EFFECT OF CHEMICAL NEUROLYSIS ON SPASTICITY AND FUNCTIONAL STATUS IN PERSONS WITH SPINAL CORD INJURY

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I am submitting herewith a thesis written by Josefina P. Castro entitled "Effect of Chemical Neurolysis on Spasticity and Functional Status in Persons with Spinal Cord Injury." I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Nursing.

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ABSTRACT

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The purpose of this mixed retrospective-prospective nonexperimental study was to determine the relationship between spasticity and functional status in spinal cord injury (SCI) patients and if reduced spasticity is associated with change in functional ability resulting from chemical neurolysis. In addition to investigator-review of medical records, the 30 subjects completed a spasticity assessment and functional status form using the Ashworth Scale and Functional Independence Measure (FIM). Spearman rho correlation revealed a moderately strong correlation (r = -.61, $p \leq .05$) between spasticity and functional status. T tests for dependent samples revealed significant reduction of spasticity ($t(29) = 8.73$, $p = <.0009$) and improved functional status ($t(29) = -6$, $p = <.0009$). ANOVAs of demographic data were significant for level of injury ($p = .036$) and chemical dosage ($p = .024$). Findings suggested that spasticity and functional status were

inversely related in persons with SCI. Chemical neurolysis was an overall effective intervention for spasticity reduction which in turn produced increased functional status.

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CHAPTER I

INTRODUCTION

Spinal cord injury (SCI) is catastrophic from both physiologic and psychologic perspectives. According to the World Health Organization (WHO, 1991), approximately 370,000 of the U.S. population are disabled: 75% of the disabilities are due to traumatic spinal cord injuries, and 7,000 to 8,000 new SCIs occur in the U.S. each year. The WHO (1991) identified three life functions predictors for SCI patients: (1) impairment (loss of sensation), (2) disability (loss of function), and (3) handicap (loss of perceived societal role of the individual). These predictors clarify the focus of rehabilitative efforts which may be distinguished from other approaches that assist persons with disability (Fuhrer, 1987; WHO, 1991).

To date there are no statistical data that address the prevalence and severity of spasticity in spinal cord injury. The rehabilitative process of the SCI patient is influenced by many anticipated complications, such as spasticity, an additional disabling factor and handicap factor imposed on the primary disability. Spasticity has important implications for restoring the patient's life functions as well as

implications for the delivery of effective nursing care. For example, the abnormal movements and limited body positions associated with the spastic state make nursing interventions more difficult to accomplish and more time consuming for the health caregivers. In addition, Sine and Liss (1988) reported that patients with spasticity are frequently vulnerable to complications, particularly decubitus ulcers and poor hygiene, because of the deformity and contractions caused by spasticity. Tardieu, Hariga, and Gaynard (1968) enumerated other inherent problems with spasticity, such as bowel and bladder problems, skin irritations in the form of sunburns and pressure sores, occult fractures below the level of the SCI, ingrown toenails, and collectively decreased life functions. These problems may adversely affect the progress of the patient's functional recovery during rehabilitation.

Measures that decrease the level of spasticity may facilitate the care of the SCI patient. Routine nursing measures such as bathing and turning the patient with spasticity may be less burdensome to the patient if the severity of spasticity is reduced.

Advances in medical and surgical management may reduce spasticity. Chemical neurolysis is gaining popularity as a medical treatment for spasticity. Although research on the

effects of chemical neurolysis dates back to the year 1916 (Halpern & Meelhuysen, 1967), there has been a recent increase in the use of chemical neurolysis to manage spasticity in patients with SCI. Chemical neurolysis refers to the application of chemical agents, usually phenol or alcohol, to a nerve to impair, either temporarily or permanently, the conduction along the nerve. When these agents are applied to the treatment of spasticity, the intent is to interrupt the reflexive contractions of muscle without affecting voluntary strength (Glenn & Whyte, 1990). Halpern and Meelhuysen reported several cases of improvement in activities of daily living (ADLs) following reduction of spasticity produced by chemical neurolysis. In another report, Glenn and Whyte stated that function and nursing care are facilitated by being able to achieve and maintain proper body positioning when the level of spasticity is eliminated as a result of effective intervention of chemical neurolysis. Katz, Knott, Feldman, and Benton (1967) reported similar effects on proper body positioning in a wheelchair, bed, or other devices which resulted in greater patient comfort, improved communication, alertness, respiration, upper extremity use, hygiene and skin care, which help facilitate patient function and nursing care.

While research on the comparative effects of interventions (chemical neurolysis versus other modalities) is lacking, nurses must be well informed about the medical-surgical interventions for spasticity in order to identify the beneficial effects of the treatment that can lead to better delivery of nursing care of the patient. In planning the care of SCI patients, the degree of spasticity must be assessed and the responses to the treatment modality must be monitored. Lastly, more ongoing research on the effects of chemical neurolysis are needed to allow accurate preselection in all cases, after considering a thorough evaluation of each patient in terms of relevant patho-physiology, degree of disability, and functional goals (Wachtel, Derby, & Fulton, 1984). This study was focused on the determination of whether chemical neurolysis is effective in reducing spasticity in order to increase the functional capabilities of SCI patients.

Problem of the Study

The problem of the study was twofold: (1) to determine the relationship between the spasticity and functional status in persons with spinal cord injury, and (2) to determine the effects of chemical neurolysis on spasticity and functional status.

Rationale for Study

Clinicians and investigators generally agree that a major consequence of spasticity is diminished functional abilities. However, very little has been published that objectively demonstrates that spasticity has a relationship to functions. Most published reports were anecdotal and suggested that spasticity decreases functional abilities in several ways, which include problems encountered in nursing care caused by the presence of spasticity (Glenn & Whyte, 1990; Haley & Inacio, 1990). This study was designed to determine if there is a relationship between spasticity and functional status in patients with SCI, while simultaneously attempting to determine if reduced spasticity is associated with any change in functional ability as a consequence of a specific intervention.

As stated previously, a gradual increase in the number of patients with SCI undergoing chemical neurolysis had been observed at the selected institution, an institution for rehabilitation and research. Although no nursing studies had been reported, professional literature often cited the nurse's role and responsibility in identifying/developing individual treatment plans for nursing care problems encountered with SCI patients with spasticity. Clinically, chemical neurolysis appears to be an extremely effective

intervention for reducing spasticity. Although the effects have not been documented in controlled trials, the results are immediate, and the clinical descriptions of relief of spasticity frequently are dramatic and explicit (Khalili & Betts, 1967). Nurses are having more frequent contact with SCI patients with spasticity, and they are becoming more involved in patient management following the chemical neurolysis.

Another reason to determine the effects of neurolysis on spasticity and functional status of SCI patients with spasticity pertained to cost-benefit implications. Bishop (1977) and Glenn and Whyte (1990) considered the cost-benefit derived from the neurolysis type of treatment modality. According to the survey on cost-containment by Glenn and Whyte, chemical neurolysis was found to be more cost-effective and practical over other modalities. For example, a patient on oral pharmacologic treatment, such as valium and baclofen, requires a four-times-per-day medication schedule for months and years. The patient is not only faced with the expense of the medications, but also with the necessity for compliance, side-effects, and other consequences of drug therapy (i.e., addiction, organ damage). Other modalities for treating spasticity have inherent problems (Glenn & Whyte, 1990). The use of

physical agents (i.e., heat, electrical stimulation) may consume a great amount of time and limit lifestyles. Devices (i.e., casts, anti-spasticity splints) may cause skin problems. Irreversible procedures (i.e., surgery) may cause pain, scarring, and infection. In contrast, chemical neurolysis is not associated with the above-mentioned drawbacks (Bishop, 1977). There are, however, potential disadvantages of chemical neurolysis, namely loss of muscle bulk, dysesthesia (impairment to sensitivity, especially touch, causing pain and burning sensation), local infection at the site of injection, peripheral edema. These possible complications are rare occurrences (Khalili & Betts, 1967).

In treating spasticity, health caregivers must be aware of the fact that interventions for spasticity are not always completely effective. The goals of treatment must be consistent with the entire neurologic, physical, medical, and psychological status of the patient. Little and Merritt (1988) emphasized that there are times when this phenomenon of spasticity is best left untreated because the cost-benefit ratio of the treatment may be too high. Thus, the decisions by health caregivers, including nurses, of timing and type of interventions to treat spasticity are quite complex.

This investigator believed that appropriate nursing care of patients with SCI is based on a proper understanding of the nature of the spasticity and its effect on functional activities. Similarly, the functional gains resulting from chemical neurolysis must be weighed against the potential for functional losses or other complications and side effects. The findings from this study may help the rehabilitation team in the management of patients with spasticity by adding to the understanding of the relationship between spasticity and functional status and the effects of chemical neurolysis on functional status.

Theoretical Framework

The framework guiding the development of this study was general systems theory, which addresses the reciprocating nature and interconnectedness of the complex body system (Killen, 1978; von Bertalanffy, 1968). From this framework, the neurophysiology of spasticity associated with the SCI can be viewed as an event of dysfunctional effects. In the patient with SCI, the most obvious adverse physiologic response to spasticity is uncontrolled, uncoordinated movements that may result in fixed contractures. The effects of fixed contractures are obvious. The bodily areas are not accessible for basic nursing care, and any range of motion

attempts may cause injury and extreme discomfort (Katz et al., 1967; Keenan, 1988).

