THE EFFECTS OF ICE MASSAGE THERAPY ON PERIPHERAL NEUROPATHIC PAIN AND SLEEP IN PERSONS WITH AIDS

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To the Associate Vice President for Research and Dean of the Graduate School:

I am submitting herewith a dissertation written by Kristin Kane Ownby entitled The Effects of Ice Massage Therapy on Pain and Sleep in Person's with AIDS. I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Ph.D. with a major in Nursing.

Mary M. Newman, R.N., Ph.D.

We have read this dissertation and recommend its acceptance:

Accepted

Associate Vice President for Research
and Dean of the Graduate School

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ABSTRACT

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Pain is a universal human experience and is the most frequent reason that people seek health care. Peripheral neuropathic pain is a unique form of chronic pain that afflicts 10% to 30% of persons with AIDS (PWAs). The pain manifests as tingling and burning sensations known as dysthesias. Dysthesias result in constant pain and impaired rest and sleep. Peripheral neuropathic pain is unique from other pain types because the dysthesias are not alleviated with the traditional pharmacological intervention of opiods or analgesics. The purpose of this quasi-experimental study was to examine the efficacy of ice massage to reduce neuropathic pain and improve sleep quality in PWAs.

A quasi-experimental, repeated measures with three treatment levels design was used for the study. The three treatment levels were ice massage, dry towel massage, and no treatment. A nonprobability, consecutive sampling technique was used to select 33 PWAs who suffered from peripheral neuropathies. Pain was measured with a Visual Analog Scale prior to each treatment, immediately after each treatment, and immediately upon waking up the next morning. The Richards-Campbell Sleep Questionnaire, a 5-item instrument with a visual analogue scale design, was used to measure sleep quality after each treatment in the morning upon waking. A data sheet was used to record descriptive information.

The first hypothesis, there will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage, was examined using a 2-way within-subjects approach. The second hypothesis, there will be a significant difference in sleep quality in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage, was examined using a multivariate

approach to ANOVA for repeated measures. None of the hypotheses were supported.

Ice massage did not significantly affect pain or sleep quality caused by peripheral neuropathies. The findings must be viewed with caution, because power analysis revealed low effect size and an inadequate sample size.

TABLE OF CONTENTS

LIST OF TABLES

TABLE

LIST OF TABLES (Continued)

TABLE

LIST OF FIGURES

FIGURE

CHAPTER 1

INTRODUCTION

Pain is a universal human experience and is the most frequent reason that people seek health care (McCaffrey & Beebe, 1989). Pain is a complex myriad of three components, initiated by a physiological response to noxious stimuli. Intertwined with this physiological response are two other responses of a psychological and a behavioral nature. Because of the latter components, pain is a unique experience from individual to individual. The individuality of the pain experience dictates that nurses need to accept what patients say about their pain and its intensity.

Patients describe many different types of pain, from sharp piercing types of pain to the tingling and numbness caused by peripheral neuropathy. Dysthesias are associated with peripheral neuropathy manifested by tingling and burning sensations.

"Neuropathy" is a general term used for diseases or lesions involving peripheral nerves (Riley & Massey, 1980). The differential

diagnosis for peripheral neuropathy is limited (Cornblath, 1989). The causes of painful peripheral neuropathy include diabetes, malnutrition, alcohol abuse, certain drugs, uremia, ischemia, Sjogren's syndrome, dysproteinemias, cancer, porphyria, Fabry's disease, insulinoma, and mononeuropathies. Peripheral neuropathies are a result of the dysfunction of small myelinated and unmyelinated nerve fibers. Peripheral neuropathies are hypothesized to be due to increased impulse generation in nerve fibers. For the increased impulses to occur there has to be abnormal unmyelinated fibers present to carry the pain impulse (Asbury & Fields, 1984). Regardless of the etiology of the peripheral neuropathy, patients complain of the same symptoms. These symptoms (Cornblath, 1989) include paresthesias such as tingling. The most distressing paresthesias are the dysthesias. The dysthesias are defined as burning, raw, and searing painful tingling sensations of the peripheral nerves. Peripheral neuropathy results in constant pain, impaired rest and sleep, and a diminished quality of life (Pfeifer, et al., 1993).

Peripheral neuropathy pain is unique from other classifications of pain because it is not alleviated with the traditional pharmacological

intervention of narcotics or analgesics. The pain is moderately alleviated in some patients through the administration of tricyclic antidepressant or anticonvulsants. However, these medications do not sufficiently relieve the pain for many people suffering from this condition.

There are different types of peripheral neuropathies that correlate with stages of cluster differentiation (CD_4) decline (Cornblath, McArthur, Parry, & Griffin, 1993) in persons with AIDS (PWAs). These include acute and chronic inflammatory demyelinating polyneuropathy, syndromes of mononeuropathies or multiple mononeuropathies, peripheral nerve vasculitis, distal symmetric polyneuropathy (DSPN), polyradiculoneuropathy due to the cytomegalovirus, and toxic neuropathy due to anti-retroviral therapy.

PWAs are susceptible to peripheral neuropathies. Between 10% and 50% of HIV-infected individuals are affected (Penfold & Clark, 1992). According to a study conducted by Newshan and Wainapel (1993) describing the pain characteristics associated with AIDS, neuropathic pain was the second major cause of pain in the sample of 100 subjects. Peripheral neuropathies may be the most frequent disorder in individuals

with HIV infection (Cornblath, 1989). Painful peripheral neuropathies occur in approximately 9% to 16% of Persons with AIDS (Dalakas, Wichman, & Sever, 1989; Levy, Bresden, & Rosenblum, 1985; Snider, Simpson, Nielson, Gold, Metroka, & Posner, 1983). Other researchers state that the number of AIDS patients with peripheral neuropathic pain could be from 10% to 50% (Gabuzda & Hirsch, 1987; Lange, Britton, Younger, & Hays, 1988; McArthur, 1987). And according to Cornblath and colleagues (1993) peripheral neuropathies may be diagnosed in 30% to 95% of individuals in the late stages of AIDS.

The most common form of peripheral neuropathy seen with AIDS, is the distal symmetric polyneuropathy (DSPN). DSPN is diagnosed in approximately 15% of persons with AIDS (Fuller, Jacobs, & Guiloff, 1992). The signs and symptoms of DSPN have a subacute onset and are chronically progressive. The signs and symptoms include hyperesthesia, dysthesias, paresthesia, sensory ataxia, weakness, and hypoactive deep tendon reflexes (Bredesen, Levy, & Rosenblum, 1988). Sixty percent of AIDS patients, diagnosed with DSPN, experience pain (Fuller, et al., 1992). DSPN is generally located in the feet and occasionally in the hands. In a

study at Johns Hopkins Hospital, the most common symptoms reported by the patients were pain on the soles (62%) and numbness of the feet (38%), along with contact hypersensitivity (Cornblath, 1989).

Dysthesias can be particularly troublesome at night when the feet are elevated and the bedsheets touch the feet (Cornblath, 1989). Sleep is generally sensitive to a person's physical and mental health. To the degree that the person's waking health is compromised, chances are sleep will be disturbed. Sleep disturbance result in physical fatigue and poor neuromuscular coordination. Psychological dysfunction from lack of sleep includes general irritability, inability to concentrate, disorientation, and confusion (Schreier, 1986). Severe pain that is intensified at night is one of the symptoms of peripheral neuropathy (Pfeifer, et al., 1993). Thus, alleviation of pain from peripheral neuropathies becomes of paramount importance to persons with HIV infection.

The most common means, by which sleep is promoted in the person suffering from sleep deprivation, is the use of pharmacological interventions, such as benzodiazepines. However, benzodiazepines are habit forming and although they help people sleep more continuously and

longer, research has shown that benzodiazepines may severely diminish the restorative dimension of sleep (Kelley, 1991). Benzodiazepines are not effective as an analgesic. Because peripheral neuropathic pain is the major causative factor for sleep deprivation for many PWAs, a nonpharmacologic means of decreasing the pain and thus enhancing sleep, are needed.

Historically, the use of cold for medicinal purposes lagged behind that of heat because of the difficulty of making ice artificially. With the advent of refrigeration, therapeutic uses of cold have emerged. Cooling the skin reduces cellular metabolism and oxygen need. Cooling also affects the release of histamine, lymph production and cellular permeability leading to diminished edema formation (Mehta, 1986; Soric & Devlin, 1989). Analgesia also is accomplished through cooling by specific effects on the small, unmyelinated nerve fibers (Mehta, 1986). According to Soric and Devlin (1989), therapeutic application of cold decreases nerve conduction velocity and spontaneous discharge, thus decreasing the pain impulses to the substantia gelatinosa.

Ice massage is one way to use cold to produce intense sensory input. The application of ice massage involves rubbing ice over the painful area. Ice is rubbed lightly and rapidly over the affected area for five to seven minutes (Jacking & Jamieson, 1990). Within this time period, the cold stimulates the large-diameter nerve fibers, thus closing the "gateway" of the brain, which interprets pain (Melzack & Wall, 1965).

Problem Statement

The problem of this research study is to investigate the role of ice massage in decreasing pain and improving sleep in PWAs. Therefore the following questions are proposed.

1. Does ice massage reduce peripheral neuropathic foot pain in PWAs?
2. Will the quality of sleep be improved in PWAs when ice massage is used to reduce peripheral neuropathic foot pain?

Rationale for the Study

According to the Centers for Disease Control (CDC), over one million persons in the United States are infected with the Human Immunodeficiency Virus (HIV). That number suggests one in every 250 Americans is believed to be infected with the HIV virus ("An HIV battle

plan", 1995). In 1991, there were over 270,000 persons in the United States with AIDS (Centers for Disease Control, 1998). The World Health Organization estimates that over 10 million persons are infected with HIV worldwide, and that number will increase to 30-40 million persons by the year 2000 (Centers for Disease Control, 1998).

As persons infected with HIV infection live longer, there is an increased risk of developing debilitating neurological complications. The HIV virus can cause detrimental effects on the nervous system, including peripheral neuropathies (Cornblath, 1989). People who are HIV-positive are at high risk of developing debilitating, painful peripheral neuropathies. HIV-associated neuropathies are highly prevalent and are a major cause of morbidity (Cornblath, McArthur, et al., 1993).

Current treatment for neuropathic pain is the use of tricyclic antidepressants, the most commonly prescribed drug being amitriptyline (Elavil). Tricyclic antidepressants provide only partial relief for patients with AIDS-related peripheral neuropathies (Cornblath & McArthur, 1988). Studies of amitriptyline to alleviate peripheral neuropathies are primarily small controlled studies or anecdotal reports (Cornblath, 1989).

The nurse's role in caring for persons with AIDS includes assessing for the presence of peripheral neuropathies and planning interventions to minimize the debilitating effects. Non-pharmacologic interventions, such as ice massage, to alleviate the pain associated with peripheral neuropathies may be an effective mode for pain relief. There are fewer side effects to contend with when utilizing a non-pharmacologic approach to pain management of peripheral neuropathies than occur with pharmacologic management. Hallett, Tandon, and Berardelli (1985) stated that many patients find temporary benefits from nonpharmacologic measures such as cold therapy; however, there have been no studies documenting their efficacy have peripheral neuropathies.

Many pain experts agree there needs to be more research examining the use of non-pharmacologic approaches to alleviate peripheral neuropathic pain (McCaffery & Beebe, 1989). Since ancient times, various non-pharmacologic interventions have been used to alleviate pain. These techniques include the application of heat or cold, massage, and acupuncture. Increasing acceptance among health care

professionals of non-pharmacologic management of pain paves the way for research examining alternative means to alleviate pain.

As the AIDS epidemic continues more persons battling this disease will experience peripheral neuropathies. Nontraumatic, cost-effective measures need to be examined to alleviate the dysthesias associated with peripheral neuropathies.

Conceptual Framework

The conceptual framework guiding this research project, is a combination of Roy's Adaptation Model (Roy, 1976) and the Gate Control Theory of pain (Melzack & Wall, 1965) (Figure 1). The Roy Adaptation Model depicts the individual as a biopsychosocial being, who adapts to environmental stimuli. Individuals have innate (generally determined) and acquired mechanisms via learning, which help them cope with a changing environment. These adaptive mechanisms are biological, psychological, and social in origin.

Positive responses to a changing environment are known as adaptation. The ability to adapt depends on the degree of the change taking place and the state of the person coping with the change. The

INPUT	**Stimuli** (Internal stimuli to small nerve fibers carrying the sensation of pain to the "gate" in the brain. Stimuli caused by HIV associated peripheral neuropathy.)	**Intervention** (Ice massage)
CONTROL PROCESSES	**Regulator mechanism** (Neural route) Impulses reach the brain and the "gate" opens to interpret the sensation of pain.	**Changes regulator mechanisms** Temperature stimulates large nerve fibers to carry the sensation of cold thus closing the "gate" in the brain to the sensation of pain and allowing the brain to receive sensation of cold.
EFFECTORS	**Physiological Response** Chronic pain responses	**Physiological Responses** Vital signs normal
OUTPUT	**Ineffective Response** Withdrawal, depression, problems with sleep	**Adaptive** Improved sleep Euthymic No or diminished pain sensation

Figure 1. Integration of Roy's Adaptation Model and The Gate Control Theory of Pain

adaptation level is determined by the pooled effect of three environmental stimuli categorized as focal, contextual, and residual (Roy, 1976). Focal stimuli are stimuli immediately confronting the person. Contextual stimuli are all other stimuli that are present. Residual stimuli are beliefs, attitudes, experience, or traits, which have an immeasurable effect on the present situation. For example, acute pain is generally a focal stimulus. A patient with an acute appendicitis will be concerned with immediate pain relief. Impending surgery for the appendicitis is perceived as important but not as urgent as the need for immediate pain relief. Reactions to pain are also based on experiences with pain in the past (residual stimuli).

Responses to stimuli result in an adaptive response, which maintains integrity. Maladaptive responses to the stimuli result in loss of integrity and are disruptive to the person's health.

Roy identified four ways in which a person adapts to change physiological, self-concept, role function and interdependence. This particular classification of adaptive modes stemmed from observations of attempts to cope with external and internal changes (Roy, 1976).

Adaptation takes place in all four modes. According to Roy and Andrews (1991), the four adaptive modes are interrelated. Responses in any one mode have an effect on or act as stimuli for any of the other modes. A change in the physiological mode, such as a diagnosis of AIDS, affects the individuals' self-concept, role function, and interdependence modes. The diagnosis of AIDS causes a change in the individual's environment requiring adaptive mechanisms to cope and adjust to the changes.

