals with re-implants) in each subscale of WHOQOL-BREF, each subscale of PRISM, and MAS. The level of significance was set at $p < .05$.

It was noted that there were no significant group differences in both WHOQOL-BREF and PRISM subscales. The results indicate that as the spasms get worse it limits the ability to perform ADL, causes psychological distress, social embarrassment, and in turn affects an individual's health, quality of life, interaction with the environment and the society. The correlation between the PRISM subscales and MAS revealed that only social avoidance and social embarrassment significantly correlated with MAS furthermore suggesting that spasticity negatively affects an individual social relationships and social interaction.

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CHAPTER 1: INTRODUCTION

Spinal cord injury (SCI) is one of the leading causes of long-term disability in the United States. The National Spinal Cord Injury Statistical Center reports an average of 12,000 new cases of SCI every year ("Spinal cord injury facts and figures at a glance," 2013). For the past few decades, the life expectancy in these patients has increased and the focus has shifted from increasing life expectancy to enhancing functional independence and quality of life. Immobility and other secondary complications like spasticity, fatigue and contracture increases the rate of disability and ultimately reduces the rate of life expectancy among these patients (Johnson, Gerhart, McCray, Menconi, & Whiteneck, 1998; Westerkam, Saunders, & Krause, 2011).

Quality of life (QoL) is an important measure that determines the impact of the chronic disease and healthcare on the individual when complete cure is not possible(Burckhardt & Anderson, 2003a). QoL depends on various objective and subjective factors such as impairment, disability, health status, depression, functional independence, socio-economic status, social participation, and perceived well-being. QoL scales are instruments that don't answer but rather assess the questions related to these factors.

Complications like fatigue, pain, pressure sores, spasticity and contractures hinder the mobility of the individual, making the condition worse and contributing to further disability. Therefore, it becomes necessary to study these complications and how patients with SCI can be helped to resolve them in more depth. Spasticity, for example, is a major complication that increases pain and restricts the range of motion, and which in turn

negatively affects activities of daily living (ADL's) (Adams & Hicks, 2005; Martin Ginis, Jetha, Mack, & Hetz, 2010). It also becomes necessary to look into the treatment plans and the effect of various treatments like Intrathecal Baclofen (ITB) pumps on spasticity and quality of life(Hallin, Sullivan, & Kreuter, 2000; Ochs, Naumann, Dimitrijevic, & Sindou, 1999; Westerkam et al., 2011; Zahavi, Geertzen, Middel, Staal, & Rietman, 2004).

1.1. Problem Statement

The goal of any rehabilitation program is to improve functional ability, increase independence and improve a patient's QoL. QoL is an umbrella term that depends on numerous factors like level of independence, physical activity, pain, and socio-economic status. However, level of independence and pain are the major factors which affect QoL in patients with SCI. It has been shown that spasticity after SCI is the major cause affecting both independence and pain, which negatively affects the QoL (Westerkam et al., 2011).

There are different clinical views on the positive and negative effects of spasticity. Spasticity has been shown to increase pain, disrupt sleep and restrict mobility. At the same time, it has also been reported to increase venous blood flow and restrict the deposition of intramuscular fat which seems to be a positive aspect of spasticity (Adams & Hicks, 2005; Hsieh, Wolfe, Miller, & Curt, 2008a; Johnson et al., 1998). It is usually expected that any anti-spasticity medication will suppress all aspects of spasticity. It becomes difficult for a single clinical test to assess all aspects of spasticity and the extent to which the spasticity is being suppressed (Arthur, Thornby, & Kharas, 1996). Such

ambiguous results make it difficult to understand the clinical line of treatment for spasticity in general. Therefore, it becomes necessary to look into the patients' perception of his/her spasticity along with the clinicians' evaluation to understand the discrepancies reported in the literature (Bhimani, Anderson, Henly, & Stoddard, 2011; Westerkam et al., 2011). Self-reported scales, like the Patient Reported Impact of Spasticity Measure (PRISM), have not been used clinically to assess a patient's perception of his/her spasticity.

There are various potential therapies/treatments used to manage spasticity. Recently, the use of Intrathecal Baclofen (ITB) for muscle specific spasticity has increased. ITB reduces spasticity after implantation of the pump, but is very expensive and may also cause various complications like catheter leaks and kinks, withdrawal, and overdose. These complications may lead to re-implantation of the pump and has minimal effect on improving long term QoL (Zahavi et al., 2004). The reasons for minimal improvements in long term QoL are yet to be explored. Although complications of the pump are thought to be one reason, a well validated questionnaire to assess these complications has yet to be developed.

1.2. Aims and Hypotheses

i. **Aim:** To compare QoL and patient reported impact of spasticity in first time ITB pump users to those who have had it re-implanted.

Hypotheses:

a. The patients with their first pump will have a higher quality of life as compared to those who have it re-implanted.

b. The perception of spasticity in the patients with re-implants will be better than those with their first pump.

c. Complications caused by the ITB pump will negatively affect the quality of life in both group of patients.

ii. **Aim:** To examine the relationship between patient reported impact of spasticity and QoL.

Hypothesis: There will be a negative correlation between quality of life and patient reported impact of spasticity.

iii. **Aim:** To compare the physician's evaluation of spasticity with patient's perception of their spasticity.

Hypothesis: There will be a positive correlation between the physician evaluation of spasticity and the patient reported impact of spasticity.

1.3. Significance

Today, there is an upsurge of the use of ITB for spasticity control. Because oral baclofen has some side effects, ITB is preferred. ITB is the last resort to treat spasticity since it is an invasive procedure and is very expensive. Science has indicated that ITB treats spasticity,(Gianino, 1998; Guillaume, Van Havenbergh, Vloeberghs, Vidal, & Roeste, 2005; Ochs, Naumann, Dimitrijevic, & Sindou, 1999; Rekand, 2010) but with long term use of ITB there is a risk of developing complications like catheter migration, leaks, surgical site infection, withdrawal and overdose (Gianino, 1998). This study utilized a newly developed questionnaire to examine the effects of ITB pump on QoL and spasticity in patients who have received their first pump and patients who have had it re-

implanted. This questionnaire specifically addressed the frequency and severity of the pump complication.

The major problems experienced by patients with SCI have included immobility, spasticity and the subsequent complications. After one year of injury, about 70% of the SCI population suffers from spasticity and resulting pain, contractures and pressure sores,(Biering-Sørensen, Nielsen, & Klinge, 2006) and almost all patients receive some form of spasticity control medication. Also, after the novelty effect of ITB wears off, the QoL may reach a plateau stage even if the spasticity reduces considerably. Spasticity is typically assessed clinically by the Modified Ashworth Scale (MAS). Along with the clinician's evaluation, the views of the patient on their spasticity becomes necessary to be assessed for an appropriate line of treatment (Bhimani et al., 2011; Westerkam et al., 2011). The Patient Reported Impact of Spasticity Measure (PRISM) is assessment of perceived spasticity, however, it is not typically administered by clinicians and therefore was included in this study.

The basic goal of any rehabilitation program is to improve the overall QoL of an individual and to restore function. When a cure for a disease is not possible, healthcare and health status is assessed with questionnaires which are disease-specific, objective and subjective(Burckhardt & Anderson, 2003b; Guillaume et al., 2005; Tate, Kalpakjian, & Forchheimer, 2002). Over the years many QoL questionnaires have been developed, however, not all questionnaires are disease and condition specific(Hallin et al., 2000; Hill, Noonan, Sakakibara, & Miller, 2010). There is a need to develop questionnaires which address and reflect subjective and objective issues specific to the condition and population. The QoL questionnaires developed to date are not unique to patients with

SCI and often lack consistency and sensitivity for the construct being measured (Tate et al., 2002). After reviewing the literature, Hill et al. (2010) suggested that the World Health Organization–Quality of Life BREF (WHOQOL-BREF) seems to be the most appropriate and sensitive questionnaire to answer the health status related questions in SCI.

1.3. Definition of Terms

a) Spinal cord injury (SCI): It refers to any injury to the spinal cord that is caused by trauma instead of disease. (Taber's Medical Dictionary).
b) Quality of life (QoL): According to Revicki and colleagues (2000), QoL is "A broad range of human experiences related to one's overall well-being. It implies value based on subjective functioning in comparison with personal expectations and is defined by subjective experiences, states and perceptions" (Revicki et al., 2000, p.888).
c) Spasticity: A hypertonic motor disorder characterized by velocity- dependent resistance to passive stretch; the result of an upper motor neuron lesion (Decq, 2003).
d) Intrathecal Baclofen (ITB) Pump: A programmable pump with a reservoir; a clear, flexible silicone catheter, and a programming device.

1.4. Overview of the Study

This study is observational. The first chapter describes the purpose and the nature of the study. The second chapter describes the literature reviewed related to the topic. The third chapter describes the methodology that was used for the study. The fourth chapter

describes all the findings or data collected. The last chapter describes the results from the data collected and discusses the limitations of the study as well as future directions.

CHAPTER 2: LITERATURE REVIEW

Today, medicine and technology have scaled great heights. Newer and better technology is being implemented to increase the life span for many health conditions. Yet, SCI still remains one of the causes of long term disability. The life span of patients suffering from SCI has increased but has it also improved QoL is doubtful. According to the 2013 census, there are approximately 273,000 patients with SCI living in the United States, and about 12,000 new cases are reported every year ("Spinal cord injury facts and figures at a glance," 2013). The major problem faced by individuals with SCI is the need of extra care in order to prevent secondary complications along with the primary manifestations of the condition. One of the common causes of death in patients with SCI is respiratory ailments, which include spasms of the respiratory muscles, pneumonia, atelectasis and others (Johnson et al., 1998). In addition to this, pain, loss of sensation and other complications negatively affect the prognosis and thus affect overall well-being post injury.

2.1. Spinal Cord Injury

In the United States, SCI has a high mortality rate during the first year after injury and the highest rate of long term disability ("Spinal cord injury facts and figures at a glance," 2012). Questionnaires used to assess QoL in patients with SCI are often used to

assess QoL in individuals living with various other conditions, thus the questionnaires are often not disease and condition specific. This results in ambiguity with regards to perceived QoL and the prognosis of the treatment being administered (Hammell, 2004; Hill et al., 2010). SCI is a trauma caused to spinal cord and should not be classified as a disease. According to 2010 census, 53% of individuals with SCI have paraplegia and 47 % are classified as tetraplegia. There is also a higher percentage of males living with SCI than females. The common clinical manifestations after SCI include, but are not limited to, spinal shock, motor and sensory impairments, autonomic dysreflexia (which is a critical situation), respiratory problems due to paralysis of respiratory muscles (seen only in quadriplegics), impaired temperature control, spasticity, bowel and bladder dysfunction, and sexual dysfunction. Out of all of the manifestations, respiratory complications are the most common cause of death in people with SCI. Other complications like pressure sores, deep vein thrombosis, contractures, heterotrophic ossification, dysesthesia, and immobility due to spasticity may also be seen.