A system is a method for bringing together parts into a meaningful whole so that the way the parts function together is clear (von Bertalanffy, 1968). The number of parts, tasks, or components of the system is totally dependent on what is needed to accomplish the goal. Additionally, a system generally consists of several components: input, output, and feedback or throughput. The term feedback is used here as a frame of reference because of nature's negative feedback control in the neuromuscular system in which its parts are related and interact with one another in a cyclic manner. Input is the information or materials that enter the system. The output is the end product of a system. Feedback is the process through which the output of a given system is returned to that system. The neuromuscular system provides a pertinent example. Muscles, nerves, and the central nervous system (CNS) normally operate as a whole and as a negative feedback control system (Guyton, 1986; Klir, 1972). In SCI patients with spasticity, the input, output and feedback mechanisms are disrupted. Information transmission and processing of both incoming and outgoing signals are exaggerated and uncontrolled. Chemical neurolysis may be viewed as the

input element, and it is introduced to the neuromuscular system to interrupt the reflexive contractions of the muscle. Functional gain is the output element of the rehabilitative process. Changes in spasticity in response to chemical neurolysis may be viewed as feedback to the neuromuscular system. Assessment of spasticity and monitoring the effects of the chemical neurolysis are interdependent components of this treatment in order to achieve the goal of improving the patient's life functions (Killen, 1978).

Assumptions

Assumptions underlying the study were as follows:

1. Body components are interrelated and rely on one another for effective functioning (Glenn & Whyte, 1990; von Bertalanffy, 1968).
2. A principal consequence of spasticity is diminished capacity of the patient to accomplish the activities of daily living (Haley & Inacio, 1990).
3. A system continually builds up and breaks down as the elements within the system change and affect the input and, in turn, affect the dynamic sequence of output, either an increased or decreased response to input (Klir, 1972; von Bertalanffy, 1968).

Research Questions

The following research questions were addressed in this study:

1. Are spasticity and functional status related in persons with SCI?
2. Will persons with SCI exhibit less spasticity as measured by the Ashworth Scale after chemical neurolysis than before the treatment?
3. Will persons with SCI demonstrate greater degrees of independent function as measured by the Functional Independence Measure (FIM) after chemical neurolysis than before the treatment?

Definition of Terms

For the purpose of the study, the following terms were defined:

1. Chemical neurolysis: viewed as the input element to the system of a patient with SCI, it is a method of reducing hypertonicity in targeted muscles (Halpern & Meelhuysen, 1967). Operationally defined, chemical neurolysis is a procedure performed by a physician, usually a neurosurgeon or anesthesiologist, in which phenol or alcohol is introduced using a 22-gauge sterile needle into the targeted nerves for the purpose of reducing tone in hypertonic muscles. The dose or amount of the

substance injected varies in accordance to the patient's body surface, based on mg/kg body weight and height.

2. Functional status: considered as the output element in the rehabilitation process of the patient with SCI, it includes tasks, or functional activities, performed for oneself, or others, to function within the society. Operationally defined, functional status was the summated score on the Functional Independence Measure (FIM) scale (Fuhrer, 1987). A higher score on the FIM equates with better (i.e., more independent) function.
3. Spasticity: a phenomenon that disrupts the input, output, and feedback mechanisms of a system; in a body system, spasticity is a syndrome associated with a persistent increase in the involuntary reflex activity of a muscle in response to stretch which occurs in muscles below the level of injury (Glenn & Whyte, 1990; Guyton, 1986; Halpern & Meelhuysen, 1967). Spasticity was operationally defined as the score on the Ashworth Scale (Bohannon & Smith, 1987). A higher score on the Ashworth Scale equates with greater spasticity.
4. Spinal cord injury (SCI): an assault to the system which causes a disruption in one of its parts, it is an injury to the spinal cord which results in impairment and paralysis (WHO, 1991). SCI was operationally

defined as any damage along the segment of the spinal cord (thoracic, level 1-8; cervical, level 4-8) producing loss of sensation and voluntary motor control.

Limitations

The mixed retrospective-prospective approach could have been a threat to internal validity of this study because the investigator lacked manipulative control of independent variables. Therefore, any attempt to draw cause and effect conclusions may be totally unwarranted, no matter how strong the existence of a relationship between variables (Polit & Hungler, 1989). For this study, the potential limitations included reliance on retrieval of patients' medical records for reviewed data and the use of a small convenience sample. Retrospective review of patients' charts for data may have created a problem because the reliability of data is often questionable. The recording of data may be inconsistent between patients and subject to interobservers' variability. Additionally, patients' recollections of their functional status before chemical neurolysis may have posed a threat to internal validity. Patients may have related their functional experiences subjectively and may have selectively provided information for a variety of reasons, including selective recall or anticipation of what the principal investigator expected to accomplish.

External validity refers to the generalizability of the research findings to other settings and samples (Polit & Hungler, 1989). This study involved only one particular population. Subjects were homogeneous in regard to primary diagnoses. Furthermore, the study was conducted in an institutional setting that was deliberately selected as a sample of excellence of rehabilitation nursing. Therefore, the possible evaluations provided by patients in this study may not apply to other clinical settings. Finally, this study was conducted by the principal investigator familiar with the particular group of patients.

Summary

Patients with SCI have problems with spasticity. Spasticity prevents patients from achieving the expected maximum levels of function. Several therapeutic interventions are available to reduce spasticity. Chemical neurolysis, a nonexperimental procedure, is currently one of the accepted modalities in managing spasticity in SCI patients. Although this technique has been available for some time, little research has been conducted to investigate its effectiveness. Moreover, the available data do not clearly describe the benefits of this procedure on level of function. This study was designed to address the relationship between spasticity and functional status and

the effects of intervention of chemical neurolysis on functional status. Von Bertalanffy's (1968) general systems theory was used as the theoretical framework of this study.

CHAPTER 2

REVIEW OF LITERATURE

The concepts of spasticity and functional status have been used extensively in disability and rehabilitation research as indicators of an individual's ability to engage in physical independence and to perform self-care activities. Guyton (1986) defined spasticity as an increased muscle tone characterized by changes in neuromuscular performance. Spasticity is a frequent sequela for spinal cord injured (SCI) patients, and when it is severe, it often impairs functional status of the individual. Functional status refers to functional skills involving self-care and mobility activities (Pedersen, 1969). Both terms, spasticity and functional status, are important for patients' self-care because the emphasis is generally placed on residual abilities and restorative potential (Kirby, 1984) in patients with SCI.

The inability to achieve optimal functional status in response to the impairments and handicaps produced by spasticity is attributed to decreased effectiveness of body function, particularly with regard to the neuromuscular system. Other sequelae may evolve, such as skin breakdown,

poor hygiene, and bowel and bladder problems (Sine & Liss, 1988; Tardieu, Hariga, & Gagnard, 1968). Therefore, the ability to maintain physical independence and perform self-care activities should be encouraged in the SCI patients so that the integrity of body systems is not further compromised.

Chemical neurolysis is one treatment modality for spasticity that appears to retard the physiologic sequelae of spasticity and to improve functional status which is necessary for physical independence (Glenn & Whyte, 1990). Although there has been increasing interest in the use of chemical neurolysis using a dilute phenol substance, little research has been reported on the particular procedure. Gibson (1987) further suggested that the simplicity and potential usefulness of the procedure argue for clinical research on this intervention.

Spasticity following spinal cord injury remains one of the most complex problems confronting both patients and health care providers. Despite the frequency with which spasticity is encountered, major differences exist among clinicians and investigators with regard to their viewpoints and perspectives of the mechanism of spasticity (Landau, 1980). According to Whitlock (1990), comprehension of this condition is limited; the clinical definition of spasticity

and the underlying pathophysiology remain controversial. Additionally, approaches to reducing the adverse effects of spasticity on functional status have changed greatly over the last 10 years. As the physiologic basis for spasticity is clarified, modalities for treatment change.

Whitlock (1990) noted that spasticity can be best understood on the basis of functional organization of neuroanatomical structures, in which there is an alteration in resting muscle tone, reflexes, and motor control resulting from central nervous system (CNS) lesions. Similarly, Landau (1980) considered the presence of spasticity as one of the most definitive physical signs of abnormal motor function secondary to lesions of cortical, subcortical, or spinal cord structures. Shahani and Young (1986) described spasticity as abnormal reflexes associated with the upper motor neuron syndrome: hypertonia (increased tone which may be velocity-dependent), increased size of the reflexogenic zones, clonus (repetitive rhythmic contractions, relaxations, and recurrent spontaneous contractions), and hyperactive tendon reflexes. Spasticity ultimately results in altering muscle voluntary control and alignment, which in turn results in decrements of motor performance and daily functional skills (Bauer, 1972; Merritt, 1981; O'Sullivan, 1988).

Limitations in either passive or voluntary movements may be caused partly by spasticity which can be identified by manual examination, testing restraint, and the observation of stretch-induced spasms and hyperactive tendon jerks (Katz, 1989). Little and Merritt (1976) cited the use of electromyography (EMG) as a means of identifying and evaluating spasticity, particularly if spasticity causes loss of function. Although the use of EMG to measure spasticity does have merit, it is neither convenient nor clinically applicable in daily nursing practice (Pettibone, 1988). The most commonly used manual testing of spasticity without the use of a technical device is the Ashworth scale. Haley and Inacio (1990) confirmed the use of the Ashworth scale to measure the degree of spasticity by documenting resistance to passive movement. The test is usually administered before and after interventional therapy to help establish the efficacy of the intervention.