Roy stated that the environment and the person are in constant interaction, one stimulating the other (Roy, 1976; Roy & Andrews, 1991). The environment represents external stimulation, which can either be acted upon or ignored by the person. Internal stimulation comes from within the person. An example of internal stimulation is pain associated with the process of inflammation. This pain is created by an internal environment; that of the human body. If there is a balance of input and output between the environment and the person, then adaptation occurs. However, if the environmental stimuli are overwhelming or not stimulating enough to the individual, or the individual's adaptive modes are

dysfunctional, then an imbalance can occur. The individual may display ineffective responses to the stimuli.

Adaptation level is defined as the "changing point that represents the person's ability to respond positively in a situation" (Roy & Andrews, 1991, p.4). The three classes of stimuli (focal, contextual, and residual) determine the individual's level of adaptation. Since the three types of stimuli determine the person's ability to adapt, they indirectly impact health.

When an individual is confronted with stimuli such as pain, reactions are evoked in response to the stimuli. Roy and Andrews (1991) defined these internal or external reactions as behavior. In response to stimuli, behaviors are elicited in an attempt to respond and adapt to these stimuli.

The physiological mode is associated with the way the person responds as a physical being to stimuli from the environment. Roy and Andrews (1991) described the behavior in this mode as a manifestation of physiological activities of all the cells, tissues, organs, and systems comprising the human body. The goal of the physiologic mode is

physiological integrity, which is the wholeness achieved by adapting to changes in physiological needs. Roy's model identified five basic needs and four complex processes inherent in physiological integrity.

One basic need is the need for balance in physical activity and rest. One complex way that stimuli are processed is through the senses, which includes the sensation of pain. The senses play an important role in the adaptive process and provide channels for input necessary to interact with the changing environment. Pain involves input to certain sense receptors and can be a source of focal or contextual stimuli to an individual. When the nurse is considering interventions for adaptation problems evolving from sensory overload such as pain, tangible and immediate management of stimuli is used (Roy & Andrews, 1991).

Activity and rest are essential to an individual's survival. During sleep, energy is renewed for future activity. Roy and Andrews (1991) stated that sleep is influenced by the physical stresses one experiences at a given time. Pain is a common cause of reduced levels of satisfactory sleep. Sleep deprivation will negatively impact physiologic integrity by reducing the person's ability to adapt to input from the environment.

Neuropathic pain, as experienced by PWAs, are stimuli. The pain experienced by the person with neuropathies may vacillate between focal and contextual stimuli. Many PWAs state that chronic, neuropathic pain is worse at night, at which time pain may shift from contextual stimuli to focal stimuli. However, neuropathic pain can become contextual in nature if, for example, the PWAs develops candidial esophagitis. The pain from the esophagitis may become stronger than the pain from the neuropathy. However, neuropathic pain can become contextual in nature if, for example, the PWAs adaptation to chronic pain is influenced by the person's beliefs, attitudes, and past experiences, known as residual stimuli.

Roy and Andrews (1991) recognized the gate control theory of pain (Melzack & Wall, 1965; Melzack & Wall, 1994) as a plausible theory that explains the physiologic process by which the sensory input of pain reaches and is interpreted by the brain. The gate control theory of pain provides the basis for use of the nonpharmacologic intervention of ice massage in the proposed study.

The Gate Control Theory of Pain (Melzack & Wall, 1965) postulates that sensory nerve impulses carry pain signals from the peripheral nerve receptors to the spinal cord. At the spinal cord, synapses act as gates that can close to keep impulses from reaching the brain where the perception of pain is realized. Closure or opening of the gate is dependent on the type of nerve fiber that is stimulated. Small-diameter nerve fibers are thought to carry the pain signal, which opens the gates, allowing the impulse to reach the brain. Large-diameter nerve fibers are thought to activate the cells that close the gate, thus inhibiting the transmission of the pain signal. Non-pharmacological methods such as massage are thought to stimulate the large nerve fibers, which have an inhibitory effect on the gate. According to Melzack, Jeans, Stratford, and Monks (1980), cold signals are transmitted to the spinal cord exclusively by A-delta fibers and not by C fibers. Cold is thought to stimulate larger diameter nerves to close synaptic gate, thus closing off gate to pain sensation.

Throughout history, a wide variety of nonpharmacologic methods have been utilized for pain relief measures. The rationale for their use is

often based on the gate control theory of pain, which stresses the interaction between sensory, motivational-affective, and cognitive inputs in the perception of pain (Laskin, 1988). Because massage and temperature are expected to close the gate to perception of pain, ice massage provides a potential method for producing analgesia, thereby managing the stimuli of pain. The theoretical proposition to be tested in the proposed study is that nonpharmacologic management (ice massage) of the focal stimuli of peripheral neuropathic pain will strengthen physiologic mode adaptation in persons with the contextual stimuli of AIDS by increasing the quality of sleep.

Assumptions

Assumptions underlying the proposed study were derived from Roy's Adaptation Model (Melzack & Wall, 1965; Roy, 1976; Roy & Andrews, 1991).

1. Focal stimuli from neuropathic dysthesias can result in maladaptive responses (sleep deprivation).
2. Loss of integrity (sleep deprivation) is a maladaptive response.

3. Individual behaviors (sleep quality) are elicited in attempts to respond to stimuli (e.g., pain).

4. Ice massage provides a type of cutaneous stimulation which would stimulate large-diameter nerve fibers to carry the sensation of cold to the brain, thus closing the "gate" to the sensation of pain.

Hypotheses

The following hypotheses were tested:

Hl: There will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage.

H2: There will be a significant difference in sleep quality in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage.

Definition of Terms

For the purposes of this study, the following terms were defined conceptually and operationally as follows:

Persons with AIDS (PWAs) was operationally defined as those persons infected with the HIV virus who have a CD_4 count of >200 cells/ml or a CD4 count of >14% (CDC, 1998).

Ice Massage was operationally defined as the process by which 100 cc of crushed ice was wrapped in a towel and was massaged lightly and rapidly over the skin of the dorsal and planter aspect of the feet bilaterally, for a period of 7 minutes (Jacking & Jamieson, 1990; Thomson, Skinner, & Piercy, 1991). The ice massage was applied to each foot; beginning with the right foot, consecutively for 7 minutes and the massage did not extend above the ankles.

Peripheral neuropathic foot pain was operationally defined as the score on the Visual Analog Scale. Asbury and Fields (1984) described the dysesthetic pain caused by peripheral neuropathy, as tingling, burning, or electric.

Sleep quality was operationally defined as scores on the Richards Campbell Sleep Questionnaire (Campbell, 1986; Richards, 1985). The items on the visual analogue scale of the Richards-Campbell Sleep

Questionnaire are designed to measure sleep depth, falling asleep, awakenings, return to sleep, and overall sleep quality.

Dry Towel Massage was operationally defined as the process by which a towel was massaged lightly and rapidly over the skin of the dorsal and planter aspect of the feet bilaterally, for a period of 7 minutes (Jacking & Jamieson, 1990; Thomson, Skinner, & Piercy, 1991). The dry towel massage was applied to each foot, beginning with the right foot, consecutively for 7 minutes and the massage did not extend above the ankles.

Limitations

Generalization of findings maybe effected by the limitation of a convenience sample selection process with random assignment of the treatment levels. Findings may be generalized back to the selected sample.

Summary

The actual and potential numbers of PWAs continues to escalate. Many of these persons develop peripheral neuropathies, with the accompanying problem of dysthetic pain. Pain from dysthesias is worse at

night and results in impaired sleep. This type of pain is only partially relieved by pharmacologic agents, which often can cause adverse effects. Nonpharmacologic interventions, such as ice massage, have the potential to mediate pain more effectively then pharmacologic interventions and do not have side effects.

The proposed study tested the hypotheses that ice massage at bedtime would decrease dysthetic pain and thus improve sleep quality in PWAs suffering with peripheral neuropathic pain. The conceptual framework guiding the research study was Roy's Adaptation Model (Roy, 1976; Roy & Andrews, 1991), supplemented with the Gate Control Theory of Pain (Melzack & Wall, 1965; Melzack & Wall, 1994), to support the physiologic effects of ice massage. The potential significance of the study was to improve adaptation to living with AIDS from the physiologic and psychological benefits of sleep. In addition, if ice massage had a beneficial effect in this study, further research on nonpharmacologic interventions for pain relief would have been indicated.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this review was to examine the literature related to pain in patients with AIDS (PWAs) emphasizing peripheral neuropathies, treatment modalities to manage peripheral neuropathic pain, and the impact of pain on sleep. The review of literature was organized according to the following subtopics: review of the Gate Control Theory of Pain, research describing the prevalence of pain in PWAs, research related to Transcutaneous Electrical Nerve Stimulation (TENS) and ice massage, research examining the use of tricyclic antidepressants for the management of peripheral neuropathic pain, and additional pharmacologic treatments studied to manage neuropathic pain in PWAs. The review of sleep quality literature was organized as follows: sleep and HIV/AIDS, sleep and chronic pain, and sleep and neuropathic pain.

Pain

Defining pain is very difficult and highly subjective. For clinical practice, most healthcare providers use the definition of pain developed

by McCaffery (1968). The definition of pain states that "pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does" (McCaffery, 1968, p.95). Furthermore, pain is a complex, multidimensional phenomenon, and those analgesic medications alone, may not adequately reduce or eliminate pain (Infante & Mooney, 1987; McCaffery & Beebe, 1989; Owens & Ehrenreich, 1991). A combination of nonpharmacologic and pharmacologic interventions may be needed to adequately control pain (McCaffery, 1990). Nonpharmacologic interventions have proven to be effective in managing pain; however, a recent study by Dalton (1989) of oncology and medical-surgical nurses showed that although these interventions were familiar to the subjects, the nurses reported using most of them less than 25% of the time. One theory as to why nurses do not utilize nonpharmacological interventions is their lack of adequate knowledge and skills necessary for implementation (Edgar & Smith-Hanrahan, 1992).

Egan, Synder, and Burns (1992) write that research on nursing interventions is essential for establishing the scientific basis of nursing practice. Identification and validation of nursing interventions through

research will enhance clinical practice (McCloskey & Bulechek, 1992). Studying alternative therapies for the management of pain falls in the realm of nursing research.

Pain is usually classified in two major categories - acute and chronic. Acute pain is distinguishable from chronic pain in that acute pain subsides as healing takes place and it is of brief duration, less than 6 months (McCaffery & Beebe, 1989). Chronic pain is prolonged, usually 6 months or longer. Chronic pain can be further categorized into recurrent acute pain such as sickle cell crises, chronic acute such as pain due to cancer and chronic nonmalignant pain such as pain caused by peripheral neuropathy. The following features characterize chronic nonmalignant pain: 1) is due to non-life-threatening causes; 2) is not responsive to currently available methods of pain relief; and 3) may continue for the remainder of the patient's life (McCaffery & Beebe, 1989).

Pain occurs when nociceptive pathways are stimulated. Nociception is the activation of primary afferent nerves with peripheral terminals that respond differentially to noxious stimuli (Fields, 1987). There are three stimuli that produce nociception: chemical, mechanical, and thermal.

Nociception occurs in three types of tissue: 1) somatic such as skin and bone; 2) visceral such as thoracic or pelvic organs; and 3) neural such as nerve root or spinal cord regions. Neuropathic pain etiology is from neural tissue involvement and is generally classified as a chronic, nonmalignant type of pain.

Gate Control Theory of Pain

Cutaneous stimulation is an noninvasive method for controlling pain that involves stimulating the skin and underlying tissues in order to moderate or relieve pain. Cutaneous stimulation methods include TENS, massage, and the application of heat or cold. These interventions are easily performed, inexpensive, and noninjurious to patients when used properly (Mobily, Herr, & Nicholson, 1994). Patients can be taught how to administer these interventions independently. Cutaneous stimulation physiologically reduces the intensity of pain during stimulation, and for a period of time afterwards (Doody, Smith, & Webb, 1991; Nelson & Currier, 1987; Owens & Ehrenreich, 1991; Weinrich & Weinrich, 1990).

Although the exact mechanism for the transmission and perception for pain is not known, one theory which provides a conceptual framework

for pain research is the Gate Control Theory (Melzack & Wall, 1965). The theory postulated that large diameter A fibers, smaller diameter A fibers, and C fibers are all activated during any noxious stimulation of peripheral receptors. The theory conjectures that there is a gate at the spinal cord level. The small nerve fibers are thought to stimulate the gate to open and the large nerve fibers (both A and C) are thought to be inhibitory and actually close the gate.

The Gate Control Theory of pain (Melzack & Wall, 1965) conceptualizes three general categories of activity that may result in pain relief or three ways to close or partially close the gate so that impulses felt as painful are less likely to reach a level of awareness. One aspect is cutaneous stimulation, which may relieve pain through activation of large diameter nerve fibers. In turn, that activation may provoke an inhibition of the pain messages carried by the small fibers: in essence, the gate is closed to the transmission of impulses felt as painful. Since the skin is heavily endowed with large diameter nerve fibers, many types of tactile stimulation have the potential for pain relief (McCaffery & Beebe, 1989). Cutaneous stimulation such as massage is an example of the direct

application of the theory. The hypothesis that enhancing the large fiber input would cause the gate to close to pain signals, lead Wall and Sweet (1967) to employ electrical current applied to the skin in an effort to stimulate large nerve fibers and thus to relieve pain. The use of afferent electrical nerve stimulation for analgesia, lead to the development of the TENS unit.

Melzack, Jeans, Stratford, and Monks (1980) conducted a study to examine the effectiveness of ice massage and TENS for relief of low back pain. The subjects were treated with both TENS and ice massage and changes in pain were measured using the McGill Pain Questionnaire. The researchers found that both TENS and ice massage were effective means of controlling chronic back pain. The mean percent decrease on the pain score was 50.4% for ice massage versus 48.7% for TENS. This pivotal study provides the basis for comparing the research conducted on TENS and extrapolating results to ice massage.

The theorized mechanism underlying the effects of ice massage is as a counterirritant. The sensation of ice on the skin may activate areas in the brainstem, which exert inhibitory influences on nerve impulses felt as

painful (McCaffery & Beebe, 1989). A second theorized mechanism of ice massage is anesthesia of the skin, which may cause a decrease in nerve conduction velocity.