All of these complications may be treated and even prevented if proper care is provided. However, given the nature of the condition, some complications like pain due to spasticity are inevitable. Pain is the major problem which negatively affects QoL and a treatment is still forthcoming. Heavy anti-spasmodic medicines are administered to reduce the spasticity and the subsequent pain, but these cannot be long term treatment protocols as a result of the negative side-effects of the drugs. Hence, alternative treatment such as intrathecal drug delivery has been devised to reduce the pain and complication.

2.1.1. Complications in Spinal Cord Injury

The list of complications after SCI is long. After injury, loss of function has been identified as a major barrier in successful recovery (Anderson, 2004; Johnson et al., 1998). Pulmonary complications, neuromuscular complications, bowel and bladder issues, and sexual dysfunction are some of the common complications. After one year of injury, primary cause of death are respiratory complications (De Vivo, Stuart Krause, & Lammertse, 1999). Respiratory failure is commonly seen in patients with high cervical injury (Jackson, 1994). Over time, pressure ulcers are the most common life threatening complication in patients with SCI (McKinley, Jackson, Cardenas, & DeVivo, 1999). Literature supports the use of various mattresses containing water or air or the use of several kinds of drugs, various kinds of dressings and nutritional supplements, and administration of electrotherapeutic agents like the ultrasound, infra-red rays, and UV rays to prevent or cure pressure ulcers (Mikulic, 1980).

Pain is one of the most common problems faced by almost all the individuals with SCI. Pain affects sleep, activities of daily living, etc., and is usually neurogenic in nature. Pain is more common in individuals with paraplegia than with tetraplegia and is more intense in individuals with incomplete injury than in those with complete (Turner, Cardenas, Warms, & McClellan, 2001). Pain is the primary reason for seeking medical intervention. Various drugs are administered to treat pain but not the cause of pain, which are typically spasm and immobility.

2.2. Spasticity

Spasticity is a hypertonic motor disorder characterized by velocity- dependent resistance to passive stretch as a result of an upper motor neuron lesion (Decq, 2003). It is caused by an injury to the corticospinal pathways and results in disordered reflexes due to loss of control of lower motor neurons. Spasticity is characterized by hypertonicity, hyperactive stretch reflexes and clonus. Stretch reflexes are absent in patients with lumbar spinal cord lesion although abnormally high muscle tone is noted. Spasticity varies from insignificant to very severe, causing pain and subsequent disability. Spasticity is usually less severe in patients with a complete spinal cord lesions (Biering-Sørensen et al., 2006) and may be classified according to its presentation.

Decq (2003) has classified spasticity as 'intrinsic tonic spasticity', 'intrinsic phasic spasticity' and 'extrinsic spasticity'. Intrinsic tonic spasticity is characterized by increase in the muscle tone. Intrinsic phasic spasticity is characterized by hyper-reflexia and clonus. Extrinsic spasticity manifests by exaggeration of extension spinal reflexes. It can be further classified on the basis of the ASIA classification of SCI. (Sköld, 2000). It is noted by Sköld and colleagues (2000) that almost 93% of individuals with cervical ASIA A and 73% of those diagnosed with cervical ASIA B-D and thoracic ASIA A-D have spasticity.

Spasticity causes pain, insomnia, and immobility. Patients suffer from insomnia due to pain and clonus. Immobility may cause contractures and pressure sores if not treated properly making the patients' condition worse (Bhimani et al., 2011). Hunter Revell (2011) noted that SCI follows a symptom cluster wherein there is presence of shooting pain due to indwelling spasticity, and if not treated may lead to depression and

reduced QoL. Skold and colleagues (2000) found that 4% of the SCI population reported to have problems with ADL due to spasticity. All these things greatly affect quality of life; therefore, a proper treatment protocol should be administered and proper measures to gauge the prognosis of the treatment needs to be devised. Since QoL and spasticity are multi-dimensional in nature, Hseih (2008) stressed the importance of using tools assessing QoL and spasticity based on the use of anti-spasmodic drugs and the impact of specific intervention on the QoL and function of the patient.

Clinically, the Modified Ashworth Scale (MAS) is commonly used. Other clinical evaluation scales like Tardieu Scale and Penn Spasm Frequency scale are also being used (Biering-Sørensen et al., 2006; Rekand, 2010). These scales are clinically tested by therapists, physicians or the nurses on the patients' affected extremity or body part by moving the part in all the ranges of motion. It has to be noted that since these scales are administered by the clinicians, there can be an inconsistency between patient and examiner's evaluation and perception of spasticity. This may lead to difficulty in establishing the treatment protocol, but it is essential to have an evaluation of the patient's perception of his/ her spasticity (Bhimani et al., 2011). The recently developed PRISM is a self-reported spasticity questionnaire in which the patient reports his/ her perception about spasticity and its effect on his daily activities and functioning. Both the clinical evaluation and patient's evaluation of spasticity helps to get a better picture of the impact of spasticity's on a patients' life and the medical intervention being employed.

2.2.1. Measurement of Spasticity

The MAS is a commonly used clinical measure that assesses spasticity. The MAS has grades from 0-5, (0- 'no increase in muscle tone' and 5- 'extremity is rigid on both flexion as well as extension'). The MAS is a quick measure used assess spasticity in a clinical setting. However, it is not adequately inclusive because it fails to address other aspects of spasticity, like clonus, and lacks good inter rater reliability. The MAS has moderate intra rater reliability, and therefore, it is recommended to use another measure (Craven & Morris, 2010; Ghotbi et al., 2009). Moreover, Fleuren and colleagues (2010) have suggested that the MAS has poor validity and reliability, and therefore cannot be used as the only measure to assess spasticity.

The PRISM is a newly developed scale which addresses spasticity from the patient's perspective. This is a unique questionnaire which has been rarely used thus far in the literature to document the impact of spasticity on the patients' overall QoL (Hill et al., 2010). The PRISM consists of 41 items, divided into 7 subscales namely anxiety, psychological agitation, daily activities, assistance, positive impact, need for intervention, social embarrassment. It uses 5 point Likert Scale for scoring, and a higher score is considered unhealthy. Additionally, it has excellent internal consistency and test/retest reliability (Cook et al., 2009; Hill et al., 2010).

2.2.2. Treatment for Spasticity

Various treatment protocols are available for the treatment of spasticity. The most commonly used treatments are anti-spasmodic drugs and rehabilitation, including physical and occupational therapy. However, many alternative treatment therapies like

acupuncture, yoga, chiropractic treatment, hydrotherapy, massage therapy, group therapy, and counseling are also administered (Turner et al., 2001; Wollaars, Post, van Asbeck, & Brand, 2007).

Rehabilitative therapies like physical and occupational therapy use techniques like stretching, cold and heat applications, relaxed passive movements, Functional Electrical Stimulation (FES), orthosis (to reduce limb spasms and prevent contractures), and biofeedback. For the lower limbs, body weight supported treadmill training has shown positive results after SCI (a L. Hicks et al., 2005; A. L. Hicks, 2008; Swinnen, Duerinck, Baeyens, Meeusen, & Kerckhofs, 2010). Group activities like strength training, walking, jogging and swimming for patients with chronic SCI have also been reported (Langhammer & Stanghelle, 2010; Moses & Edwards, 1989; Tasiemski, Kennedy, Gardner, & Taylor, 2005). Any kind of physical activity or rehabilitative treatments have shown improvement in the function of the patients (Hammell, 2004; a L. Hicks et al., 2005; A. L. Hicks, 2008; Martin Ginis et al., 2010).

Various pharmacological treatments may also be used to control spasticity. Currently, Baclofen is a common drug administered to treat spasticity. There has been about a 75-96% improvement in spasms after administration of the drug (Dario & Tomei, 2004). Davidoff (1985), reported that Baclofen is a GABA agonist that inhibits the excitability of the motor neurons by damping the release of excitatory neurotransmitters. Therefore, it helps in reducing spasticity. Baclofen can be delivered either orally or intrathecally. Both methods of delivery have pros and cons. Oral Baclofen can be taken as a daily dose, while ITB requires surgery. Oral Baclofen is reported to have various side effects like sedation, confusion, hallucinations, drowsiness, vertigo, ataxia, and

respiratory and cardiovascular depression. Additionally, spasticity increases once the effect of the drug wears off (Dario & Tomei, 2004; Gianino, 1998; Ochs et al., 1999). As a result of the side effects, oral Baclofen has been replaced by ITB, which has fewer side-effects and is reversible.

ITB is delivered through a pump which is implanted in the intrathecal space. The infusion of the drug is continuous and with an average a dosage of 40µg/day. This dosage is increased gradually by the physician, according to the patients' requirement (Ochs et al., 1999). ITB has been shown to have improvement in spasticity and spasms (Campbell et al., 2002; Dario & Tomei, 2004; Jagatsinh, 2009; Ochs et al., 1999; Ucar, Kazan, Turgut, & Samanci, 2011; Zahavi et al., 2004). It also helps in reducing pain (Teasell et al., 2010). However, the pump is implanted only in those patients who can afford the high cost of the treatment and who respond positively to the bolus test of the drug before implantation. The improvement in spasticity is measured by spasticity scales like the MAS. The effect of ITB on spasticity has proven to be remarkable in first year after implantation of the pump. However, there are not many follow- up studies that confirm the results of the pump on spasticity for durations of greater than one year after implantation or after re-implantation of the pump, which makes it difficult to conclude that ITB is the best treatment for spasticity (Dario & Tomei, 2004; Gianino, 1998; Zahavi et al., 2004). One study (Zahavi et al., 2004) suggested that there was considerable improvement in the spasticity scores but small yet significant worsening was reported in the perceived level of well-being. The reason for this contradictory result has not been studied yet.

There are some complications of Intrathecal Baclofen which have been reported in last few years. Complications including catheter malfunction, catheter migration, catheter leakage, catheter occlusion, granuloma at the tip of the catheter, infection at the pump site, cerebrospinal fluid leak, pump defect, battery exhaustion of the pump, paralytic ileus, withdrawal symptoms, and seizures have been reported (Dario & Tomei, 2004; K. A. Follett & Naumann, 2000; K. a Follett et al., 2003; Haranhalli et al., 2011; Ross, Cook, Stewart, & Fahy, 2011; Staats, 2008; Ucar et al., 2011; a B. Ward, 2008; A. Ward, Hayden, Dexter, & Scheinberg, 2009; Watve, Sivan, Raza, & Jamil, 2012). These complications are considered to have a negative effect on the prognosis and QoL of the patient. Some complications like withdrawal symptoms, delirium, seizures etc. are reversible and can be prevented by reducing the dosage of the continuous drug. Other device related malfunction needs to be managed as this is an expensive and lifelong therapy and it affects the presentation of the condition.