An important focus of the evaluation of spasticity is the examination of daily functional activities. Guccione, Cullen, and O'Sullivan (1988) considered functional status to be a good outcome measure of an intervention in persons with spasticity. Examination of how tasks are performed suggests the extent of functionally important changes resulting from spasticity-reducing modalities (Pedersen,

1969). Instruments developed for this purpose include the Barthel Index (Mahoney & Barthel, 1965) and Tufts Motor Assessment (Gans, 1988) which address basic physical functions of persons with upper motor neuron syndromes and associated spasticity. The most recent and widely used instrument is the Functional Independence Measures (FIM) (Hamilton, 1987). The FIM assesses the amount of personal and device assistance required by an individual to accomplish certain daily living tasks (Granger, 1986; Jette, 1985; Mahoney & Barthel, 1965). Guccione et al. (1988), however, emphasized that none of these functional measures are likely to change in response to a specific treatment of spasticity, unless that spasticity is a major limiting factor of task performance. Moreover, Knudsen and Martensen (1980) indicated that the success of an intervention is proportional to the degree of the understanding of specific effects of spasticity on passive restraint, postural alignment, and voluntary movements.

Researchers continue to seek an ideal treatment modality for spasticity. Glenn (1990) stipulated that an ideal treatment is one that has the inherent property of reduction of the reflexal contractions of muscles without affecting voluntary strength. Kelly and Gauthier-Smith

(1959) claimed that chemical neurolysis and paravertebral blocks meet this criterion.

Chemical neurolysis, as defined and described previously, is a nerve block using chemical agents such as phenol or alcohol injected intrathecally or intramuscularly. Garland, Lucie, and Walters (1982) reported that chemical neurolysis can be an extremely effective intervention for reducing spasticity. When the agents are applied specifically for the treatment of spasticity, the intent is to interrupt the stretch reflex arc (Glenn, 1990). Chemical neurolysis has been performed at every level of the peripheral nervous system from the root to the motor end-plate. The therapeutic result obtained and the potential side-effects depend to some extent on the anatomical site at which the nerve is injected. Kelly and Gauthier-Smith (1959) reported on the successful use of phenol during a nerve block. However, the report did not specify the number of patients nor the primary diagnoses.

Garland et al. (1982) noted similar successful effects when they performed phenol blocks to motor point of spastic forearm muscles in brain injured patients. Garland et al. described how the relief of spasticity allowed passive range of motion and attempted functional training to prevent permanent deformities. Garland's et al.'s work was

supported by Schaumberg, Byck, and Weller (1970), who demonstrated that the use of phenol nerve blocks allowed a patient who was previously unable to sit secondary to hip extension caused by severe spasticity to sit. Halpern and Meelhuysen (1970) found that of 394 muscles treated with chemical neurolysis using 5% phenol in 95 patients, 374 muscles responded favorably and resulted in a decreased level of spasticity. Consequently, the functional activities of these 95 patients improved. These reseachers, however, did not report whether these 95 patients continued to maintain prolonged functional skills over time.

Tardieu et al. (1967) published the only controlled study of chemical neurolysis using animal models. In this study, 35% alcohol was injected adjacent to the right posterior tibial nerve. Results showed that the tension elicited by passive stretch of the gastrocnemius muscle was significantly lower on the right extremity where the chemical neurolysis was performed.

The choice of site for a nerve block depends upon a variety of factors. The size and accessibility of the muscle and the potential risk for developing dysesthesia should be considered (Labib & Gans, 1984). The paravertebral approach is most important for locating the nerve supply to muscles such as psoas major. In this

technique, the needle is placed adjacent to the vertebral column at the lumbar 2 and 3 level.

The duration of the effects of chemical neurolysis varies widely. Halpern and Meelhuysen (1967) reported that in their study the effect lasted from several months to a few years and it usually was not permanent. The advantage of the lack of permanency for both patient and physician is that if adverse effects occur from the block, they are not likely to be permanent. The major disadvantage is the need to repeat the procedure. Moritz (1973) reported that relief of spasticity lasted from a few days to more than 1 year, with average duration of effect of 8 months. Similarly, Khalili and Betts (1967) reported that in 94 peripheral nerve blocks, using 2% to 3% phenol, the effect lasted anywhere from 10 to 850 days with an average of 317 days. Copp and Keenan (1972) have observed effects for as long as 3 years. In contrast, Katz, Knott, Feldman, and Benton (1967) reported in their study that in 31 effective peripheral nerve blocks using 3% phenol, only 9 lasted for longer than one month. The short duration of effect was not explained. According to Glenn (1990), the issue of duration of effect of nerve blocks with phenol remains unresolved. Although there are numerous reports on the variability in the duration of effect, most of the investigators did not

offer any specific reasons or factors influencing the duration of effect of chemical neurolysis. Halpern and Meelhuysen (1967) assumed that the length of axon growth, the technique used to perform the block, the quantity and concentration of solution (which may influence the number of axons affected), the degree of spasticity, and individual neurophysiologic profile may affect the duration of the block.

Most of the nursing literature was focused on spasticity in cerebrovascular accident and brain injury patients. No studies were found that were designed to specifically address the effects of chemical neurolysis on spasticity and functional status of the SCI patient. In general, the literature tended to support the assumption that chemical neurolysis has direct effects on reduction of spasticity and increased functional status. The assumption is strongly supported by the works of Khalili, Harmel, Foster, & Benton (1964) and Keenan (1988). These researchers found that nerve blocks using the agent phenol were effective in reducing spasticity of 19 patients with head injury or cerebral palsy.

From the related literature, it can be concluded that patients with spasticity respond favorably to chemical neurolysis. Most of the studies, however, did not specify

the primary diagnoses of subjects, and many were conducted in laboratory settings. Further research is needed to determine the effect of chemical neurolysis on spasticity and functional status of the patient with SCI.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

A mixed retrospective-prospective, nonexperimental design was used to answer the research questions in this study. Polit and Hungler (1989) described retrospective studies as ex post facto (from after the fact) research in which manifestation of some phenomena existing in the present is linked to other phenomena occurring in the past. Prospective studies include data collected over a period of time to study changes resulting from treatment or interventions. For this study, the present phenomena were spasticity and functional status post chemical neurolysis as compared to spasticity and functional status before chemical neurolysis (past phenomena). The mixed retrospective-prospective research approach is appropriate when the investigator has no control over the independent variable (chemical neurolysis) (Polit & Hungler, 1989; Rintala, 1987). Therefore, this study was retrospective-prospective in that the principal investigator had no control over the introduction of chemical neurolysis. Moreover, the data on the treatment were collected after patients had received chemical neurolysis. The posttest data on the dependent

variables (spasticity and functional status) were collected through personal interview and assessment of spasticity, and these data were then compared to pretest data obtained through review of patients' charts. To minimize selective biases, the principal investigator insured that only spinal cord injury (SCI) patients with documented well-established clinical signs of spasticity before chemical neurolysis and who had received chemical neurolysis comprised the sample.

Setting

The setting was a small community hospital located in a metropolitan area of the southwestern United States. This institution specializes in rehabilitation of patients recovering from major disabilities. A 24-bed SCI unit and the SCI outpatient clinic were the sites of all data collection (medical records reviews; assessments of post chemical neurolysis spasticity and functional status; and follow-up telephone interviews). The SCI unit in this rehabilitation facility consists of four private rooms, two rooms of 4-bed semi-wards, and six 2-bed rooms. Occasionally about 5 to 7 patients of other services, such as amputee, stroke, and traumatic brain injury patients, are admitted to this unit. Therefore, at any given time, this unit houses approximately 18 patients with SCI. Approximately 25-30 outpatients are seen per month for

routine follow-up in the SCI outpatient clinic. The data were collected over approximately 6 to 8 weeks.

Population and Sample

The target population for this study consisted of SCI inpatients and outpatients at the rehabilitation facility. The available population (Polit & Hungler, 1989) consisted of approximately 45 patients.

The sample for this study consisted of patients with a primary diagnosis of SCI who met the following criteria:

1. Were between 18 to 60 years of age.
2. Had a primary diagnosis of SCI, with well established clinical signs of spasticity.
3. Were alert enough to be interviewed.
4. Understood English.
5. Had undergone chemical neurolysis.
6. Had no complications from chemical neurolysis.

According to the power analysis formula and tables by Cohen (1987) for paired *t* test, a significance criterion of 0.05--one-tailed, power of 0.80, and a medium effect size of 0.50, a sample size of 28 was needed. A total of 30 subjects was recruited to accommodate possible attrition. The effect size of 0.50 determines the realistic estimate of the number of subjects needed (Cohen, 1987; Munro, Visintainer, & Page, 1986), based on the amount of

anticipated impact of the chemical neurolysis on spasticity and functional status. The anecdotal reports on chemical neurolysis (Glenn & Whyte, 1990; Halpern & Meelhuysen, 1967; Katz, Knott, Feldman, & Benton, 1967) suggested a medium effect size.

The sample was recruited from the target population using the nonprobability convenience sampling technique described by Polit and Hungler (1989). This sampling technique was selected by the investigator because of prior knowledge of the character of the group, the homogeneity of the attribute to be studied, and the small available population (Polit & Hungler, 1989). Patients who had undergone chemical neurolysis between 1989 and 1992 were recruited for this study. At least 30 patients were available for recruitment.