Pain in the Patient with AIDS

Pain is a common occurrence in the PWA and causes considerable disability and discomfort. Studies conducted by Lebovits, et al. (1989) and Schofferman (1989) of hospitalized and hospice/home care patients based on chart reviews indicated that approximately 50% of HIV infected patients were admitted to the hospital for pain-related suffering. Pain was the primary reason for admission to the hospital in 30% of the patients. The most frequently reported pain syndromes were chest pain, headache, abdominal pain, esophageal and oral cavity pain, anorectal pain, pain related to peripheral neuropathies, and musculoskeletal pain (Lebovits, et al., 1989).

In another study of 148 ambulatory HIV infected patients surveyed, 55% (n = 81) experienced pain resulting from their HIV infection in the last month (McCormack, Li, Zarowny, & Singer, 1993). In a study of 191 ambulatory men with HIV, 28% (n = 53) of the asymptomatic patient

reported having pain compared to 56% (n = 83) of patients with symptomatic HIV and 80% (n = 118) of subjects with AIDS (Singer, et al., 1993).

Characteristics and impact of pain were evaluated in a prospective cross-sectional survey of 438 ambulatory AIDS patients recruited from health care facilities in New York City. The researchers used the Brief Pain Inventory to measure pain. Sixty percent of the subjects reported frequent or persistent pain during the 2 weeks preceding the study (Breitbart, et al., 1996). Subjects reported an average of 2.5 different pains and reported a mean pain intensity of 5.4 (on a 1-10 numerical scale). The researchers found that the presence and intensity of pain are associated with more advanced HIV disease.

A retrospective study conducted to determine the prevalence and management of pain during the last 2 weeks of life in PWAs being cared for at a hospice, found that 93% of the patients experienced at least one episode of pain in a 48-hour period (Kimball & McCormick, 1996). The researchers reviewed 185 charts. The most prevalent pain location was

chest pain, followed by peripheral neuropathies, headache, back pain, mouth pain, and abdominal pain.

Another study analyzed data obtained from charts. The researchers analyzed the charts for complaints of pain, the proportion of day's patients experienced pain, and analgesic treatment prescribed. Of 2650 patients, 73% (n = 1942) patients had complaints of pain (Loveless, Delaney, Moorman, & McCabe, 1997). Thirty-four percent of the subjects complained of peripheral neuropathic pain, 28% of headaches, 26% of abdominal pain, and 22% of myalgia. The proportions of patients with pain were similar across age, sex, and race groups, but varied by HIV risk with: 83% of injection drug users versus 72% of non-injection drug users had pain.

A study to evaluate the prevalence of pain, how the pain affected the subject's lives, and the treatments used by the subjects, was conducted by researchers in an ambulatory clinic for persons with HIV infection. A self-administered pain survey based on the Wisconsin Brief Pain Questionnaire was given to 148 patients. Fifty-five percent (n = 82) of the 148 patients surveyed had pain due to their disease the month

prior to completing the survey. Of those reporting the pain, 60-70% stated that the pain interfered with aspects of their daily lives from a moderate to severe degree (McCormack, Li, Zarowny, & Singer, 1993). Of the subjects with pain, 40% reported that they did not receive any pain treatment and that receiving treatment stated that they obtained a mean pain relief of 65%. Ability to sleep was also asked on the questionnaire. Seventeen percent of the patients who reported pain, stated that they had a "little bit" of trouble with sleep; 22% reported having a "moderate" difficulty with sleeping; 24% reported having "quite a bit" of trouble sleeping; and 15% stated that they had an extremely difficult time with sleep.

A retrospective chart review was conducted to study the prevalence and characteristics of pain in persons with terminal-stage AIDS. A convenience sample of 50 patient charts was reviewed. The patients were administered the McCaffery Initial Pain Assessment Tool upon admission to the hospice. The instrument is composed of 10 sections that collectively describe the patient's pain experience. Out of the total sample of 50 subjects, 30% (n =15) were able to complete the

pain rating scale upon admission. Ten percent (n = 5) reported having present pain, but could not rate their pain (Eldridge, Severance-Lossin, Nicholas, & Leuner, 1994). Seventy-five percent (n = 15) subjects, who reported having pain, had an average pain rating of 7.47 (on a pain scale of 0-10). Twenty-two percent of the subjects with pain, stated that their pain was located in the lower extremities and 4% stated that their pain followed a "stocking/glove distribution". The most common words used to describe pain was "aching" (n = 18), sharp (n = 8), "throbbing" (n = 5), and "burning" (n = 3). Ten subjects stated that their pain impacted their ability to sleep. The researchers concluded that pain is widespread in PWAs and should be a priority consideration.

Peripheral neuropathy is one of the most common and distressing problems experienced by PWAs that can lead to severe pain and immobility. Hall et al. (1991) found that 43% of a group of patients infected with HIV experienced some degree of peripheral neuropathy. In a study of 100 AIDS patients experiencing pain, 24% had neuropathic pain, which was the second most common type of pain, described (Newshan & Wainapel, 1993). Abnormalities of peripheral nerves occur in 10-50% of

HIV-infected individuals (Gabuzda & Hirsch, 1987; Lange, Britton, Younger, & Hayes, 1988; McArthur, 1987).

Two hundred and seventy-four AIDS patients were assessed for various pain syndromes through a process of clinical interview, neurologic examination, and review of medical records. Twenty-eight percent of the patients experienced peripheral neuropathies (Hewitt, et al., 1997). The researchers also found that lower CD_4+ cell counts were significantly associated with polyneuropathy.

Numerous studies have explored the incidence of peripheral neuropathies namely distal sensory peripheral neuropathy. Distal sensory peripheral neuropathy has been described in 10 to 35% of patients with advanced HIV disease and is uncommon in persons with peripheral blood CD_4 T-cell counts higher than 300 cells/ml (Marra, Boutin, & Collier, 1998).

Transcutaneous electrical stimulation

Transcutaneous electrical nerve stimulation (TENS) is a method of applying controlled, low-voltage electricity to the body via electrodes placed on the skin. The primary purpose of TENS is the relief of pain. The

mechanism by which TENS alleviates pain is not well understood. One explanation is that TENS acts as a counterirritant, masking the pain or activating a complex neural inhibitory system that alleviates more intense or prolonged pain at near or distant sites (McCaffery & Beebe, 1989). The counter-irritation influences local circuits in the spinal cord to block incoming painful nerve impulses (Hallett, Tandon, & Beradelli, 1985).

Two hundred eleven patients with different pain syndromes were treated with TENS, using a standardized protocol. After a 6-month treatment period, an independent investigator estimated the effect of TENS retrospectively through assessment of patient's files, standardized questionnaires, and diaries. Ninety-four of the subjects suffered from peripheral neuropathy and after using TENS for six months, 53% of the subjects who suffered from neuropathy showed a favorable response to the treatment (Meyler, de Jonste, & Rolf, 1994).

A study designed to compare TENS and gentle massage was conducted on 41 subjects who suffered from acute or chronic back pain. One group (n = 20) received TENS stimulation and the other group (n = 21) received massage twice a week for 30 minutes until one-of-four

conditions occurred. The McGill Pain Questionnaire was administered before and after each treatment to measure pain. The researchers found significant differences in pain scores, measured with the pain rating index between TENS and gentle massage (69.5% vs. 37.2%, $p \leq .001$) (Melzack, Vetere, & Finch, 1983). The researchers also found differences on the Present Pain Intensity (PPI) scores between TENS and massage (80.8% vs. 40.9%, $p \leq .001$) (Melzack, Vetere, & Finch, 1983).

Gersh, Wolf, and Rao (1980) presented a case study of a subject who had severe burning pain in both feet following coronary artery bypass surgery. The patient was treated with tricylic antidepressants and anticonvulsant without changes in pain intensity. Because of the unsuccessful results with conventional therapies, the physicians decided to try TENS. Pain was measured pre and post treatment using the PPI component of the McGill Pain Questionnaire. After the first treatment, there was a 100% reduction of pain in the right leg, but no change of pain in the left leg. After the second treatment, there was 100% reduction of pain in both legs. The patient continued to use TENS successfully at home.

A study to evaluate the efficacy of TENS for chronic painful peripheral neuropathy in-patients with diabetes was performed by Kumar and Marshall (1997). Thirty-one subjects were randomized to the TENS or to a "sham" treatment. The subjects administered a treatment for 30 minutes daily for 4 weeks. The subject's degree of pain was graded on a scale of 0 to 5. Thirteen subjects received the sham treatment and 18 received the TENS treatment. In the TENS group, the subjects reported greater reduction in pain ($p \leq 0.05$). The researchers concluded that TENS ameliorated pain from diabetes-associated peripheral neuropathy.

Armstrong, Lavery, Fleischli, and Gilham (1997) evaluated the effect of high-voltage, pulse-galvanic electrical stimulation through a conducting sock. The researchers administered 4 weeks of nocturnal electrical stimulation, dosed as a 50-volt/100 hertz direct current, to 10 subjects. Pain was assessed with a visual analog scale after 4 weeks of treatment and 1 month after termination of the treatment. Prior to beginning the study, the average pain score was 7.0 ± 1.5 cm. At the end of the 4-week evaluation period, the mean pain score was 1.5 ± 0.9 cm

($p \leq .005$). The researchers concluded that diabetic neuropathic pain might well be reduced through the application of TENS.

Twenty-six subjects with diabetic-related peripheral neuropathy were treated with 50mg amitriptyline daily for 4 weeks (Kumar, Alvaro, Julka, & Marshall, 1998). After 4 weeks, 88% ($n = 23$) subjects failed to respond to amitriptyline or had only partial relief were randomized between a sham treatment group or to TENS. TENS was given for 12 weeks. The degree of pain was measured on a visual analog scale. Wilcoxon's rank sum test was used for analyzing changes in pain scores. For 58% ($n = 15$) subjects, amitriptyline provided some degree of pain relief; pain scores decreased from 3.8+/- 0.1 to 2.9+/- 0.2 ($p \leq .1$). Nine subjects who were randomized to amitriptyline and the sham treatment had pain scores declined from 2.8+/-0.3 to 1.9+/-0.5 ($p \leq .03$). The group of subjects ($n = 14$) who received both amitriptyline and TENS treatments had a reduction of pain from 3.2+/-0.2 to 1.4+/-0.4 ($p \leq .01$). The degree of reduction in pain scores and the incremental relief (above the amitriptyline effect) were significantly greater ($p \leq .03$) with TENS as compared with the sham treatment. The researchers concluded

that TENS is effective in reducing pain associated with peripheral neuropathy and may be an effective adjunctive modality when it is combined with a pharmacological agent, such as amitriptyline to augment pain relief.

From a population of 2,003 chronic pain patients who acquired a TENS unit for pain management, a randomly selected sample of 376 patients who used TENS for 40-60 months, were interviewed by telephone. The survey assessed a variety of outcome variables including changes in medication use, number of pain-related medications, and use of physical therapy. The sample reported a statistically significant reduction in the use of pain medications including narcotics ($p \leq .0001$), tranquilizers ($p \leq .05$), nonsteroidal anti-inflammatory drugs ($p \leq .003$), and muscle relaxants ($p \leq .01$). The data was analyzed using paired t-test. The researchers demonstrated that medication costs could be reduced by 55% when using a TENS unit to manage chronic pain (Chabal, Fishbain, Weaver, & Heine, 1998).

A sample of 506 chronic pain patients were randomly selected from a population of 2,003 chronic pain patients who had been using TENS as

a method of pain control for at least 6 months. The subjects were interviewed via a telephone survey. Using paired t-test to analyze the data, the results of the survey showed that the respondents had less pain that interfered with work, home, and social activities; and an increased activity level ($p \leq .001$) (Fishbain, Chabal, Abbott, Heine, & Cutler, 1996).

A recent study exploring the use of TENS for patients with chronic back pain and induced acute experimental pain was conducted on thirty young subjects. The researchers randomly allocated the 30 subjects into two groups: one group received TENS stimulation to the lumbosacral region for 60 minutes and the second group receiving a placebo stimulation during the same time frame. The researcher also induced acute pain by stimulating the subject's right sole with electrical stimulation. Chronic and acute pain was measured separately using a visual analog scale. Pain measurements were taken before, during, and after TENS and placebo stimulation and were analyzed using repeated measures ANOVA. The scores on the visual analog scale were significantly reduced to 63.1% of the prestimulation value after the TENS treatment

($p \leq .001$), but the reduction was negligible after the placebo stimulation (to 96.7%, $p = .786$) (Clueing & Hui-Chan, 1999). The researchers found no significant change in the visual analog scores for the stimulation which induced acute pain ($p = .666$). The TENS seemed to have reduced pain in the subjects with chronic back pain that received this treatment modality.

Twenty-four subjects who suffered chronic pain, were treated with TENS alone, vibratory stimulation alone both used in conjunction, and with a placebo (sham TENS). The subjects received four 35-minute treatment sessions; one session dedicated to each treatment. The short form of the McGill pain questionnaire was used to assess the subject's pain levels. Pain was measured immediately after all of the treatments, again at 4 hours and 24 hours. The results showed that dual stimulation not only alleviated pain in more cases than either TENS or vibration alone, but also had stronger and more long-lasting analgesic effects (Guieu, Tardy-Gervet, & Roll, 1991). Tens and vibration together significantly reduced pain as compared to the sham treatment ($F = 35.98$, $p \leq .001$). The researchers also found that each treatment separately (TENS, vibration,

and the combination) were significantly better in reducing pain than the placebo (Guieu, Tardy-Gervet, & Roll, 1991).

Application of Ice for Pain Management

Pharmacological intervention, rather than alternative methods have been the most common means of managing pain in western medicine. The use of alternative methods to control pain is in its' infancy and research examining these methods is sparse. Cutaneous stimulation, including ice massage, ha not yet been adequately researched. Research examining the potential benefits of ice in reducing pain has been limited to acute pain and in animal models. Very little research exists examining the use of ice for the management of chronic pain.

Grant (1964) reported using ice massage therapy on 7,000 outpatients with various acute and chronic musculoskeletal conditions. The researcher reported that 80% of the subjects achieved a rapid and satisfactory treatment result with no more than three formal treatments. The limitations to this study include no randomization or blinding of the treatment to the subjects.