Intrathecal morphine has also been used to reduce spasticity. Morphine has been used to treat pain caused by cancer- granulomas, multiple sclerosis, lumbar arachnoiditis and spasticity (Paice, Penn, & Shott, 1996; Penn, 2004). Botolinum toxin type A (commonly known as Botox) has been suggested to be a useful drug for spasticity control, but is primarily used for muscle specific spasticity and is therefore more commonly used for people living with stroke. There is research to suggest that Botox may be used in treatment of spasticity as an adjunct to Baclofen (Al-khodairy, Gobelet, & Rossier, 1998; Richardson, Edwards, Sheean, Greenwood, & Thompson, 1997). Botox is suggested to be useful in reducing upper-limb spasticity in individuals with tetraplegia, cerebral palsy and stroke. A study noted that Botox may reduce lower limb spasticity to

some extent, but may not guarantee improvement in the functional activities of the lower limb (Bensmail et al., 2009). Although this drug is useful, it cannot be used for generalized spasticity control and therefore has limits in patients with SCI.

2.3. Quality of Life

According to Revicki and colleagues (2000), health status and quality of life are multidimensional constructs and takes into consideration the patient's perspective on his/her physical and mental state of being. Improving QoL is one of the ultimate goals of any treatment or rehabilitation program. The factors contributing to a better QoL are often found to be ambiguous. Literature has identified several physical, psychological, socio-economic, and environmental factors that define QoL as a whole. Certain measures which divide these factors into multiple questions have been designed over the years and are being validated (Burckhardt & Anderson, 2003a). These measures are known as the Quality of Life Questionnaires. Several studies have used questionnaires that are generic or have used a part or whole components of a questionnaire which was designed for stroke or other conditions.

2.3.1. Measurement of Quality of Life

QoL depends on several factors including physical, psychological, socioeconomic, environmental, cultural, and level of satisfaction. The scales for QoL were created originally by John Flanagan in the 1970s. These scales were formulated for generic use. They are comprised of 5 domains describing the patients experiences and expectations from life under the keywords "needs met" and "importance", respectively

(Burckhardt & Anderson, 2003b). As a result of Flanagan's work, several new questionnaires were devised and were more specific to certain age groups and conditions.

After thorough review of the literature, it was noted that there are many questionnaires that are specific to assessing QoL after stroke, and there are limited questionnaires that are specific to SCI (Tate et al., 2002). Currently, there are several questionnaires, of which almost 15-20 of them are used for stroke and SCI combined. The questionnaires used for stroke are specific to the needs of the disease and are well formulated and validated. However, no such questionnaire has been developed that is unique to SCI patients. The dearth of questionnaires prevents researchers and clinicians from drawing a conclusion regarding the prognosis of the disease. After reviewing the literature, Short Form (SF)-36V, Sense of Well Being Index (SWBI), Quality of Life with Physical Disabilities (QOL-PD), World Health Organization Quality of Life (WHOQOL)- BREF, Sickness Impact profile (SIP) 68, Qualiveen and Patient Reported Impact of Sickness Measure (PRISM) were close contenders and looked promising to cover all the aspects of QoL specific to SCI (Hill et al., 2010; Tate et al., 2002).

The SF36 and SF12 are the most commonly used generic questionnaires to assess health related quality of life for any kind of physical disability. (Tate et al., 2002). SF36 has been previously used to assess QoL in patients with SCI (Forchheimer, McAweeney, & Tate, 2004; Hays, Hahn, & Marshall, 2002). This questionnaire is the easy and takes the less amount of time to administer. It includes several subscales like physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, mental health, Physical Component Summary (PCS) and Mental Component Summary (MCS). Despite the benefits it has to offer it cannot be used for

SCI alone for various reasons. This being a generic questionnaire, it was developed commonly for arthritis, stroke, Traumatic Brain Injury (TBI), orthopedic pain, and SCI. The PCS and MCS measures two different constructs and the MCS does not contribute towards assessing QoL in patients with SCI. Moreover this questionnaire lacks the sensitivity to answer the questions related to the complications of SCI (Tate et al., 2002). The SF12 is a shorter version of SF36. According to Tate et al. (2002), SF12 is quicker to administer and has good psychometric properties. But, the limitation with SF12 is that certain terms in questionnaires are ambiguous which makes it difficult for the patient to interpret the term.

The Qualiveen is specific to urinary disorders seen in patients with SCI and could not be used to assess QoL. WHOQOL-BREF is a generic health related QoL measure consisting of 26 items divided into 6 sub-scales. It was formulated from the original WHOQOL questionnaire which consisted of 100 items. It has 4 domains namely physical health, psychological health, social relationship and environment, and 2 individual subscales on overall quality of life and general health. It can be self-administered and has good internal consistency (0.75-0.87), lower percentage of floor and ceiling effects, good validity, and responsiveness (Lin, Hwang, Chen, & Chiu, 2007). WHOQOL–BREF is suggested as the most appropriate generic health related QoL questionnaire in patients with SCI (Hill et al., 2010; Lin et al., 2007; Martin Ginis et al., 2010). Thus, a questionnaire which would closely address the issues specific to SCI was chosen. Amongst all the questionnaires reviewed, the WHOQOL-BREF was most appropriate (Hill et al., 2010).

2.4. Relation of all these factors with Quality of Life

After reviewing the research, it was noted that spasticity adversely affects prognosis, and that there is a need for evaluation of spasticity from both the physicians' and patient perspective (Hill et al., 2010). Information on the effect of specific treatments incorporated for reducing spasticity along with rehabilitation on QoL needs to be studied. It is important to note that a treatment like ITB reduces spasticity but is very expensive. Additionally, the side effects and complications caused by these drugs reduce the overall QoL and life expectancy of the patient, even though it significantly reduces pain. Therefore, it is important to study in depth the effect of these treatments in order to make a difference in the functioning and well-being of the patients with SCI (Biering-Sørensen et al., 2006; Martin Ginis et al., 2010). Various QoL and spasticity measures should be administered and a note of complications and side effects of the drugs should be made in order to produce this information.

CHAPTER 3: METHODOLOGY

After detailed study of the literature it was noted that it was essential to study QoL in patients with SCI who are on ITB therapy. It was identified that designing a study which involves use of various tools and questionnaires will help to quantify the nature of spasticity and QoL in these patients.

3.1. Patient Selection

A total of 36 patients with SCI receiving ITB therapy were selected from a clinic at TIRR Memorial Hermann Rehabilitation Center and Outpatient Clinic in Houston TX. Patients receiving ITB through a pump implanted for the first time as well patients who have their pump re-implanted were selected and distributed in two groups. The study was done in collaboration with Dr. Gerard Francisco (M.D.) at the clinic, who helped in selecting the patients based on the eligibility criteria. The patients could not be divided equally in two groups (based on gender and number of pumps administered) because of the limited availability of the chosen study population. Eligible patients were introduced to the Principal Investigator through an initial in-person meeting at the clinic to give an overview of the study. The protocol and the rationale behind conducting the study was explained to the patient, and a recruitment flyer containing important information was provided. If the patient was willing to participate, consent form was signed and the patient was assessed by the clinician for the inclusion and exclusion criteria.

3.2. Criteria

Inclusion	Exclusion
Patients with SCI receiving Intrathecal Baclofen (ITB). Only patients with tetraplegia post SCI (complete and incomplete). Patients will be at least 18 years of age. Patients who can read and understand English. Patients who are on the 1st pump for at least 6 months.	Patients who do not have a detailed medical history. Patients with paraplegia.

3.3. Instrument

Before administering the questionnaires, a chart review of every patient along with evaluation of spasticity according to the MAS was done. Chart review provided patient information such as age, medical history, pharmacological history, number of pumps, other details like surgical interventions (if any) and rehabilitative interventions including physical and occupational therapy.

Based on the above literature review of the various questionnaires available for SCI, the WHOQOL-BREF (Appendix A) questionnaire to assess QoL and the PRISM (Appendix B) was used in the present study. The WHOQOL-BREF consists of 26 questions, and the PRISM consists of 41 questions. Both of these questionnaires use a 5-point Likert scale.

Table 3. 1. Number of questions and score range in WHOQOL-BREF and PRISM

	# of questions	Score range
WHOQOL-BREF		
Overall QoL	1	1-5
Overall Health	1	1-5
Physical (Domain 1)	7	7-35
Psychological (Domain 2)	6	6-30
Social Relationships (Domain 3)	3	3-15
Environmental (Domain 4)	8	8-40
PRISM		
Social Avoidance	11	0-44
Psychological Agitation	5	0-20
Daily Activity	6	0-24
Need for assistance/Positioning	5	0-20
Positive Impact	4	0-16
Need for Intervention	5	0-20
Social Embarrassment	5	0-20

The WHOQOL-BREF has 6 subscales, while the PRISM is divided into 7 subscales. The subscales of both questionnaires are summarized in Table 3.1. In both the questionnaires, the score of each subscale is calculated and analyzed independently; a

grand total of all subscales cannot be derived. In WHOQOL-BREF, a ‘raw score’ of all the domains is obtained and is then converted into a ‘transformed score’ on the scale of 0-100. A questionnaire called the "Pump Complications Questionnaire" (Appendix D) was developed to assess the severity and frequency of the complications experienced due to the implanted pump. This questionnaire is based on 5 point Likert scale (1-Never, 5-Very Often). The WHOQOL-BREF, PRISM and Pump Complications Questionnaire took about 30 minutes for administration.

3.4. Consent

Patients were met at the clinic and an overview of the study was provided. It was explained that the current study is a onetime process that would require the patient to contribute a total of 30 minutes for a telephonic interview to answer all the questionnaires after signing the informed consent at the clinic around the time of pump refill. The usage and privacy of the data collected and the patients’ right to withdraw at any time was also explained. The informed consent was given to the patient and the patient had an opportunity to read it in private.

3.5. Data Storage

Data collected on each patient is stored electronically on a password protected computer for a period of 3 years. The paper forms filled in by the patient was stored in a locked cabinet at the faculty sponsor’s office and is accessible to the PI or their assigned research team only. The names of the patients were replaced with ID codes after screening and during data collection sessions.