Protection of Human Subjects

Permission to conduct the study was obtained from the institutional review boards of the agency where the research took place and the Human Subjects Review Committee at Texas Woman's University (Appendix A). Potential risks included the following: (1) Mild physical discomfort might have been experienced by subjects during testing to determine the degree of spasticity. (2) Psychologically, patients might have felt their privacy was compromised. (3) The potential

existed for loss of confidentiality. Informed consent (Appendix B) was obtained from all subjects. All prospective subjects were notified of their right to withdraw from the study at any time without any compromise to their care. The study was explained to prospective subjects as a before and after comparison of the effect of chemical neurolysis on spasticity and functional status. Confidentiality was maintained for all patients who participated in this study. Names were not identified on the forms. Information obtained was kept in a secured file located in the investigator's office (access to the locked file was restricted to the investigator only) until data collection and analysis were completed. Thereafter, this information was destroyed.

Instruments

Three instruments were used for data collection: the Patient's Demographic Data Form (Appendix C), the Ashworth Rating Scale (Bohannon & Smith, 1987; Fuhrer, 1987) (Appendix D), and the Functional Independence Measure (FIM) Scale (Fuhrer, 1987) (Appendix E). Permission to use these instruments was obtained (Appendix F).

The Patient's Demographic Data Form (Appendix C), developed by the investigator, was completed for all subjects. Demographic data contained in the form, along

with their rationale, include the following: age, gender, height and weight to determine differences in chemical neurolysis dosages; marital status and living arrangements as an indication of assistance with patients' functional activities; educational attainment to explain differences in patient understanding of the treatment; primary diagnosis and level of SCI injury to help identify homogeneity of the sample; date and cause of injury; date spasticity first noticed; and complications from chemical neurolysis to help explain functional status findings post treatment. The above variables may have affected the findings and could have been sources of extraneous variables which were beyond the investigator's control.

The Ashworth Rating Scale (Appendix D) provided a means to quantify the measurement of the degree of spasticity by documenting resistance to passive movement. Bohannon and Smith (1987) described this scale as assigning a numeric grade to the amount of resistance felt by the examiner. The Ashworth Scale had been widely used clinically and was the only quantified measure of spasticity. The scale had been shown in recent studies to have good interrater reliability and validity (Bohannon & Smith, 1987). Bohannon and Smith performed manual tests of elbow flexor muscle spasticity using the Ashworth Scale and had agreement on 86.7% of their

ratings of the level of spasticity (r = .84, $p \leq .001$). Their interrater reliability coefficients had been found to vary from .84 to .93. Rothstein (1985) questioned the reliability of any quantitative measure of spasticity, because spasticity may vary considerably secondary to time of day, patient's positioning and emotions, and other factors. However, with regard to validity, Rothstein inferred that the Ashworth Scale is a good measure of resistance to passive stretch of the muscle. In contrast, the Ashworth Scale has little validity when used to assess functional parameters of spasticity such as ambulation, in which quantitative measures of spasticity may be valid for some purposes but not for others. More recently, Haley and Inacio (1990) confirmed this statement, particularly with regard to passive stretch of muscles.

The Functional Independence Measure (FIM) Scale (Appendix E) offered the best available practical strategy in assessing a patient's functional changes following treatment. According to Fuhrer (1987) and Hamilton (1987), the FIM is considered to be a valuable instrument to be used in measuring functional competency and independence in activities of daily living (ADLs). The FIM uses a 3-point scale, ranging from 1-3, to divide the performance into (1) unable to do the activity, (2) can complete the activity

with help, or (3) can complete the activity independently (Hamilton, 1987). The FIM includes 18 functional items that measure level of independence with key activities of daily living. The 18 items are arranged into six subscales with 2 to 6 items each that tap the dimensions of functional status during the rehabilitation process. Activities of the six subscales include the following: (1) self-care: feeding, grooming, bathing, dressing upper body, dressing lower body, toileting; (2) sphincter control: bladder maintenance, bowel maintenance; (3) mobility: transfer to bed, chair, wheelchair, transfer to toilet, transfer to tub, shower; (4) locomotion: walk/wheel chair, stairs; (5) communication: comprehension, expression; and (6) social cognition: social interaction, problem solving, memory. The possible range of scores is 1 to 3 for each item and 18 to 54 for the total FIM score. The higher the score, the greater the functional status.

According to Hamilton (1987), validation of the FIM has been limited to face validity. The interrater reliability based on the sum of all FIM items appears consistent and acceptably high. One-way analysis of variance (ANOVA) was used to assess 303 pairs of clinicians administering the FIM to patients at admission and 184 pairs at discharge. The interrater reliability was $r = .86$ upon admission and

r = .88 at discharge which indicated good agreement between observers (Hamilton, 1987).

Although using these standardized instruments with published reliability figures, the investigator planned to further test their reliability. This action occurred through results of a pilot study conducted by the investigator.

Data Collection

Data were collected by the investigator in the selected facility. Patients were contacted during their routine follow-up clinic visits or on admission to the SCI unit. The following steps were undertaken by the investigator to collect the data.

1. Patients were assessed for the inclusion criteria previously listed.
2. Each patient who met the criteria was assigned a code number.
3. Prospective subjects were approached and asked to participate in the study.
4. Patients who agreed to participate were informed of the purpose, benefits, the time involved, and potential risks of the study, as outlined and explained in the consent form.
5. After consent was obtained, the investigator retrieved

the demographic information and documented these data on the patient's demographic data sheet.

6. Patients were then assessed by the investigator for the presence and degree of spasticity by using the Ashworth Scale. The lower extremity muscle groups which are the sites of the chemical neurolysis were tested. These muscle groups were consistently tested with the Ashworth Scale, by testing the muscle strength and resistance to passive movement. The scale assigns a numerical grade to the amount of resistance felt when affected extremity is extended or stretched.
7. Patients were asked questions relating to their functional performance by using the FIM constructed checklist.
8. A review of the patient's medical records was conducted to obtain Ashworth and FIM ratings before chemical neurolysis and to validate the findings from steps 6 and 7.

Pilot Study

Prior to data collection, a pilot study was conducted in the selected institution to test the methodology and usability of the instruments. In addition, reliability of the instruments was tested. Two subjects were selected from the SCI unit. Data sets were collected on each patient by

the investigator. Intrarater reliability was calculated for the instruments by using the formula recommended by Polit and Hungler (1991, p. 373):

$$\frac{\text{Number of agreements}}{\text{Number of agreements + disagreements}}$$

The intrarater reliability of the Patient's Demographic Data Form was $r = 1.0$ ($p \leq .05$), the Ashworth Scale was $r = 0.8$ ($p \leq .05$), and the FIM was $r = 0.88$ ($p \leq .05$). Usable data from the pilot study were incorporated into the sample data.

Treatment of Data

The sample was described using measures of central tendency and variability. Means and standard deviations, as well as frequencies and percentages, were used for age, height, weight, chemical neurolysis dosage, and duration of time between chemical neurolysis and posttesting. Frequencies and percentages were used for the remaining demographic data.

The levels of measurement of the Ashworth Scale and Functional Independence Measure are ordinal and interval, respectively. Frequency distributions were computed on the Ashworth scores, items of the FIM, and the demographic data variables. The median and the range were used to describe the sample's level of spasticity. The mean and standard deviation were used to describe the sample's level of

function. The Spearman rho correlation coefficient which indicates the magnitude of relationship between two variables (Munro et al., 1986) was used to evaluate the relationship between spasticity and functional status. To compare the degree of spasticity before and after chemical neurolysis, parametric statistical analysis of the scores on the Ashworth Scale was conducted using the Student's *t* test for paired data. According to Munro et al. and Swinscow (1978), Student's *t* test is a parametric test used for analyzing the difference between two means of a sample. Differences in functional status (before and after chemical neurolysis treatment) were analyzed with a paired *t* test. Alpha was set at .05.

CHAPTER 4

ANALYSIS OF DATA

A mixed retrospective-prospective, nonexperimental design was used to study (1) the relationship between spasticity and functional status in persons with SCI and (2) the effects of chemical neurolysis on spasticity and functional status.

Data were obtained through personal interviews and assessments and through the review of patients' medical records. The two primary variables, spasticity and functional status, were measured with established instruments that yielded ordinal-interval level data. Information that was extracted from the medical records included the pretest Ashworth and FIM scores, dosage of phenol, and the time interval between the intervention and posttesting.

A sociodemographic profile of the subjects was obtained from analysis of descriptive statistics. Bivariate analysis included paired *t* tests to compare the two sets of scores on pre-post Ashworth and FIM measurements. Spearman rho correlation was used to test the relationship between spasticity and functional status.

The sample was composed of all SCI patients with well-established spasticity who had undergone chemical neurolysis to reduce spasticity and who met the study criteria. Of the 30 subjects, no one declined to participate; all cooperated freely during the interview and assessment process. All data obtained from the patients and the patients' medical records were recorded on the forms developed by the principal investigator.

All instruments were reviewed for content and tested for stability and equivalence in data collection. Intrarater reliability was performed by the principal investigator on two patients (one male and one female) on two separate occasions (24 hours apart). The findings were as follows: Patient Demographic Data, $r = 1.0$ ($p \leq .05$); Ashworth Scale, $r = 0.8$ ($p \leq .05$); and the FIM, $r = 0.88$ ($p \leq .05$). The low correlation on the Ashworth Scale may have been due to the limited number of items on the instrument and the small number of subjects. Therefore, no revision of the above instruments was done.

Description of Sample

The sample of 30 subjects was recruited from the target population using the nonprobability convenience sampling technique (Polit & Hungler, 1991). The ages ranged from 18 to 60 years with a sample mean of 37.9 years ($SD = 9.41$)

(Table 1). There were 19 males (63%) and 11 females (37%). Of the 30 subjects, 12 (40%) were single. The mean height was 68.78 inches (SD = 3.78). The mean weight was 151.18 pounds (SD = 32.74). The majority of the subjects lived with a spouse, relatives, or paid attendant (n = 21; 70%). Eleven (37%) completed high school, and 10 (33%) had 2-3 years of college and were working toward liberal arts and bachelors degrees. One (3%) subject indicated a post graduate education toward a doctor of philosophy in social work. Of the 30 subjects, 17 (56.7%) were quadriplegics and the rest were paraplegics.

For this sample, the mean phenol dosage 6.5% (converted to milligrams by multiplying percentage of phenol in milligrams by the volume injected), standardized for body weight, was 729 mg (SD = 239 mg). The mean time interval between the chemical neurolysis and the posttest was 5.26 weeks (SD = 1.07 weeks).

Findings

The findings are presented according to the research questions addressed.

Research Question 1

The Spearman rho correlation (Munro, Visintainer, & Page, 1986) was employed to answer the research question: Are

Table 1

Frequency and Percentage Distribution of the Sample (N = 30) by Age, Gender, Marital Status, Educational Status, Living Arrangements, and Level of Injury

Variable	n	%
Age (Years)		
18-29	5	17
29-39	12	40
40-49	10	33
50-59	2	7
60	1	3
Gender		
Male	19	63
Female	11	37
Marital Status		
Single	12	40
Divorced	7	24
Married	10	33
Separated	1	3
Educational Level		
Post Graduate	1	3
Some College	10	33
High School	11	37
Grade School	8	27
Living Arrangements		
Alone	4	13
With Paid 2-5 Hour Attendant	7	23
Spouse	5	17
Family Member	10	33
Institution	4	14
Level of Injury		
Paraplegics	13	42
Quadriplegics	17	58

spasticity and functional status related in persons with SCI? The difference scores for the Ashworth and the difference scores for the FIM were correlated. The mean of the Ashworth difference scores was M = -.8 (SD = 0.5). The mean of the FIM difference scores was M = 4.73 (SD = 4.32). Spearman rho yielded a moderately strong, significant correlation between spasticity and functional status (r = -.61, $p \leq .05$) (Table 2). The negative direction of the correlation coefficient suggested that spasticity and functional status were inversely related, that is, as Ashworth scores decreased, FIM scores increased, indicating that reduction of spasticity was associated with increased functional ability.

Research Question 2

The paired t test (Swinscow, 1978) was used to answer the research question: Will persons with SCI exhibit less spasticity as measured by the Ashworth Scale after chemical neurolysis than before the treatment? The mean scores of the 30 subjects on pretreatment decreased from M = 3.85 (SD = .54) to M = 3.05 (SD = .56) on the posttreatment ($t(29)$ = 8.73, p = <.0009) (Table 3). However, on inspection of individual Ashworth scores, 7 (23%) of the 30 subjects had no change in Ashworth scores post chemical neurolysis.

Table 2

Spearman Rank Correlation Between Ashworth Difference Scores and FIM Difference Scores for 30 Subjects

Variable: Difference Scores	N	Mean	SD	Minimum	Maximum
Ashworth	30	-0.8000	0.5017212	-2	0
FIM	30	4.7333	4.3226220	0	16

Spearman Rank Correlation Matrix (N = 30)

	Ashworth Difference	FIM Difference
Ashworth Difference	1.0000	-0.6146
FIM Difference		1.0000

Research Question 3

The paired t test (Swinscow, 1978) was used to answer the research question: Will persons with SCI demonstrate a greater degree of independent function as measured by the Functional Independence Measure (FIM) after chemical neurolysis than before the treatment? The mean scores of the 30 subjects on the FIM pretest increased from $M = 36.77$ ($SD = 7.39$) to $M = 41.5$ ($SD = 9.78$) on the FIM posttest ($t(29) = -6$, $p = <.0009$) (Table 3). However, examination of individual FIM scores showed 10 (33%)

subjects had no or minimal change in FIM score post chemical neurolysis.

One-way analysis of variance (ANOVA; Munro et al., 1986) was used to test the significance of the effects of the nondemographic variables (level of injury, chemical dosages, and posttest timing) and demographic variables on changes in Ashworth and FIM difference scores (Tables 4 and 5). The level of injury was significant; paraplegics demonstrated lower spasticity and higher functional status than quadriplegics. The effects of level of injury on change in Ashworth scale and FIM scores are reflected in Table 6. The dosage of phenol injected had a significant effect ($F = 5.69$, $p = .024$) on the Ashworth score, but not on the FIM score. Males had a more favorable response to chemical neurolysis when compared to females, but the gender effect was not significant. The mean responses for pretest and posttest Ashworth and FIM scores in males and females are presented in Table 6. None of the demographic variables of age, gender, educational level, living arrangement, marital status, height, or weight had a significant interaction effect with change in the Ashworth and FIM scores.

Table 3

Comparison Between Pre-Posttest Ashworth Scores and Pre-Posttest FIM Scores (N = 30)

Subject	Ashworth Scores		FIM Scores	
	Pretest	Posttest	Pretest	Posttest
1	4.0	3.0	42	48
2	4.0	3.0	43	49
3	4.0	3.0	43	51
4	4.0	4.0	28	30
5	4.0	3.0	37	39
6	4.0	3.0	38	42
7	4.5	3.0	41	51
8	4.0	4.0	25	26
9	3.0	2.0	43	52
10	4.0	3.0	24	26
11	4.0	3.0	35	36
12	4.0	3.5	30	31
13	4.0	4.0	30	31
14	4.0	2.0	39	53
15	2.0	2.0	27	28
16	2.0	2.0	28	28
17	4.0	3.0	47	51
18	4.0	3.0	36	40
19	4.0	3.0	50	51
20	4.0	3.0	30	32
21	4.0	3.0	49	49
22	4.0	4.0	45	49
23	4.0	3.0	38	54
24	4.0	3.0	40	48
25	4.0	4.0	40	46
26	4.0	3.0	43	53
27	4.0	3.0	30	31
28	4.0	3.0	31	42
29	4.0	3.0	29	30
30	4.0	3.0	42	48
Mean	3.85	3.05	36.76	41.5
SD	.543	.562	7.393	9.785
	($t(29) = 8.73$, $p = <.0009$)		($t(29) = -6.00$, $p = <.0009$)	

Table 4

One-Way ANOVA Showing Effects of Demographic Data for Ashworth Scale Difference Scores

Source	Partial SS	df	MS	F	p
Interaction Effect	2.97574196	5	.595148391	3.30	.0207
Dosages	1.07578989	1	1.07578989	5.69	.0240*
Post Time	.00306003	1	.00306003	0.02	.8974
Injury	.88832977	1	.88832977	4.93	.0361*
Weight	.10344893	1	.10344893	0.57	.4560
Height	.34294307	1	.34294307	1.55	.2263
Gender	.58729051	1	.58729051	3.26	.0836
Age	.08984999	1	.08984999	0.41	.5310
Marital Status	.22039335	1	.22039335	0.99	.3297
Living Arrangements	.23565769	1	.23565769	1.06	.3139
Educational Level	.14978744	1	.14978744	0.68	.4200
Residual	4.32425804	25	.18017742		
Total	7.30	29	.25172414		

*$p \leq .05$

Table 5

One-Way ANOVA Showing Effects of Demographic Data for FIM Scale Difference Scores

Source	Partial SS	df	MS	F	p
Interaction Effect	310.342495	5	62.068499	6.43	.0006
Dosages	16.695746	1	16.695746	1.62	.2150
Post Time	.531518	1	.531518	0.06	.8164
Injury	211.559189	1	211.559189	21.93	<.0009*
Weight	12.834054	1	12.834054	1.33	.2601
Height	2.186556	1	2.186556	0.11	.7445
Gender	36.763817	1	36.763817	3.81	.0627
Age	10.377187	1	10.377187	0.52	.4798
Marital Status	.697896	1	.697896	0.03	.8538
Living Arrangements	8.553870	1	8.553870	0.43	.5207
Educational Level	.351211	1	.351211	0.02	.8960
Residual	231.524172	24	9.648405		
Total	541.866667	29	18.685058		

*$p \leq .05$

Table 6

Mean Pre and Posttest Ashworth and FIM Scores for Variables of Level of Injury and Gender (N = 30)

Variable	No.	Mean	SD	Minimum	Maximum
Injury					
Paraplegics	13				
Pre-Ashworth	13	3.96154	.320256	3	4.5
Post-Ashworth	13	2.92307	.493548	2	4.0
Pre-FIM	13	40.23077	5.246488	24	45.0
Post-FIM	13	48.38769	7.122554	26	54.0
Quadriplegics	17				
Pre-Ashworth	17	3.76471	.664211	2	4.0
Post-Ashworth	17	3.14706	.606339	2	4.0
Pre-FIM	17	34.11765	7.825298	25	50.0
Post-FIM	17	36.29412	8.312376	26	51.0
Gender					
Male	19				
Pre-Ashworth	19	3.86842	.522869	2	4.5
Post-Ashworth	19	2.94737	.524265	2	4.0
Pre-FIM	19	36.94737	7.419746	24	49.0
Post-FIM	19	42.63158	10.006720	26	54.0
Female	11				
Pre-Ashworth	11	3.81818	.603023	2	4.0
Post-Ashworth	11	3.22000	.606780	2	4.0
Pre-FIM	11	36.45455	7.698878	28	50.0
Post-FIM	11	39.54545	9.531729	28	51.0

Not all categories of the FIM demonstrated significant changes following chemical neurolysis. The Fisher's exact test (Swinscow, 1978) was used to analyze the changes, given that each item of the FIM scale is nominal level datum. Changes in self-care (eating, bathing, grooming, and dressing) were not statistically significant ($p = .291$). Changes in problem solving and memory (subject cognition) were not apparent ($p = 1.00$). In contrast, changes in toileting, locomotion, mobility, and social interaction were significant ($p \leq .05$). Subjects demonstrated a greater degree of independent function, particularly in locomotion in which 27 (90%) subjects post chemical neurolysis responded favorably compared to 2 (7%) subjects before chemical neurolysis. In mobility, 13 (42%) subjects responded favorably post treatment compared to 4 (13%) subjects before the treatment. In social interaction, 22 (75%) subjects responded favorably post chemical neurolysis compared to 11 (36%) subjects prior to chemical neurolysis. Responses to each FIM category pre and post chemical neurolysis are presented in Table 7.

Based on the findings, all three null hypotheses were rejected. A moderately strong and significant inverse relationship was found between spasticity and functional status in persons with SCI. Although 7 (23%) subjects had

Table 7

Fisher's Exact Test for Changes in Frequency Distribution in Pre and Posttest Scores (N = 30) for Categories of FIM (1 = Dependent, 2 = Assisted, 3 = Independent)

Variable	Pretest Scores			Total	Posttest Scores			Total	p*
	1	2	3	No.	1	2	3	No.	Values
Feeding	3	13	14	30	3	7	20	30	n.s.
Grooming	9	10	11	30	9	5	16	30	n.s.
Bathing	11	15	4	30	10	10	10	30	n.s.
Dressing									
Upper Body	11	10	9	30	10	5	15	30	n.s.
Lower Body	12	15	3	30	10	6	14	30	n.s.
Toileting	11	16	3	30	10	9	11	30	.037
Bladder									
Management	12	17	1	30	10	15	5	30	n.s.
Bowel									
Management	12	17	1	30	10	15	5	30	n.s.
Mobility:									
Transfers:									
Bed	11	15	4	30	10	7	13	30	.020
Chair	11	15	4	30	10	7	13	30	.020
Wheelchair	11	17	2	30	10	7	13	30	.002
Toilet	11	17	2	30	10	7	13	30	.002
Tub/Shower	11	18	1	30	10	9	11	30	.003
Locomotion:									
Walking/									
Wheelchair	3	25	2	30	0	3	27	30	.0009
Stairs	23	7	0	30	11	19	0	30	.004
Communication:									
Comprehension	0	3	27	30	0	3	27	30	n.s.
Expression	0	5	25	30	0	5	25	30	n.s.
Social Cognition:									
Social									
Interaction	0	19	11	30	0	8	22	30	.009
Problem Solving	0	8	22	30	0	8	22	30	n.s.
Memory	0	5	25	30	0	5	25	30	n.s.

*Fisher's exact p values for significant differences between pretest and posttest items are shown. n.s. = $p \geq .05$.

no change in Ashworth scores, overall, the sample exhibited less spasticity after chemical neurolysis compared to before chemical neurolysis. Finally, subjects in general demonstrated a greater degree of independent function particularly in locomotion, mobility, and social interaction, even though 10 (34%) subjects had no change in FIM score post chemical neurolysis.

Summary of Findings

Descriptive and inferential techniques were employed to describe the 30 subjects and answer the study's three research questions respectively. The sample of 30 SCI persons was recruited from the target population using the nonprobability convenience sampling technique. The majority of the subjects were male (63%) between the ages of 18 to 60 years and with varying levels of injury.

Inferential statistics were used to analyze the data on spasticity and functional status. Using the Spearman rho correlation, spasticity and functional status were inversely related ($r = -0.6146$, $p \leq .05$). Using the t test for dependent samples, the mean pretest scores were compared with the mean posttest scores. Posttest spasticity was lower than pretest spasticity ($t(29) = 8.73$, $p = <.0009$), which indicated that chemical neurolysis produced a significant reduction of spasticity. Posttest functional

status was higher than pretest functional status ($t(29) = -6$, $p = <.0009$), indicating that chemical neurolysis produced a significant increase in functional independence.

CHAPTER 5

SUMMARY OF THE STUDY

A mixed retrospective-prospective nonexperimental design was used to (1) determine the relationship between spasticity and functional status in spinal cord injury (SCI) patients, and (2) determine the effects of chemical neurolysis on spasticity and functional status. General systems theory (von Bertalanffy, 1968) was the theoretical framework used to examine the association between spasticity and functional status and the effects of chemical neurolysis on spasticity and functional status of SCI patients.

The study consisted of 30 subjects with well-established clinical signs of spasticity. They were recruited from an accessible population using nonprobability convenience sampling technique. These patients had undergone chemical neurolysis to decrease the level of spasticity in order to increase the performance of functional skills. All 30 subjects recruited participated in the entire interview and testing process.

The Ashworth scale (Bohannon & Smith, 1987) was used to measure spasticity and the Functional Independent Measure (FIM) scale (Fuhrer, 1988) was used to measure functional

status. Pretest scores on the Ashworth and FIM were obtained retrospectively from the medical records. Posttest scores were obtained prospectively by the principal investigator with clinical assessment of spasticity, using the Ashworth scale, and patient interviews using the FIM scale. Data obtained were recorded on the designated forms developed by the principal investigator.

Descriptive and inferential statistics were used for data analysis. The Spearman rho correlation demonstrated a significant inverse relationship between difference scores for spasticity and difference scores for functional status (r = -.6146, $p \leq .05$). The t test for dependent samples demonstrated lower spasticity ($t(29) = 8.73$, $p = <.0009$) and improved functional status ($t(29) = -6.00$, $p = <.0009$) after chemical neurolysis.

Discussion of Findings

In SCI patients who present with severe spasticity, optimal functional status may only be achieved once spasticity has been reduced. Tardieu, Hariga, and Gagnard (1968) reported that severe spasticity is not only associated with impairment in functional skills, but also causes other severe sequelae such as contractures, pain, skin breakdown, and bladder and bowel problems which

collectively retard the progress of the patient's functional recovery during rehabilitation.

The findings of this study are consistent with the hypotheses of other investigations that there is an inverse relationship between spasticity and functional status in persons with SCI, that is, as Ashworth scores increased, FIM scores decreased prior to chemical neurolysis or intervention. Post chemical neurolysis Ashworth scores decreased and FIM scores increased indicating the reduction of spasticity was associated with increased functional ability. These findings are congruent with Glenn and Whyte's (1990) and Haley and Inacio's (1990) assumptions and principles. Glenn and Whyte postulated that the major consequence of severe spasticity is diminished functional abilities. Haley and Inacio suggested that spasticity decreases functional status in several ways because of the impairments and handicaps produced by spasticity.

Overall, the statistical data support research findings which documented that chemical neurolysis can be an extremely effective intervention for reducing spasticity (Garland, Lucie, & Walters, 1982; Keenan, 1988). Garland et al. reported on a study showing successful effects when they performed phenol blocks to motor point of spastic forearm muscles in brain injured patients. Khalili and

Betts (1967) reported similar effects in 94 peripheral nerve blocks performed in patients with cerebral palsy, and, as a result, these patients were able to perform functional mobility.

Despite extensive literature and the findings of this study documenting the effectiveness of chemical neurolysis, a total of 7 (23%) patients in this study did not respond favorably to the intervention. The likely explanation for this occurrence may be related to several factors. First, these subjects were quadriplegics, in whom the degree of completeness and specific location of the lesion influences the severity of spasticity. Spasticity of quadriplegic origin tends to be more severe compared to paraplegics. Second, the duration of effect, posttest timing, length of axon growth, and patients' neurophysiologic profile may have contributed to no response to chemical neurolysis. These possibilities are consistent with Halpern and Meelhuysen's (1967) assumptions about factors affecting duration of effect of the chemical neurolysis. According to Halpern and Meelhuysen, the duration of the effects of chemical neurolysis varies widely. Khalili and Betts (1967) found that the effect lasted from several days to weeks.

An awareness of the limitations of this study is essential to an appropriate interpretation of the results.

First, the study involved a mixed retrospective-prospective, nonexperimental approach in which the principal investigator lacked manipulated control of chemical neurolysis. Although the principal investigator had proposed originally to perform posttesting 5-6 months after intervention, most of the posttesting was performed 6-8 weeks after chemical neurolysis because of time constraints of the principal investigator and availability of subjects. The time interval of 6-8 months was selected to allow stabilization of the chemical neurolysis and functional performance to take place following the procedure. While most studies did not indicate a time frame for evaluation of the effect of chemical neurolysis on functional status, a greater effect from the intervention might have been observed if the time between chemical neurolysis and posttesting had been extended. It is interesting to note that, in this study, the posttest timing did not have an interaction effect on the dependent variable.

Another limitation of this study was that the investigator relied on retrieval of patients' medical records to obtain the necessary data. The validity and reliability of data obtained retrospectively are often questionable. Recorded data may have been inconsistent between patients because of interobserver variability.

Additionally, conflicting information and findings may reflect the difference between recall and current data obtained in a retrospective and prospective design. Patients may have selectively provided information about their functional experiences for a variety of reasons, such as selective recall or anticipation of what the principal investigator expected to accomplish.

The fourth limitation of this study lies in the instrument used to assess spasticity before and after intervention. While the Ashworth scale is considered simple, practical, and reproducible (the interrater reliability was 0.8), because of the limited number of items, the range of the instrument is restricted. In this study, the range of the changes of the pre and post Ashworth scores was 3.85 to 3.05, which suggests the limited range of the instrument itself in which scoring from 1 to 5 was used. The FIM scale had a much larger range of changes between pre and posttest scores (36.76 to 41.8) because of the scoring of 1 to 18.

The demographic variables studied, with the exceptions of phenol dosage and level of injury, did not appear to produce an interaction effect. The greater the dosage of phenol injected, the greater the neurolytic effect, and therefore the greater the effect on spasticity. This

finding is congruent with Halpern and Meelhuysen's (1967) statement that the greater the amount of the substance injected, the greater the effect on spasticity; however, both emphasized that the patient should be closely monitored when increasing amounts of the substance being injected to prevent complete loss of voluntary strength of the muscle. The level of injury was statistically significant with paraplegics demonstrating lower spasticity and higher functional status than quadriplegics, post chemical neurolysis. Sine and Liss (1988) reported that the degree of completeness and specific location of the lesion influence the severity of spasticity. Spasticity of quadriplegics tends to be more severe and difficult to manage than that of paraplegics. However, these quadriplegics had slight changes in FIM, particularly in mobility, locomotion, and social interaction post chemical neurolysis. An explanation for this finding might be attributed to the nature of the disability of SCI patients. It has been observed that when not affected by severe spasticity, these patients will use whatever remaining function they have in the upper extremities to drive an electric wheelchair, whether it is controlled by a joy stick or chin control. Furthermore, these patients retain a clear mind and can direct their personal care even if they are

unable to assist in its implementation (Yarnell, 1988). Therefore, these changes in the FIM scale scores may not be the result of chemical neurolysis. These findings contradicted the expected results based on previous research showing a significant improvement in mobility, locomotion, and other functional activities as a result of chemical neurolysis (Halpern & Meelhuysen, 1967).

Finally, the overall lack of statistical significance between gender and Ashworth and FIM scores may be attributed to the predominance of males in the sample. More randomized, heterogeneous samples should be used in future research to test the influence of gender on spasticity and functional status following chemical neurolysis.

Although there were patients who did not respond to chemical neurolysis, overall the results of the study demonstrate that spasticity and functional status significantly impact the life of persons with SCI. The majority of the subjects responded to chemical neurolysis as a therapeutic modality that decreases spasticity and increases the functional status of patients.

Conclusions and Implications

Based on the findings in this study, spasticity and functional status are co-dependent in SCI patients. Spasticity is associated with less independence and less

activities, suggesting that spasticity is an additional handicap and disabling factor. Chemical neurolysis is an effective intervention of spasticity reduction, which in turn produces greater functional status.

There were exceptions however; 7 of the 30 subjects did not respond favorably to chemical neurolysis. These subjects were quadriplegics and therefore, it can be concluded that chemical neurolysis may not be the ideal modality for this type of patient. The absence of studies in this area made it impossible to compare the study findings with prior research.

These findings have implications for nursing roles in the care of patients with spasticity. Due to their continuous involvement in the patient's daily activities, nurses are in the position to influence and encourage research efforts directed toward objective and careful assessment methods in order to empirically evaluate any specific intervention. Unfortunately, the choice of intervention measures is often random with the practitioners simply trying another approach if the measure fails. Spasticity is likely to be a lifelong enigma. Careful assessment and thoughtfully directed intervention are warranted in order to associate it with improved functional status.

Recommendations for Further Study

Based on the findings, conclusions, and implications of this study, future studies should encompass the following:

1. A larger sample size that would allow for stratification based on level of injury and gender to identify specific groups of patients who would benefit most from chemical neurolysis in reducing spasticity and increasing functional status.
2. The use of experimental designs to test the effect of chemical neurolysis on spasticity and functional status.
3. An evaluation of each category on the FIM following a variety of treatments.
4. The development and testing of more sensitive instruments to measure spasticity.
5. Testing the evidence for the psychometric properties of the Ashworth scale and the Functional Independence Measure scale.

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APPENDIX A

APPROVALS TO CONDUCT STUDY

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
1130 M.D. ANDERSON BLVD.
HOUSTON, TEXAS 77030-2897

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE The Institute for Rehabilitation and Research (TIRR)

GRANTS TO Josefina P. Castro
a student enrolled in a program of nursing leading to a Ph.D. in nursing at Texas Woman's University, the privilege of its facilities in order to study the following problem:

To determine the effects of chemical neurolysis on spasticity and functional status in persons with spinal cord injury.

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.
3. The agency (wants) (does not want) a conference with the student when the report is completed.
4. The agency is (willing) (unwilling) to allow the completed report to be circulated through interlibrary loan.
5. Other_____

Date:_____

Signature of Agency Personnel

Josefina P. Castro
Signature of Student

Signature of Faculty Advisor

*Fill out and sign three copies to be distributed as follows: Original-Student; First copy - agency; Second copy - TWU College of Nursing.

DR:lt
1/13/92

The Institute for Rehabilitation and Research (TIRR)

1333 Moursund, Houston, Texas 77030-3405
In the Texas Medical Center
Telephone (713) 799-5000, 797-5790 (TDD)
Fax (713) 799-7095

MEMORANDUM

TO: Josie Castro, R.N.

FROM: Marcus J. Fuhrer, Ph.D.

DATE: August 7, 1992

RE: Your application to the TIRR Research Committee entitled, "Effect of Chemical Neurolysis on Spasticity and Functional Status in Persons with Spinal Cord Injury"

The modifications made in the consent form are fully responsive to the committee's recommendations, so the project now can be considered "approved," and your work may begin. Nice job!

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON
HUMAN SUBJECTS REVIEW COMMITTEE - HOUSTON CENTER

HSRC APPROVAL FORM

Name of Investigator(s): Josefina P. Castro

Social Security Number(s): 460-92-1203

Name of Research Advisor(s): Jeanette G. Kernicki, R.N., Ph.D.

Address: 1130 M.D. Anderson Blvd.
Houston, Tex. 77030-2897

Dear: Ms. Castro

Your study entitled: Effect of Chemical Neurolysis on Spasticity and Functional Status in Persons with Spinal Cord Injury

(The applicant must complete the top portion of this form)

has been reviewed by the Human Subjects Review Committee - Houston Center and it appears to meet our requirements in regard to protection of the individual's rights.

Please be reminded that both the University and the Department of Health and Human Services regulations typically require that signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee Chairman. Any exception to this requirement is noted below. Furthermore, according to HHS regulations, another review by the HSRC is required if your project changes or if it extends beyond one year from this date of approval.

Any special provisions pertaining to your study are noted below:

_____ Add to informed consent form: "I understand that the return of my questionnaire constitutes my informed consent to act as a subject in this research".

_____ The filing of signatures of subjects with the Human Subjects Review Committee is not required.

_____ Other: see attached sheet.

__X__ No special provisions apply.

Sincerely,

Anne Young

Anne Young, Ed.D.
Chairperson, HSRC - Houston Center

10/21/92
Date

APPENDIX B

INFORMED CONSENT

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
HOUSTON CENTER

CONSENT FORM TO PARTICIPATE IN RESEARCH

TITLE OF STUDY: EFFECT OF CHEMICAL NEUROLYSIS ON SPASTICITY AND FUNCTIONAL STATUS IN PERSONS WITH SPINAL CORD INJURY

PRINCIPAL INVESTIGATOR: Josie Castro, RN, BSN, Master's Student in Nursing, Texas Woman's University and Nursing Clinical Coordinator at The Institute for Research and Rehabilitation (TIRR).

1. **The purpose and length of study**: I understand that Josie Castro, RN, a Master's student at Texas Woman's University, is assessing the degree of spasticity (tightness of my muscles) and effects of chemical neurolysis procedure (deadening my nerves) on functional activities for patients with spinal cord injury (SCI). This study will only take approximately 1 to 1½ hours of my time during my hospital stay or routine clinic follow-up visit.

2. **Description of the study including procedures**: I understand that I am being asked to be a part of a research study that will be focused on the effect of the chemical neurolysis, to find out if indeed the chemical neurolysis had lessened my spasticity (tightness of muscles) and has improved my ability to carry out daily activities. I further understand that personal interview and assessment of my spasticity will be done 72 hours after my admission or one hour after my physician had examined me during my routine clinic visit. These activities will all take place at TIRR. Therefore, if I agree to participate, I will sign this document, giving my consent for the following:

2.1 That I will cooperate by participating in a personal interview. I will be asked questions about myself and the date when I received the chemical neurolysis.

2.2 That my muscle function will be tested. I understand that the Ashworth Scale instrument to grade the degree of spasticity will be used to find out the extent of my spasticity.

2.3 That I will be asked questions on how I carry out my daily activities, if I do these activities alone or with the help of others.

2.4 That my medical records at TIRR may be reviewed at any time by the principal investigator to gather information about my injury, spasticity, treatment received and progress on how I carry out my daily tasks.

I know that I may stop at any time to rest or ask questions. Additionally, if I have any questions after the procedure, I may call Josie Castro at 728-0187 during office hours.

3. **Description of risks, discomforts, or inconveniences**: A possible risk is some discomfort during testing of tightness of my muscles. I am free to interrupt the assessment at any time to rest or ask questions. I may request that the assessment procedure be terminated if I wish. In the event I feel uncomfortable during the interview, I can stop the interview at any time, and I can decline to answer individual questions I so choose. My decision will not affect any present or future care that I receive at this hospital. I understand that all my answers to questions will be documented and will not be given to anyone else and no reports of this study will ever identify me in any way. I have been informed that confidentiality will be protected by using a code number instead of my name in order to keep the data separate. The data will be kept in a locked file accessible to the investigator only.

4. **Expected benefits of the study**: Although there will be no direct benefit to me from participation in this study, the findings may help health care givers to improve the life functions of SCI patients with spasticity.

5. **Other treatment available**: There is no alternative study being conducted that I may participate in.

6. **Compensation**: In the event of injury resulting from the research, I understand that neither Texas Woman's University nor The Institute for Rehabilitation and Research are able to offer financial compensation nor absorb the cost of medical treatment. However, first aid will be provided as necessary and necessary facilities,

emergency treatment, and professional services will be available to research participants, just as they are to the community generally.

7. **Research subjects' rights**: An offer to answer all my questions regarding the study has been made. If alternative procedures are more advantageous to me, they have been explained. A description of possible discomforts or risks reasonably expected have been discussed with me. I understand that I may terminate my participation in the study at any time without intimidation or prejudice to me. My signature below acknowledges my voluntary participation in this research project, but in no way releases the investigator from her professional and ethical responsibility to me.

Participant Signature	Date
Witness	Date

APPENDIX C

PATIENT'S DEMOGRAPHIC DATA FORM

DEMOGRAPHIC DATA FORM

Study No. _____

1. Age _____
2. Gender _____
3. Height _____
4. Weight _____
5. Marital Status
   - ____ Single
   - ____ Married
   - ____ Divorced
   - ____ Widowed
   - ____ Separated
6. Living Arrangements
   - ____ With spouse
   - ____ With friend
   - ____ With family member(s)
   - ____ With paid companion/caretaker
   - ____ Alone
   - ____ Other (specify; i.e., institution) _____
7. Educational Attainment
   - ____ Grade school (highest grade attended)
   - ____ High school diploma or equivalent
   - ____ Technical school certificate
   - ____ College degree
   - ____ Postgraduate level
8. Occupation Prior to Injury _____
9. Primary Medical Diagnosis _____
10. Secondary Medical Diagnosis _____
11. Date of Onset of Injury _____
12. Cause of Injury _____
13. Date Spasticity First Noticed _____
14. Other Medical Conditions _____
15. Chemical Neurolysis Agent _____
16. Chemical Neurolysis Dosage _____
17. Date of Chemical Neurolysis _____
18. Complications from Chemical Neurolysis _____

APPENDIX D

ASHWORTH RATING SCALE

Ashworth Scale

0 = No increase in muscle tone.

1 = Slight increase in muscle tone manifested by catch and release when affected part(s) is moved in flexion or extension.

2 = Slight increase in muscle tone manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of motion.

3 = More marked increase in muscle tone through most of the range of motion, but affected parts, easily moved.

4 = Considerable increase in muscle tone, passive movement difficult.

5 = Affected part(s) rigid in flexion or extension.

Source: Bohannon, R. W., & Smith, M. B. (1987). Interrater reliability of Ashworth Scale of muscle spasticity. Physical Therapy, 67, 206-207. Permission to use and reproduce was granted.

APPENDIX E

FUNCTIONAL INDEPENDENCE MEASURE

Functional Independence Measure

Study No. _____

Functional Independence Measure--samples 18 items, assesses the amount of person and device assistance needed by an individual to accomplish certain daily functional tasks. These functional measures are likely to show change related to treatment of spasticity when major limitation of task performance is present.

Grading Key: 1 = Assisted
2 = Moderate Assistance
3 = Independent

			1	2	3
A.	Self-Care				
	1. Feeding	1			
	2. Grooming	2			
	3. Bathing	3			
	4. Dressing - Upper Body	4			
	5. Dressing - Lower Body	5			
	6. Toileting	6			
B.	Sphincter Control				
	7. Bladder Management	7			
	8. Bowel Management	8			
C.	Mobility				
	9. Transfer - Bed, Chair, Wheel Chair	9			
	10. Transfer - Toilet	10			
	11. Transfer - Tub, Shower	11			
D.	Locomotion				
	12. Walk/Wheel Chair	12			
	13. Stairs	13			
E.	Communication				
	14. Comprehension	14			
	15. Expression	15			
F.	Social Cognition				
	16. Social Interaction	16			
	17. Problem Solving	17			
	18. Memory	18			

Source: Fuhrer, M. (Ed.). (1987). Rehabilitation outcome, analysis and measurement (2nd ed.). Baltimore: Paul Brookes. Permission to use and reproduce was granted.

PATIENT'S ASSESSMENT FORM

STUDY NO. _____ DATE OF INJURY _____

LEVEL OF INJURY _____

PROCEDURE CHEMICAL NEUROLYSIS DOSAGE _____

DATE OF INTERVENTION _____ AGENT _____

ASHWORTH SCORE:	PRE TREATMENT	POST TREATMENT
SITES OF INJECTIONS:		
INDICATE MUSCLE GROUP (i.e., Upper or Lower Extremity)		
1		
2		
3		
4		
FUNCTIONAL INDEPENDENCE MEASURE (FIM)		
Use Grading Key:		
1 = Dependent		
2 = Moderately Assisted		
3 = Completely Independent		
A. Self-Care		
1. Feeding		
2. Grooming		
3. Bathing		
4. Dressing Upper Body		
5. Dressing Lower Body		
6. Toileting		
B. Sphincter Control		
7. Bladder Management		
8. Bowel Management		
C. Mobility		
9. Transfer-Bed, Chair Wheel Chair		
10. Transfer-Toilet		
11. Transfer-Tub, Shower		
D. Locomotion		
12. Walk/Wheel Chair		
13. Stairs		
E. Communication		
14. Comprehension		
15. Expression		
F. Social Cognition		
16. Social Interaction		
17. Problem Solving		
18. Memory		

APPENDIX F

PERMISSION TO USE INSTRUMENTS

The
Institute for
Rehabilitation
and Research

MEMORANDUM

TO: Josie Castro, R.N.

FROM: Marcus J. Fuhrer, Ph.D.
Vice President for Research

DATE: June 10, 1992

RE: Your letter of June 8

Be assured that it is entirely appropriate for you to use information about the Modified Ashworth Scale and the Functional Independence Measure described in my book, Rehabilitation Outcomes: Analysis and Measurement.

I hope that your study goes smoothly and that a good deal is learned from it.

1333 Moursund
Houston, Texas 77030-4405
Texas Medical Center
Telephone (713) 799-5000
Toll-Free (800) 44[illegible]48

6633 West Airport #1402
Houston, Texas 77035
October 21, 1992

Richard Bohannon, Ph.D.
University of Connecticut
School of Allied Health Professionals
358 Mansfield U-101
Storrs, Connecticut 106269-2101

Dear Dr. Bohannon,

My name is Josefina Castro. I am a graduate student at Texas Woman's University Houston Center and a nursing clinical coordinator at The Institute for Research and Rehabilitation (TIRR), in Houston. At present I am working on a research project for my thesis entitled, " Effect of Chemical Neurolysis on Spasticity and Functional Status in Persons with Spinal Cord Injury. " Part of this study involves the use of the Ashworth Scale. I am therefore, asking permission to use legally the Ashworth scale published in the 1987 Physical Therapy magazine entitled, " Interrater Reliability of a Modified Ashworth Scale of Muscle Spasticity." This was also described in Glynn and Whyte's book of Practical Management of Spasticity in Children and Adults entitled, " Bohannon and Smith's Modified Ashworth Scale."
I enclosed a self-addressed stamped envelop and thanking you for time and attention to this matter.

Respectfully,
Josefina Castro, R.N.

Its o.k. w me.
I appreciate your veracity in writing. The APTA (Physical Therapy), however, holds the copyright should you reproduce the scale for publication

R. W. Bohannon

UNIVERSITY AT BUFFALO
STATE UNIVERSITY OF NEW YORK

Center for Functional Assessment Research
Department of Rehabilitation Medicine
82 Farber Hall
Buffalo, New York 14214
(716) 831-2078
FAX: (716) 831-2080

May 19, 1992

Ms. Josie Castro, R.N.
6633 West Airport #1402
Houston, TX 77035

Dear Ms. Castro:

This letter gives you permission to use the March 1990 edition of the FONE FIM, for your research proposal, per Dr. Carl V. Granger, Director, Center for Functional Assessment Research.

I hope that the information that the FONE FIM contains will be helpful to you in your research proposal.

Best Wishes and the Best of Luck to you!

Sincerely,

Patricia A. Mc Millon
Administrative Assistant

/pam