In 1941, Gammon and Starr studied the effect of counterirritants (e.g., ice) on pain. The two researchers initially induced pain on one another by rubbing capsicum to the skin. The researchers also injected 10% normal saline into one another to produce a tingling, burning type of pain. The painful stimuli were applied over 50 times to each researcher. Different counterirritants including cold, heat, tactile, and electrical counterirritation were studied for their potential to relieve pain. The researchers judged the relative effectiveness of the counterirritants to relieve pain to be in the following descending order: cold, electric stimulation, heat, tactile stimulation, and vibration. The authors did not indicate how pain was measured, so the findings are subjective. There was no statistical analysis of the data.

The second phase of the research by Gammon and Starr (1941), used an animal model (cats). Ten cats were anesthetized, one of their extremities shaved and cutaneous nerve twigs exposed and covered with an amplifier. Control records of the effect of the counterirritants on the cats, were made. Capsolin ointment was applied to the exposed limbs to stimulate the pain response. The application of capsolin brought a steady

discharge of nerve impulses of high frequency. The various counterirritants were applied and analyzed for their effect on the nerve impulse discharge. The application of cold by ice bags decreased or abolished the discharge. In contrast, the application of heat increased the discharge of nerve impulses (Gammon & Starr, 1941). The researchers concluded that the application of ice had benefit in reducing the pain response.

A case report was presented by Marshall (1971) in which a patient suffered with chronic shooting pain from herpes ophthalmicus. Numerous medications had been tried for management of the pain; none alleviated the pain. The physical therapist administered ice for 20 minutes to an area above the focal point of pain. The pain was greatly alleviated and the patient was able to control further pain with the application of ice. The case report does not warrant scientific merit, but does suggest that there is a role for ice in the management of pain.

Kirk and Kersley (1968) conducted a study comparing the application of heat and cold to relieve pain and increase range-of-motion in-patients with rheumatoid arthritis. The researchers enrolled 14 subjects

into the study and applied the treatments to 20 knees. The study lasted 5 weeks. Each patient received a 5-day period of ice packs or a 5-day period of hot packs followed by a 9-day treatment-free interval. The other treatment was given in a crossover fashion. Two observers assessed each knee at the same time of day for three time intervals. Variables measured included pain and stiffness, range-of-motion, and joint temperature. The study found that the improvements in the grade of pain and stiffness in the 20 knees coincided more with cold than heat therapy. The authors did note that the data was insufficient to reach statistical significance.

Massage Therapy

Seven HIV-positive individuals, who suffered from painful peripheral neuropathy of the feet and had not experienced improvement in pain after pharmacological therapy, were enrolled in a study to explore massage as an alternative therapy. The subjects each received eight sessions of massage therapy provided by an occupational therapist. The Brief Pain Inventory was used to measure pain prior to the first treatment and after the eighth treatment. Seventy-one percent (n = 5) of the

subjects had a mean decrease in pain of 3.2 (Accost, Chan, & Jacobs, 1998). Sixty-nine percent (n = 2) subjects did not experience improvement in pain and the researchers noted that both subjects also suffered from diabetes mellitus.

Tricyclic antidepressants

Tricyclic antidepressants such as amitriptyline, has been the mainstay of management for peripheral neuropathies in diabetic patients and PWAs. Those patients, who receive tricyclic antidepressants for management of their peripheral neuropathies, have had varying responses.

Max, et al. (1987) conducted a randomized, double-blinded, crossover study with 20 subjects to determine whether amitriptyline was effective in alleviating painful diabetic neuropathy. Each subject received 6 weeks of amitriptyline and 6 weeks of an "active" placebo, which mimicked the side effects of amitriptyline. The researchers concluded that amitriptyline was superior to placebo in relieving pain in weeks 3 through 6.

The results of the study appeared positive, but the study had several flaws: 1) the patients completed a 2 week drug free baseline, but there was no wash out between the administration of amitriptyline and placebo; and 2) the researchers used a diary for the subjects to report pain. There were verbal descriptors of pain describing intensity and unpleasantness. After the study, the verbal descriptors (ordinal level data) were elevated into interval/ratio level data so that parametric statistics (paired *t*-test) could be used to analyze the data (Max, et al., 1987).

Fifty-two subjects were enrolled in a study comparing amitriptyline to a placebo in the treatment of chronic intractable pain using a double-blind crossover design. Thirty-eight percent (n = 20) subjects withdrew before completing the study primarily due to side effects (Pilowsky, Hallett, Bassett, Thomas, & Penhall, 1982). Pain was measured at hourly intervals for 2 weeks before entering the study, then at 2-week intervals during the study. The researchers found that there was a significant difference on the pain scores between placebo and amitriptyline groups at week 2 (57.85 vs. 51.80, $p \leq .05$) and at week 4

(54.15 vs. 47.45, $p \leq .05$). However, at week 6, there was no significant difference between the two groups (53.05 vs. 50.62). The researchers proposed several explanations as to the findings of the study. One theory was that the continuation of the amitriptyline dose (150mg) may obliterated the analgesic effect or may produce side effects, which mask any positive response. The researchers also noted that compliance might have deteriorated with time. The results suggest that amitriptyline may not have benefit overtime.

Kingery (1997) conducted a meta-analysis of 47 studies, which tested 31 different treatments for peripheral neuropathic pain. The research studies were evaluated for treatment effect, based on statistically significant differences between the treatment and the control groups at the 5% level. According to Kingery (1997), the data indicated that tricyclic antidepressants are effective analgesics in approximately half of the patients. The analysis supports the premise that neuropathic pain is difficult to treat for many patients suffering from this pain manifestation.

A double blind, placebo-controlled, crossover study analyzing the effectiveness of amitriptyline and fluphenazine was conducted with a sample of 6 diabetic patients. A graphic rating scale was used to measure changes in pain. Although the researchers noted that the statistical power of the study was low, there was no difference between placebo and the combination of the two drugs (Mender, et al., 1986).

Patients receiving tricyclic antidepressants may also experience side effects from the drug such as dry mouth, dizziness, sedation, and urinary retention (Harley, 1993). A case report by McArthur and Schlough (1991) demonstrates how the side effects of a medication can outweigh the drug's potential benefit in alleviating pain. A client with AIDS and peripheral neuropathies chose to stop amitriptyline therapy because he found that the side effect of a dry mouth was more aggravating.

A randomized, double-blinded, 10-week trial of 145 HIV-positive patients were assigned equally to amitriptyline, mexiletine, or a placebo that had side effects mimicking a tricyclic antidepressant. The researchers measured changes in pain intensity between baseline and at week ten. The improvement in the amitriptyline group and mexiletine

group was not significantly different from the placebo. The researchers concluded that neither amitriptyline nor mexiletine provide significant pain relief in-patients with HIV-related peripheral neuropathy (Kieburtz, et al., 1998).

A randomized, placebo-controlled, multicentered clinical trial was conducted to evaluate the efficacy of a standardized acupuncture regimen and amitriptyline for the relief of pain due to HIV-related peripheral neuropathy (Shlay, et al, 1998). The 250 patients were randomized to either standardized acupuncture versus control points and amitriptyline versus placebo. Changes in mean pain scores were obtained at 6 and 14 weeks, using a pain scale ranging from 0.0 (no pain) to 1.75 (extremely intense). Patients in all four groups showed reduction in mean pain scores at 6 and 14 weeks. The researchers used a 2X2 factorial design to determine whether amitriptyline, acupuncture, or a combination was more effective than placebo for managing neuropathic pain. For both the acupuncture and amitriptyline comparisons, changes in pain scores were not significantly different between the two groups. At 14 weeks, the difference in pain scores for those in the acupuncture group

compared for those in the control points group was not significant (p = .26) and amitriptyline compared to placebo was also not significant (p = .99). The researchers concluded that neither acupuncture nor amitriptyline was more effective than placebo in relieving pain caused by HIV-related peripheral neuropathy.

Peptide T

Peptide T had been found in anecdotal reports to be beneficial in decreasing the pain due to neuropathy in PWAs. A multicentered, double blind, randomized study was conducted to determine the safety and efficacy of Peptide T. Forty subjects received Peptide T and 41 received a placebo. The change in pain scores were not significantly different (p = .32) in the Peptide T group as compared to the placebo group (Simpson, et al., 1996). The researchers concluded that the drug is safe, but not effective in treating painful neuropathy. This is the only study conducted at this time using Peptide T. The study was methodological sound with an adequate sample size.

Mexiletine

A study was conducted to determine the effectiveness and tolerance of mexiletine in HIV-related painful peripheral neuropathy. Twenty-two patients were randomized to receive mexiletine or placebo for 6 weeks, followed by the alternative intervention for 6 weeks after a 1-week washout period. Pain was assessed daily using a visual analogue scale. The Wilcoxon test was used to compare mean visual analogue scale scores for the groups as a whole between the first and second phases of the study. The mean daily pain score for those patients randomized first to mexiletine was 30.8 ± 16.1 mm, whereas it was 34.0 ± 29.6 mm while they were receiving placebo ($p = .78$) (Kemper, Kent, Burton, & Deresinski, 1998). The mean daily pain score for those subjects randomized first to placebo was 54.2 ± 19.5 mm compared with 45.7 ± 27.3 mm while receiving mexiletine ($p = .45$). The researchers examined the mean weekly visual analogue scale scores for each subject using multivariate repeated measures analysis and found that neither the treatment effect ($p = .37$) nor the sequence effect ($p = .25$) was found

to be significant. The researchers concluded that there was no evidence to support the benefit of mexiletine to treat neuropathy pain.

Sleep

Most people spend from one-quarter to one-third of their lives sleeping, yet research of sleep and function during sleep is in it's infancy (Shaver & Giblin, 1989). Sleep is a period of natural suspension of consciousness during which restorative processes occur within the body (Hodgson, 1991). Many sleep abnormalities are caused by, or are secondary to, physical pathology one being pain (Hodgson, 1991). According to Lamberg (1999) sleep laboratory studies show that pain patients have more light sleep and less deep slow-wave sleep, as well as more frequent brief arousals and more waking do healthy people. The sleep efficiency, a ratio of time asleep to time in bed, is substantially lower in persons who suffer from pain. There is a strong correlation between changes in sleep architecture and patient's reports of nonrestorative sleep.

Sleep is known to be an active process, although it appears passive. Sleep is characterized by cycling of the stages of sleep thoughout the

sleep period time. Sleep is categorized into nonrapid eye movement (NREM) sleep and rapid eye movement (REM) sleep. During NREM sleep, electroencephalogram (EEG) waveforms become synchronized, slower in frequency and of greater amplitude as deeper sleep ensues (Shaver & Giblin, 1989). The EEG waveforms depict the different stages of sleep. Stage 1 is a transition stage from waking to sleeping; Stage 2 is a light sleep, and Stage 3 and 4 are characterized by deep sleep.

The two stages of sleep, NREM and REM have different functions. REM sleep occurs in stage 1 and is characterized by a paradoxical sleep where the person is variably responsive to external stimuli. (Hodgson, 1991). REM sleep occupies about 20% of an adult's sleep. NREM is believed to be necessary for physiological restoration, maintenance of orientation, and emotional stability (Beck, 1992).

Sleep and HIV/AIDS

Sleep disturbances are common in PWAs. Fourteen HIV-positive patients without opportunistic infections of the central nervous system were examined for sleep quality. The researchers found that the subjects exhibited an impaired nocturnal sleep with longer sleep onset latency,

reduced total sleep time, reduced sleep efficiency, and more time spent awake and in Stage 1 sleep (Wiegand, et al., 1991). Subjects were found to have decreased Stage 2 sleep and REM latency was reduced.

Another research study explored the incidence of variables such as sleep quality, anxiety, well being, and symptom severity. The researchers also explored whether there was a difference in the study variables between subjects who reported HIV infection thorough male-to-male sex as compared to infection through injecting drug use. The HIV Assessment Tool (HAT) and Pittsburgh Sleep Quality Index (PSQI) were used to measure the variables. The HAT had a test-retest reliability of .96 and a reliability coefficient of .88. The PSQI had a reliability coefficient of .83. A convenience sample of 56 HIV-infected people receiving health care at a New York clinic participated in the pilot study. There was a significant difference on the global PSQI (t = -3.22, p = .003) and on the well-being factor of HAT (t = 2.05, p = .04) in that injecting drug users reported both significantly worse sleep quality and perception of well being (Nokes & Kendrew, 1996).

A convenience sample of 50 HIV-infected outpatients were enrolled in a study assessing the quantitative and qualitative aspects of sleep and examining sleep parameters in regard to the degree of immune function and selected demographic variables. The normal amount of sleep needed by adults is 6 to 10 hours and study respondents' sleep hours ranged from 3 to more than 10 hours of sleep. Forty-three percent of the subjects had either insomnia or excessive sleepiness (Cohen, Ferrans, Vizgirda, Kunkle, & Cloninger, 1996). Sixty-six percent of the subjects reported some degree of difficulty falling asleep and 70% of the respondents reported awakening more than once per night. Sixty-five percent of the subjects stated they got out of bed more than once during the night and many of the reasons for arising at night were due to HIV-related symptoms. Sixty percent of the sample rated their sleep as less than satisfactory and 26% rated it as very poor or poor. Fifty-six percent of all subjects reported some degree of tiredness in the morning (Cohen et al.). This descriptive study showed that sleep disturbances are a problem with people suffering from HIV infection.

One hundred and fifteen HIV-positive outpatients were enrolled in a study designed to determine the prevalence, characteristics, and clinical recognition of insomnia. The PSQI, Mini Mental State Exam, Trail Making Test A and B, and Hospital Anxiety and Depression Scale were the instruments utilized. Seventy-three percent of the respondents were classified as having sleep disturbance according to the PSQI. Patients with cognitive impairment had a higher prevalence of insomnia (100% versus 70%; $p = .034$). The researchers found a trend that drug-using patients reported a higher prevalence of insomnia than nondrug users (86% versus 69%; $p = .07$) (Rubinstein & Selwyn, 1998). Only 33% of the participants had documentation of sleep disturbances noted in their medical records. The researchers concluded that insomnia is widespread and underdiagnosed in the HIV positive population.

Sleep and Chronic Pain

According to Glyn, Lloyd, and Folkard (1976), chronic pain may have a circadian rhythm of increasing intensity at night. Fifty-four subjects were enrolled into the study with 30 actually completing the study. The participants were asked to rate their pain intensity every 2

hours starting at 8:00 a.m. until 10:00 p.m. There was a linear increase in pain intensity at the day's end.