3.6. Procedure

If the patient was willing to participate, the informed consent was signed and the patient was evaluated for inclusion and exclusion criteria. After signing the informed consent, the patient was asked to remain completely relaxed on the bed and the spasticity assessment was performed for both the upper and lower limbs by the nurse. The spasticity examination was done as follows: patient was asked to lie flat on the bed. The muscle being tested was either flexed or extended depending on its function in its maximum available range over one second, and the muscle group was graded depending on the tone. All the questionnaires were administered via telephone by the Principal Investigator at a time which would suit the patient. The interview lasted for about 30 minutes.

3.7. Sample Size Calculation:

The sample size analysis was based on the article by (Gianino, 1998). A free software was used for sample size calculation (Brant, n.d.). The sample size was calculated on the basis of the sickness impact profile scores at 6 months and at 12 months with the use of ITB in the above mentioned study. The mean score at 6 and12 months were 22.5 and 21.5 respectively. The standard deviation used was 1.53. The default values of type 1 error and power was set at .05 and .80 respectively. All the values were inserted in the software and a sample size of 18 was obtained for each group for a total of 36.

CHAPTER 4: RESULTS

Out of 38 patients recruited, 36 patients (34 males and 2 females) completed the study. These patients were divided in two groups. Group 1 consisted of 14 patients who received ITB through a pump implanted for the first time and group 2 consisted of 22 patients who received ITB through re-implanted pumps. The mean age of patients was 43.06 years (SD=14.7). The patients were disproportionately divided in two groups based on gender and number of pumps administered due to the limited availability of the chosen study population. Since SCI is more common in males, it was not surprising to have a larger number of males as compared to females in this study. Table 4.1 summarizes the characteristics of the patients.

Table 4. 1. Descriptive statistics of the patient sample

	Group 1 (N=14)	**Group 2 (N=22)**	**Total (N=36)**
Gender (M/F)	12/2	22/0	34/2
Age (years)	43.36±15.92	42.86±14.27	43.06±14.71
Race (Caucasian/Black/Hispanics)	4/7/3	13/6/3	17/13/6
Time since injury (years)	8±4.1 (8)	14.29±5.29 (14)	12.00±5.70
Duration of Pump (years)	3.86±2.85	9.77±4.49	7.47±4.86
Number of Pumps	1.00±0.0	2.32±0.47	1.86±0.77

4.1. Data Analysis

This study was observational. All the analyses were performed using SPSS statistical software (IBMSPSS Statistics for Windows Version 20.0). Descriptive statistics for all variables (age, time since injury, race/ethnicity, gender, no. of pump, duration of pump) were generated. Independent *t*-tests were performed to compare the group differences (first time pump users versus individuals with re-implants) in each subscale of the WHOQOL-BREF, each PRISM, and the MAS. Pearson's correlation coefficient, *r*, was determined for all subscales of WHOQOL-BREF versus all subscales of PRISM and PRISM versus MAS. The level of significance was set at $p < .05$. To make comparison between the PRISM subscales and MAS possible, it was decided to sum the score on each muscle group on both sides of the body and obtain to a percentage based on the maximum score and the score obtained.

4.2. Between group differences

Multiple independent samples *t*-tests were conducted to compare differences in individual subscales of WHOQOL-BREF, subscales of PRISM and total MAS between Group 1 and Group 2.

There were no significant differences in any of the six subscales of WHOQOL-BREF between groups. No significant differences were reported between groups for any PRISM subscales. Similarly, there were no significant differences in scores for total MAS between groups.

Five patients had orthotic braces on one or more limb, and one patient was a lower limb amputee. It was not possible to perform the MAS on these body parts. So, the

percentage of total MAS for each patient was calculated and a normalized value for the MAS was used in this analysis.

Table 4. 2. Group means and *t*-scores

Groups				
Measures	**1***	**2***	***t*-score**	***p*-value**
WHOQOL-BREF (transformed score: 0-100)				
Overall QoL	73.93±14.43	84.09±19.74	-1.66	0.072
Overall Health	67.85±22.85	76.13±23.75	-1.03	0.880
Physical	55.85±7.99	59.72±11.79	-1.07	0.289
Psychological Health	60.71±14.59	68.00±11.84	-1.62	0.114
Social Relationships	75.50±19.31	82.40±16.58	-1.14	0.261
Environment	67.71±14.40	73.36±11.45	-1.76	0.086
PRISM				
Social Avoidance	14.10±7.90	12.82±9.72	0.35	0.728
Physical Agitation	9.71±4.41	8.72±4.85	0.61	0.542
Daily Activities	11.35±5.32	10.45±4.22	0.56	0.576
Positive Impact	70.56±28.06	70.77±31.20	-0.47	0.639
Need Intervention	11.21±2.32	11.63±2.76	0.44	0.662
Social Embarrassment	4.64±2.30	5.40±4.18	-0.62	0.536
Need Assistance	10.00±2.98	9.95±3.41	0.04	0.966
MAS (%)	0.06±0.12	0.11±0.23	-0.708	0.179

*** Mean ± SD**

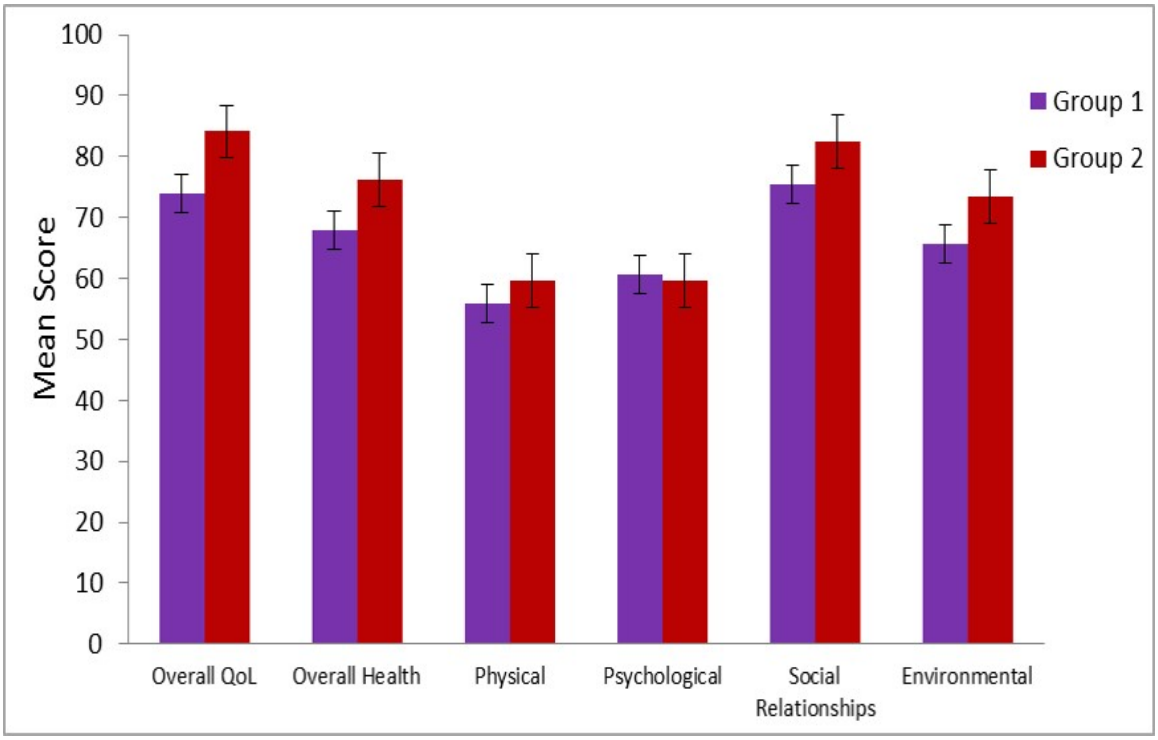


Figure 4. 1. Group differences in WHOQOL- BREF subscales

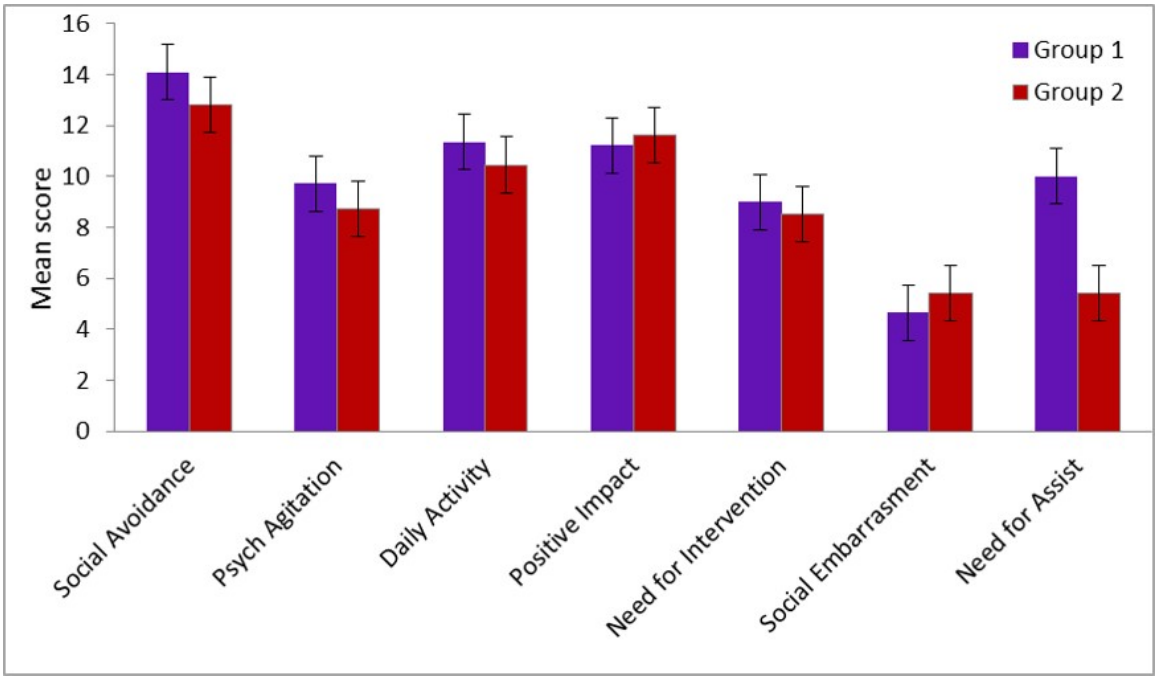


Figure 4. 2. Group differences in PRISM subscales

Figure 4.1 shows the mean differences in subscales of WHOQOL-BREF. Figure 4.2. indicates that the impact of spasticity in both groups was small overall and insignificant. The difference in the means for both groups for 'need for assistance' subscale is comparatively larger than other subscales. It suggests that, need for assistance is higher in Group 1 (higher score is considered unhealthy).