Marks and Sacher (1973) in a study of medical patients, found that sleep was the function most commonly affected by pain. The subjects were asked if their pain affected their ability to sleep, concentrate, eat, or carry on a conversation. Twenty-nine of the 37 subjects rated sleep as the activity most affected by their pain.

Moffitt, Kalucy, Kalucy, Baum, and Cooke (1991) used multiple regression to analyze variables, which might contribute to sleeping problems. Variables that had a strong correlation with sleep problems were, in order of importance, pain, anxiety, age, somatic health and annual household income, all which accounted for 22% of the variance. Pain, as well as anxiety and poor somatic health were most strongly associated with lying awake at night or sleeping badly, and anxiety and pain were most strongly correlated with taking longer to get sleep. Pain was also the most important variable in taking medication to induce sleep.

Sleep disturbance can be due to pain. During a typical night's sleep, the healthy adult alternates between periods of Rapid Eye Movement

(REM) and slow-wave sleep (NREM). REM stages reoccur at regular intervals four to six times each night (Kelly, 1991). REM sleep occupies 20% to 25% of the sleeping period, while Stage 2 (i.e., slow-wave sleep) occupies about 50% of total sleep time. Stage 3 and Stage 4, which are more periods of slow-wave sleep, occupy about 15% of sleep time.

Studies using polysomnography have shown decreased total sleep time when a person has pain (Roth & Zorick, 1988). A study monitoring sleep patterns in persons with nocturnal angina, reported that the subjects had increased Stage I and 2 sleep cycles and a reduction in Stage 4 and REM sleep cycles (Cassano, Maggini, & Guazzelli, 1981). REM and Stage 4 sleep cycles are associated with duration of sleep. In sleep studies performed in patients with fibrositis syndrome and healthy subjects undergoing Stage 4 sleep deprivation, the normal volunteers developed appearances of musculoskeletal and mood symptoms comparable to the ones seen in patients with fibrositis (Moldofsky, Scarisbrick, England, & Smythe, 1975).

Forty subjects with insomnia associated with chronic musculoskeletal pain were asked to complete a sleep diary and wear an

actigraph for two consecutive nights. The researchers were interested in examining the nature and severity of sleep disturbance in the study population. Both the sleep diaries and actigraphs documented sleep disturbances in the subjects. Both methods showed low sleep efficiency (means 65-76%), long periods of wakefulness after sleep onset (means 1.4-2.1 h), and low total sleep times (means = 4.9-5.9 h) (Wilson, Watson, & Currie, 1998). The study confirmed the significance of the problem of insomnia for many patients with chronic pain.

Sleep disturbance and chronic pain are closely related phenomena. The purpose of the study was to evaluate the prevalence and nature of sleep disturbance in a sample of chronic pain patients and to examine potential factors distinguishing chronic pain patients with and without sleep disturbance. The sample consisted of 105 consecutive patients, of which 63% had suffered from pain for longer than six months (Morin, Gibson, & Wade, 1998). All patients were asked to complete a sleep survey that assessed several dimensions of sleep disturbances including usual latency to sleep onset, the number of awakenings, the amount of time spent awake after sleep onset, and total hours slept at night. Sixty-

five percent of the subjects described themselves as poor sleepers and 35% classified themselves as good sleepers.

The poor sleepers reported that pain interfered moderately to severely with their sleep and to a significantly greater extent than for those who did not consider having sleep problems (t (104) = 10.6, $p \leq .0001$). Poor sleepers felt that pain interfered significantly more frequently with both sleep onset (67% of the nights) and sleep maintenance (74% of the nights) than did good sleepers. Patients who rated themselves as poor sleepers reported taking significantly longer to fall asleep compared with good sleepers ($p \leq .001$). Poor sleepers reported more time awake after sleep onset ($p \leq .001$), awakened more frequently from sleep ($p \leq .001$). The poor sleepers had an average sleep onset latency of 43.54 minutes as compared to the good sleepers whose sleep onset latency was 16.13 minutes. Poor sleepers also reported that their pain sensation intensity was greater than ratings of the good sleepers ($p \leq .005$). Fifty-eight patients indicated that the onset of the sleep problem coincided with or followed the onset of their pain ($\chi^2 = 15.6$, $p \leq .005$). The researchers concluded that chronic pain patients

who also suffered from poor sleep, had longer sleep latency, more frequent and prolonged awakenings, and less total sleep time (Morin, Gibson, & Wade, 1998).

Sleep and Neuropathic Pain

A retrospective study examining the epidemiology of herpes zoster in 164 patients found that the most common significant problem caused by the virus, was insomnia. Twenty-five percent of the subjects complained of insomnia (Goh & Khoo, 1997).

Kvinesdal, Molin, Froland, Lars, and Gram (1984) enrolled patients with diabetic neuropathy into a study to examine the use of a tricyclic antidepressant to manage pain. The researchers had the subjects complete a six-item scale, which measured numbness, pain, dysesthesia, paresthesia, nightly aggravation, and sleep disturbances. All subjects (n = 12) complained of mild/moderate to severe sleep disturbances. The subjects were treated with imipramine and placebo in a fixed-dose, double blind, and crossover study of 5 plus 5 weeks. A Wilcoxon's test, a nonparametric statistical test, was used to analyze the data. The results of the study did not show a change in the subject's rating of sleep

disturbance caused by the neuropathies. The researcher's concluded because the natural course of painful diabetic neuropathy is highly variable and that the perception of pain is highly responsive to placebos.

Another study examining insomnia inpatients, who suffer from chronic pain, was conducted. The purpose of the study was to polysomnographically evaluating the complaint of insomnia in-patient complaining of chronic pain. The study had a sample of 26 chronic pain patients who also complained of insomnia. The sample was compared to two other groups who complained of insomnia: 12 patients whose disturbed sleep was judged secondary to psychiatric disorder, and 16 patients whose disturbed sleep was not attributed to any demonstrated reason. All the subjects received one night of polysomnography. The patients complaining of chronic pain had polysomnographic evidence of disturbed sleep. The sleep efficiency was 89.5 percent for the subjective insomnia patients and only 74.6 percent for the chronic pain patients (t = 4.54, df = 40, $p \leq .01$) (Wittig, Zorick, Blumer, Heilbronn, & Roth, 1982). Pain patients spent more time awake during the night than patients with subjective insomnia did. The chronic pain patients showed increased wake

time in both sleep onset (t = 2.62, df = 40, $p \leq .01$) as well as wake during the night (t = 3.84, df = 40, $p \leq .01$). The researchers concluded that the chronic pain patients do experience significant sleep disturbance.

Seventy-five diabetic patients with chronic painful peripheral distal symmetrical polyneuropathy were enrolled in a study to evaluate a model for treating this affliction. Twenty-two patients were untreated and 53 patients were treated with imipramine plus mexiletine for deep pain, capsaicin for superficial pain, and stretching exercises for muscular pain. Each type of pain was scored separately and the total of all three types was used as an index of overall pain. Ability to sleep through the night was also evaluated. No significant differences were observed in the initial pain scores or sleep scores. Paired t-test was used to analyze the data. After 3 months, a significant difference was found in the change of scores between the treated and untreated patients: total pain (-18+2 vs. 0+2) and sleep (1.2+0.2 vs. 0.2+0.2) all $p \leq 0.0001$) (Pfeifer, et al., 1993) In treated patients 21% became pain-free and 66% had improved pain, but not total elimination of painful symptoms. This study continues

to support the supplication that current treatment strategies for neuropathies are not effective at totally relieving pain.

Summary

AIDS is associated with many different pain syndromes including distal symmetrical peripheral neuropathies. According to the literature reviewed, 10% to 35% of PWAs suffer with this pain affliction. Peripheral neuropathy pain is not unique to those with AIDS, but can afflict patients with diabetes. Most research exploring treatments to manage the pain associated with neuropathies has been conducted on diabetic patients and has centered on the use of tricyclic antidepressants. The studies reviewed show that tricyclic antidepressants provide some relief of the burning and tingling pain corresponding with neuropathies. However, total relief of neuropathic pain eludes many patients suffering from this problem. The literature also noted that many patients who use tricyclic antidepressants experience side effects common to the medication.

The review of literature revealed that the use of non-pharmacologic methods to alleviate pain has not been well studied in western medicine. Several studies exploring the use of TENS suggest that this treatment

modality may provide an alternative to medications to manage various chronic pain syndromes. The literature also revealed that there are very few studies examining the application of ice for pain management. The lack of research accentuates the need to conduct research in this area of pain management.

Lastly, the review of literature supported the link between chronic pain and its impact on sleep. The connection between chronic pain and sleep disturbance provided the support of the need to explore sleep quality as a variable when exploring means of alleviating pain.

CHAPTER 3

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

The purpose of this study was to investigate the role of ice massage on peripheral neuropathic pain and sleep quality in PWAs. The design of the study was a non-probability, quasi-experimental, repeated measures with three treatment levels. The target population was PWAs who were afflicted with peripheral neuropathy of both feet. The three treatment levels were ice massage, dry towel massage, and no massage. Each subject received all three-treatment levels: the order in which the subject received the treatments was randomly assigned. Pain was measured immediately before and 15 minutes after each treatment as well as in the morning upon waking for a total of nine measurements and each treatment was randomly assigned. Each treatment took 15 minutes to administer. Sleep quality was measured prior to the first treatment and was measured the following morning after each intervention, for a total of four measurements.

The nonprobability technique of consecutive sampling was used

(Hulley & Cummings, 1988; Pedhazur & Schmelkin, 1991). This sampling process involves enrolling every patient who meets the eligibility criteria until the sample size is reached. Sampling may be slow due to decreased admission rates. Consecutive sampling would not allow random selection of subjects; the three treatment levels for each subject were done by random assignment.

The independent variable was a type of nonpharmacologic intervention. The dependent variables were pain as measured by the Visual Analog Scale (VAS) and sleep quality as measured by the Richards-Campbell Sleep Questionnaire. A potential extraneous variable was the use of amitriptyline. The dose of amitriptyline (Elavil) was compared to the initial pretest scores on the VAS, to determine whether there was a correlation. If a correlation existed, then the dose of amitriptyline would have been used as a covariate. Amitriptyline is often prescribed to alleviate peripheral neuropathic pain. One of the drug's major side effects is sedation. This extraneous variable will be controlled statistically (Pedhazur & Schmelkin, 1991) by collecting the different

doses of the medication the participants are taking and using dosage as a covariate.

To control variability in the administration of the intervention, the researcher administered all ice massage treatments. Variability in individual differences are also controlled through the within subjects, repeated measures design (Maxwell & Delaney, 1990). Other causes of peripheral neuropathic pain were controlled with subject eligibility criteria. Lastly, the treatment levels (ice massage, dry towel massage, or no intervention) were randomly assigned and each treatment was administered twice to each subject.

Setting

The community in which the study took place was a large metropolitan city in the southwestern United States. There were several settings for this study. One setting was an eight-bed hospice dedicated to PWAs (Appendix A). The hospice admits both men and women of all ethnicities who have no health insurance. The hospice consists of six private rooms and one semi-private room. A nursing staff as well as a volunteer staff cares for the residents. Family members, friends, or

significant others are allowed to stay with the resident during daytime hours.

The second site was an apartment complex for PWAs who have experienced recent relapses in their recovery from substance abuse (Appendix B). The clients have either abused alcohol or illicit drugs or both. The complex can accommodate 24 clients, both males and females. There are two registered nurses as well as nursing assistants on site. The daily activities for the residents are very structured and the goal is to help the clients maintain sobriety.

Population and Sample

The target population was PWAs admitted to an apartment complex dedicated to PWAs or who resided in an AIDS dedicated hospice, who suffer with distal symmetrical peripheral neuropathies (DSPN) of their feet. Eligibility for study participation was based on the following exclusion and inclusion criteria. Exclusion criteria were the presence's of disease processes, which are associated with peripheral neuropathy pain or that, interfere with cognitive capacity to complete the dependent

measures. Potential subjects, who have received treatments with the known side effect of peripheral neuropathy, were also excluded.

1. Diabetes mellitus (Cornblath, 1989; Riley & Massey, 1980).
2. Chronic alcoholism (Cornblath, 1989; Riley & Massey, 1980).
3. Vitamin B12 deficiency (Riley & Massey, 1980).
4. ddI (dideoxyinosine) or ddC (dideoxycytosine) during the past six months (Cornblath, McArthur, Parry, & Griffin, 1993).
5. Anti-tuberculosis medications (isoniazid or ethambutol) (Riley & Massey, 1980).
6. Chemotherapeutic agents (Velban or Oncovin) (Riley & Massey,
7. 1980).
8. AIDS dementia.
9. Cryoglobulins (Lehmann & deLateur, 1990).
10. Residing in an intensive care unit.
11. Current substance abuse.
12. Rheumatoid arthritis (Lehmann & deLateur, 1990).

Inclusion criteria were:

1. The ability to read, speak, and write English.

2. Age ≥ 18 years.

No exclusions were made based on race or gender; however, because most of the population was male, fewer female subjects were expected.

The findings from the pilot study of four subjects suggested that the sample size required for the major study was 20. The sample size needed to measure pain was based on an effect size of 0.94, and determined that the sample size needed to be 8 for a power of 0.80. The recalculated sample size required to measure sleep quality was 18. The recalculated sample size was based on an effect size of 0.30 and the calculated power was 0.80.

Protection of Human Subjects

The study underwent a review by Texas Woman's University Human Subjects Review Committee (Appendix C). Permission was sought from the various institutions. Provisions for protection of the subjects was as follows:

1. An explanation of the study was given to the physicians and nurses whose patients were recruited for the study.

2. All subjects prior to participation in the study (Appendix D) signed a written consent form.

3. Assurance was given to the subjects that confidentiality of records identifying the subject was maintained and that no information was shared with other persons, except in the aggregate.

4. Assurance was given to the subjects that they were free to withdraw from the study at any time or to refuse to participate without affecting their treatment in the facility.

5. Provision of the principal investigator's phone number was given for use if questions arose.

6. The university was not responsible for any expenses incurred by the subject.

The potential risks to the subjects participating in the research study included:

1. Public embarrassment due to improper release of data,

2. Fatigue or anxiety during completion of the forms,

3. Discomfort from application of ice to feet including itching and shivering (McCaffery & Beebe, 1989) and

4. Tissue damage to the feet.

Steps that were taken to prevent the potential risks included keeping the subject's name confidential by using only a code number on forms to keep answer sheets separate and private. The subject was instructed to tell the researcher to stop if the subject became fatigued during the study. If any of the treatments caused discomfort, the researcher stopped. To prevent damage to the skin, the researcher examined each potential subject's feet. If the potential subject had numbness or an abnormal response to cold, the person was not enrolled into the study. The potential benefit from participating in the study was identifying an intervention that alleviates pain from peripheral neuropathies and promotes sleep quality.

Instruments

Three instruments were used in this study: the Demographic Data Sheet, a Visual Analog Scale (VAS), and the Richards-Campbell Sleep Questionnaire (Campbell, 1986; Richards, 1985).

Demographic Data Questionnaire

The investigator, for use in this study, developed the Demographic Data Questionnaire (Appendix E). The demographic data form includes the nominal level information of gender, ethnicity, and level of education. Age of the subject and current CD_4 count were also collected. The use of amitriptyline was assessed. If the subject was currently taking amitriptyline to alleviate the pain, then the current dose of the medication was requested. This information was compared to the score on the VAS for a possible correlation between the dose of amitriptyline and the pain score. If a correlation existed, then the analysis of the data for the actual research study would change to analysis of covariance (ANCOVA) with the amitriptyline dose as the covariate. The dose of amitriptyline was interval/ratio data. The researcher also collected information regarding history of opportunistic infections, opportunistic neoplasms, current medications, and other health conditions.

Visual Analog Scale

The second instrument utilized to measure changes in pain was a Visual Analog Scale (VAS) (Appendix F). The VAS is a 100-mm horizontal

line with verbal anchors at either end. Interval level data was collected with the Pain VAS. The subject marked a response on the line that best represented the sensation of pain. The line was measured with a 100mm ruler and the mark on the line that corresponds with the number on the ruler was the actual pain score. Possible scores ranged from zero meaning no pain to 100 meaning the worse imaginable pain. The researcher used the same ruler to measure the 100-mm line to determine the actual pain rating score of each subject. The researcher was the only person measuring responses on the VAS, so inter-rater reliability was not an issue.

Psychometric properties of reliability have been described through various research studies utilizing the VAS. Reville, Robinson, Rosen, and Hogg (1976) reported adequate reliability using the test-retest method to estimate stability (r = .95). Test-retest reliability of the VAS was conducted by Price, McGarth, Raffi, and Buckingham (1983) with results suggesting high stability (r = .97).

Price, McGarth, Raffi, and Buckingham (1983) conducted a study testing concurrent validity of the VAS. The investigators conducted a

study in which ten subjects with low back pain were treated with TENS and acupuncture. The VAS scores were correlated with the physician's ratings of the patients' improvement (r = .70).

Test-retest reliability was appraised through administration of the VAS to nine subjects by the researcher. There was adequate test-retest stability (r^2 = 0.845) of the VAS for the assessment of pain in persons with AIDS who suffer from peripheral neuropathic pain. Validity was not examined.

Richards-Campbell Sleep Questionnaire

The Richards-Campbell Sleep Questionnaire (Campbell, 1986; Richards, 1985) is a 5-item instrument that uses a visual analog scaling technique to measure sleep quality (Appendix G). The components of sleep quality include ease with which the subject falls asleep at bedtime, duration of sleep, ease of falling back to sleep after awakening, and feelings of restfulness in the morning, and overall sleep quality. The instrument measures a 100-mm line with anchors at each end to indicate the extremes of sleep. The subject was instructed to mark a point on the horizontal line that best indicated the intensity of the sleep sensation.

The visual analog scale is scored from 0, which indicates poor sleep quality to 100 indicating optimal sleep quality. Interval level data is collected from the Richards-Campbell Sleep Questionnaire. Adding the individual scores for each question and dividing by five derived the total sleep score. The maximum score possible is 100.

Campbell (1986) conducted reliability testing in a sleep study of 30 subjects and 30 nurses in an intensive care unit. Internal consistency reliability (Cronbach's alpha) yielded an alpha coefficient of .82 for the subjects and .95 for the nurses. Inter-rater reliability was .94, which indicated sufficient reliability.

Criterion related validity for the Richards-Campbell Sleep Questionnaire was established with EEG. The correlation coefficients were as follows: (1) sleep depth (r = .59 for percent stage 4 N-REM; r = .56 for percent stage 3 N-REM); (2) sleep quality (r = .64 for percent stage 2, r = .70 for sleep efficiency index, r = .678 for total sleep time, r = -. 59 for percent awake, r = .55 for percent REM) and (3) falling asleep (r = -. 5 1 for latency to sleep onset) (Richards, 1985).

Nine subjects were administered the Richards-Campbell Sleep Questionnaire (Campbell, 1986; Richards, 1985) to determine reliability of the instrument. Internal consistency of the instrument was examined to determine the reliability of the instrument. The alpha coefficient (r = .9025) demonstrated adequate internal consistency reliability.

Content validity was assessed using the Index of Content Validity (CVI) (Waltz, Strickland, & Lenz, 1986). Seven experts, who have conducted research in the area of sleep and rest, were chosen to analyze the Richards-Campbell Sleep Questionnaire (Campbell, 1986; Richards, 1985) for content validity. The qualifications of the seven experts included having a doctoral degree and having conducted at least one research study involving adult subjects with sleep quality being the variable of interest. All seven experts have received funding for their sleep research and have published their research findings in nursing or related health journals. The experts had used sleep instruments to measure sleep rather than EEG.

The CVI scores of the individual items ranged from .71 to .857. The quantification of CV items was calculated to be .83. Items 2,3,4, and 5 all

have content validity of .857 (CVI = .86) which is significant at .05 (Lynn, 1986). However, item 1 has a CVI of .71, which is not significant at .05. In regards to the quantification of CV for the instrument, the total CV calculated for the RCSQ was .857 (30/35). According to Lynn, if six out of seven experts (CVI = .86) rate the items as relevant or very relevant, the content validity is significant at a .05 level. The researcher has decided to keep item 1 as part of the RCSQ despite its low CVI score.

Pilot Study

A pilot study was conducted to test the methodology and statistical analysis. A sample size of 4 males received the study protocol. Pain was measured before and immediately after each treatment, using the McGill Pain Questionnaire and a Visual Analogue Scale. Sleep quality was measured using the Richards-Campbell Sleep Questionnaire. The researcher found the McGill Pain Questionnaire difficult to administer to the subjects. The Richards-Campbell Sleep Questionnaire was adequate to measure sleep quality. Based on the findings of the pilot study, the researcher chose the Visual Analogue Scale to measure pain in the major

study. The researcher also added an additional pain measurement taken in the morning upon waking.

Data Collection

Prior to data collection, approval to conduct this research study was obtained from the Human Subjects Review Committee at the Texas Woman's University and from the institutions Institutional Review Boards. The intervention was administered to subjects who were admitted as inpatients at the approved facilities.

The intent and nature of subject participation in the study was fully explained to the subjects. Potential risks of participation in the study including loss of confidentiality and fatigue discussed with the subjects. Subjects were instructed that they were free to withdraw consent at any time. The subjects who agreed to participate in the study signed a written consent form.

The researcher contacted the Nurse Managers weekly for information regarding new admissions to the hospice and transitional care facility. Any patients admitted with a diagnosis of AIDS and peripheral neuropathies were approached. This process began by checking with the

nurse on duty, to determine whether the patient had a documented case of peripheral neuropathies. If the patient did, the nurse was asked the patient if the researcher could approach him. If the patient refused, then the researcher did not have contact with the patient. If the patient agreed to meet with the researcher, then the researcher explained the purpose and procedure of the study to the patient. Only inpatients enrolled into the study for the administration of the intervention.

Following subject enrollment in the study, information for the initial data sheet was obtained through subject interview and review of the medical chart. The first VAS and the baseline RCSQ instrument were administered. Following the completion of the VAS, the subject received the first intervention. Each intervention took 15 minutes and after that time, the subject completed a second VAS. The researcher returned the following morning. At that time, the subject answered the Richards-Campbell Sleep Questionnaire and a VAS. Upon completion of the RCSQ and VAS, the researcher arranged with the subject to return later in the evening for the second intervention. The subject received a total of three interventions randomly assigned and administered on three

consecutive nights. Pain measured for a total of nine times. Sleep quality was measured for a total of four times.

Data Analysis

The data collected from the Demographic Data Sheet, the Richards-Campbell Sleep Questionnaire, and the VAS was numerically coded and entered into a mainframe computer using the SPSS program (Norusis, 1990) and examined for accuracy. Data from the demographic sheet includes age, gender, whether the subject was currently receiving amitriptyline for control of the neuropathic pain, and the dose of the amitriptyline if the drug was being administered for the neuropathic pain. Descriptive statistics were used to present the data from the demographic data sheet. Gender and number of subjects receiving amitriptyline were presented as frequencies and percentages. Age was presented in terms of a range, mean, median, and standard deviation. Level of education and dose of amitriptyline were analyzed and described using means, medians, standard deviations, and ranges. Attrition data were presented as frequencies and percentages.

Visual Analog Scale

Descriptive statistics were used to report scores from the VAS, before, 15 minutes after, and immediately upon waking in the morning of every treatment for each subject. The median and mean of the pain and sleep quality scores were calculated. The median is especially important if the raw data are skewed. Standard deviation was the measure of variability calculated for the scores of pain and sleep quality.

Histograms were used to visualize skewness and kurtosis of the variables. The data were examined for outliers through the use of histograms and no outliers were identified, therefore the data did not require transformation (Tabachnick & Fidell, 1989).

Multivariate analysis of within-subjects design with three treatment levels was used to test the hypotheses concerning the administration of ice massage on pain. There are several advantages to the repeated measures statistical design. The first advantage is that more information is obtained from each subject because each subject contributes several scores instead of one. Another advantage of the within-subjects design, where subjects serve as their own control, is that the variability in

individual differences is removed (Maxwell & Delaney, 1990). Within-subjects design also allows enrollment of fewer subjects than required for a between-subjects design.

The pain scores were examined for assumptions underlying MANOVA: (1) homogeneity of variance using the Fmax; (2) random selection or assignment; and (3) independence of observations (Glass & Hopkins, 1984; Tabachnick & Fidell, 1989; Maxwell & Delaney, 1990). The multivariate approach to MANOVA, rather than the univariate approach was used to test the hypotheses. The multivariate approach has several advantages over the univariate approaches. The multivariate approach does not require an assumption of sphericity . The multivariate approach assumes multivariate normality which, if violated, is regarded as less serious than violations of the assumption of sphericity. Another advantage of the multivariate approach comes when testing contrasts. The multivariate approach uses a specific error term where, according to Maxwell and Delaney, the univariate approach uses a pooled error term for testing contrasts. If the assumption of sphericity is violated, the pooled error term can lead to very misleading results. Lastly, if the assumptions

underlying the multivariate approach are met, then the Type I error rate is exact. If the assumptions underlying the univariate approach are not met, then the Type I error rate may be double or triple the nominal value (Maxwell & Delaney, 1990).

Homogeneity of variance was tested using the Hartley test (Maxwell & Delaney, 1990). The SPSS command for the Hartley Fmax test is FMAX (Tabachnick & Fidell, 1989). The omnibus test for the hypotheses pertaining to ice massage, was determined using the Pillai Bartlett trace. The Pillai-Bartlett trace is the most robust F test to violations of the assumption of homogeneity (Maxwell & Delaney, 1990).

A planned comparison using orthogonal contrasts was used to analyze the pain scores collected with the ice massage intervention and the pain scores collected with no intervention. A comparison was made between the pain scores collected with the dry towel intervention and the pain scores of the ice massage intervention. A comparison was made between the sleep scores collected with the ice massage intervention and the sleep scores collected with no intervention. A comparison was made between the sleep scores collected with the ice massage and with the dry

towel interventions. Bonferroni approach was used to establish the alpha level for the planned comparisons. The alpha level for each contrast was 0.0125 (.05/4) for the time intervals that pain will be measured. The alpha level for each contrast was 0.025 (.05/2) (Maxwell & Delaney, 1990) for the sleep quality data. Comparisons were made for pain or sleep scores between the dry towel treatment and no intervention. The dry towel intervention is a control. Including a comparison of the dry towel intervention and no intervention would result in a smaller alpha level for each contrast.

Hypothesis one: Ice massage administered to the dorsal and planter aspects of the feet bilaterally for seven minutes to each foot, prior to bedtime, will make a difference in pain of dysthesias of the feet perceived by AIDS patients with peripheral neuropathic pain. Differences were determined using a two-way within-subjects approach.

Hypotheses two: Ice massage administered to the dorsal and planter aspect of the feet bilaterally, for seven minutes prior to bedtime, will make a difference in sleep quality for AIDS patient with peripheral

neuropathic pain. Differences were determined using repeated measure analysis of covariance.

Summary

The methodology was a quasi-experimental repeated measures design with subjects serving as their own controls. Nonprobability consecutive sampling was used to enroll subjects into the study. The subjects received three treatments: ice massage, dry towel massage, and no massage. The order that the subjects received the treatments was randomized. The Richards-Campbell Sleep Questionnaire and the VAS was used to measure the two dependent variables of sleep quality and pain.

Using the VAS, pain was measured before, 15 minutes after each intervention, and in the morning immediately upon waking. Sleep quality measured by the Richards-Campbell Sleep Questionnaire; was recorded the following morning after each intervention.

Descriptive statistics were used to report the information gathered from the Demographic Data Sheet. The hypothesis examining ice massage and pain was analyzed using repeated measures analysis of variance. The hypothesis examining ice massage was analyzed using a two-way

within-subjects approach and sleep quality was analyzed using repeated measures analysis of covariance.

CHAPTER 4

DATA ANALYSIS

The purpose of this quasi-experimental study was to examine the efficacy of ice massage to reduce neuropathic pain and improve sleep quality in persons with AIDS (PWAs). A convenience sample of PWAs with neuropathic pain was utilized. Data were collected using a Demographic Data Sheet, a Visual Analog Scale (VAS), and the Richards-Campbell Sleep Questionnaire (RCSQ). The subjects received three treatments in random order: ice massage, dry towel massage, and no treatment. Each treatment was administered in the evening prior to bedtime. Pain was measured with the Visual Analog Scale (VAS) prior to each treatment, immediately after each treatment, and immediately upon waking up the next morning. Sleep quality was measured after each treatment in the morning upon awakening. Data were analyzed using descriptive and inferential statistics. Information presented in this chapter includes description and analysis of the sample and findings related to the proposed hypotheses.