4.3. Correlation between QoL and spasticity

Pearson's correlation test was performed on all of the subscales of the WHOQOL-BREF and subscales of PRISM. Weak to moderate yet significant correlations were observed between some subscales of WHOQOL-BREF and the PRISM. The results are presented in Table 4.3.

Table 4. 3. Pearson correlation (r) between subscales of WHOQOL-BREF and subscales of PRISM

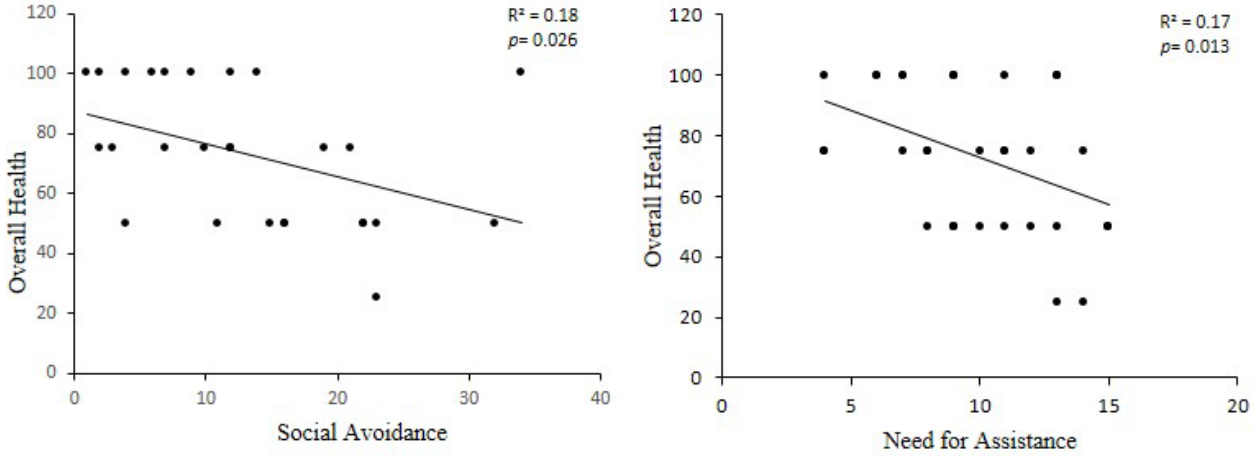
	Social Avoidance	**Physical Agitation**	**Daily Activities**	**Positive Impact**	**Need for Invention**	**Social Embarrassment**	**Need for Assistance**
Overall QOL	.171	.092	-.236	-.167	.037	.196	-.131
Overall Health	**-.428***	-.293	-.313	-.314	-.325	-.186	**-.416***
Physical	-.147	-.142	-.292	-.046	-.184	-.191	-.140
Psychological	-.122	-.239	**-.361***	-.173	-.233	-.273	-.322
Social Relationships	-.287	**-.417***	**-.533****	.203	-.302	**-.448****	-.324
Environmental	-.115	-.299	**-.340***	-.118	-.134	-.193	**-.343***

***Correlation is significant at 0.05 level (2-tailed)

**** Correlation is significant at 0.01 level (2-tailed)

Overall Health

Results indicated that Overall Health subscale of WHOQOL-BREF has a moderate negative correlation with social avoidance (r = -0.428, p = 0.026) and need for assistance (r = -0.416, p = 0.013) subscales of the PRISM. Correlations with Daily Activities, Positive Impact and Need for Intervention were not statistically significant.



(a) (b)

Figure 4. 3. Scatterplot for overall health of WHOQOL-BREF versus (a) social avoidance and (b) need for assistance of the PRISM.

Psychological Health

Psychological Health subscale consists of questions based on effect of the condition on patient's mood and psychological state. There was a weak, significant, negative correlation between psychological health and daily activities (r = -0.361, p= 0.033). Also, the Need for Assistance subscale was found to be approaching, but not reaching, the level of significance. (r = -0.322, p =0.059).

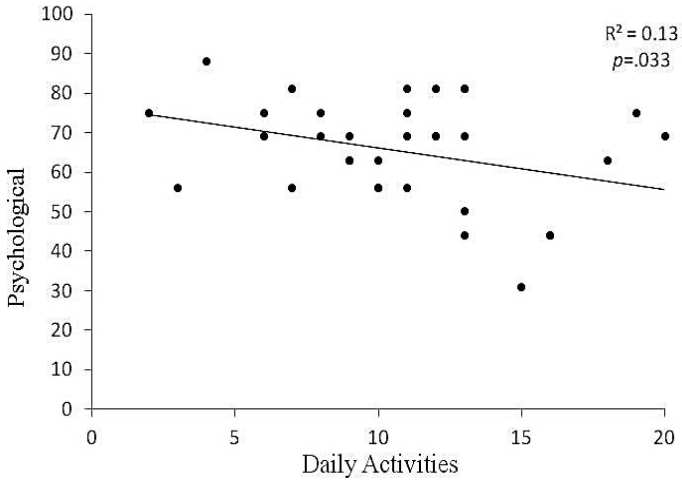


Figure 4. 4. Scatterplot for Psychological subscale of WHOQOL-BREF and daily activities of PRISM

Social Relationships

The Social Relationships subscale of the WHOQ0L-BREF consists of the questions of the patient's personal life and the support from friends and family. Daily Activities had a moderate negative correlation and a strong statistical significance with Social Relationship (r =-0.533, p = 0.001), followed by Social Embarrassment (r = -0.448, p = 0.006) and Psychological Agitation (r = -0.417, p = 0.012).

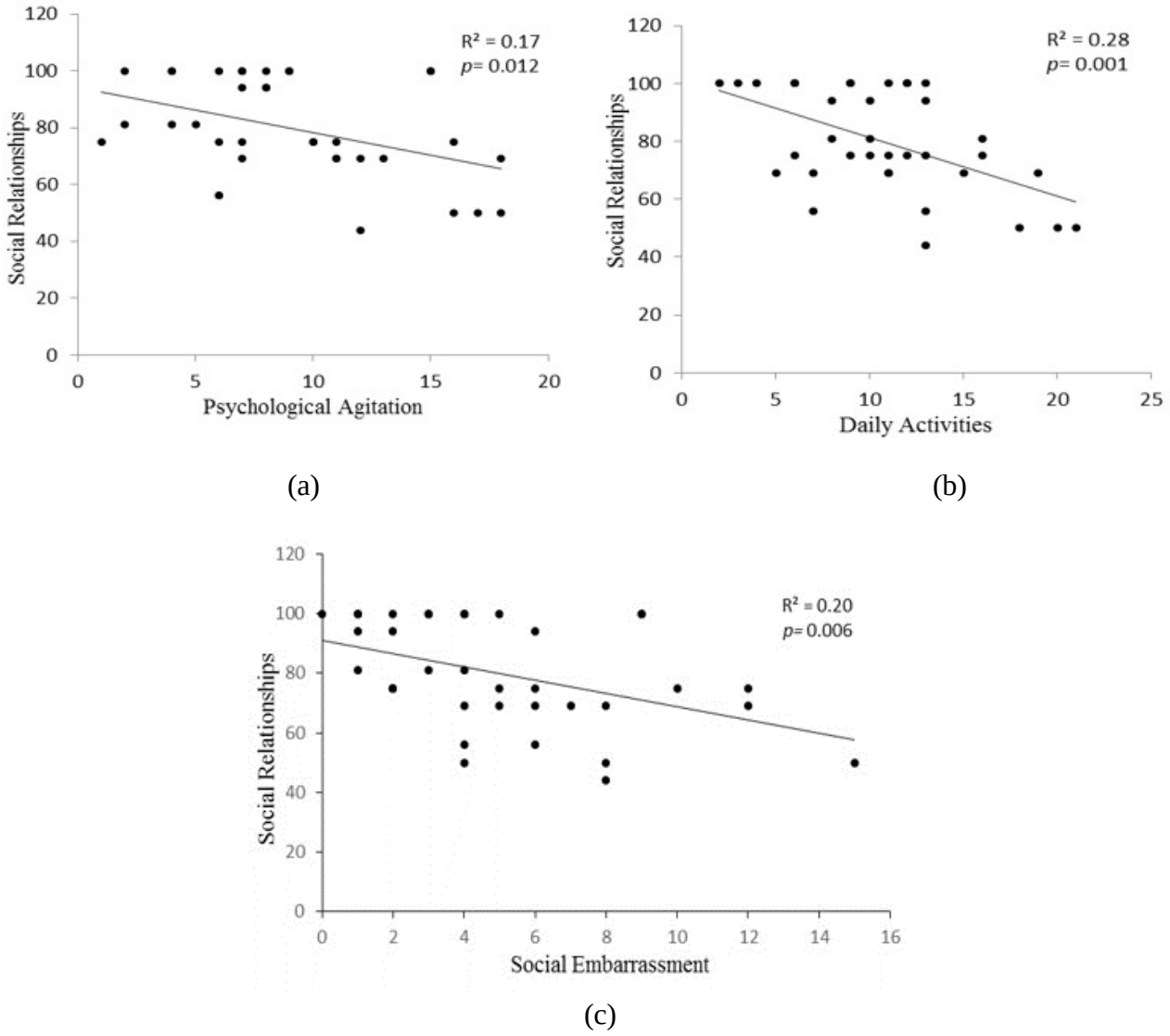
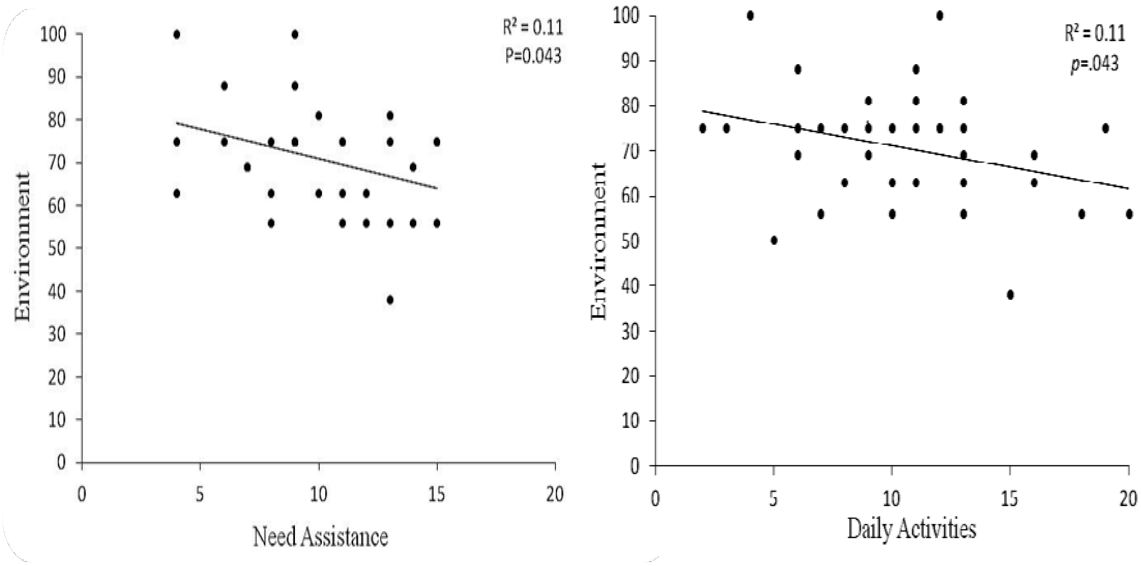


Figure 4. 5. Scatterplots for Social Relationship against (a) Psychological Agitation, (b) Daily Activities and (c) Social Embarrassment.