Description of the Sample

Thirty-four subjects were accrued to the study. One subject withdrew from the study while receiving the ice massage intervention. Data analysis was conducted on 33 subjects. Those who completed the study met all sample inclusion criteria: ability to read, speak, and write English, be 18 years of age or older, and have the HIV+, and suffer from neuropathic foot pain. Subjects ranged in age from 21 to 51 years, with a mean of 36.4 years (SD = 1.144) and a median of 36.0 years. The sample consisted primarily of Afro-American (n = 24, 73%) and male (n = 21, 64%). The education level ranged from seventh grade to four years of college, with a mean of 11.6 years of schooling (SD = 2.207) and a median of 12.0 years (Table 1).

As part of the baseline demographics, variables assessed included medications the subject was currently taking, history of opportunistic infections and cancers, other medical history, most recent CD_4 count and viral load, and whether the subject was taking amitriptyline for neuropathic pain and if so, what dose. Twenty-four percent (N = 8) of the

Table 1

Frequencies and Percentages of Demographic Variables for PWAs with Neuropathic Pain

Variable	n	(%)
Age (years)		
20 – 29	5	(15)
30 - 39	18	(55)
40 - 49	9	(27)
50 - 59	1	(3)
Gender		
Males	21	(64)
Females	12	(36)
Ethnicity		
Caucasian	8	(24)
Afro-American	24	(73)
Hispanic	1	(3)

Table 1 (Continued)

Frequencies and Percentages of Demographic Variables for PWAs with Neuropathic Pain

Variable	n	(%)
Education		
Seventh grade	1	(3)
Eighth grade	2	(6)
Ninth grade	4	(12)
Tenth grade	4	(12)
Eleventh grade	1	(3)
Twelfth grade	11	(33)
One year of college	2	(6)
Two years of college	6	(18)
Three years of college	1	(3)
College graduates	1	(3)

subjects used amitriptyline for control of their neuropathic pain. The dose range from 25 mg to 150 mg. The CD_4 counts (n = 26) ranged from 18

to 500 with a mean of 312 (Table 2). Four of the subjects had a history of seizure disorder and were taking Dilantin to control seizure activity.

Table 2

Frequencies and Percentages of CD4 Counts for PWAs with Neuropathic Pain

Variable	n	(%)
CD4 Count		
0 - 100	2	(7)
101 - 200	5	(19)
201 - 300	5	(19)
301 - 400	5	(19)
401 - 500	9	(35)
> 500	0	(0)

The four subjects took their Dilantin prior to bedtime. Five of the subjects were receiving medical treatment for bipolar disorder. Three subjects had been treated for *Pneumocystis carnii* pneumonia, one for toxoplasmosis, one for Mycobacterium avium complex, and one for CMV retinitis. One

subject suffered from hypertension and another had a cerebral vascular accident in the past.

Findings

Pain was measured using a linear visual analogue scale in this study. Subjects completed the VAS prior to receiving one of the three interventions, immediately after completing the intervention, and upon awakening in the morning. The VAS scores ranged from 0-100 with higher scores reflecting greater pain intensity.

Descriptive statistics were used to summarize the pain data. Minimum and maximum scores obtained using the VAS at the completion of each intervention, as well as the means and standard deviations for each measurement are presented in Table 3. Table 4 presents the minimum and maximum scores obtained using the VAS upon awakening in the morning, as well as the means and standard deviations.

The RCSQ was used to assess sleep quality in this study. Subjects completed the RCSQ post treatment upon waking in the morning. The RCSQ scores can range from 0-100 with higher scores reflecting improved sleep quality. Scores were determined by measuring the distance between

Table 3

Descriptive Statistics for VAS Scores Immediately After Receiving an Intervention for PWAs with Peripheral Neuropathic Pain

Treatment	Min	Max	M	SD
Ice massage	0	100	28.303	27.088
Towel treatment	0	95	27.879	25.521
No treatment	0	100	36.424	27.305

Note. Min = Minimum score; Max = Maximum score Treatment

Table 4

Descriptive Statistics for VAS Scores upon Waking in the Morning for PWAs Who Suffer with Peripheral Neuropathic Pain

Treatment	Min	Max	M	SD
Ice massage	0	92	33.030	26.168
Towel treatment	0	83	37.000	25.081
No treatment	0	87	37.606	25.044

Note. Min = Minimum score; Max = Maximum score Treatment

zero end of the line to the subject's mark. The total sleep score was obtained by adding the individual scores for each of the five questions and dividing the sum by five. Minimum and maximum scores obtained using the RCSQ as well as the means and standard deviations for each treatment are presented in Table 5. The data revealed no outliers or extremes.

Table 5

Descriptive Statistics for RCSQ Scores upon Waking in the Morning for PWAs with Peripheral Neuropathic Pain

Treatment	Min	Max	M	SD
Ice massage	4.2	100.0	64.433	26.233
Towel treatment	5.3	100.0	54.606	25.932
No treatment	13.8	100.0	59.252	28.015

Note. Min = Minimum score; Max = Maximum score Treatment

Correlations

The relationship between the dependent variables (pain and sleep quality scores) and the covariate (dose of amitriptyline) was examined to determine whether an analysis of covariance (ANCOVA) was necessary.

Since one of the side effects of amitriptyline is sedation, the pain scores obtained in the morning were used to analyze the possible relationship between pain score and amitriptyline dose. Pearson product-moment correlation coefficients were calculated. None of the correlation coefficients met the .05 level of significance, therefore, an ANCOVA was not indicated. Table 6 presents the correlation coefficients obtained for the relationship between the pain scores measured upon

Table 6

Correlation Between Pain Scores Measured Immediately Upon Waking and the Dose of Amitriptyline (n = 8)

Variables	r
Ice massage	-.0814
Dry Towel Massage	-.1872
No treatment	.1518

wakening and the dose of amitriptyline. Table 7 presents the correlation coefficients obtained for the relationship between sleep quality scores obtained after each treatment level and the dose of amitriptyline.

Table 7

Correlation between Sleep Quality Scores and the Dose of Amitriptyline (n = 8)

Variables	r
Ice massage	-.0944
Dry Towel Massage	.0375
No treatment	-.3055

Hypotheses

The first hypothesis, there will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage, was examined using a 2-way within-subjects design. The hypothesis that ice massage would reduce peripheral neuropathic foot pain, was not supported ($E = 1.51$, $df = 2,64$, $p = .237$). The effect sizes between the different treatments at the two time intervals pain was measured are presented in Table 8 and Table 9.

Table 8

Effect Sizes between the Three Treatment Levels with Pain Measured Immediately After Each Treatment

Treatments	Effect Size
Ice massage vs. Towel massage	.016
Ice massage vs. No treatment	.300
Towel massage vs. No treatment	.320

Table 9

Effect Sizes between the Three Treatment Levels With Pain Measured Immediately Upon Waking in the Morning

Treatments	Effect Size
Ice massage vs. Towel massage	.156
Ice massage vs. No treatment	.180
Towel massage vs. No treatment	.024

Although there was no significant difference between ice massage and the other two treatments, 15 (45%) of the subjects had a decrease in pain intensity as measured by a VAS. Figure 2 depicts the differences

in pain scores as measured by the visual analogue scale among responders to the ice massage therapy at the three time intervals .

The second hypothesis, there will be a significant difference in sleep quality in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage, was examined using a multivariate approach to ANOVA for repeated measures. The hypothesis was not supported ($E = 1.95$, $df = 1,32$, $p = .159$). The power was .37 and the effect size between the three treatment levels is presented in Table 10.

Reliability of the Instrument

Although the reliability of the instrument used in this study was previously established during the pilot study, internal consistency was assessed in this study by analyzing the pretreatment scores for the RCSQ. The RCSQ was administered to every subject at the fist visit, prior to the subject receiving the first treatment. Cronbach's alpha for the RCSQ was .85.

Table 10

Effect Sizes Between the Three Treatment Levels and the Measurement of Sleep Quality

Treatments	Effect Size
Ice massage vs. Towel massage	.368
Ice massage vs. No treatment	.194
Towel massage vs. No treatment	.174

Summary of Findings

A total of 33 subjects participated in this quasi-experimental study to determine if ice massage therapy would reduce neuropathic foot pain in PWAs and quality of sleep would be improved in PWAs when the ice massage was used to reduce the peripheral neuropathic foot pain. A data sheet was used to record descriptive data, pain was measured with a VAS, and sleep quality was measured using the RCSQ. Pain was measured before the subjects received one of the three interventions, immediately after receiving one of the interventions, and upon awakening in the morning. Sleep quality was measured upon awakening in the morning.

The first hypothesis, there will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage, was not supported. The second hypothesis, there will be a significant difference in sleep quality in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage was not supported. The reported effect size and power of the tests were small and consistent with the nonsignificant findings.

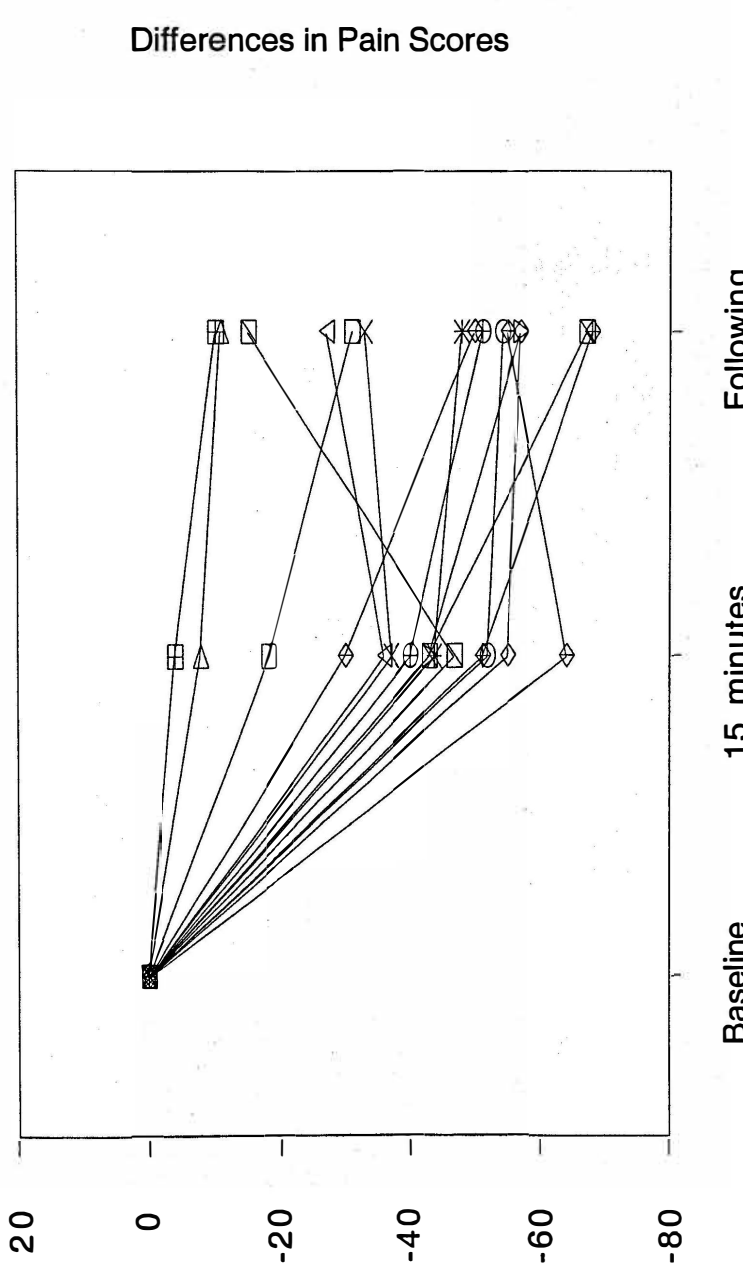

Figure 2. Differences in pain scores among responders to ice massage therapy measured with the visual analogue scale

CHAPTER 5

SUMMARY OF THE STUDY

Although ice is recognized as a treatment modality for pain management, there has been scant research assessing the role of ice in this endeavor. The purpose of this study was to determine if ice massage therapy would reduce neuropathic foot pain in patients with AIDS (PWAs) and quality of sleep would be improved in PWAs when the ice massage was used to reduce the peripheral neuropathic foot pain. The conceptual frameworks utilized in this study were the Roy Adaptation Model (Roy, 1976; Roy & Andrews, 1991) and the Gate Control Theory of Pain (Melzack & Wall, 1965). Neuropathic pain was a source of either focal or contextual stimuli for the subjects of this study. To assist the subject with achieving an adaptive response to neuropathic pain, the nurse intervened by massaging the afflicted area with ice. The gate control theory of pain provided the rationale for examining the use of ice massage as a means for reducing pain. Ice massage provided a type of cutaneous stimulation which, in theory, would stimulate large-diameter

nerve fibers to carry the sensation of cold to the brain, thus closing the "gate" to the sensation of pain.

Summary

A quasi-experimental, 2-way within-subjects approach was used to determine whether ice massage could reduce pain and thus improve sleep quality in PWAs with neuropathic foot pain. Sleep quality was determined by using a multivariate repeated measures approach. Subjects were selected using a nonprobability, consecutive sampling technique at a hospice dedicated to PWAs and at an apartment complex for PWAs who have recent histories of substance abuse.

Obtaining permission to conduct the study from the Texas Woman's University Human Subjects Review Committee ensured protection of human subjects. In addition, the investigator gave the subjects a full explanation of the intent, protocol, and nature of participation in the study. Procedures to safeguard confidentiality were explained and observed throughout the course of the study and after the study was completed. A written consent form was obtained from all of

the subjects that addressed potential risks and steps that would be taken to reduce the risks.

Pain was measured using a Visual Analogue Scale (VAS) which is a 100-mm horizontal line with verbal anchors at either end. Possible scores ranged from zero meaning no pain to 100 meaning the worse imaginable pain. Subjects were asked to complete the VAS three times: before receiving a treatment, immediately after receiving a treatment, and immediately upon waking up the next day.

Sleep quality was measured using the Richards-Campbell Sleep Questionnaire (RCSQ) which is a five-item instrument that uses a visual analogue scaling technique. The instrument measured a 100-mm line with verbal anchors at each end to indicate the extremes of sleep. The visual analogue scale was scored from 0, which indicated poor sleep quality to 100 indicating optimal sleep quality. The total sleep score was obtained by adding the individual scores for each of the five questions and dividing the sum by five. Subjects were asked to complete the RCSQ immediately upon waking up the next day. The investigator to record subject's demographic information used a data sheet.