Environment

The Environmental subscale of WHOQOL-BREF consists of how patient's conditions affect his/her interaction with their surroundings. Environment had a weak

significant, negative correlation with Daily Activities (r = -.034, p= 0.043) and Need for Assistance/Positioning subscale (r = -0.0343, p= 0.044) of PRISM.



(a) (b)

Figure 4. 6. Scatterplot for Environmental subscale of WHOQOL-BREF against (a) Need for Assistance and (b) Daily Activities of PRISM.

4.4. Relationship between clinician evaluated spasticity and patient's perception of spasticity.

Table 4. 4. Pearson correlation (r) between PRISM subscales and MAS

PRISM Subscales	% of MAS
Social Avoidance	**.402***
Psychological Agitation	0.228
Daily Activity	-0.021
Need for Assistance	-0.141
Positive Impact	-0.117
Social Embarrassment	**.334***
Need for Intervention	0.215

***Correlation is significant at 0.05 level (2-tailed)

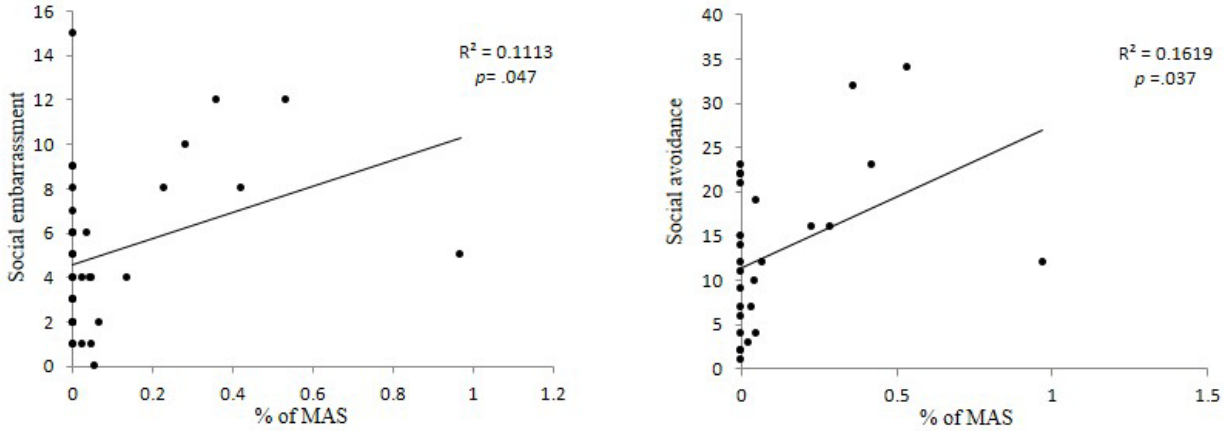


Figure 4. 7. Scatterplot for percentage of total MAS and Social Avoidance and Social Embarrassment subscales of PRISM

The correlation analysis between all the subscales of PRISM and percentage of total MAS of each patient suggested that Social Avoidance (r = 0.402, p =.037) and Social Embarrassment (r = 0.334, p = .047) of the PRISM had a weak positive correlation with the percentage of total MAS. (Fig. 4.7)

Several patients received a score of "0" on the MAS, making the distribution skewed. Hence, it was decided to divide the patient population into 2 sub-groups, i.e., the ones who had a score of zero on the total MAS and the ones who had a score above zero on the total MAS. Then, a correlation analysis was utilized to create scatterplots on the non-zero group and also on the group having scores above zero against the PRISM subscales. It was observed that the non-zero group had no significant correlations with any of the subscales.

4.5. Complications of ITB

Currently, there is no tool to calibrate and analyze the complications and adverse effects of an intrathecal pump. A pump complications questionnaire was developed based on the complications listed in the literature. This tool served as a reference to the number and frequency of complications experienced by the patient. This also helped to understand the effect of complication on QOL. The data obtained through this questionnaire was not a part of the statistical analysis. The number of complications obtained was reported.

It should be noted that the there was a strong floor effect for the questionnaire because of the difference in understanding and reporting the complications in the patient

history. There was a lack of consistency in how the complications were interpreted by the various clinicians and reported in the literature.

Table 4. 5. Patient response to complications encountered.

Complications	Never	Rarely	Sometimes	Often	Very often
Edema at the surgical site	29	0	5	2	0
Infections	32	2	1	0	1
Drowsiness	27	2	4	1	2
Seizures	36	0	0	0	0
Increase in spasticity	34	2	0	0	0

Table 4. 6. Group differences in encountered complications

Complications	Group 1	Group 2
Edema at the surgical site	1	6
Infections	0	4
Drowsiness	1	8
Seizures	0	0
Increase in spasticity	0	2

Tables 4.5 and 4.6 shows that 9 patients reported edema at the surgical site and 7 patients reported drowsiness. Patients in group 2 encountered more complications than these in group 1. None of the patients experienced seizures as reported in the literature (Dario & Tomei, 2004; Francisco, Saulino, Yablon, & Turner, 2009; Ochs et al., 1999; Ross et al., 2011; Watve et al., 2012). It is worth noting that most patients answered 'never' to all questions, suggesting that the questionnaire has a floor effect and may not have been correctly developed.

The questionnaire also included an open-ended question with regards to the experience after having the pump. This allowed the investigators to gain a better sense about how the patients felt about his/her condition and the difference the pump has made to their lives. This question helped to better understand the complications from the patient's point of view which the literature could not highlight. Almost all patients were satisfied with their pump and reported that pump was better than receiving oral Baclofen. Some patients stated that they experienced clonus on sudden movement after a long period of inactivity. Table 4.7 explains the positive and negative experiences of ITB that were reported by the patients.

Table 4. 7. Chart explaining the positive and negative experience of ITB therapy

No. of Patients	Patient ID	No. of Pumps	Positive	Negative
01	01-01	1	Spasticity is not as bad as it was earlier.	
02	01-02	1	ITB controls spasticity.	
03	01-03	1	The pump is pretty good. It had reduced the spasticity.	
04	01-04	1	The experience has been positive. It is good to have ITB than having oral	

No. of Patients	Patient ID	No. of Pumps	Positive	Negative
			baclofen.	
05	01-05	1	I like having ITB. It has been very helpful. ITB has reduced my spasticity to negligible amount.	
06	01-06	1	It is good to have ITB as compared to oral baclofen.	
07	01-07	1	It has helped to reduce spasticity. I do not flip out of my chair anymore.	I experience sudden increase in spasticity during transfers.
08	01-08	1	The pump is good. It has reduced the spasticity.	Pump is bulky. Position of the pump is weird. It feels as if the pump is pressing on the nerve. The feeling of having a pump is nasty. It moves a lot inside the abdomen.
09	01-09	1	I am happy with the pump. ITB is good.	The pump beeps a lot and is noisy.
10	01-10	1	ITB is okay. Spasticity and leg stiffness have reduced.	Initially encountered hallucinations. Have been taking Botox injections for hand spasticity for the past 2 years.
11	01-11	1	It is good to have ITB. It has reduced my spasticity.	
12	01-12	1	Spasms are not bad anymore. No night spasms.	Experience spasms when I cough. Spinal fluid was leaking from the pump implant and the patient had to undergo surgery
13	01-13	1	It is better to have a pump than not	Nothing spectacular.

No. of Patients	Patient ID	No. of Pumps	Positive	Negative
			having one.	
14	01-14	1	Spasticity is not bad at all.	
15	02-01	3	Spasms are crazy without the pump.	It hasn't changed my life.
16	02-02	2	Spasticity has reduced after receiving the pump.	Oral baclofen for upper extremity.
17	02-03	3	It is good to have ITB. It controls spasticity.	
18	02-04	2	ITB is great. Spasticity is now manageable.	I felt drowsy when I was receiving the drug through 1st pump.
19	02-05	2	The pump is okay.	Much better than having oral baclofen.
20	02-06	2	ITB is okay. It is better than not having it.	The pump is not as great as it is expected to be.
21	02-07	2	"Pump is my best friend" Patient gained more independence.	
22	02-08	3	The pump is great. It has made me independent.	
23	02-09	2	It is an awesome device. It has reduced spasticity drastically.	
24	02-10	3		Doesn't help a lot. Spasticity is bad. I have been receiving it for 10 years now, bust doesn't help during transfers.
25	02-11	3	Having a pump is way better than taking medications by mouth.	
26	02-12	2	Life is better after having the pump replacement. Oral medications need	Pump implanted for the first time worsened the spasticity, made ADL

No. of Patients	Patient ID	No. of Pumps	Positive	Negative
			not be taken anymore. Pain has reduced drastically. Legs free loose and free.	difficult.
27	02-13	2	I am very happy with the pump. Spasticity has reduced. It has changed my life.	Initially the pump did not function normally. Body was very stiff. I experienced hallucinations, drowsiness and listlessness on replacement of the pump.
28	02-14	2	It is good to have a pump.	Need to take Botox for upper extremity spasticity.
29	02-15	2	The pump has started showing an effect after a lot of trial and error. It is better to have a pump along with oral baclofen.	The pump that had been implanted had a kink in the catheter. Only the catheter was replaced and not the entire pump. 2 years ago experienced problems like fever, drowsiness, and the spasticity increased suddenly.
30	02-16	3	Spasticity has reduced because of the pump. Moving around and transfers have been easier.	
31	02-17	2	The pump has reduced spasticity drastically.	The catheter of the pump implanted for the 1st time was loose and leaking. I was experiencing withdrawal, sweating when I was receiving the drug via 1st pump. It wasn't helping in wound healing. Sex life is affected due to the pump. It also the sleeping position. I cannot sleep on the side where the pump is implanted.

No. of Patients	Patient ID	No. of Pumps	Positive	Negative
32	02-18	2	It has changed my life. Spasticity has reduced. Transfers were easier after receiving ITB.	Had to replace first pump due to infection. Had to replace second pump due to cyst/swelling. Complications of pump like swelling and battery failure.
33	02-19	2	I like it. I stay awake and get more work done. Biggest impact- I am off oral baclofen.	
34	02-20	2	It helps during activities.	Need to take oral baclofen along with ITB
35	02-21	3	It has been good so far to have ITB.	
36	02-22	3	It is good to have ITB. I have become independent.	

CHAPTER 5: DISCUSSION

The purpose of this study was to investigate the relationship between spasticity and QoL under the influence of ITB treatment for spasticity after SCI. The study findings suggest that spasticity still remains a problem to be solved in helping the individual have a better QoL despite the advances in technology and medicine with treatments like ITB. This study compared the differences in spasticity and QoL between first time pump users and patients with re-implants. Surprisingly, no significant group differences were found. This may be due to inadequate statistical power due to lower sample size. Also, patients with re-implants did not experience a lot complications as suggested earlier in the literature (Adams & Hicks, 2005; Bensmail et al., 2009; Boop, 2001; Flückiger, Knecht, Grossmann, & Felleiter, 2008; K. A. Follett & Naumann, 2000; Guillaume et al., 2005; Jagatsinh, 2009; Ross et al., 2011; Staats, 2008; Zahavi et al., 2004). The most common complication that was found to be similar with those listed in literature was catheter leakage or kinking. Patients did not report hallucinations, infections at pump site, drowsiness, nausea or withdrawal after having the pump.

As expected, the patients who had severe spasms perceived their spasticity to have a very negative impact on their lives, and this was reflected in the PRISM scores. Also, some subscales of the WHOQOL-BREF showed that spasticity did affect an individual's well-being. The distribution of the MAS was skewed, because most patients were reported to have score of "0" or negligible spasticity; this might not be the true picture given that spasticity is affected by various factors. On the other hand, the scores on PRISM were high on some subscales like the Social Embarrassment and Social

Avoidance, which is an aspect that the MAS does not cover. It was interesting to see that the MAS had no significant correlation with the daily activities subscale of PRISM.

5.1. QoL and patient perceived spasticity in both groups

This study examined the impact of ITB treatment on spasticity and QoL amongst first pump users and those individuals with re-implants. The literature suggested that the QoL in patients with newly installed pumps is higher than individuals who have had multiple pumps, possibly due to the novelty effect (Biering-Sørensen et al., 2006; Westerkam et al., 2011). This study found no significant differences between groups in terms of QoL. It is possible that the study was underpowered due to a lower sample size. From the results, it can be stated that overall health and overall QoL of patients with re-implants was similar to those receiving the drug through 1st pump and that there is no conclusive evidence of a novelty effect.

Along with QoL, perceived spasticity was compared in both groups in order to gain a better understanding of how the experience of spasticity differs in patients who are new to the pump and these who have had it for a long time. There were no significant group differences, which might be attributed to the lack of statistical power. The *t*-values of all subscales were consistently below -1, suggesting a trend. In the future, studies with a larger sample size can be very useful to bring about important information about the differences in two groups.

Currently, no studies have been done to examine the differences in QoL and spasm score in patients on their first pump and patients who have had re-implants. Previous research has suggested that the long term effects of use of ITB improved the

spasm score (MAS), but it negatively affected the psychological state of the individual (Zahavi et al., 2004). Our results did not lead to the same conclusion; however, it is possible that the sample size we chose was insufficient to reveal a small effect size. Our sample size calculation was based on an article by Gianino, (1998) which closely related to this study. Gianino and colleagues, (1998) did a longitudinal study to see the difference in QoL in ITB pump users in patients with SCI, and they used different dependent variables. In this study, sample size could have been under estimated, because the questionnaire used is different than the one used in the study for sample size calculation.

5.2. Relationship between QoL and PRISM

Spasticity is a multi-faceted condition and Westerkam and colleagues (2011) noted that there was a need to look for relationships between QoL and patient perceived spasticity. In this study, the correlation between the 6 subscales (4 domains and 2 questions forming independent subscales) of WHOQOL-BREF and 7 PRISM subscales was examined to look for a pattern of symptoms and its effect on health. It was noted that 4 out of 6 WHOQOL-BREF subscales correlated with 5 out of 7 PRISM subscales.

Overall health had a significant negative correlation with Social Avoidance and the Need for Assistance subscales of the PRISM. It is worth noting that patients who perceived themselves to have severe spasticity need help in positioning, which affected their overall health and that in turn might be causing them to avoid society and social relationships. It was surprising to note that the effect of spasticity on daily activity, need for intervention and positive impact did not significantly affect the overall health of the

patients. It suggests that patients with higher and better overall health do not require a lot of assistance and also do not face the problem of social avoidance.

Patients who reported poor psychological health also had a difficulty in performing their daily activities due to their spasticity. The presence of spasticity may make daily activities like grooming, dressing, transfers, and positioning difficult which reduces the acceptance towards one body, affects self-image, self-confidence, hence affecting psychological health. Previous research (Post & van Leeuwen, 2012; Voerman, Erren-Wolters, Fleuren, Hermens, & Geurts, 2010) has described the relationship between mental fitness and ability to perform daily activities. This study supports those findings and sheds more light on the importance of the ability to perform ADL on psychological health.

Personal and social relationships are affected by spasticity and muscle stiffness. Daily activities are affected by spasms, which causes physical agitation, affects inter-personal relationships and in turn causes social embarrassment. Co-morbidities of the condition causes social embarrassment and social adjustment and has been reported before in the literature (Elfström, Rydén, Kreuter, Taft, & Sullivan, 2005; Müller, Peter, Cieza, & Geyh, 2012; van Leeuwen, Kraaijeveld, Lindeman, & Post, 2012). However, according to the results, it is surprising that even though spasticity was been reported to lead to social embarrassment, it did not to lead to social avoidance.

The individual's interaction with his/her environment largely depends on the ability to move and function effortlessly. Patients with SCI and spasticity may find it difficult to function as normal as possible. The ITB makes it manageable to a great extent but even

then there is a deficit which hinders day to day interaction with the surroundings and the environment.

5.3. Relationship between clinician evaluated spasticity and patient perceived spasticity

As the literature indicated, so far only the clinician's evaluation of spasticity is used as a parameter to gauge spasticity (Bhimani et al., 2011; Rekand, 2010; Westerkam et al., 2011). As pointed out by Revell, (2011) and Bhimani (2011), spasticity is a symptom cluster and needs more than one tool for its assessment. Patient's perception about his/her spasticity forms a good basis to understand spasticity in areas which the clinically evaluated spasticity tools, like MAS, Tardieu score, and spasm frequency score lack.

The Social Embarrassment and the Social Avoidance subscales of the PRISM were found to correlate significantly with MAS. No other scales of the PRISM were significant with the MAS. This suggests that MAS is independent of the daily activities, need of medical intervention, etc. and the degree of spasticity. Interestingly, we found that patients who had severe spasms shy away from social interaction of all sorts and also tend to have a lot of embarrassment. MAS cannot explain the extent to which the severity of spasms limits the patient in day-to-day activities. It is therefore important to consider the incorporation of a patient perceived spasticity measures, like PRISM, in the routine assessment and treatment of spasticity. Also, it is noteworthy that the patient population selected for this study had spasms that were manageable by the ITB, and the effect of spasticity on the activities and health as a whole may not be generalizable to all patients with SCI.

Spasticity is a complicated topic (Hsieh, Wolfe, Miller, & Curt, 2008b; Hunter Revell, 2011). Using one measure of spasticity, like the MAS, to assess the problem is not appropriate and does not offer a complete picture. MAS has limited inter-rater reliability (Fleuren et al., 2010). Spasticity can be affected by weather, emotional state, change in position etc. Also, spasticity is not observed consistently at regular time intervals. This constant change is not recorded on regular intervals which might result in a discrepancy affecting the line of treatment (Bhimani et al., 2011). Additionally, the MAS does not record clonus which is an important aspect to consider when reporting spasms. Spasticity in patients with SCI are often seen to exaggerate with any kind of movement or activity and are accompanied with clonus. Tardieu scale is one such measure which reports clonus (Rekand, 2010). Clinically, it would help in understanding and initiating a better line of treatment if Tardieu scale is used instead of MAS as it captures one more dimension. Tardieu scale has high inter-rater, test-retest reliability when compared to the MAS (Mehrholz et al., 2005).

PRISM looks into multiple aspects of spasticity from a patient's point of view offering valuable information which might be missed by only performing a clinician evaluation of spasticity. So far, no study has looked into the relationship between clinician evaluated spasticity and patient's perception of his/her spasticity (Hill et al., 2010; Westerkam et al., 2011). This study adds important information to the pool of knowledge by utilizing a multifaceted methodology of examining spasticity. MAS may only offer insight into the social aspect that is affected by spasticity as noted earlier. Having the patient's perception about his/her spasticity helps the clinician have a better idea about the patients expectations from the medical intervention and thus the treatment

can be tailored as per the needs, expectations and outcomes. Hence this tool must be made a part of the clinical evaluation in the future.

5.4. Complications of ITB and QoL

A pump complications questionnaire was created to report complications of ITB (Appendix D). The questionnaire listed questions based on the literature reviewed for complications of the pump. Questions regarding presence of edema and/or infections at the surgical site, drowsiness, seizures, sudden increase in spasticity or tone were included in the questionnaire. (Dario & Tomei, 2004; K. A. Follett & Naumann, 2000; K. a Follett et al., 2003; Haranhalli et al., 2011; Ross et al., 2011; Staats, 2008; Ucar et al., 2011; a B. Ward, 2008; A. Ward et al., 2009; Watve et al., 2012). Most patients reported that they never encountered the complications that were listed in the questionnaire. The questionnaire that was created had a floor effect due to the discrepancy in acknowledging complications. Patient records did not reveal the complications of the ITB. The side-effects, or complications reported, were secondary to SCI, and included things such as urinary tract infections, pressure sores, spasms, and irritable bowel syndrome, but nothing with regards with to the ITB.

The questionnaire had one open-ended descriptive question about the patient's experience after instillation of the pump. Patients reported that the pump made their life easy and manageable. Typically, patients who have been on more than one pump reported battery failure or the pump reaching its shelf life (5-6 years) as the common cause, followed by catheter leaks and kinking of the catheter. Change in any part of the pump or surgical opening of the pump site was considered as change in pump or re-

implant. A better way of quantifying, comparing and analyzing this data with various QoL and spasticity variables needs to be devised.

5.5. Qualitative data on experience with ITB and spasticity

The open ended question in the pump complications questionnaire helped in accumulating a lot of opinions and experiences from the patients after receiving the pump. It helped in creating a better understanding of the pros and cons of having a pump from the patient's perspective and provided insight on the problems faced because of the pump. There were mixed reviews, with most directed towards having positive aspects of the pump. Patients in both groups reported drastic reduction in spasticity after implantation of the pump, and experienced sound sleep; the pump enabled activities to a great extent. Although a few patients reported that despite the positive effects of pump, the spasms and clonus seemed to occur consistently during transfers and sudden movement. A patient thought the pump to be a bulky and an uncomfortable device implanted in the abdomen which tends to move and hindered sleeping position. Another patient reported that despite the reduction in spasms to a great extent, it did not help during sudden movement, in stressful conditions, or in colder weather. Additionally, there was great distress during any kind of sexual activity.

Patients reported that ITB helped in reducing the lower limb spasticity and was better than oral Baclofen. Oral Baclofen had lot of side-effects as reported earlier in the literature (Dario & Tomei, 2004; Rekand, 2010; Ucar et al., 2011). A lot of patients were either on Botox or some other kind of anti-spasmodic medications or therapy for upper limb spasticity. ITB does not help in reducing severe upper limb spasticity.

5.6. Limitations of the study

The greatest limitation of this study was the lack of statistical power. Furthermore, this study was purely observational and hence lacks evidence for causal relationships. There was no control over the confounding variables like alternative treatments and therapies along with ITB, drug concentration and dosage. In this study, the MAS was administered by two nurses who performed the ITB refill. The administration of MAS by one health personnel could not be controlled because of various clinical difficulties. This may have affected the validity of the conclusions drawn from those data, given that MAS has poor inter-rater reliability (Craven & Morris, 2010; Ghotbi et al., 2009; Hsieh et al., 2008a; Waninge, Rook, Dijkhuizen, Gielen, & van der Schans, 2011).

There was no quantitative measure to analyze the complications of the ITB. There is a discrepancy in the way the complications are listed in the literature and in the clinical notes. There needs to be a consistent definition for each complication encountered and a proper record needs to be maintained. There was no structured method to quantify the experiences listed by the patients about ITB and spasticity. A tool or measure to quantify the same would have added valuable information.

5.7. Conclusion and future direction

Improving the QoL of a patient is one of the ultimate goals of rehabilitation and an important indicator of the prognosis of any treatment or intervention (Hill et al., 2010). Spasticity affects the daily activities of an individual with SCI to a great extent. This, in turn, affects the individual's interaction with the surroundings, society and self on many levels. The individual suffers from psychological problems owing to limited interaction

with the surroundings, decreased self-esteem, and low self-confidence which leads to lack of social interaction and social avoidance. A tool like PRISM encapsulates major issues faced by patients with spasticity after SCI and helps in acquiring valuable information for the diagnosis and treatment of a complex issue like spasticity and secondary changes related to it. Hence, it should be made a part of the diagnostic and prognostic tool along with other traditionally used instruments like the MAS for assessing spasticity in patients with SCI.

Despite the use of a pump for a long term and having the condition for a good span of time, patients still tend to experience social embarrassment due to their spasticity and awkwardness to fit into a social network. Treatments should focus on easing the social stigma of the patients through alternative therapies and counseling along with the traditional line of treatment. The social and environmental set up needs to be modified to suit the needs and concerns of people with problems related to SCI.

Traditionally, the MAS is the most commonly used instrument to assess spasticity. Due to the validity and reliability concerns (Fleuren et al., 2010), a second instrument needs to be introduced into regular practice. Furthermore, an individual experiences spasticity as well as clonus after SCI. It becomes necessary to evaluate the severity of clonus along with spasticity. The MAS does not record clonus which is an important aspect. Tardieu scale is one such instrument which reports both spasticity and clonus together. Along with clinically evaluated spasticity measures like the MAS and Tardieu scale, patient evaluated spasticity measures like PRISM and activities of daily living scales (for e.g. Functional Independence Measure) should also be made a part of the assessment in order to have a complete picture of the problem.

WHOQOL-BREF is one such tool that may be appropriate for assessing many issues faced by patients with SCI. More research needs to be done using this tool to look into various secondary problems of SCI. In the future, a longitudinal or randomized study on QoL and spasticity should be done with a larger sample size and with a healthy control population.

A tool to define, categorize and analyze the complications of ITB needs to be devised in order to have uniformity in maintaining records. A method of analyzing the list of complications can help understand the patient's perception, and in turn help in better treatment and ultimately reduce the cost of treatment. Also, the qualitative data obtained through the open ended question can be used to develop a questionnaire based on intrathecal pump complications and spasticity.

APPENDICES

A. World Health Organization Quality of Life –BREF (WHOQOL-BREF)

WHOQOL-BREF

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores*	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:

B. Patient Reported Impact of Spasticity Measure (PRISM)

PATIENT REPORTED IMPACT OF SPASTICITY MEASURE

The following questions are about your experience of abnormal muscle control or involuntary muscle movement. Different people have different terms they use for abnormal muscle control and involuntary muscle movement. Some of these terms are:

- Spasticity
- Muscle stiffness (tone
- Spasms
- Clonus (bouncing)
- When muscles don't cooperate together like they're supposed to
- When trying to move one part of the body causes another part to move also

By circling or marking one of the numbers in the boxes on the right, please indicate how well each of the following statements applies to your experience during the **PAST WEEK**.

Over the PAST WEEK, my abnormal muscle control or involuntary muscle movement:	**Never true for me**	**Rarely true for me**	**Sometimes true for me**	**Often true for me**	**Very often true for me**
1. Made me anxious about going out in public.	0	1	2	3	4
2. Bothered me a lot.	0	1	2	3	4
3. Made grooming (hair, teeth) difficult for me or my attendant.	0	1	2	3	4
4. Made me need someone to reposition me.	0	1	2	3	4
5. Helped me keep my muscles exercised.	0	1	2	3	4
6. Made me need more treatment than I could afford.	0	1	2	3	4
7. Kept me from going out among strangers.	0	1	2	3	4
8. Caused me to feel hopeless.	0	1	2	3	4
9. Made me feel out of control of my body.	0	1	2	3	4

The development of this scale was supported by a grant from Veterans Affairs Rehabilitation R&D
For an electronic copy of this measure, e-mail Karonc2@u.washington.edu

Over the PAST WEEK, my abnormal muscle control or involuntary muscle movement:	Never true for me	Rarely true for me	Sometimes true for me	Often true for me	Very often true for me
10. Made dressing difficult for me or my attendant.	0	1	2	3	4
11. Kept me from being as happy as I could be.	0	1	2	3	4
12. Caused me to depend on others.	0	1	2	3	4
13. Helped me stretch my muscles.	0	1	2	3	4
14. Caused me to increase the amount of prescription medication I took.	0	1	2	3	4
15. Kept me from wanting to go out in public.	0	1	2	3	4
16. Made me feel frustrated.	0	1	2	3	4
17. Made personal hygiene (e.g. toileting, cleaning) difficult for me or my attendant.	0	1	2	3	4
18. Made me want to find alternative, non-medical therapies.	0	1	2	3	4
19. Made me anxious about going out with friends.	0	1	2	3	4
20. Caused me to need safety devices (bed rails, foot loop).	0	1	2	3	4
21. Made eating or feeding difficult for me or my attendant.	0	1	2	3	4
22. Interfered with romantic relationship.	0	1	2	3	4
23. Made me feel powerless.	0	1	2	3	4
24. Caused me embarrassment.	0	1	2	3	4
25. Made me want encouragement or emotional support from friends and family.	0	1	2	3	4
26. Interfered with sexual activity.	0	1	2	3	4
27. Caused strangers to notice me.	0	1	2	3	4
28. Helped with transfers (e.g. from chair to bed).	0	1	2	3	4
29. Caused me to avoid physical contact with other people.	0	1	2	3	4

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For an electronic copy of this measure, e-mail Karonc2@u.washington.edu

Over the PAST WEEK, my abnormal muscle control or involuntary muscle movement:	Never true for me	Rarely true for me	Sometimes true for me	Often true for me	Very often true for me
30. Caused me to use over-the-counter medications.	0	1	2	3	4
31. Caused others to avoid touching me.	0	1	2	3	4
32. Put me in a bad mood.	0	1	2	3	4
33. Helped me or my attendant change my position.	0	1	2	3	4
34. Made me feel depressed.	0	1	2	3	4
35. Interfered with my ability to exercise.	0	1	2	3	4
36. Drastically changed the position of my body.	0	1	2	3	4
37. Made me fearful that I would cause myself physical injury.	0	1	2	3	4
38. Made transfers hard for me or my attendant.	0	1	2	3	4
39. Caused strangers to stare at me.	0	1	2	3	4
40. Kept me from going out with friends.	0	1	2	3	4
41. Made it hard to keep my arms or legs inside my chair.	0	1	2	3	4

The development of this scale was supported by a grant from Veterans Affairs Rehabilitation R&D
For an electronic copy of this measure, e-mail Karonc2@u.washington.edu

C. Modified Ashworth Scale

Modified Ashworth Scale for Grading Spasticity	
Grade	**Description**
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the ROM when the affected part(s) is moved in flexion or extension
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2	More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3	Considerable increase in muscle tone, passive movement difficult
4	Affected part(s) rigid in flexion or extension

D. Pump Complications Questionnaire

a. Please check/circle the appropriate choice for each of the following questions:

Have you encountered edema at the surgical site?	Never 1	Rarely 2	Sometimes 3	Often 4	Very often 5
Do you often experience infections at the site of implant?	Never 1	Rarely 2	Sometimes 3	Often 4	Very often 5
Do you often experience drowsiness?	Never 1	Rarely 2	Sometimes 3	Often 4	Very often 5
Have you ever had seizures after the pump implant?	Never 1	Rarely 2	Sometimes 3	Often 4	Very often 5
Do you often experience sudden increase in spasticity or tightness?	Never 1	Rarely 2	Sometimes 3	Often 4	Very often 5

b. How do you feel about the pump in general? How has it changed your life?
Comments:

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