The first hypothesis of this study, there will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, then when receiving dry towel massage or no massage, was examined using a multivariate approach to a 2-way within-subjects design. The second hypothesis of this study, does ice massage reduce peripheral neuropathic foot pain in PWAs and will the quality of sleep be improved in PWAs when ice massage is used to reduce peripheral neuropathic foot pain, was examined using a multivariate approach to ANOVA for repeated measures.

Discussion of Findings

Although 34 subjects were initially enrolled in the study, the final sample size consisted of 33 subjects who completed three treatment levels. The one subject, who withdrew from the study, was randomized to receive no treatment, dry towel massage, and ice massage. The subject tolerated the first two treatments, but found the ice massage to be too painful to complete. The resulting attrition rate for the study, was 3%.

The sample consisted primarily of Afro-American (n = 24, 73%) males (n = 21, 64%). The greater number of Afro-American males

recruited for this study is consistent with the changing demographics of who is being afflicted with AIDS (Centers for Disease Control, 1998).

Hypotheses

The first hypothesis, there will be a significant difference in peripheral neuropathic foot pain in PWAs who receive ice foot massage prior to bedtime, than when receiving dry towel massage or no massage was examined using a multivariate approach to ANOVA for 2-way within subjects design. The results showed no significant differences between the ice massage and pain scores ($F = 1.51$, $df = 2,64$, $p = .237$).

The second hypothesis, does ice massage reduce peripheral neuropathic foot pain in PWAs and will the quality of sleep be improved in PWAs when ice massage is used to reduce peripheral neuropathic foot pain, was examined using a multivariate approach to ANOVA for repeated measures. The results showed no significant differences between ice massage and the sleep quality scores ($F = 1.95$, $df = 1,32$, $p = .159$).

The findings of the present study, on the surface, do not support the theoretical discussions proposed by Roy in the Adaptation Model (1976) or by Melzack and Wall (1965) with the gate control theory of

pain. In regards to the Roy Adaptation Model, the nursing intervention of ice massage may not provide an adequate means of modifying the focal or contextual stimuli of neuropathic foot pain. Without ice massage causing an adequate alteration to the focal and/or contextual stimuli of neuropathic pain, the individual continues to have an ineffective response to the stimuli. Ineffective responses to a stimulus result in maladaptation. The sensation of pain continues.

The gate control theory of pain theorizes small-diameter nerve fibers carry pain impulses to the portion of the brain that processes the sensation. The theory hypothesizes that large-diameter nerve fibers carry sensations such as vibration or temperature to the brain and the "gate" that controls the impulses reaching the part of the brain that synthesizes the information, favors impulses carried by large-diameter nerve fibers. Melzack and Wall (1965) hypothesize that cutaneous stimulation as caused by ice massage, would stimulate the large-diameter nerve fibers to carry the impulse to the brain, thus causing the brain to process the sensation of cold over the pain sensation carried by the small-diameter nerve fibers. The present research study did not support the theory.

There was no difference between ice massage and no treatment, thus ice massage did not appear to stimulate large-diameter nerve-fibers to carry the sensation of cold to the brain causing the "gate" to close to the sensation of pain and open to the sensation of cold.

To date, there are very few, methodologically sound research studies exploring the application of ice massage to reduce pain. The results of the current study differ from the few studies reported in the review of literature. Grant (1964) stated that 80% of 7,000 patients with various acute and chronic pain conditions, found that ice massage reduced pain. Grant's study was fraught with serious limitations including no randomization or blinding of the treatment to the subjects. Kirk and Kersley (1968) conducted a study comparing ice and heat for alleviating pain caused by rheumatoid arthritis. The researchers concluded that cold was better than heat for reducing pain; however, the researchers acknowledged that their data were not sufficient to reach statistical significance. No studies reported in the review of literature, compared ice massage to any treatment, as did the current study. Although the current research did not find that the application of ice reduced pain in PWAs,

this may have been due to the small effect size seen with the treatments and with an inadequate power. Because of the small effect size, a larger sample size would be required to achieve a power of .80. Ice massage has not been well studied and further research should be conducted to determine its potential usefulness in the management of pain.

Melzack, Jeans, Stratford, and Monks (1980) conducted a study to examine the effectiveness of ice massage and TENS for relief of low back pain. The researchers found that both TENS and ice massage were effective means of controlling chronic back pain. The mean percent decrease on the pain score was 50.4% for ice massage versus 48.7% for TENS. This pivotal study provides the basis for comparing the research conducted on TENS and extrapolating results to ice massage.

Although the findings of the study were non-significant, 15 (45%) of the subjects experienced a reduction in pain intensity as measured by a VAS when receiving ice massage. Management of pain caused by peripheral neuropathies is difficult. In light of the study conducted by Melzack, et al. (1980), the results of the study may suggest that a trial of ice massage may be of benefit to some patients. Since ice massage is

relatively simple to apply and inexpensive, trying the treatment for a patient who suffers from peripheral neuropathies, may be indicated. The application of ice is an independent nursing order and an intervention that a nurse may try to alleviate pain due to peripheral neuropathic pain. If the treatment is not effective for the individual, there is minimal risk of adverse reactions.

Conclusions and Implications

Peripheral neuropathic pain continues to be a form of pain difficult to management. Conclusions derived from the findings of this study and implications for nursing practice are presented in this section.

Conclusions

Based on the findings of this study, the following conclusions were drawn:

1. Ice massage therapy is not effective in reducing pain intensity in PWAs with peripheral neuropathic pain.
2. Ice massage therapy does not impact sleep quality in PWAs with peripheral neuropathic pain.

3. The application of ice was tolerated by the subjects as evidenced by low attrition rate ($\underline{n}$ = 1, 3%). The data for this study was analyzed on 33 subjects.

Implications

Although the findings of this study need further research validation, the following implications for nursing practice were derived from the study conclusions.

1. A single application of ice may not be sufficient to reduce chronic pain caused by peripheral neuropathy in PWAs.

2. A moist towel holding crushed ice may not be a sufficient means to deliver cold therapy. Based on observations made during the study, the sensation of coldness took time to penetrate through the towel permitting the subject to feel the full impact of the cold.

3. The RCSQ demonstrated adequate reliability and was easy to administer to the subjects.

4. The VAS was easy to administer. The subjects exhibited no difficulty understanding the instructions for answering the VAS.

Recommendations for Further Study

Recommendations for future research concerning the reduction of pain in PWAs with peripheral neuropathic foot pain, thus improving sleep quality, were generated from this quasi-experimental study:

1. Replication of this study, using an ice Popsicle method rather than a moist towel holding crushed ice so as to increase the intensity of cold, should be undertaken.
2. Replication of this study, increasing the administration time of the ice massage from 7 minutes per foot to 10 minutes per foot (Jacking & Jamieson, 1990; Thomson, Skinner, & Piercy, 1991).
3. Replication of this study using a larger sample size.
4. Replication of this study using diabetics who suffer from peripheral neuropathies.
5. Conduct a study examining the impact age, ethnicity, sex, and illegal drug use has on the PWAs perception of neuropathic pain.
6. Conduct a qualitative study to document the anecdotal reports by PWAs as to why they have peripheral neuropathic pain and the means by which they try to control the pain.

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APPENDICES

APPENDIX A

Approval Letter

Bering Omega
Community Services

March 9, 1999

To Whom It May Concern:

SUBJECT: KRISTIN OWNBY

Please be advised that from June 1995 the above mentioned Ms. Ownby had the permissions of upper management to approach residents at our facility, regarding a study for a research paper she was working on.

Sincerely,

Sandy Stacy RN

Sandy Stacy, RN, ACRN
Director of Nursing Services
Omega House

APPENDIX B

Approval Letter

Project Life Road

August 12, 1999

To Whom It May Concern:

Ms. Kristin Ownby has authorization to conduct a study on volunteer clients to evaluate the effect of ice massage on pain relating to neuropathy.

Please contact me at 713-283-6237 should you have further questions.

Sincerely,

Nancy Hoff

Nancy Hoff R.N.
Case Manager

APPENDIX C

Human Subject's Review Board Approval

TEXAS WOMAN'S UNIVERSITY
DENTON ' DALLAS HOUSTON
HUMAN SUBJECTS REVIEW COMMITTEE
1130 M. D. Anderson Blvd., Houston, Texas 77030 713/794-2114

MEMORANDUM

TO: Kristin Ownby

FROM: HSRC

DATE: June 13, 1995

SUBJECT: HSRC Application

Proposal Title: Effects of ice massage onperipheral neuropathic pain and sleep in persons with AIDS

Your application to the HSRC has been reviewed and approved The committee suggests that you obtain medical information from the chart thereby reducing the risks of anxiety. Also on the application delete second sentence on page three, The researcher will stop the treatment if the subject complains of numbness or discomfort. Submit a revised copy of this page of the application for the file.

This approval lasts for 1 year. If your study extends beyond that time you must notify the Human Subjects Review Committee.

REMEMBER TO PROVIDE COPIES OF THE SIGNED INFORMED CONSENT TO ME WHEN THE STUDY HAS BEEN COMPLETED. GRADUATION MAY BE BLOCKED UNLESS CONSENTS ARE RETURNED.

Thank you for your patience in awaiting the committee's decision. The committee extends its best wishes for a productive and very successful project. Should you have any further questions about your application, please contact me at 794-2114.

Doris E. Wright, Ph.D.
Chairperson

APPENDIX D

Patient Consent to Participate in Research

"Effects of Ice Massage on Peripheral Neuropathic Pain and Sleep in Persons with AIDS"

I am being asked to be in a study called "Effects of Ice Massage on Peripheral Neuropathic Pain and Sleep in Persons with AIDS" being done by Kristin K. Ownby, RN, a doctoral student in nursing at Texas Woman's University. The purpose of this study is to test the effects of foot massage on foot pain and quality of sleep.

I hereby authorize Mrs. Ownby to apply different treatments to my feet for three nights before I go to sleep. The three treatments are: (1) wet towel with crushed ice rub, (2) dry towel rub, and (3) no towel rub. The treatment each night will be decided by chance. Treatment 1 and treatment 2 will be done by Mrs. Ownby for about 15 minutes, with a maximum 7-minute rub to each foot.

I understand that I will be asked to complete three forms, two that measure pain and one that measures how I slept. The two pain forms will be filled out by me before and after each treatment in the evening. The sleep form will be filled out by me the next morning. The pain forms will take me about 5 minutes to complete each evening and the sleep form will take me about 5 minutes to complete each morning. In addition, I will complete a short form when I agree to be in the study. This form asks for information such as how old I am and my level of education.

I am being asked to be in this study for 3 days in a row. The treatment (about 15 minutes) and the completion of the forms (about 10 minutes) will take about 25 minutes of my time each day, or a total time of less than I 1/2 hours over the three days of the study. I understand that the treatments will be done by Mrs. Ownby in my hospital room with the door c10sed. I will also fill out the forms in my room.

The possible risks to me from being in the study are four: (I) My name might be known to others. (2) I might get tired or anxious filling out the forms. (3) The towel rubs to my feet might be uncomfortable. (4) The treatment may cause damage to my feet.

To keep my name confidential, I understand that only a code number will be put on my forms to keep my answers separate from the other 25 people who are participating in this study. My name will not appear on any data forms.

If I get tired, I can either take a break to rest or stop my participation in the study. If filling out the forms makes me anxious I can talk to Mrs. Ownby, who will stay in my room after the treatment to answer any questions or to discuss any concerns I have.

If the towel rubs to my feet cause discomfort, I can ask Mrs. Ownby to stop the treatment.

There is a potential risk of damage to the skin of my feet. To reduce the chance of damage, Mrs. Ownby will examine my feet. If I had numbness or an abnormal response to cold, I would not be in the study. Mrs. Ownby will be watching my feet and will stop the treatment immediately if important skin changes occur.

I understand that there is no direct benefit to me from being in this study. I understand that I am free to participate or not to participate. The choice is mine. If I choose to be in the study, I can stop my participation at any time without my care at this hospital being affected in any way.

In the unlikely event of injury from my participation in this study, medical services and compensation are not available. I understand that I should report any complications from this research to Kristin Ownby at the phone numbers listed below. If I wish to report a research-related problem, I may also call the Office of Research & Grants Administration during office hours at (817) 8983375 or 794-2480.

An offer to answer my questions about this study has been made. If I have questions later, I can call Kristin Ownby at 7942100 or 794-2147 during office hours. There are no other procedures that the researcher can offer which would be advantageous to me.

_____ _____

Patient's Signature Date

_____ _____

Witness Date

APPENDIX E

Demographic Data Sheet

Code Number _____

Demographic Information Sheet

Gender _____

Age _____

Level of Education (number of years attending school) _____

Are you currently using amitriptyline (Elavil) for pain control for the peripheral neuropathies in your feet? _____

If so, what is the current dose of the amitriptyline that you are taking? _____

What is your most recent CD_4 count? _____

What is your most recent viral load? _____

Have you been diagnosed with any opportunistic infections? If so, which ones? _____

Have you been diagnosed with any HIV-associated cancers? If so, which one(s)?

Any other medical problems?

Current medications:

APPENDIX F

Visual Analogue Scale

Visual Analogue Scale for Pain

Code Number _____ Date _____

Worst Pain

No Pain

APPENDIX G

Richards-Campbell Sleep Questionnaire

You are now ready to begin to answer the questions. Place your "X" *anywhere* on the answer line that you feel *best* describes your sleep last night.

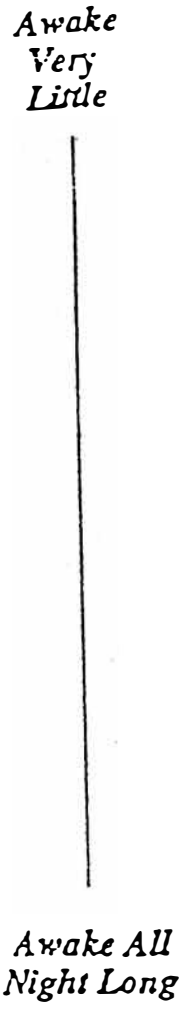
1. My sleep last night was:

2. Last night, the first time I got to sleep, I:

Fell
Asleep
Almost
Immediately

Just Never
Could Fall
Asleep

3. Last night I was:



4. Last night, when I woke up or was awakened, I:

5. I would describe my sleep last night as: