EFFECT OF HEPARIN INJECTATE VOLUME ON PAIN AND BRUISING USING THE ROY MODEL

by

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ABSTRACT OF DISSERTATION
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This quasi-experimental study examined the effect of heparin injectate volume on pain and bruising using the Roy model. The study was undertaken to provide nurses with information on responses produced by two injectate volumes.

The focal stimulus manipulated in this study was the injectate volume. In this crossover design, subjects (N=50) served as their own control. Order of treatment and order of side of injection were randomized.

Contextual stimuli held constant included dose, technique, syringe, needle, length of injection time, and injection site. Those stimuli not held constant were analyzed for variance within the sample and for effect on patient response. These variables included depression, age, sex, diagnosis, surgery, adipose tissue, side of injection site, time of injection, and two classes of medications administered in addition to heparin.

Residual stimuli were partially controlled by the study design but not further analyzed. These variables included but were not limited to fear of injection, pain tolerance and threshold, some medications administered during the study, and skin color.

The patient responses analyzed included pain of injection, bruise occurrence and size, and pain of injection site measured postinjection. Instruments used to measure the above responses were the Visual Analogue Scale, bruise count, scan of bruise tracing, and the McGill Pain Questionnaire - Short Form.

In addition, the cost of preparation for administration of the two injectate volumes was analyzed via timed trials (N=5). Five registered nurses prepared one injection of each volume for administration while being timed with a stop watch. Cost per vial of the two injectate volumes also was analyzed. All eight null hypotheses were accepted.

It was concluded that the focal stimulus manipulated did not produce differences in responses measured. The proposed effect of injectate volume on pain of injection, bruise occurrence and size, and pain of injection site was not supported. There was no significant association found for depression and pain responses. There was no association between bruise occurrence or size and pain of injection site. Analysis highlighted areas of difference in the sample. The conceptual framework did guide the exploration of contextual stimuli and their influence on output as well as variance among the sample.

Abstract Approved by: Committee Chairman [redacted]

Program Director

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CHAPTER 1

Introduction

Within the Roy adaptation model, nursing interventions are focused on manipulation of stimuli. By promoting adaptive responses and decreasing ineffective responses the nurse facilitates the negentropic qualities of the system. Roy (1984) summarizes the goal of nursing as ". . . the promotion of adaptation in the four adaptive modes thereby contributing to health, quality of life and dying with dignity" (p. 38).

Many nursing interventions have been established first through experience, followed by publication in textbooks and procedure manuals, and then by inclusion in nursing education. Kirchhoff (1982) argues that this flow of practice into the literature, instead of practice flowing from empirically based literature, weakens the fabric of nursing as a science. As nurse theorists, scientists, and clinicians strive to build a body of knowledge for the profession, there is a need to move away from experientially based nursing interventions to those that are empirically based.

In an environment where swift, efficient care and patient satisfaction are economic essentials, many administrators have realized that nurses are key professionals who influence positive patient care outcomes. Nursing is empowered to influence many patient care decisions in today's health care delivery system. Efforts to change policy or current practice within an institution, to influence patient care outcomes, are more likely to be successful if they are empirically based.

One nursing intervention that has been based almost solely on experience is the administration of subcutaneous heparin. Nurses can control or influence many variables surrounding this procedure. An example of one variable in this procedure is the selection of the concentration of heparin to deliver a prescribed dose. Although an institution's pharmacy traditionally has decided which concentration of heparin to supply for low-dose

subcutaneous injections, nurses can influence this decision. The concentration of heparin available in an institution may have a direct effect on patient response to a routinely used medication. Heparin is available commercially in a wide range of concentrations for subcutaneous injection. A more concentrated solution requires less injectate volume to deliver a given dose of medication. A variety of concentrations may be used to deliver the prescribed dose of heparin subcutaneously. Two commonly used concentrations are heparin 5,000 units (u) : 1 milliliter (ml) and 10,000 u : 1 ml. To deliver a prescribed 5,000 u of heparin subcutaneously, the nurse may administer 1 ml injectate of the 5,000 u : 1 ml solution of heparin or 0.5 ml injectate of the 10,000 u : 1 ml solution. Nurses need empirically based information about patient responses to injectate volumes and thus concentrations of heparin to select the concentration of heparin to be used in low-dose subcutaneous heparin therapy.

Coagulation

To understand how heparin can be effective in preventing pathologic intravascular clotting, a basic understanding of the mechanisms of hemostasis is helpful. Hemostasis is the balance between the coagulation and fibrinolytic subsystems in the clotting system. If these two subsystems are not in balance, then either pathologic intravascular clotting or bleeding occurs. The degree of alteration in hemostasis can vary from inconsequential to catastrophic for an individual. Imbalances in hemostasis can come from inherited or acquired stressors (Hubner, 1986). Stressors can be considered situational or developmental. An example of an inherited situational stressor is the disease hemophilia, which is a decrease in the procoagulation part of factor VIII or VIIIC. This imbalance leads to a tendency to hemorrhage, especially in the areas of joints. Another inherited situational stressor is the antithrombin III deficiency that results in hypercoagulability, manifested in pathologic clot formation and extension. Acquired situational stressors that lead to excessive clotting include immobility or even a decrease in mobility as is often seen in hospitalized patients. Surgery causes injury to the vascular wall and thus can be considered

an acquired situational stressor that could lead to pathologic clotting. Anticoagulation therapy can be considered an acquired situational stressor that could lead to bleeding. An example of acquired developmental stressors is the tendency toward coagulation in the later phase of pregnancy.

Hubner (1986) offers an excellent representation of how the coagulation subsystem functions. Intrinsic and extrinsic pathways serve to activate the coagulation subsystem. There are documented and speculated crossover points between the extrinsic and intrinsic paths. Factors in the coagulation subsystem usually are represented by Roman numerals. When a factor has been activated, a small a is used in conjunction with the Roman numeral. Prior to activation, these factors are neutral circulating plasma proteins. When tissue injury occurs, the extrinsic pathway is activated. Tissue thromboplastin is released with endothelial tissue injury and in the presence of calcium leads to plasma protein activation of VII. There is strong speculation that VIIa has two roles. The first is initiation of the common pathway by assisting the conversion of X to Xa. At the same time VIIa is suspected in a jump to the intrinsic pathway at the point where IX is activated. Both IXa and VIIa influence the activation of X at the common pathway. Although the exact mechanism is unknown, Hubner speculates that Xa binds with Va and calcium when platelet phospholipids are present in the intrinsic pathway. Platelets are not necessary in the extrisic pathway. At this point factor II, prothrombin, is converted to thrombin, leading to the formation of fibrinogen monomers from fibrinogen. Fibrin polymer is created when firbrinogen monomer is exposed to XIIIa and calcium. Fibrin polymer attaches to the injured tissue and an insoluble clot begins to form. Activation of the intrinsic pathway begins when XII is activated through exposure to collagen or some foreign surface. XIIa activates XI, which in turn activates IX. Again, the VIIa from the extrinsic pathway can cross over at this point of bonding or at the next step as the activation of X occurs. At the time IXa begins to activate X, calcium must be present. As the activated factors IXa, VIIIa, and Xa come together, they bond on the surface of a platelet.

When imbalance in the hemostasis system leans toward over-activation of the coagulation system, pathologic intravascular clotting occurs. Heparin often is given prophylactically in low doses to the patient who is undergoing a surgical procedure, has decreased mobility, or is acidotic and deemed to be at high risk for acquired situational stressors that could lead to pathologic intravascular clotting (Sohn, Tannenbaum, Cantwell, & Rogers, 1981). Hubner (1986) reports that 12 -15% of all hospital deaths have been attributed to episodes of pulmonary emboli that are thought to occur in about 600,000 cases per year. The primary precursor to pulmonary embolus, i.e., deep vein thrombosis, is estimated to occur 2.5 million times per year. Medical research has established that low-dose heparin is an effective treatment for preventing pathologic intravascular clotting, including deep vein thrombosis and pulmonary embolus (Collins, Scrimgeour, Yusuf, & Peto, 1988).

Heparin

Heparin occurs naturally in the tissue of humans and other animals. Howell was credited with the discovery of the anticoagulation properties of heparin in 1922 (Hanson, 1987). Heparin reportedly has a mucopolysaccharide structure and is water soluble. Heparin works via inactivation of the procoagulant plasma proteins IX, X, XI, and XII in addition to thrombin. This anticoagulant substance also inhibits fibrin formation via blockage of the conversion of fibrinogen to fibrin.

Side effects of heparin may be considered to be in three classes. The first class includes action on body systems other than those included in blood coagulation. An example is transient alopecia. The second class includes allergic reactions. These are rare occurrences but can be quite serious. The third class includes what Zinn (1964) terms ". . . inappropriate manifestations of heparin's therapeutic properties" (p. 38). These side effects include the major problem of hemorrhage, usually associated with a dose that is too high or underlying blood dyscrasias. Surgical hematomas can form if the heparin enters the lymphatic system and is retained in local tissue near the surgical site for a long period of

time (De Lange, 1982). Also included in this category of side effects is the bruising that occurs in 50-90% of subcutaneous heparin injections (Stewart Fahs & Kinney, 1991; Wooldridge & Jackson, 1988).

Bruise

In the literature the terms contusion, hematoma, and ecchymosis often are used interchangeably with the term bruise. Bruise comes from Old French and means to break. It is defined as "a contusion with ecchymosis followed by discoloration due to the breaking down of the diffused blood" (Skinner, 1961, p. 80). The term has been used in the English language since the time of King Alfred, circa 871 A.D. Bruising secondary to blood dyscrasias such as purpura simplex, primary capillary hemorrhage, and thrombocytopenia purpura may or may not be associated with trauma. These disease states represent an extreme in the alteration of hemostasis.

Bruise also has been used to describe the result of psychogenic trauma as with the term bruised ego (Marshall, 1987). Psychogenic bruising first was described in 1500; this state occurs without trauma and without hematologic abnormalities. The sequence of events in psychogenic bruising begins with an erythematic flush of a local area of skin, usually involving the lower extremities. The flushing is followed by a discoloration and pruritus. The etiology of psychogenic bruising is unknown, but one hypothesis is that the episodes are preceded by emotional trauma. All the previously mentioned bruises in this section are considered abnormal in some fashion.

There are bruises that are considered to be within the normal adaptive responses of an individual. It is the bruise that falls within this normal adaptive range that is of interest in this study. The common link between abnormal bruises and those that are considered to be within normal limits is the attribute of discoloration.

Discoloration of tissue is a common characteristic of a bruise identified in the literature (Pye, Wijewardane, & Crumplin, 1987; VanBree, Hollerbach, & Brooks, 1984; Wooldridge & Jackson, 1988; Woolley, 1986). This discoloration is due to blood

products, particularly hemoglobin, seeping into the tissue. A bruise does not blanch with pressure because it is an extravascular collection of hemoglobin (Champion, 1986; Woolley, 1986). The breaking down of hemoglobin in the tissue causes a bruise to change color. This discoloration is formed by fresh hemoglobin in the tissue that produces a reddish to bluish hue, biliverdin that produces a greenish color, bilirubin that produces yellowish discoloration, and hemosiderin that produces a brownish discoloration (Woolley, 1986). A bruise is usually noted as a soft tissue injury (McIlwain, 1985; Woolley, 1986) and may or may not be considered painful.

The discomfort of a bruise can be physiologic or psychologic in nature. Physiologic discomfort at a bruise site may be described as tenderness or pain, especially with palpation (VanBree et al., 1984).

In summary, the characteristics of a bruise include a discolored, purpuric lesion that changes color and fades over time and does not blanch with pressure. A bruise most often is a soft tissue injury, resulting from trauma that may cause physiologic or psychologic pain.

Pain

Pain is a universal experience, yet it varies from person to person. Throughout history pain has intrigued and frightened humanity. Expression of the pain experience can be seen in daily living and in the arts. Many nurses have been taught that pain is what the patient says it (pain) is. This definition is a simple one, but it does reflect the clinical observation that apparently the same type and intensity of stimulus can produce very different responses. Theories of pain have been around for a long time. Demons and spirits were thought to be the cause of pain in the middle ages. Pain as a punishment from a higher being also was embraced by many cultures in the not so distant past (Donovan, 1989). Pain as an emotional response first was proposed by Aristotle in the 4th Century B.C. Although few health care providers today would say that pain is purely emotional, neither do they accept a purely physiologic explanation of pain.

The role of the nervous system in pain response was not clearly identified until the 19th Century. The physical and emotional aspects of pain were combined in 20th Century theories. The Gate Control Theory of Pain was proposed in the 1960s (Melzack & Wall, 1977) and has been refined as new information has emerged from pain research. Melzack and Wall found the two primary theories of pain in the 1960s, i.e., the specificity and pattern theories, to be unsatisfactory. The Gate Control Theory of Pain was the first to blend physiologic and psychologic explanations of the pain experience. Essentially, the Gate Control Theory of Pain notes that a stimulus is input to the system via nociceptive fibers. These fibers may be large or small, myelinated or unmyelinated. Pain theorists speculate that the cells of the substania gelatinosa (SG) control the gate, thus controlling the number and kind of impulses that arrive at the central transmission (T) cells. Stimulation of the small afferent fibers is speculated to open the gate, while stimulation of the larger fibers can partially or completely close the gate.

Melzack (1986) notes that there may be multiple sets of nociceptive pathways through the spinal cord. The author discusses one set of pathways as including the dorsal column postsynaptic system (DCPS), the spinocervical tract (SCT), and the neospinothalmic tract (nSTT). This pathway set rapidly conducts stimuli and is well suited to transmit signals from an acute pain stimulus. Once the impulse reaches the T cells, these cells activate selective brain processes, including those that are responsible for perception of pain and other factors that might modulate a response to pain. This is the portion of the Gate Control Theory of Pain that accounts for psychologic influences on pain perception.

Chemical substances throughout the system also function to mediate the pain experience. Guyton (1986) lists ". . . bradykinin, histamine, prostaglandins, acids, excesses of potassium ions, serotonin, and proteolytic enzymes . . . " (p. 594) as simulating chemosensitive pain endings and decreasing the threshold for mechanosensensitive and thermosensitive receptors. The discovery of endorphins in the

mid 1970s added to the knowledge of internal analgesia and pain. Although the Gate Control Theory is widely accepted, there are some who question the ability of the theory to be predictive in all cases (Crue, 1983). Although Roy (1989) classifies pain within the physiologic mode as a source of sensory overload, she (Roy, 1984) notes that the pain response relies heavily on the communication of the cognator and regulator systems. Both purely physical pain and purely psychologic pain responses are unlikely. The Roy view of pain is compatible with the Gate Control Theory of Pain.

Depression

Several authors (Hagglund, Haley, Reveille, & Alarcon, 1989; Keefe, Wilkins, Cook, Crisson, & Muhlbaier, 1986; Otto, Yeo, & Dougher, 1987) theorize that there is a connection between depression and pain. Descriptions of depression abound, from Freud's view that depression is anger turned inward to modern theories of biochemical imbalances. Rogers (1985) notes that a triad of chemical, experiential, and behavioral factors presents a workable model of depression. Hollandsworth (1990) describes a continuum of symptoms of depression that range from feelings of sadness, hopelessness, and despair to an extreme of panic, agitation, and phobias. Although the Diagnostic and Statistical Manual of Mental Disorders (DSM-III R) (American Psychiatric Association, 1983) provides a flow chart of factors that lead to a diagnosis of depression, there are self-report tools such as the Beck Depression Inventory (BDI) and Center for Epidemiologic Studies Depression Scale (CES-D) that often are used to evaluate the presence of depressive symptoms (Devins & Orme, 1985). Ensel (1986) discusses the differences between the terms mood, symptom, syndrome, and illness with respect to depression. This author notes that epidemiologic tools often are used in research and community assessments and specifically are designed to measure depression as a group of symptoms.

Comstock and Helsing (1976) reported that depressive symptoms occurred in approximately 20% of subjects in an epidemiologic study undertaken with adult citizens in Kansas City, MO, and Washington County, MD. These investigators identified

differences in depressive symptoms by age, group, sex, and race. Subjects under 25 years of age had depression rates of approximately 30%, while only 3-10% of those over 65 were judged to be experiencing depression. Women had a higher incidence of depression than men and blacks were more frequently depressed than whites. Of the 526 non-psychiatric medical outpatients seen in an ambulatory clinic, Nielsen and Williams (1980) reported that approximately 20% were depressed. Of those subjects experiencing depression, 12.2% were classified as mildly depressed, 5.5% were moderately depressed and 0.6% were experiencing severe depression. Devins and Orme (1985) note that depression is thought to occur in 4-11% of the general population.

Hagglund et al. (1989) noted a correlation between depression and pain in a study of patients with rheumatoid arthritis. Keefe et al. (1986) reported that depression was related to increased pain behaviors in a study where the population of interest was experiencing chronic low back pain. There are many reports of depressed patients complaining of pain and patients with chronic pain experiencing depression. Otto et al. (1987) stipulate that as the right hemisphere is activated, there is increased perception of negative stimuli such as pain and the cycle is perpetuated. There is speculation in the literature that pain is perceived at a lower stimulus level when experienced on the left side by those individuals who are primarily right handed. The links between depression, acute or experimental pain, and laterality have received little attention in the literature.

Injectate Volume

Two of the most commonly used concentrations of heparin in subcutaneous injections are 5,000 u : 1 ml and 10,000 u :1 ml. Both concentrations can be used to deliver the same amount of medication using different volumes. A prescription for 5,000 u of subcutaneous heparin can be administered by the nurse as a 1 ml volume injection using the 5,000 u : 1 ml concentration or as a 0.5 ml volume injection using the 10,000 u : 1 ml concentration. Both injections will be equally effective in raising the partial thromboplastin time a small but statistically significant amount, thus providing the desired therapeutic effect

. How these two injectate volumes would affect responses of bruising and pain is a question that is unanswered but one that could influence clinical nursing practice.

Cost Effectiveness

The issue of cost effectiveness of nursing interventions has come to the attention of the profession and the health care industry. Shortridge et al. (1989) noted that cost effectiveness must be a variable in any nursing intervention study in today's competitive health care delivery market. In addition to looking at response to the intervention of subcutaneous heparin administration, nurses need information about the issue of cost with regard to concentration of heparin. Choosing an intervention that does not include analysis of cost is of questionable benefit to clients in the delivery of health care.

Purpose

The purpose of this study was to observe effect of injectate volume of subcutaneous heparin on three dependent variables. The dependent variables studied included responses of pain at time of injection, occurrence and size of bruises, and sensation of pain experienced at the injection site postinjection. In addition, the responses of pain of injection and pain of injection site postinjection were examined in relation to each subject's level of depression. The questions arising from the nursing intervention of administration of subcutaneous heparin were questions of patient responses to stimuli as viewed within a nursing conceptual model, namely, the Roy adaptation model.

Conceptual Framework

Model Overview

Roy (1984) views the metaparadigm of nursing within the Roy Adaptation Model as person, environment, health, and nursing. The discussion of person focuses on the individual as the recipient of nursing care. The same principles used to deal with the individual within this model, however, can be employed when the recipient of nursing is a family, group, community, or society. Environment as discussed in the Roy Adaptation Model includes all internal and external stimuli. Health is both a process and a state of

being. Health is not tied to illness in Roy's most recent concept clarification (Roy, 1990). Fulfillment of potential is essential in Roy's definition of health. Roy views nursing as a science that generates knowledge which is applied to the practice of nursing (Andrews & Roy, 1986). Person is an adaptive organism that utilizes coping mechanisms to facilitate goal attainment. Coping mechanisms are innate and learned. Adaptation occurs in four modes. Energy saved through adaptive responses is fed back into the system for utilization within the adaptive modes. Ineffective responses place further energy demands on the system (Roy, 1971).

Interrelationship of Concepts of the Model

Person is seen within the Roy Adaptation Model as holistic and adaptive. The whole is equal to more than the sum of the parts, indicating that the person is more than the sum of physiologic, intellectual, and emotional components. The holistic person is a system that functions in an integrated manner in a purposeful way. The hierarchial and functional order of the system utilizes stimuli from the internal and external environment along with feedback mechanisms to adapt in a purposeful manner.

Environment as discussed in the Roy adaptation model (Andrews & Roy, 1986) includes all internal and external stimuli. These stimuli provoke a response within the system. Stimuli can be grouped into three general classes: focal, contextual, and residual stimuli. Focal stimuli include the internal and external input that directly confront the system. Contextual stimuli are the remainder of internal and external stimuli that can be identified in the situation. Residual stimuli include those stimuli that might be affecting the system but are not easily validated. The individual responds to focal, contextual, and residual stimuli and the combined effects of these stimuli comprise the adaptation level of the person. Environmental stimuli, external and internal, may be manipulated.

Adaptation level is a system boundary. On one side of the boundary is an effective or adaptive response; on the other side of the boundary is an ineffective response. The adaptation level is constantly changing. Adaptive responses are those that are effective and

promote the integrity or wholeness of the system, thus leading toward the goals of the system. Ineffective responses are those that are not adaptive and do not contribute to the system goals.

The Roy Adaptation Model discusses coping mechanisms as providing for the hierarchical and functional order of the system. Coping mechanisms can be viewed as regulator or cognator subsystems. The regulator subsystem includes the individual's neural, chemical, and endocrine channels that allow response to stimuli. The cognator subsystem allows response to stimuli through cognitive-emotive channels. Coping mechanisms are innate or acquired. Innate mechanisms are those that are with the person at birth by virtue of genetics or they are common to the species. Acquired mechanisms are those that are learned to maintain system order. Coping mechanisms cannot be viewed or measured directly; rather, the behavior or response to stimuli is the attribute that is an observable output from the person as a system.

Observable behavioral responses to stimuli are classified into four modes. The modes are physiologic, self-concept, role function, and interdependence modes. The physiologic mode has undergone changes in its classification system since inception of the model. Roy (1971) states physiologic needs include ". . . circulation, body temperature, oxygen, fluids, sleep and activity, elimination and the appetitive system" (p. 254). In later works (Roy & Roberts, 1981; Roy, 1984) some categories, such as oxygen and circulation, have been combined. Andrews and Roy (1986) list the areas of need in the physiologic mode as including ". . . oxygenation, nutrition, elimination, activity and rest, and protection." (p. 42). In addition, the regulatory mechanisms of the physiologic mode are said to include ". . . complex processes involving senses, fluid and electrolytes, neurological function, and endocrine function." (p. 42). Fawcett (1989) includes behaviors in eight areas of needs within the physiologic mode. These are exercise and rest, nutrition, elimination, fluids and electrolytes, oxygen and circulation, the senses, the endocrine system, and regulation of temperature. The self-concept mode is subdivided into

the perceptions of physical self and personal self. Physical self includes behavioral responses of body sensation and body image. Personal self includes behavioral responses of self-consistency, self-ideal, and moral-ethical-spiritual self. Role function mode pertains to the individual's perception of societal expectations of self and others. Interdependence mode also involves relationships between and among persons. The relationships in this mode, however, generally are more personal than those of the role mode (Roy, 1984).

Health is both a process and a state of being. Fulfillment of potential is essential in Roy's definition of health. Integration of the person is another major premise in Roy's definition of health. The absence of health is viewed as a lack of integration of the individual (Andrews & Roy, 1986).

Roy views nursing as including application of the science of nursing to the practice of nursing. Roy describes a six step problem solving process as a means of setting nursing apart from other disciplines. The nursing process as described by Roy builds upon the traditional nursing process. The nurse performs a two level assessment when practice is guided by the Roy model. The first level includes assessing behaviors in each of the adaptive modes, while the second level is designed to identify the focal, contextual, and residual stimuli that contribute to behavior within the four modes. Nursing interventions are focused on manipulation of focal, contextual, or residual stimuli to change the magnitude of the stimuli or broaden the person's adaptation level. By promoting adaptive responses and decreasing ineffective responses, the nurse facilitates the negentropic qualities of the system. The nurse assists the individual toward achieving goals of the system.

Problem

Problem in View of Conceptual Framework

Focal stimuli may be large or small, complex or simple. The person hospitalized with uterine fibroids may experience the disease process as the focal stimulus for the hospitalization, while feeling the surgical intervention is the focal stimulus for postoperative

pain. This same person may be receiving low-dose heparin injections to prevent postoperative thrombophlebitis.

An overview of the problem in view of the conceptual framework is represented by the model in Figure 1. The injectate volume of the medication heparin is considered the focal stimulus in this study. Because heparin is poorly absorbed from the gastrointestinal system, it is administered parenterally. In the case of low-dose heparin therapy, the route of administration is subcutaneous. As an anticoagulant, heparin affects the clotting mechanism, possibly delaying clot formation at the site of injection, and the sequela of bruising is likely to be a response in the physiologic mode. Although needle size and length for administering subcutaneous medications vary from institution to institution, a routinely used needle is 25 gauge and 5/8 inch in length. This needle is extremely fine and small. The needle is used to puncture the skin and deliver the medication at the proper depth, avoiding intramuscular injection. The contextual stimulus of an injection, including penetration of tissue and delivery of the volume of medication, can be considered trauma to the system. Any trauma has the potential of producing a response such as an unpleasant sensation, for example, pain at the time of injection. Roy and Roberts (1981) explicate the following theoretical proposition within the regulator subsystem: "The magnitude of the internal and external stimuli will positively influence the magnitude of the physiological response of an intact system" (p. 62). Hypotheses 1, 2, and 3 were derived from the above theoretical proposition. The increased amount of injectate is likely to produce an increased physiologic response of bruise occurrence and size, and an increased perception of pain at the time of injection.

Although bruising is minor in consequence when compared to hemorrhage as a sequela of heparin administration, it has been reported as a physiologic response that is distressing to patients. There is speculation in the literature (Hanson, 1987; Hubner, 1986) that bruises resulting from the focal stimulus of heparin administered via subcutaneous injections are painful. Andrews and Roy (1986) classify sensation involving pain within

the physiologic mode of adaptative responses. One can hypothesize that the focal stimulus of heparin injectate volume delivered via subcutaneous injection would cause trauma to tissue. This stimulus is processed through the regulator subsystem and produces the response of bruising at injection site. A bruise results from seepage of blood components, including hemoglobin, from the vascular space into the soft tissue, secondary to trauma. This extravasation of blood components causes pressure at the site of the bruise. The stimulus of pressure goes through the feedback loop, inputs the system as a stimulus into the regulator subsystem, and may be perceived as pain.

Roy (1984) notes that regulator mechanisms do not act alone. Theoretically, any output from the system can feed back into the system as a stimulus. Roy's conceptualization of the crossover of psychologic stimuli to affect physiologic response is supported by the Gate Control Theory of Pain (Melzack & Wall, 1977) and the proposed association between depression and pain (Otto et al., 1987). The hypothesized associations of level of depression and perceptions of pain at injection and pain of bruises are derived from the theoretical crossover of cognator and regulator subsystem processing of stimuli.

Contextual stimuli are those factors that are present from the external or internal environment that contribute to the effect of the focal stimuli. They can be measured. An output of the physical self portion of the self-concept mode is sensation of self. Roy (1984) describes sensation of self in terms of the individual's feelings about self. This output can feed back into the system as a stimulus. In this study, symptoms of depression were viewed as contextual stimuli. The contextual stimulus of depression was viewed in relation to responses reported for pain at time of injection and the pain of bruising.

In addition to depression, contextual stimuli have been identified as variables that include but are not limited to age, sex, medical diagnosis, injection technique, and amount of adipose tissue at injection site. Time of day of heparin injection has been considered a contextual stimulus in relation to the response of pain perception. Residual stimuli are those factors that may be suspected of influencing responses but that have not been or

cannot be measured. In this study some possible residual factors are pain perception, pain threshold/tolerance, cultural beliefs regarding pain, fear of injections, effect of bruising on self-concept, ease of bruising within normal limits, and handiness. The contextual and residual stimuli were partially controlled by the study design. For a list of stimuli and responses identified or explored in the study, see Table 1.

Research Questions

1) What is the effect of injectate volume of subcutaneous heparin on the patient's physiologic response of bruise occurrence 60 - 72 hours postinjection?

2) What is the effect of injectate volume of subcutaneous heparin on the patient's physiologic response of bruise size 60 - 72 hours postinjection?

3) What is the effect of injectate volume of subcutaneous heparin on the patient's physiologic response of pain at time of injection?

4) What is the association between bruise occurrence and the patient's physiologic response of pain at injection site 60 - 72 hours postinjection.

5) What is the association between bruise size and the patient's physiologic response of pain at injection site 60 - 72 hours postinjection.

6) What is the association between level of depression, measured prior to injection, and the intensity of pain of injection?

7) What is the association between level of depression, measured prior to injection, and the perception of pain at injection site measured 60 - 72 hours postinjection?

8) What is the effect of injectate volume of subcutaneous heparin on the cost of preparation of a subcutaneous heparin injection?

Research Hypotheses

The research hypotheses tested in this study were as follows:

1) 0.5 ml volume , 10,000 u : 1 ml concentration (dose 5,000 u), will produce fewer bruises than a 1 ml volume, 5,000 u : 1 ml concentration (dose 5,000 u), of heparin when administered subcutaneously.

2) 0.5 ml volume, 10,000 u : 1 ml concentration (dose 5,000 u), will produce smaller bruises than a 1 ml volume, 5,000 u : 1 ml concentration (dose 5,000 u), of heparin when administered subcutaneously.

3) 0.5 ml volume, 10,000 u : 1 ml concentration (dose 5,000 u), will produce less pain of injection than a 1 ml volume, 5,000 u : 1 ml concentration (dose 5,000 u), of heparin when administered subcutaneously.

4) There will be a positive association between the physiologic response of occurrence of bruising and the response of pain at injection site measured 60-72 hours postinjection.

5) There will be a positive association between the physiologic response of size of bruise and the response of pain at injection site measured 60 -72 hours postinjection.

6) There will be a positive association between level of depression and the response of pain at time of injection.

7) There will be a positive association between level of depression and the response of pain of injection site measured 60-72 hours postinjection.

8) Injectate volume of dose will not affect cost of preparation of a subcutaneous heparin injection.

Definition of Terms

Heparin - A medication utilized for its anticoagulant, antithrombotic, and lipemia-clearing properties. Heparin can be in the form of either a sodium or calcium salt. This medication cannot be absorbed through the gastrointestinal system and thus is administered parenterally (Hanson, 1987; Hubner, 1986). Heparin utilized in this study for administration to subjects was LyphoMed brand, a sodium salt heparin, administered via subcutaneous injection. Heparin used in the timed trials for preparation of heparin injections was Upjohn brand, a sodium salt heparin.

Dose - Exact amount of medication to be administered. The most common dose of heparin when used for its prophylactic properties in preventing pathologic intravascular

clotting is 5,000 u administered every 8 to 12 hours. For the purpose of this study, dose was limited to 5,000 u administered every 12 hours.

Concentration - The strength of a solution. In this study the concentrations included 5,000 u : 1 ml and 10,000 u : 1 ml of heparin.

Volume - In this study, the liquid measurement of heparin injectate to be administered via subcutaneous injection. Two volumes were administered: 0.5 ml to deliver the 10,000 u : 1 ml concentration of heparin and 1 ml to deliver the 5,000 u : 1 ml concentration of heparin. Both volumes delivered 5,000 u of heparin.

Physiologic response - Reaction to a stimulus that occurs through the regulator mechanism,which includes the individual's neural, chemical, and endocrine channels (Roy, 1984). In this study, the physiologic responses of interest were bruise formation, including occurrence and size, pain at time of injection, and postinjection pain at the sites of heparin injection.

Bruise - A discoloration of the skin that does not blanch with pressure, resulting from seepage of blood components, including hemoglobin, from the vascular space into the soft tissue secondary to trauma. The bruise changes colors as the hemoglobin breaks down over a period of time and is gradually reabsorbed. As reabsorption occurs the bruise becomes smaller. Complete reabsorption of hemoglobin indicates complete resolution of the bruise. Bruise is operationalized in this study as the surface area of discoloration that forms at the injection site within 60 hours of injection and has not resolved within 72 hours after the injection (Stewart Fahs & Kinney, 1991).

Bruise (occurrence) - A bruise existing at injection site and given a count of one. If no bruise occurred, there was a count of zero.

Bruise (size) - The surface area of the bruise. Surface area was calculated by placing a piece of plastic wrap over the bruise and tracing the bruised area. The tracing was scanned on an Apple Scanner and analyzed for surface area using the Image computer software for the Macintosh Computer.

Depression - Sensation of self of low spirits, gloominess, dejection as measured on the Center for Epidemiologic Studies Depression Scale (CES-D). This tool is designed for self-report of depressive symptoms. Scoring can be used as a continuous variable or to provide levels of depression as follows: (a) 0-15.5, no depression; 16-20.5, mild depression; 21-30.5, moderate depression; and >31, severe depression (Devins & Orme, 1985) or (b) 0-15.5, low depression and > 15.5, high depression. Both continous and discrete level scores on the CES-D were used in analysis of data for this study.

Pain - Whatever the patient says it (pain) is (Roy, 1984). There are two main classifications of pain: acute and chronic. In this study the variable of interest was acute pain that results from either a treatment, i.e., heparin injection, or response to a treatment, i.e., pain at injection site postinjection. Pain at time of injection was quantified using the Visual Analogue Scale (Gift, 1989). Pain at injection site measured 60-72 hours post-injection was measured with the McGill Pain Scale, Short Form (Melzack, 1987).

Assumptions

The assumptions underlying this study included:

1) The Roy Adaptation can be utilized to guide research (Fawcett, 1989).

2) Low-dose heparin is an effective medical treatment for preventing intravascular pathologic clotting (Collins et al., 1988).

3) Administration of medically prescribed heparin therapy is a nursing intervention.

4) The time of day that heparin is administered has no effect on bruising response.

5) An acceptable site of heparin subcutaneous injection is the abdomen (Stewart Fahs & Kinney, 1991; Wooldridge & Jackson, 1988).

6) The concentrations of heparin used in this study, 5,000 u : 1 ml and 10,000 u : 1 ml, are equally effective in preventing intravascular pathologic clotting. Although this assumption has not been found explicitly stated in the literature, both concentrations are routinely used throughout the United States. Bender, Aronson, Hougie, and Moser

(1980), when studying the bioequivalence between sodium and calcium heparin preparations, implied that differences in concentration would not affect outcome measures.

7) Self-report scales are appropriate tools to quantify subjective states.

Significance

Subcutaneous low-dose heparin is an accepted medication to prevent pathologic intravascular clotting. Collins et al. (1988) report that over 30% of surgeons in this country prescribe low-dose heparin therapy, while over 75% of European surgeons currently prescribe low-dose heparin therapy. Collins et al. concluded that the use of low-dose heparin therapy is a cost effective means to prevent postoperative mortality. In addition, new medical studies have concluded that high-dose subcutaneous heparin is an effective treatment for patients who already have developed deep vein thrombosis (Bentley et al., 1980; Doyle et al., 1987). This increased interest by the medical community in the use of subcutaneous heparin may lead to increased prescriptions for heparin administered subcutaneously. Nurses administer this medication in acute care facilities. Data provided by this study on the response of patients to two concentrations of subcutaneous heparin injections can be utilized by nurses to guide manipulation of the stimuli to obtain the most adaptive response to a nursing intervention. Nurses can utilize the data to have input into the decision making process regarding volume of injectate used in subcutaneous injections of heparin. Thus, the significance of this study is two fold. First, a specific nursing intervention can be viewed in terms of patient outcomes. Second, the data may empower nurses to influence direct patient care.

Summary

This study was designed to examine a common nursing practice, administration of subcutaneous heparin. The focal stimulus of concern was the injectate volume of heparin. Nurses need empirically based information about patient response to this intervention if they are to influence the decision about which concentration to use in practice. The responses of pain at injection, pain of bruising postinjection, bruise formation, and surface

area of bruise were studied. The response of pain also was analyzed in relation to the psychologic response of depression. The Roy model was utilized to guide the development, implementation, and evaluation of this research project.

CHAPTER 2

Review of Research

Chapter 2 presents a review of the research literature. Included are studies focused on the effectiveness of heparin administered subcutaneously, bruising and pain in response to injections, the co-occurrence of depression and pain, and response to injectate volume of heparin.

Effectiveness of Subcutaneous Heparin

Heparin currently is well accepted as a treatment to prevent pathologic intravascular clotting. The question of efficacy, however, raged in the medical literature of the early to mid 1970s. Three classic studies were reviewed concerning the efficacy of low dose heparin therapy in the prevention of deep vein thrombosis. Gordon-Smith, Grundy, LeQuesne, Newcombe, and Bramble (1972) reported a prospective study in which a convenience sample of 150 subjects was randomly assigned into three groups. Group 1 (n=50) was the control group in which routine nursing care was given to patients pre- and postoperatively. This care consisted of early ambulation, ankle exercises, and hydration. Group 2 (n= 52) received subcutaneous heparin in three doses. Dose 1 was given preoperatively and doses 2 and 3 were given postoperatively, 12 hours apart. Group 3, (n=48) received subcutaneous heparin for a total of 10 doses. Dose 1 was given preoperatively and doses 2 through 10 were given post-operatively, twelve hours apart. All subjects received a 2,500 u : 1 ml injection. All injections were given with a 25 gauge needle. This study used the abdomen and the thigh as the sites for injections. The main dependent variable was the formation of deep vein thrombosis as measured by I fibrinogen radiologic studies. A Fisher's exact test was used to examine statistical differences between groups. The results included lower incidences of deep vein thrombosis in both experimental groups when compared with the control group. The difference between

group 1 and group 2 was significant at the p <.003 level. The difference between group 1 and group 3 was significant at the p <.001 level. When groups 2 and 3 were examined as a whole, the difference between the treatment groups was not significant. However, when subjects within groups 2 and 3 were stratified for malignant or benign diseases within each group, those with malignant diseases in group 2 had a significantly higher rate of deep vein thrombosis than those subjects with malignancies in group 3. This study had a sufficiently large sample size and was prospective. The results may have been strengthened had the subjects been randomly selected prior to inclusion rather than randomly assigned to group from a convenience sample (Waltz & Bausell, 1981). The issue of true randomization, however, is one that is not resolved easily in a clinical setting. The larger sample size is an attempt to overcome the lack of true randomization. Randomization, however, should have been recognized as a limitation of the study.

Nicolaides et al. (1972) also examined the effectiveness of low dose heparin therapy. Their study included a large sample size of 244 subjects. There were 122 subjects in the control group, who received routine measures to prevent deep vein thrombosis, and 122 in the treatment group. The treatment was 5,000 u of subcutaneous sodium heparin administered 2 hours before surgery and every 12 hours after surgery for 7 days. The dependent variable again was deep vein thrombosis as diagnosed by I fibrinogen radiologic studies. Variables held constant in this study included the use of sodium heparin, dose of 5,000 u, 26 gauge needles, and abdomen as injection site. The findings mirrored those of the Gordon-Smith et al. (1972) study. The treatment group had 1 episode of deep vein thrombosis in 122 subjects compared to the control group, in which 29 diagnoses of deep vein thrombosis were made. The difference using Fisher's exact test was highly significant ($p < .01$). This prospective study seems to have been well designed.

A 1973 medical study (Gallus et al.) examined the effectiveness of subcutaneous low dose heparin in relationship to classification of 350 medical and surgical cases. Subjects were stratified into three classes: (a) elective surgery; (b) emergency surgery; in this case,

hip fracture and laminectomy; and (c) medical case of rule out myocardial infarction. Although the sample was one of convenience, care was taken to randomize subjects in treatment and control groups in each class. In class A, randomization included surgeon, because there were seven surgeons participating in elective surgery. Subjects having emergency surgeries were randomized considering the two types of surgeries involved. Those in the medical class were randomized via electrocardiograms on admission according to recent evidence of myocardial infarction. All patients in this study were considered to be at high risk for development of deep vein thrombosis and were older than the age of 40. The variables held constant in the treatment groups included the use of a 10,000 u : 1 ml concentration of heparin with a dose of 5,000 u every 8 hours. The sites used to deliver the medication included the abdomen and the arm. The dependent variables were the development of deep vein thrombosis as diagnosed by I-fibrinogen scanning; laboratory studies, including partial thromboplastin time and hematocrit; and number of blood transfusions. When the results of deep vein thrombosis were analyzed in all groups, fewer episodes were found in the treatment groups than in the control groups. This difference was significant at $p < .001$. When groups were examined individually and subjects were compared to their own control, groups 1 and 3 showed significantly fewer episodes of deep vein thrombosis than group 2. In the emergency surgery group, however, there were fewer episodes in the treatment group but the difference was not significant. Partial thromboplastin times showed a slight but significant rise between pretreatment and posttreatment levels in those patients who received heparin ($p < .01$). Patients treated with heparin who had abdominal or thoracic surgery required significantly more transfusions than their control counterparts. Surgeons, who were unaware at the time of surgery of who had received preoperative heparin doses, did not report differences in intraoperative bleeding. This study was large, was prospective, and was the last major study of that time period to address the effectiveness of subcutaneous heparin on the formation of deep vein

thrombosis. The evidence for the effectiveness of prophylactic heparin in patients at risk for deep vein thrombosis is strong.

The next major question in the literature regarding low-dose heparin therapy addressed the effectiveness of sodium and calcium salts of this drug and any differences in bruising produced by the two salts. Bender et al. (1980) examined bioequivalance of heparin preparations. The independent variables were four heparin preparations. One preparation was from a calcium salt, while the other three were from a sodium salt. There were four dependent variables, including Lee White clotting time (LWCT), activated partial thromboplastin time (APTT), thrombin calcium clotting time (TCCT), and plasma heparin level. All sodium preparations were 20,000 u : 1 ml concentration, while the calcium salt was 25,000 u: 1 ml concentration. The two salts were not available in the same concentration. The implied assumption was that the difference in concentration of dose between the salts would not change the efficacy as long as dose did not differ. Bender concluded that the three preparations of sodium heparin and the calcium heparin preparation were equally effective in producing similar anticoagulation responses in healthy subjects. This study used only healthy male subjects whose ages ranged between 18 and 50 years. Subjects were randomly assigned to one of four treatment groups (total N = 48). This study had some design weaknesses, including a relatively small sample size for each cell. If there was a total sample size of 48, it is assumed that they were equally distributed among the 4 treatment groups, with 12 subjects in each cell. The power for this sample size in each cell, assuming a medium effect size of .50, would be P= .33 and B = .67, making the chance of a type II error quite high. The authors of this study noted that their results disagreed with one other study but were in accord with four previous studies. These authors offered no explanation for the differences between their study and the one study that had different outcomes. Nevertheless, both sodium and calcium heparin preparations are routinely used in the clinical setting for low-dose heparin subcutaneous injections.

Collins et al. (1988) reported a meta-analysis of studies using subcutaneous heparin in reduction of deep vein thrombosis and pulmonary emboli. These researchers reviewed data from 770 studies with more than 16,000 subjects. They concluded that perioperative heparin could prevent approximately 50% of all pulmonary emboli and 66% of all episodes of deep vein thrombosis. Collins et al. reported as particularly significant the reduction in fatal pulmonary emboli.

Bruise Formation

In a study reported by Barbaccia, Perry, Dellatore, and Mendelson (1984), the two heparin salts, sodium and calcium, were compared with respect to bruise formation at injection site. There were 44 subjects in this trial. Half received sodium heparin and half received calcium heparin. The variables held constant were concentration of 5,000 u: 0.2 ml injection with a 27 gauge, 1/2 inch needle. The injection site was the abdomen. Staff nurses administered injections after being trained in technique. During evaluation of bruise occurrence and size, data collectors were blinded to preparation of heparin. When both groups were compared, there was no significant difference in the proportion of bruises produced. There were, however, significantly more injection sites with bruises in the group receiving calcium heparin. When subjects who received other medications known to affect anticoagulation or who had increased bleeding times were factored out, there was no significant difference between the groups. The finding of bruises at more injection sites in the calcium group points out a design flaw in this study. If the groups had been more carefully screened for medications and/or bleeding times before inclusion, or if the study had used a paired design, this problem may have been avoided. The overall impression, given the limitations of the study, is that calcium and sodium preparations of heparin do not produce differences in the occurrence or size of bruises at injection site. This study also could have been strengthened if the researchers had used one person to give the injections. Another limitation was the use of only Caucasian subjects due to an inability to assess accurately the discoloration of bruising in a non-Caucasian group.

Bruise is a term used in everyday language and at first glance can be deceptively simple. The concept of bruise is relevant to nursing in that it is a physiologic response of clients to certain stimuli. In the Barbaccia et al. (1984) study, bruising at injection site was the dependent variable when two preparations of heparin were used. Bruises have been noted as variables in several nursing research studies concerning injection technique with subcutaneous injections of heparin (Brenner, Wood, & George, 1981; VanBree et al., 1984; Wooldridge & Jackson, 1988). Brenner et al. used two techniques that varied replacement of needle after drawing up medication and prior to injection, angle of injection, aspiration, and massage of tissue after injection. The variables held constant in this study included needle size, type of syringe, and abdominal injection site. Two researchers administered all injections, using both techniques. There was blind evaluation of the outcome variable. The dependent variables were number and size of bruises at injection site. The researchers noted a clinical difference with technique B producing fewer and smaller bruises; however, the difference was not statistically significant. The sample included only 33 subjects, but subjects served as their own control, thus strengthening the design. Hanson (1987), in a review of research on hematoma formation from subcutaneous heparin injections, noted that the Brenner et al. study attempted to manipulate too many variables. There was no mention of randomization of the order of treatment, dose, or concentration of dose used in the study. Bruises were measured by diameter rather than surface area, which could be a serious limitation. In addition, there was no mention of analysis of number or size of bruises in relation to sex or age. Later studies found differences given the variables of sex and age.

VanBree et al. (1984) also examined techniques of injection with subcutaneous heparin. They compared three injection techniques using 43 subjects. Each subject received 3 injections, one with each technique. Bruises were measured 48 hours after the third injection. This time frame was devised after a pilot study to see when bruising peaked and resolved. The authors found that bruises had formed within 48 hours and had

not begun resolution at 72 hours postinjection. The study, however, failed to demonstrate any significant differences among techniques. The investigators did note that women over 60 years of age had more and larger bruises than any other subgroup of subjects. They did not mention whether this difference was significant. Again, many variables were manipulated at once. The investigators concluded that the clinical picture of more and larger bruises with injection technique 1 was due to the aspiration component in the technique. However, with injection technique 1 the skin was held bunched during the injection and in technique 2 the skin was released. It seems plausible that manipulation of tissue could have led to more bruising. The sample included only Caucasians due to the inability to assess accurately bruising in non-Caucasian subjects.

The latest reported study on injection technique with subcutaneous heparin injections was the only one to report significant findings. Wooldridge and Jackson (1988) used a cross-over design where 50 subjects were their own control. Order of treatment was assigned randomly. Each subject received two injections, for a total of 100 sites. The variables manipulated included type of syringe, use of an air bubble, changing the needle prior to injection, and type of sponge used to apply pressure postinjection. Technique A used a 3 ml syringe, 0.2 ml air bubble, a needle change prior to injection, and a sterile dry sponge was employed after injection. Technique B used a 1 ml syringe, no air bubble, no change of needle, and an alcohol sponge postinjection. Variables held constant included needle size (27 gauge, 5/8 inch), no aspiration, concentration of dose (5,000 u : 1 ml), dose (5,000 u), skin preparation, angle (90 degrees), and length of injection (10 seconds). The hypothesis that technique A would result in fewer bruises than technique B was rejected. The other three hypotheses, however, were accepted. These hypotheses were that (a) technique A would produce fewer areas of induration at injection site than technique B; (b) technique A would produce smaller bruises than technique B; and (c) technique A would produce smaller areas of induration than technique B. Technique A was shown to be a superior technique in this sample for producing smaller bruises and fewer and smaller

areas of induration. Although this study was well designed, there were important limitations. Again, many variables were manipulated at one time. There was no analysis of data reported regarding the amount of variance explained by each variable, but the sample size was too small to support multiple regression procedures. Although the authors reported some subjective comments regarding pain at time of injection, they did not examine any differences in pain between techniques. This study also used only Caucasian subjects, which limits the generalization of findings to the population receiving subcutaneous heparin injections.

Pain of Injections

Only one of the studies reviewed examined the variable of pain with subcutaneous heparin injections. Coley, Butler, Beck, and Mullane (1987) studied the effect of needle size with subcutaneous heparin injections on two dependent variables: number and size of bruises and pain at the time of injections. In this study injections delivered a slightly higher dose of heparin, 7,500 u in a 10,000 u : 1 ml concentration, than in previous studies. Sodium heparin was used for all injections, which were given in the abdomen with one technique. The needle sizes evaluated were the 28 gauge, 1/2 inch needle on an insulin syringe and a 25 gauge, 5/8 inch needle on a tuberculin syringe. The sample size was 73 subjects. There was no significant difference in the number or size of bruises produced. There was, however, a significant difference in the number of subjects who reported pain at injection and severity of pain rated on a subjective scale. The smaller of the two needles (28 gauge, 5/8 inch) produced fewer episodes of injection pain and less severe pain. The design of this study could have been strengthened if the investigators had used a paired or cross-over design or if they had increased the sample size. Bruises were measured only at 24 hours after injection. According to VanBree et al. (1984), not all bruises have appeared until 48 hours postinjection. Stewart Fahs and Kinney (1991) noted that bruises did not become stable in size until 60 hours postinjection. Coley et al. found that 19 more bruises appeared between 24 and 48 hours; however, these data were not included in the analysis.

Injections were given by a variety of staff nurses, a factor that could confound the findings regarding pain. There was no mention of whether all nurses used both needles in giving injections. The reader is left wondering whether those nurses who used the smaller needle had a more gentle injection style or whether they gave the injection more slowly than those who used the standard size needle. Wooldridge and Jackson (1988) reported a subjective view regarding length of injection time and pain. Some subjects in the study volunteered information that the injections given by the investigators seemed to hurt less than those given by the staff. These subjects also noted that the investigators took longer to give the injections than the staff nurses.

The subjective asides noted in the Wooldridge and Jackson study (1988) seem to be supported by a study reported in a research abstract by Perez (1984). This study examined pain of intramuscular injections. The medication delivered was morphine sulfate for preoperative sedation. The sample included 48 males divided into three groups. In the first group the medication was delivered over a 5 second period; group 2 received medication in 20 seconds; group 3 served as a control, where there was no manipulation of time but time for injection was measured (mean time was 12 seconds). The measuring device for pain intensity was a mechanical device called a finger dynamometer pinch gauge. The researcher reported that the slower injection of 20 seconds brought about a lower level of pain at time of injection and a shorter duration of pain after injection. Although this study would seem to support the notion that injections given slowly produce less pain, there are some questions regarding the study. Because the report was an abstract and the complete report of the study could not be located by this writer, information about the study is limited. The size for each cell in this study is questioned. A cross-over design would have strengthened the study. There is no mention of other factors that might have contributed to the pain response such as anxiety about surgery, type and amount of pain medication previously received, or cultural differences. Another question relates to the age of subjects. Levin (1982) examined pain with injections in relation to sex and age. The Perez study

controls for sex in that only male subjects were studied but does not mention age of subjects.

In the study reported by Levin (1982), the independent variables were choice or no choice of site for injection in two groups, those viewed as having a primarily internal locus of control and those who had an external locus of control. The injections in this study were intramuscular. A 21 gauge, 1 1/2 " needle was used to deliver 2 ml of medication. There is no mention of the medication given in the study. The outcome variable was pain as measured with a visual analogue scale. There was no difference between choice and no-choice groups in terms of perception of intensity of pain. Locus of control did not influence pain perception. Despite the rejection of the primary hypothesis of this study, there were two additional findings that were significant and of interest when discussing pain with injections. Levin found that there was a moderate, negative relationship between age and pain and a strong positive relationship between sex and pain. The 138 subjects were stratified by age and sex. The age categories were 21-30, 31-40, 41-50, and 51-65 years. The females in the study who were identified as younger perceived more pain on injection than any other group. Another finding that relates to the design of the current study is the difference in subjects' perception of pain when injections were given by two different nurses. The sample size in this study was sufficiently large. Because there was no mention of the medication used for injection, one does not know whether medication was a variable held constant. Another concern with this study was the use of two nurses to give the injections. It is obvious that the attempts to standardize technique were not successful, and technique must be considered a confounding variable for pain of injection.

The effect of time of day of injections on the pain of injection has not been explored in the research literature despite speculation by nurses that a patient's pain threshold decreases at night. Puntillo (1991) discussed case studies where at least one patient reported a connection between time of day and intensity of pain produced by the disease state. The connection between time of day and pain response needs careful examination.

Depression and Pain Co-Occurrence

The co-occurrence of depression and pain in patients experiencing chronic pain has been documented in several studies. Keefe et al. (1986) studied 114 men and 93 women with a diagnosis of lumbar disc disease (N=207). There was little information given regarding sampling procedures in this study. Those subjects reporting rheumatoid or metabolic disease were excluded. Severity of depression was assessed with the Beck Depression Index (BDI). Other variables included physical examination findings, overt pain behaviors, pain measures, medication intake, and activity level. Pain measures included a pain intensity rating for the past 24 hours in addition to current pain on visual analogue scales, pain intensity word descriptors, and pain-unpleasantness word descriptors. Analysis of data included a regression analysis procedure to determine whether level of depression was predictive of pain measures and pain behavior. Higher scores on the BDI were related to increased pain behaviors. BDI scores did predict a significant proportion of total pain measures beyond those predicted by physical examination. The authors of this study cautioned that the analysis did not allow assumption of depression as a factor in the onset of pain or in the reoccurrence of pain. Thus, there can be no assumption of a cause and effect relationship for depression and pain. Logically, one would consider whether chronic pain also was a stimulus in depressive symptoms.

Summers, Haley, Reveille, and Alarcon (1988) reported a descriptive study involving 56 subjects who were diagnosed with primary osteoarthritis. The non-probability sample was obtained from patients being seen at a specialized clinic. There were several exclusion criteria. Variables in this study included radiographic readings of involved joint, depression level as assessed with the BDI, anxiety, coping style, pain assessed with the McGill Pain Questionnaire (MPQ), and functional impairment. The BDI was reported to be significantly related to increased pain intensity scores for present pain in addition to the

affective pain measures of the MPQ. Again, the authors cautioned against assumptions that depression was causal in relation to increased pain perception.

Hagglund et al. (1989) studied 53 subjects who were diagnosed with definite or classic rheumatoid arthritis. Depression measured on the BDI and perceptions of pain measured via the MPQ were among the variables examined. Correlations between BDI and pain measures of the MPQ were statistically significant and reported to have a moderate magnitude of correlation. Regression analysis was computed for each outcome measure. For the MPQ pain rating index, the BDI accounted for 27% of the total 41% of explained variance. Subjects with higher levels of depression perceived pain in a more negative manner.

Otto, Dougher, and Yeo (1989) selected subjects from 1027 students who completed the Edinburgh Inventory and the BDI, and who were female, right handed, and willing to participate in the study. Sixteen subjects were chosen when they scored in the depressed level of the BDI and met all other criteria; the non-depressed students were selected from the same sample. The investigators reported having selected all subjects who scored high on the BDI and met other criteria; originally, this was 26 females, but 10 of them scored below depressed levels on the BDI during the experimental sessions and thus were not included in the study. There is no information as to how many of the students were male or left handed, but the percentage of those who were viewed as depressed seems low when compared to the literature rates for young adults (Comstock & Helsing, 1976). Pain threshold was reported every 10 seconds by subjects as they had their hand immersed in a cold pressor water bath. Pain threshold was defined as the length of time it took for subjects to rate pain as slight (3 on the scale of 1 to 5) or higher. Pain tolerance also was measured and operationalized as the time needed to produce a score of 5 or 80 seconds, whichever came first. Scores on two pain trials for each hand were averaged to produce one pain threshold and one pain tolerance rating. The hypothesis of co-occurrence of depression and pain was not supported. Actually, the opposite was noted as a trend but not

at a significant level. Subjects rated as depressed had higher pain thresholds and tolerances than non-depressed subjects. In posttest interviews, there was no significant difference between depressed and non-depressed subjects in terms of their perception of the amount of pain they had experienced.

There was lack of support for a link between depression and perception of experimental pain in the Otto et al. (1989) study. Given the findings of co-occurrence of depression and pain in subjects with chronic pain, however, the contextual stimulus of depression is worthy of investigation in relation to pain perceptions of subjects receiving subcutaneous heparin injections.

Injectate Volume

Only one study has been found in the literature that examined the use of two concentrations and thus two volumes of injectate on the outcome of bruising (Mitchell & Pauszek, 1987). In this study (N=49), 24 subjects received a 10,000 u : 1 ml concentration, 0.5 ml volume injection, and 25 received a 20,000 u : 1 ml, 0.25 ml volume injection. The dose of heparin was held constant at 5,000 u every 12 hours. This study reported a significant difference between groups with the group receiving the more concentrated dose and thus smaller volume exhibiting fewer and smaller bruises. This research report was an abstract and the full report has not been found in the literature. Staff nurses administered all injections in this study. The sample was drawn from all patients who entered an intensive care unit with a diagnosis of myocardial infarction. They were assigned randomly to treatment groups (G. Mitchell-Overbee, personal communication, June 1990). Some concerns regarding this study include the small sample size. Although each subject received four injections, there was no attempt to implement a cross-over design so that subjects served as their own control. Another issue is the concentrations chosen for study; a common concentration of 5,000 u : 1 ml was not used in this study. The reported measurement of bruises was by diameter only, without calculation of surface area. Two bruises could have the same diameter but have very different surface areas.

Even with the limitations of this study, there were significant differences between groups. Although the design requires strengthening, this study underscored the need to examine the variable of injectate volume in relation to bruise formation. Pain of injections is a question that was not addressed in the study but is a question of interest.

In the analysis of two of the studies related to technique of injection, a notable difference is detected in percentage of bruising occurring when a 10,000 u: 1 ml concentration was used (VanBree et al., 1984) and when a 5,000 u:1 ml concentration was used (Wooldridge & Jackson, 1988). The former study reported a 56% bruise rate, while the latter study reported an 88% bruise rate. In both of these studies the investigators administered the injections. The difference in percentage of bruising suggests that concentration of dose and thus volume might affect bruise formation.

Summary

The effectiveness of low-dose heparin has been thoroughly investigated by medical researchers. These studies support the use of low-dose heparin therapy for those patients at risk for intravascular pathologic clotting. Nurse investigators have studied the human response to the administration of subcutaneous heparin, mainly by manipulation of injection technique. Most of these studies use bruising as a dependent variable (Brenner et al., 1981;VanBree et al., 1984; Wooldridge & Jackson, 1988). There have been a few isolated studies that considered such variables as needle size (Coley et al., 1987) and site selection (Stewart Fahs & Kinney, 1991) in relation to bruising. Coley et al. also used pain of injection as a dependent variable.

Several gaps in the research on human responses to the administration of subcutaneous heparin have been identified. There is an underlying assumption in most of the studies reviewed that bruising at injection site causes pain or psychologic distress, yet perceptions of pain at bruised injection sites have not been studied. Work reported in the chronic pain literature suggests a co-occurrence of depression and increased perceptions of pain. This link needs further study in the area of acute and experimental pain and the

current study could contribute to that body of knowledge by investigation of the co-occurrence of depression and perceptions of pain of injections and pain of bruise post-injection.

Finally, only one study has been found that addresses injectate volume of subcutaneous heparin injections. Mitchell and Pauszek (1987) examined the relationship of two injectate volumes, .05 ml and .25 ml, to bruising with subcutaneous heparin injections. Because there was a significant difference in the size of bruises produced, this study needs to be extended to include the more commonly used injectate volumes of heparin, .05 ml and 1 ml, and other dependent variables that include perceptions of pain of injection and pain of bruise postinjection.

CHAPTER 3

Methodology

This chapter contains a discussion of the methods employed in this study. The design, variables, instrumentation with scoring of the data collection tools, sample, protection of human subjects, treatment, and plan for analysis of data will be presented.

Design

A cross-over quasi-experimental design was used in this study. This design is ideal when there are many confounding variables (Beck, 1989). The design uses matching to control for variance. In this case the subjects are paired with themselves to control for residual stimuli such as ease of bruising, perceptions and cultural bias regarding pain, and some medications. The order of treatment, i.e., 0.5 ml or 1 ml injectate volume, was randomized to meet the assumptions of the cross-over design. In addition, the sequence of side of the abdomen used as injection site, i.e., left / right or right / left, was randomized.

Variables

Each variable in this study was classified as either a stimulus or a response. The main independent variable was the focal stimulus of heparin injectate volume. Subjects were assigned randomly to the order in which they received the treatments. Treatment A was heparin 10,000 u : 1 ml concentration; treatment B was heparin 5,000 u : 1 ml concentration. Thus, treatment A required a 0.5 ml injection, while treatment B required a 1 ml injection. Both treatments delivered the prescribed dose of heparin (5,000 u), administered subcutaneously in the fat pad of the abdomen. No injection was given within a 2 inch diameter of the umbilicus because of the increased vascularity of this area. Contextual stimuli such as age, sex, time of injection, medications, depressive symptoms, and diagnosis also were included as independent variables for data analysis. Dependent variables included the number and size of any bruises that formed at the injection sites and

the subject's perception of pain of each injection at the time of injection and pain at injection sites post-injection.

Instrumentation

Center for Epidemiologic Studies Depression Scale (CES-D)

Depression was measured using the CES-D. This tool is a self-report scale that was specifically designed for use in research of depressive symptoms in the non-psychiatric population. The tool assesses feelings of state depression focusing on levels of functioning during a preceding 1 week period of time. The CES-D Scale has several advantages that made it useful in this study. It is short, with 20 items that were administered by the principal investigator. The tool can be seen in Appendix A. It is in the public domain and may be used without copyright permission (Bourden, 1990; personal communication).

The CES-D Scale was developed by pooling items that reflected depression, as discussed in the literature, from several previously validated depression scales (Radloff, 1977). Four of the 20 items are worded in a positive direction. These items are numbers 4, 8, 12, and 16 and require reverse scoring. The remaining items are scored 0 to 3. Possible scores range from 0 to 60 (Radloff & Locke, 1986).

Based on the literature, the CES-D Scale is considered to have adequate reliability (Devins & Orme, 1985). Test - retest scores have been correlated at r=.51-.67 over a period of time ranging from 2 weeks to 2 months. Longer test - retest scores produced coefficients of r=.48 to .54 over a 3 month to 1 year period of time. Cronbach's alpha has been used to measure the internal consistency of the CES-D Scale. Cronbach's alpha coefficients have been reported for this tool between .84 -.90.

Criterion validity was established during field testing when the CES-D Scale items were incorporated among 300 items that included other scales designed to measure many affective attributes, including depressive symptoms (Radloff, 1977). The CES-D Scale correlation coeffiecients were .51 and .70 with the Lubin Scale and .60 and .55 with the Bradburn Negative Affect Scale at the two test sites. Radloff (1977) reported ". . . the

pattern of correlations of the CES-D with other scales gives reasonable evidence of discriminant validity" (p. 393).

Weissman, Sholomskas, Pottenger, Prusoff, and Locke (1977) conducted a study to validate the CES-D Scale via testing across five psychiatric populations and compared results with community statistics. Subject groups in the study included inpatients diagnosed as being acutely depressed, patients who had recovered from acute depressive episodes, drug addicts, alcoholics, and schizophrenic patients. Subjects with a psychiatric diagnosis numbered 406; these individuals were compared with a community sample of 3845 randomly selected adults. Correlations between the CES-D Scale scores and Raskin Depression Scale, the Symptom Checklist ,and the Hamilton Clinical Rating Scales were all highly significant (Weissman et al.). The Weissman et al. study also found that the CES-D Scale was able to differentiate psychiatric subjects from community subjects. The acutely depressed subjects all scored high on the CES-D Scale (x= 38.10). Recovered depressed subjects had a mean of 14.85, below the cutoff of 15.5 for a depressed rating but above the community mean. Subgroups of depressed patients among the drug addict, alcoholic, and schizophrenic populations were accurately assessed via the CES-D Scale.

Discriminate validity can be assessed by comparing a tool to variables with which there should be little or no correlation. Both Radloff (1977) and Weissman et al. (1977) reported that the CES-D Scale had adequate discriminate validity.

Scores on the CES-D Scale were calculated by summing responses to items 1 through 20. Although official scoring was not done until after both injections were given, if the investigator administering the tool saw indication of a particularly high score the tool was summed and some intervention occurred. Intervention occurred for any CES-D score over 31.

Visual Analogue Scale (VAS)

The VAS was used to measure the dependent variable of perception of pain intensity at the time of injection. The visual analogue scale was a vertical design. The

bottom anchor of the scale indicated no pain and the top anchor indicated the worst possible pain; the scale was 10 centimeters (cm) long. Scores can range from 0 to 10 cm. It is assumed that this tool is in the public domain, because the scale has been used extensively and was developed over 60 years ago. See Appendix B for a copy of the VAS that was used in this study.

Gift (1989) reported that the vertical VAS has increased sensitivity, produces higher scores, and is easier to use than the traditional horizontal VAS. Gift notes that criterion referenced validity of the VAS often has been obtained by comparison with the Present Pain Intensity (PPI) portion of the McGill Pain Questionnaire (MPQ). Melzack (1987) reported using a VAS to validate the pain intensity segment of the MPQ-SF. The two tools correlated at a significant to highly significant level across groups of subjects experiencing musculoskeletal, postsurgical, and labor pain. Levin (1982) established criterion validity of the VAS by correlating pain scores and a verbal descriptive scale that was ". . . divided into one inch intervals and labeled 0= no pain; 1 = mild pain; 2 = moderate pain; 3 = quite a lot of pain; and 4 = very bad pain" (p. 29). The two scales were highly correlated (r=0.843) when measuring perceptions of momentary pain caused by intramuscular injections.

Price, McGrath, Rafii, and Buckingham (1983) reported that the VAS was reliable and valid as a measure of intensity in both experimentally induced and chronic clinical pain. Comer Davis (1989) reported a moderate concurrent validity (p=0.58) for the measure of pain intensity when comparing the PPI segment of the MPQ with a VAS. The tools were tested in a study that measured pain perceptions of two groups (N=60), one experiencing chronic pain and the other experiencing acute pain.

McGuire (1984) compared the use of instruments to measure the concept of pain. The validity of the VAS often is assumed in the literature; thus, McGuire rated the VAS as having probable validity and good reliability. In a later review of tools to measure pain, McGuire (1988) stated that the reliability of the VAS in measuring pain intensity was ". . .

relatively well established" (p. 340). Gift (1989) stated that the VAS was reliable when test-retest is carried out. Gift did note that reliability coefficients have been found to be higher when testing was done at closer intervals; the relationship was closer when retest was done at 2 hours versus 2 weeks.

Because the current study used the VAS 12 hours apart, there should be adequate reliability. Roy (1984) defined pain as what the patient says it (pain) is, and intensity is one attribute of pain. The VAS is a self-report of the subjective attribute of pain intensity; thus, face validity of the VAS was assumed in this study.

A ruler was used to score the VAS scales used in this study. A measurement in centimeters (cm) was taken from the bottom of the scale to the point where the subject marked to indicate pain intensity. This was considered a continuous interval level measurement (McGuire, 1984). Each subject had two vertical VAS measurements, one for each injection included in the study.

McGill Pain Questionnaire- Short Form (MPQ-SF)

Melzack (1987) reported the development and testing of the MPQ-SF, which was specifically developed for research in areas such as pharmacologic studies where it is desirable to obtain data more quickly than with any of the other four forms of the MPQ. The SF seems applicable to the current study for two reasons: (a) it is easily administered to patients who may be experiencing other types of discomfort during this study from disease states or treatments other than the heparin injections being studied; and (b) it is short enough to be less likely a deterrent to participation. The MPQ-SF consists of three parts with five scores. Part 1 lists 20 words descriptive of pain sensations. Terms 1-11 represent the sensory attributes of pain experience, while terms 12-15 indicate the affective dimensions of pain. Each descriptor is ranked on a scale 0 = none to 3 = severe. The entire fifteen item list is considered representative of the total pain score. The evaluative portion of the MPQ-SF provides two measures: (a) a horizontal VAS anchored no pain and worst possible pain and (b) a present pain intesity forced choice scale that ranges from 0 =

no pain to 5 = excruciating pain. This tool can be seen in Appendix C. Permission to use the MPQ-SF was obtained from the tool originator (R. Melzack, personal communication, July, 1990).

The MPQ-SF was tested with the McGill Pain Questionnaire-Long Form (MPQ-LF) by Melzack (1987). The original testing included three groups of subjects- those experiencing postsurgical pain, those with obstetrical pain, and subjects with musculoskeletal pain -for a total sample size of 70. The LF always was followed by the SF in this study. A second study was completed in which the order of administration of the LF and SF was randomized. Melzack (1987) reported that total pain scores and the two subgroups of affective and sensory scores were significantly correlated with the same areas on the MPQ-LF. Sensitivity was assessed by Melzack (1987) by comparing changes in pain intensity before and after analgesic administration or pain therapies, including transcutaneous electrical nerve stimulation and epidural blocks. The MPQ-SF was able to pick up the changes in pain intensity at a significant level.

There is much discussion in the literature regarding the use of the MPQ in the assessment of pain. Funk, Tornquist, Champagne, Archer Copp, and Wiese (1989) note that the MPQ is widely used and accepted in pain research. It is considered to be a valid and reliable instrument. This writer was unable to find studies that have utilized the newest form of the MPQ, the SF. This is understandable because the tool first appeared in the literature in 1987, and research using this tool is unlikely to be reflected in the literature this soon. The tool has been well constructed and subjected to rigorous testing by the originator, who is well known for tool development in the area of measurement of pain perception. Roy (1984) noted that sensation and character as well as intensity are important components of pain assessment. The MPQ-SF encompasses sensory, affective, and intensity indicators and thus is judged to be an appropriate tool to use in the current study for assessing the subjective perception of pain of bruise at injection site postinjection. In the evaluative section of the MPQ-SF, the VAS is horizontal. It was felt by this writer that

this VAS visually was different from the vertical VAS used to measure pain of injection. Thus, subjects would be more likely to distinguish which attribute was being measured. Because measurement of pain of injection and measurement of pain of injection site were done only a few days apart, it was imperative that the subjects be able to distinguish what was being measured. It is particularly important to measure more than intensity for the variable of pain of bruise, because there are no empirical data regarding perceptions of pain of bruising at injection site, yet pain of bruise often has been assumed as a reason to study response to heparin injections.

In this study, the MPQ-SF was administered twice to each subject, by either the PI or research assistant. This occurred at the 60-72 hour mark postinjection for each injection. Each of the 15 one-word terms had a possible score of 0 to 3. The sensory portion of the tool (items 1-11) had a possible score of 0 to 33. The affective portion (items 12-15) had a possible score of 0 to 12. The total pain score included all 15 items and could range from 0 to 45. In the evaluative portion, the 10 cm VAS was scored by using a ruler to measure from the left edge, no pain, to the point that the subject had marked. This measurement was reported in centimeters. The PPI score consisted of the numerical value indicated by subjects as reflective of their present pain intensity at injection site. The possible scores for PPI ranged from 0 to 5.

Bruise Measurement

Each injection site was observed for bruising within 60 to 72 hours post-injection. VanBree et al. (1984) and Brenner et al. (1981) used a similar time frame that encompassed the 60 hour point for measurement because it follows the physiologic principle of bruise formation. VanBree et al. noted that bruises peaked within 48 hours of insult and resolved no sooner than 72 hours. Stewart Fahs and Kinney (1991), however, found that bruises had not reached full size by the 48 hour postinjection time period but were fully formed by 60 hours and had not resolved by 72 hours. The method of tracing the bruise at injection site to calculate surface area has been used in several research studies (Stewart Fahs &

Kinney; Wooldridge & Jackson, 1988) and found to be highly accurate when compared with direct surface measurement, r =.86 to .91, thus establishing reliability. The method that was used also had high face validity for measuring bruising at injection sites. Inter-rater reliability of measuring the surface area by means of tracings was established at r=0.94 to 0.99, significant at the p=0.001 level on a total of 105 injection sites at four points over a period of 4 months among four raters (Stewart Fahs & Kinney). Once a tracing is taken, the calculation of surface area can be done by hand or computer.

In this study if a bruise was present at the injection site 60 to 72 hours after injection, it was counted as a one; if no bruise existed, a zero was used to denote count. Surface area was calculated by placing a piece of plastic wrap over the injection site at the 60 to 72 hour postinjection time period. Any discoloration was traced with a fine tip ball point pen. The traced bruise outline then was traced onto the back of the subject's data collection sheet via carbon paper. The area within the outline tracing was blackened with a felt tip marker. The surface area of the bruise was calculated from the tracings. An Apple Scanner was used and the scan was analyzed for surface area using the Image computer software for the MacIntosh Computer. This software is in the public domain. The scan was done at 300 pixels per inch and converted to mm^2 by the computer with the conversion of 283 pixels per mm. If no bruise was present the surface area was noted as 000.00 mm^2.

Medications

The American Hospital Formulary Service (AHFS) was used to classify medications into groups for analysis (McEvoy, 1990). Only medications that might affect the contextual stimulus of depression or the subject responses of bruising or pain were classified. A list of medication class and numbers of subjects who received each class can be seen in Table 2.

Drugs that fell within the 28:08.08 class included but were not limited to morphine, meperidine, acetaminophen with oxcodone, and acetaminophen with codeine. This class included both oral and parenteral routes of administration. The drugs also varied in

potency. The system reported by Spencer (1989) for calculating the equivancy of units of pain medication and whether the medication commonly is used to relieve mild, moderate, or severe pain was used in this study. The equipotent doses for moderate and severe pain were expressed in intramuscular (IM) or oral, per os (PO), doses approximately equivalent in total analgesic effect to 10 milligrams (mg) of morphine IM. The equipotent doses of analgesics most often used for mild pain relief were expressed in doses approximately equivalent in total effect to aspirin 650 mg PO. Spencer also gives directions for calculating intravenous (IV) doses of analgesics in equipotent units. The analysis of effects of medications included breaking down the 28:08.08 class of analgesics into equipotency units and severity level. For example, if a subject received meperidine 75 mg IM it was coded as 1 equipotent unit and as a 1 on the severity level because meperidine 75 mg is approximately equivalent to morphine 10 mg IM and is used for relief of severe pain. Acetaminophen with oxcodone 30 mg PO is rated as being approximately equilavent to morphine 10 mg IM; thus, acetaminophen with oxcodone 60 mg received a code of 2 equipotent units and a 3 or moderate on the severity level.

Subjects

Sample

The non-probability sample consisted of 50 individuals who each received two treatments. The ordering of treatments was randomized in this cross-over, quasi-experimental study. One of the major advantages of the cross-over design is the decreased number of subjects required (Beck, 1989).

To calculate the sample size for this study, a power analysis was completed. The following steps were used to project the sample size of 50 subjects.

1. Significance criterion = .05
2. Effect size = a medium effect size of .50 was expected, based on review of the literature regarding the incidence of bruise formation from subcutaneous heparin injections (Stewart Fahs & Kinney, 1991; Wooldridge & Jackson, 1988).

3. Desired power level = A conventional power level of 80 was used.
4. Given a =.05, power =80, and effect size =.5, the sample size is 50 (Cohen, 1977).

To protect the power of any statistical analysis done in this project, the investigator collected data on an additional 5 subjects. This was 10% above the required sample size and decreased the likelihood that the power would be decreased due to missing variables or loss of subjects from the study. The power analysis was for the major question of bruise occurrence and size. No power level was calculated for the other hypotheses because no previous studies have measured the response of pain of heparin injections or pain of bruising; thus, projection of effect size was not possible.

Inclusion Criteria

Potential subjects were 18 years of age or older and classified as general medical surgical patients. The sample was drawn from patients who were hospitalized at an acute care facility in the northeast United States. To be included in the study, patients had a written prescription for low-dose heparin (5,000 u every 12 hours), had received heparin injection number 1 as prescribed, and were free from blood dyscrasias or active liver disease as indicated on medical history and physical examination. Subjects had a minimum of 25 mm of subcutaneous tissue as measured by caliper at injection site. A randomized list of order of treatments and side of injection was constructed prior to the study and was used to assign subjects to treatment order.

Medications other than subcutaneous heparin that lengthen clotting time were a factor that excluded participation in this study. Examples included intravenous heparin prior to measurement of responses, coumadin, and aspirin in doses greater than 975 mg per day.

Procedure

Protection of Human Subjects

This study was approved via expedited review by the Institutional Review Board for Human Use at the University of Alabama at Birmingham. Study site approval was gained from the Institutional Review Board at United Health Services in Johnson City, New York.

Physicians were approached as a professional courtesy prior to patients under a physician's care being asked to participate in the study. All physicians in the institution who would possibly prescribe heparin received a letter explaining the study. These physicians were asked to give permission to approach any of their patients who met inclusion criteria. Physicians had the option of signing a form requesting notification prior to approaching any patient or declining the request to approach any patient where that physician was listed as the attending physician. Potential subjects were given information regarding the project prior to participation. Data collection procedures, analysis, and reporting of findings were undertaken in a manner designed to protect confidentiality of subjects.

Treatment

When a patient had a prescription for low-dose heparin, the nursing staff notified the principal investigator via phone or beeper. All hospital units except the Critical Care Unit were used for data collection. The staff was instructed to administer dose 1 as prescribed. The PI saw all patients with a prescription for low-dose heparin if their physician had agreed that they be approached for participation. The study was explained to the patient and any questions answered. If the patient met inclusion criteria and agreed to participate, a note was made on the medical record and nursing Kardex indicating participation in the study. A note was sent to pharmacy and placed on the medication kardex indicating that the principal investigator would administer doses 2 and 3 of prescribed heparin. Adipose tissue measurements of the abdomen were taken with calipers prior to injection 2 and reported in milimeters.

The CES-D Scale was administered after all inclusion criteria were met. The typed 20 item tool was presented on one page. Although the tool may be self-administered, most subjects preferred that the PI mark their responses on the tool. All subjects were given the same explanation of the tool, which was that the items were designed to find out how they had been feeling in the past week. Subjects were instructed to answer each item in relation to how often the item had been experienced in the past 7 days. They were given the choice

of providing a numerical value or word answer for each question. The responses for each item included 0 or none, 1 or a little, 2 or a moderate amount, and 3 or most of the time. Each item was read to the subject. If the subject indicated a need the item was reread.

All subjects had received injection 1 of the subcutaneous heparin prior to inclusion. Injections 2 and 3 only were considered during this study. This standardization was designed to add homogeneity to the sample. Avoiding the first injection had the added advantage of controlling for those subjects who have never had an injection into the abdomen and in whom fear of the injection site might influence perception of injection pain.

The injectate volume for injection 2 was chosen from the radomized list. Thus, if the injectate volume for injection 2 was 1 ml, then injection 3 was 0.5 ml. Prior to injection, the abdominal site was inspected for excoriation, lesions, and bruising. Site identification included the principles of general consideration for subcutaneous injections as detailed in Sorensen and Luckmann (1986). These authors note " . . . any site is acceptable if it meets the following criteria: It is not over a bony prominence, it is free of large blood vessels or nerves and it is free of inflammation, excoriation, itching, tenderness, edema and scar tissue" (p. 1081). Application of these principles was incorporated into inspection of the abdomen for appropriate injection site.

The side of the abdomen for site of injection 2 was indicated by the randomized list generated prior to the study. Injection 3 was given in the opposite side of the abdomen. Thus, if injection 2 was given in the left side, then injection 3 was administered in the right side of the abdomen. This randomization was done to control for pain perception and laterality with increased right hemisphere activation (Otto et al., 1989).

The principal investigator administered heparin injections 2 and 3, using a protocol that was consistent with the standard of practice for subcutaneous heparin injections at the data collection site. The area around the injection was marked with a felt tip pen so that the area could be identified when the bruise response was measured. The principal investigator

is a registered nurse in the state where data were collected and by virtue of education and experience is qualified to administer subcutaneous injections.

The standardized procedure for injection of low-dose heparin was as follows: A 1 ml tuberculin syringe with 25 gauge, 5/8 inch needle was used. The injection was given deep subcutaneously at a 90 degree angle without aspiration. Injectate was administered over a 10 second period of time. The needle was withdrawn at the same angle as insertion. Gentle pressure of no more than 10 seconds was applied with an alcohol swab. The dose of medication was documented on the medication sheet that is a permanent part of the subject's medical record. The injection number, site, date, and time also were recorded on a diagram of the abdomen. This diagram was placed in the medication kardex until bruise response was measured. This sheet gave the prinicpal investigator and research assistant a point of reference as to which injection site was to be measured for each injection. The sheet was removed from the medication kardex at the time of measurement of response at the injection 3 site.

The vertical VAS tool was administered at the time of each injection. The tool was explained as measuring how much pain, if any, the subject experienced with each injection. The topic of pain of injection was introduced to each subject by the statement "Some people think these injections cause some pain while others do not believe they cause any pain." Subjects were given a pen or pencil and asked to place a mark across the VAS at the point they believed best indicated how much pain they had with the injection, with the bottom of the scale indicating no pain and the top indicating the worst possible pain. Subjects were told they could mark the pain scale when the principal investigator walked away from the bedside to dispose of the needle after the injecion. They were instructed to fold the VAS when it was completed and place the paper in the envelope provided. The tool had previously been coded for subject and injection number. The envelopes for the two injections were sealed and not opened for analysis until after both treatment injections had been administered.

Between 60 and 72 hours after injection 2 and again after injection 3, the prinicipal investigator or research assistant saw the subject to measure the response of bruise occurrence, size, and pain at the respective injection site. Most measurements were taken while the subject still was an inpatient at the data collection site. If the patient had been discharged, however, the prinicipal investigator asked permission to come to the home to take the measurements. For all subjects, bruise occurrence was noted and if present a tracing of the bruise outline was taken.

At the time of each bruise measurement a McGill Pain Questionnaire - Short Form was completed. Subjects were instucted to mark the tool to indicate the sensation they currently felt at the site of the injection. This tool was completed regardless of whether there was a bruise at the injection site. The tool may be self-administered but most subjects preferred for the researcher to read each of the 15 terms. Responses were given either numerically or verbally. The choices were 0 or none, 1 or mild, 2 or moderate, and 3 or severe. The evaluative portion of the form included a horizontal VAS and the Present Pain Intensity (PPI). Subjects were asked to put a mark across the VAS at a point that indicated how much pain they currently were experiencing at the injection site. They then were asked to mark the PPI in regard to the intensity of current pain experienced at the injection site. Choices for the PPI were 0 indicating no pain, 1 or mild, 2 or discomforting, 3 or distressing, 4 or horrible, and 5 or excruciating. After the measurement of injection site 3, subjects' participation in the study was completed.

Demographic Data

Information was collected on age, sex, primary diagnosis, and surgical interventions for each subject. The type, date, and time of surgery were noted. In addition, data were collected on medications received from 24 hours before injection 2 to the time of measurement of injection 3 site. Medication information included brand or generic name, dose, and time of administration.

Cost of Preparation

Calculation of variance in cost of preparation between concentrations was based on cost per dose. Vials of heparin were used in this study instead of prepackaged injectable cartridges. Because nursing time is required to draw up the prescribed dose when vials of heparin are used, preparation time was calculated for each concentration and analyzed based on nursing time.

A pilot study was conducted to calculate cost of preparation of the injection. Five registered nurses each drew up 2 heparin injections, 1 of each injectate volume included in this study. The order of preparation was randomized and the time to prepare each injection was assessed via use of a stop watch. In addition, information was obtained from the pharmacy at the data collection site regarding the acquisition cost per vial of each concentration of heparin studied.

Data Analysis Plan

The chi square measure of association was used in the analysis of hypotheses 1 and 4. The chi square statistic does not show causality between variables but rather is a test for independence. This analysis is used to determine whether membership in one group, in this case injectate volume, is related to membership in another group, bruise occurrence (Visintainer, 1986). If the chi square has a cell with an expected frequency of less than 2 or a count of 0, then the Fisher's exact test is the appropriate statistic (Waltz & Bausell, 1981).

The focal stimulus of volume is a discrete independent variable and was used in the analysis of variance (ANOVA) to test hypotheses 2, 3, and 8. Waltz and Bausell (1981) note that ANOVAs are used to test whether group means differ, both between and within groups. To use the ANOVA procedure appropriately, the independent variable should be discrete and the dependent variable should be at the interval level or higher. The dependent variable of bruise surface area is at the interval level. The general linear model (GLM) is a type of analysis of variance procedure that may be used when groups are unequal in size.

This statistical procedure was carried out for both injections 2 and 3. The class or independent variable had 2 levels, 1 = 0.5 ml and 2 = 1.0 ml of injectate volume. The model for this test was bruise surface area.

A Pearson correlation coefficient was computed for testing hypotheses 5, 6, and 7. This test was also performed in addition to the chi square for hypothesis 4. Correlations indicate the strength of relationship between variables and whether the relationship is positive or negative.

CHAPTER 4

Analysis

This chapter addresses the analysis of data. Data analysis was accomplished using the Statistical Analysis Software available on personal computer (SAS PC) version 6.03 (SAS, 1988). This statistical package has a full range of descriptive and inferential statistics that allowed for appropriate analysis of the data from this project. The research hypotheses were stated in a directional manner to increase the power of analysis. The alpha was preset at the .05 level. Statistics were reported by symbol, including degrees of freedom, sample size (N), value, and probability (p).

Null Hypothesis

The following null hypotheses are stated in written and proposition form. The proposition form also contains the alternative hypothesis.

1. There will be no difference in bruise occurrence produced by 0.5 ml and 1 ml injectate volume of heparin administered subcutaneously.

$H_0: \mu = \mu_0$ vs. $H_1: \mu \neq \mu_0$

2. There will be no difference in bruise size produced by 0.5 ml and 1 ml injectate volume of heparin administered subcutaneously.

$H_0: \mu = \mu_0$ vs. $H_1: \mu \neq \mu_0$

3. There will be no difference in pain of injection produced by 0.5 ml and 1 ml injectate volume of heparin administered subcutaneously.

$H_0: \mu = \mu_0$ vs. $H_1: \mu \neq \mu_0$

4. There will be no association between physiologic respoonse of occurrence of bruising and the response of pain at injection site measured 60 - 72 hours postinjection.

$H_0: p = 0$ vs. $H_1: p \neq 0$

5. There will be no association between physiologic respoonse of size of bruise and the response of pain at injection site measured 60 - 72 hours postinjection.

$H_0 : p = 0$ vs. $H_1 : p \neq 0$

6. There will be no association between level of depression and the pain at time of injection.

$H_0 : p = 0$ vs. $H_1 : p \neq 0$

7. There will be no association between level of depression and the response of pain at injection site measured 60 - 72 hours postinjection.

$H_0 : p = 0$ vs. $H_1 : p \neq 0$

8. There will be no difference in cost of preparation of a subcutaneous heparin injection between 0.5 ml and 1 ml injectate volumes.

$H_0 : \mu = \mu_0$ vs. $H_1 : \mu \neq \mu_0$

Description of Subjects

Number of Subjects

Data were collected on 56 subjects. Six subjects were dropped from the study for the following reasons: (a) 2 received the third heparin injection from a staff nurse (1 due to miscommunication early in the study and the other due to a major snow storm that kept the PI from traveling to the data collection site); (b) 1 subject received intravenous heparin between the time of injection 3 and time of injection site measurement; (c) 1 subject decided not to participate in the study after signing the consent form; and (d) 2 subjects had bleeding at one injection site that was witnessed by the PI at the time of the injections. The first round of analysis was completed on 50 subjects.

Demographic Data

The mean age of subjects was 52.36 years, with a mode of 28 years. There was a span of 57 years between the youngest subject (age 20) and the oldest (age 77). Thirty-two subjects were 60 years of age or younger, comprising 64% of the sample, while 18

subjects were 61years or older (36%). There were 36 females and 14 males. Of the 61 years or older group, 10 were females and 8 were males. All subjects were Caucasian.

Information was gathered on primary diagnosis and was grouped according to the body system affected. In descending frequency, 19 subjects had diseases affecting the female reproductive system, 18 had gastrointestinal problems, 3 had cardiovascular illness, 3 had genitourinary problems, 2 had skin afflictions, 2 were classified as other, and 1 subject had a musculoskeletal problem. The catagory of other, included sequelae from previous surgical interventions, including adhesions and surgical hernias.

Forty-six subjects had surgery. Surgeries also were grouped by system affected. Twenty subjects had gynecologic surgery, 18 had surgery of the gastrointestinal system, 2 had genitourinary procedures, 2 had surgical repair of sequela of previous surgical procedures, 2 had circulatory surgeries, and 2 had orthopedic surgery.

Data Analysis

The first round of data analysis was completed on 50 subjects. The second round of data analysis included 48 subjects when the response of interest was bruise surface area. This second round of analysis was necessary to rid the data set of 2 outliers in bruise surface area measurement. To identify these outliers, a calculation was done to detect the amount of difference in bruise surface area between bruises 2 and 3. There was a mean difference between bruises 2 and 3 of .61 mm^2. Two observations showed a difference of more than 900 mm^2 between bruises. The extremely large bruise occurred at injection 2 site (1 ml injectate volume) for one subject and injection 3 site (0.5 ml injectate volume) for the other subject. Although the reason for these outliers in surface area measurement is unknown, this writer speculates that the sites in question may have bled post injection without the subject or PI being aware or that the site may have been rubbed or bumped post injection and prior to bruise measurement. The mean surface area for each injection on rounds 1 and 2 of data analysis is plotted in Figure 2. In round 1 (N = 50) the standard

deviation of bruise 2 surface area was 71.09 mm^2, while bruise 3 surface area standard deviation = 65.15 mm^2. When all bruises in round 2 analysis were considered (N = 96), the mean surface area was 30.40 mm^2, standard deviation = 67.83 mm^2.

Instrument Measurements

CES-D

The range of the CES-D Scale was 0 to 42 from a possible 60 points. The overall mean was 17.24 points with a standard deviation of 11.38. The mode was 8. Total scores, means, and standard deviations for each subject can be seen in Figure 3. Depending on the analysis procedure used, the CES-D scores could be continous (n = 50) or discrete. Used as a discrete variable, there could be four levels of symptoms of depression: none (n = 28), mild (n = 6), moderate (n = 7), and severe (n = 9); or two levels of sypmtoms of depression: low (n = 28) and high (n = 22). Subjects who received intervention for severe CES-D scores (n=9) were told by the researcher that the test indicated they had experienced a difficult time in the past week and might be feeling depressed. They were told about the master's prepared Psychiatric Clinical Nurse Specialist (CNS) at the hospital and that this person would be in to talk with them about how they were feeling. In addition, the principal investigator made a note as to the score and possible interpretation in the patient's progress notes and a referral was made to the CNS who saw these patients at least once.

Those subjects 60 years or younger had a mean CES-D score of 13.94, standard deviation of 11.07, while those 61 or older had a mean CES-D score of 19.09 points, standard deviation of 11.30. When sex was analyzed, females (n =42) had a mean CES-D score of 18.64, standard deviation of 11.79, while males had a mean score of 13.64, standard deviation of 9.76. The Pearson correlation coefficient values and probability levels of the CES-D with pain of injection (VAS) and pain of postinjection site (MPQ-SF) can be viewed in Table 3.

VAS

The vertical VAS pain of injection scale was completed (N=50) for both injections 2 (n= 50) and 3 (n= 50). The mean VAS for injection 2 was 0.77 cm on the 10 cm scale, standard deviation 1.15 cm. Injection 3 VAS mean was 1.19 with a standard deviation of 1.95 cm. The Pearson correlation coefficient used to analyze the relationship between injections and VAS scores was r=.33, indicating a moderate positive relationship. Difference was calculated by subtracting injection 3 VAS scores from those of injection 2. The difference (M=-0.42 cm) was not statistically significant, p=.12. Figure 4 shows the relationship of VAS scores by injection using the original data. One subject rated pain of injection 3 as 10 cm. On the second round of analysis this outlier was excluded from the data set. Descriptive analysis of the new data set (N=49) produced a mean of .78 cm, standard deviation = 1.15 cm, on injection 2 and a mean of 1.01 cm, standard deviation = 1.50 cm, on injection 3. The Pearson correlation coefficient of the VAS scores on injections 2 and 3, using the new data set, was r=.50, indicating a moderate positive relationship between the two scores.

Very few subjects reported pain of injection site postinjection, mode = 0. The number of responses other than zero can be seen for each section of the MPQ-SF in Table 4. There was consistency in scoring between injections 2 and 3 for most subjects. The response on individual items 1-15 was low with the range of means 0.02 to 0.14. Tender was the description with the highest mean for both injections. The scores on the MPQ-SF were extremely similar on all measures for the two injections. The mean scores and standard deviations for injection 2, injection 3, and both injections superimposed can be seen in Figure 5. The overall means for the sensory, affective, and total pain score portions of the MPQ-SF for both injections can be seen in Figure 6.

Bruise Measurement

Most bruises were measured 12 hours apart because injections were administered 12 hours apart. If a subject was discharged from the institution, an attempt was made to go to the subject's home to measure the injection site response as close to 72 hours as possible. Occasionally, it was necessary to obtain the measurements for injection sites 2 and 3 at the same time. In these cases the sites were measured 72 hours after injection 2 and 60 hours after injection 3.

Interrater reliability for bruise occurrence and surface area was calculated between the prinicpal investigator and another nurse researcher who was not otherwise involved in the data collection and between the prinicpal investigator and a research assistant for a total of 36 injection site measurements. The agreement for bruise occurrence was 100% ($r = 1.00$) among all three researchers. The Pearson correlation coefficient for surface area measurements ranged from $r = 0.91$ to $r = 0.99$.

Medications

All 50 subjects received medications other than heparin, the focal stimulus in this study. Most medication classes had numbers too small to use in data analysis as seen in Table 2. Forty-six subjects received medication, however, in the 28:08.08 class that includes analgesics that are opiate agonists. Opiate agonists bind at receptor sites in the central nervous system and other tissue. They produce analgesia. These drugs reportedly alter perception of pain (McEvoy, 1990). The prototype in this class is morphine.

Hypothesis 1

To examine the relationship between injectate volume and bruise occurrence at the injection site, two nominal level variables were needed. Bruise occurrence was rated as 1=yes or 2=no. Injectate volume was labled .5 ml = 1 and 1 ml = 2. The frequency of bruise occurrence, regardless of volume, for both injections is represented in Figure 7. A further analysis of occurrence by injectate volume indicated that for injection 2, there were

19 bruises for the 26 doses of heparin given using 0.5 ml injectate volume and 16 bruises for the 24 injections of the 1 ml injectate volume. With injection 3, the 0.5 ml injectate volume group, 17 of 24 sites bruised, while 16 of the 26 sites in the 1 ml injectate volume group bruised. Chi square analysis of injection 2 showed χ^2 (1, N=50) = 0.24, p=.62. For injection 3, χ^2 (1, N=50) = 0.48, p=.48. These results were not statistically significant, leading to failure to reject null hypothesis 1.

Hypothesis 2

The GLM with injectate volume and bruise 2 surface area was F(1. 49) = 2.15 and p=.15. For injectate volume and bruise 3 surface area, the F (1,49) = .98 and p=.33. There were no statistically significant differences among the means of surface area for injectate volume in either bruise surface area 2 or 3. The analysis of bruise surface area produced by injectate volume was repeated in round 2 analysis with the data set that was purged of outliers. With N = 48, again, no significant difference was found, F (1,47) = 1.46, p =.23, for injection 2 and F (1,47)=.03, p =.85, for injection 3. Less variance, however, was evident in injection 3 for round 2 analysis. There was failure to reject null hypothesis 2.

Hypothesis 3

ANOVA was computed for both injections 2 and 3 with volume as class and pain of injection as the dependent variable. Injection 2 produced F (1, 49) = 0 .11, p =.74 (M =.77 cm), among the two injectate volumes, and injection 3 produced F (1, 49) = 3.08, p =.08 (M = 1.19). Neither ANOVA was statistically significant.

Because the ANOVA for pain of injection 3 indicated a great deal of variance, a post hoc Tukey test was performed on the first round of analysis. For injection 3 the mean pain score of subjects receiving the injectate volume of .5ml was 1.69 cm, while those receiving injectate volume of 1 ml had a mean pain score of 0.73 cm; the difference was not significant at an alpha of .05. The variance for injection 3 VAS scores led to a second

round analysis where 1 outlier was identified and removed from the data . The repeat analysis of volume and injection 2 VAS pain scores (M = .78 cm) resulted in F (1,48) = 1.92, p = .17, and in injection 3 VAS (M = 1.01), F (1,48) = 0.82, p = .36. Because there was less variance in VAS scores on round 2 analysis the post hoc analysis was not repeated. There was failure to reject null hypothesis 3.

Hypothesis 4

There was a weak negative correlation between the occurrence of bruise at injection site 2 and the total pain score on the MPQ-SF at r=-.14, p=.30. A similar relationship existed with bruise occurrence and total pain score for injection 3, r=-.16, p=.25. Bruises occurred in 35 subjects (70%) for injection 2 and 33 subjects (66%) for injection 3. Few subjects reported pain of bruising for either injection. Of those 15 subjects who did not bruise with injection 2, none experienced postinjection site pain as measured on the MPQ-SF. Similar data were produced by injection 3. For the third injection 6 (18%) of those who bruised reported pain at the injection site postinjection. No pain was reported by those who did not bruise.

A 2x2 table of bruise occurrence and pain of injection site 2 can be seen in Table 4. The 2x2 table of bruise occurrence and pain of injection site 3 can be seen in Table 5. There was a weak to moderate positive association between bruise occurrence and pain of injection site. The results were not statistically significant; thus, there was failure to reject null hypothesis 4.

Hypothesis 5

To test hypothesis 5, a correlation was computed between the bruise surface area and each of the five scores derived from the MPQ-SF. The correlation coefficients and two and one tailed rho can be seen in Table 6. Injection 2 bruise surface area showed a weak negative correlation with the MPQ-SF. Injection 3 had both positive and negative

correlations between bruise surface area and MPQ-SF. Again, all the relationships were weak and none were statistically significant. There was failure to reject null hypothesis 5.

Hypothesis 6

The CES-D Scale measuring depressive symptoms prior to either injection 2 or 3 was given once to each subject. In the statistical analysis, the CES-D Scale total score was kept as a continous variable. A Pearson correlation coefficient was performed to determine the strength of the relationship between the CES-D Scale score and the pain of injection for both injections 2 and 3.

The minimum CES-D Scale score was 1 with a maximum of 42 out of a possible score of 60. The mean CES-D score was 17.24 with a standard deviation of 11.33 (N=50). Immediately after injection 2, subjects indicated they experienced pain from 0 to 4.7 cm on the vertical VAS pain scale, with a mean of .77 cm and a standard deviation of 1.15 cm. The Pearson correlation coefficient was r=.07 between CES-D score and pain of injection. This was a weak positive relationship and not significant at $p = .66$ two tailed and $p = .33$ one tailed.

Injection 3 had a range of pain of injection from 0 cm to 10 cm with a standard deviation of 1.95 mm. The Pearson correlation coefficient between CES-D and pain of injection 3 was r=.19, $p = .18$ two tailed and $p = .09$ one tailed. The mean for injection 3 pain levels was higher than for injection 2. This probably occurred because one observation in injection 3 was an outlier with a score of 10 cm on the pain scale. The correlation coefficient indicated a mild positive relationship but at a level that was not statisically significant.

The correlation analysis was redone without the outlier and the results were r=.05 $p = .72$ two tailed and $p = .31$ one tailed, again revealing no significant difference for CES-D score and pain of injection as measured on the VAS. There was failure to reject null hyposthesis 6.

Hypothesis 7

The analysis for hypothesis 7 had several components. The MPQ-SF provided the data on pain at injection site postinjection. The components of the MPQ-SF include the sensory, affective, and evaluative portions of the tool for both injections 2 and 3.

Again, the CES-D score was retained as a continous variable for this analysis. Scores ranged from 0 to 42 out of a possible 60. For injection 2 the sensory portion of the MPQ-SF indicated a mean of .50 points and a standard deviation of 1.88 points with a range of 0 to 11 out of a possible 33 points. The Pearson correlation coefficient indicated a weak positve relationship, r=.16 p=.24 two tailed, p=.12 one tailed. The affective pain for injection site 2 was a mean of .20, standard deviation of 1.41, and the range was 0 to 10 out of a possible 12 points. The r=0.22, p=0.11, p=0.06, showed a slightly stronger relationship but failed to meet the alpha level of .05. The total pain score for the injection 2 site had a mean of 0.70 and a standard deviation of 3.13. The range for this portion of the MPQ-SF was 0 to 21 out of a possible 45 points. The correlation again was weak in a positive direction, r=.20, p=.16, p=.08.

The evaluative portion of the tool under discussion includes both the horizontal pain line (VAS) and the present pain index scale (PPI). Each of these scales was analyzed for correlation with the CES-D score. The VAS mean was 0.19 cm with a standard deviation of .52 cm; the range was 0 to 2.7 cm out of a possible 10 cm. In this analysis, the correlation coefficient was r=.15, p=.29, p=.15. The PPI had a mean of .14 points with a standard deviation of .49 points. The range was 0 to 3 out of a possible 5 points. The correlation coefficient was r=.16, p=.26, p=.13. Again, in the evaluative scores a weak positive relationship existed between the CES-D score and the VAS for pain of injection site 2.

When the data were analyzed for pain of injection site 3, it was noted that the means and standard deviations for the five portions of the MPQ-SF were remarkably similiar to

those for pain of injection site 2. The correlation coffecients and p values for each portion of the MPQ-SF for injection 3 were as follows with two tailed and one tailed rho listed respectively: Sensory r=.17, p=.23, p=.12; Affective r=.22, p=.11, p=.06; Total Pain r=.20, p=.15, p=.08; VAS r= .07, p=.58, p=.29; and PPI r=.13, p=.34, p=.17.

None of the correlations between the CES-D score and MPQ-SF for either injection 2 or 3 showed more than a weak positive relationship. There was failure to reject null hypothesis 7.

Hypothesis 8

The aquisition cost of a single dose vial of the sodium heparin used in this study was $0.33 for the 5,000 u : 1 ml concentration and $0.43 for the 10,000 u : 1 ml concentration. In the timed trials to draw up appropriate injectate volume from each concentration, the 5,000 u : 1ml or 1 ml of injectate volume took the longest time in each case. An ANOVA was computed to analyze these data. There was no significant difference in the amount of time needed to prepare each concentration, $F(1,9) = 1.08$, $p=.32$. Although the 10,000 u : ml concentration is slightly more expensive and the 5,000 u : ml took a few seconds longer to draw up, these differences were not statistically significant. There was failure to reject null hypothesis 8.

Analysis of Residual/Contextual Stimuli

Residual stimuli were controlled through the study design. According to Roy (1984), these are factors that have not been measured but which may be identified by the nurse as stimuli that could affect response. By collecting data for injections 2 and 3 only, the residual stimulus of fear of abdomen as injection site was somewhat controlled because all subjects had experienced a heparin injection in the abdomen prior to participating in the study. Although an attempt was made to control most contextual stimuli though the study design, the following section reviews the analysis for each identified stimulus that has not already been addressed in the main hypotheses.

Age

Age was partially controlled through the use of the block design in which subjects serve as their own controls. The contextual stimulus of age was analyzed in relation to the response of bruise occurrence. The Chi square analysis was carried out for ages grouped into catagories of younger (60 years or younger) and older (61 years or older). With injection 2 (n=50), there were 24 subjects in the younger category who bruised at the injection site (75%) and 8 in that age group who did not bruise (25%). For those older than 60 years, 11 bruised (61%) and 7 did not (38.89%). Injection 3 bruise occurrence frequencies and percentages indicated that the younger group had 22 bruises (68%, n=32), while the older group had 11 bruises (61%, n=18). There was no significant difference in bruise occurrence by age grouping of younger and older for either injection 2, p=0.30, or injection 3, p =.58, when considered independent of sex.

Bruise surface area was analyzed to investigate whether age grouping (younger/ older) influenced the size of bruises. A GLM was performed with $F(1,47) = 2.24$, p=.14, for injection 2 and $F(1, 47) = .26$, p =.61, for injection 3. There was no significant difference for bruise surface area by age group for either injection.

The effect of age, grouped into younger and older, was analyzed by pain of injection (VAS). This GLM procedure was done on N=49 without the outlier for VAS scores and resulted in $F(1,47) =0.65$, p =.42, for injection 2 and $F(1, 47) = 4.78$, p =.03 for injection 3. The variance on pain of injection was significant, $p < .05$ for injection 3. To discover where the variance existed within this analysis of variance, a post hoc Tukey test was performed. On injection 3 VAS scores, subjects 60 years or younger (n=31) had a mean of 1.36 cm, while their older counterparts (n=18) had a mean pain score of 0.42 cm. The Tukey test supported the finding of significance on pain of injection 3 (VAS scores).

The contextual stimulus of age also was analyzed for effect on pain of injection site postinjection. The GLM procedure was carried out with age group as class and scores on

the MPQ-SF as model and can be seen in Table 8. The findings are reported by the 5 components of the MPQ-SF for each injection. There was no significant difference among MPQ-SF scores by age group for either injection 2 or 3.

When the contextual stimulus of age was analyzed for effect on the level of depressive symptoms reported via the CES-D, a Chi square statistic was used. The levels of depressive symptoms, low, mild, moderate, and severe, used in this analysis were those reported by Devins and Orme (1985). Age was grouped into categories of younger and older for this analysis based on the findings in the literature that subjects in younger age groups scored higher on the CES-D scale than those over 65 (Comstock & Helsing, 1976). The Chi square result was $\aleph^2$ (1, N=50) =5.30, p =.15. Because 63% of the cells had an expected frequency of less than 5, the 4 x 2 table of CES-D by age was converted into a 2 x 2 table by further collapsing CES-D scores into low ($\leq$ 15.5) and high ($\geq$ 16) with a resulting $\aleph^2$ (1, N=50) =3.00, p =.08. There was no significant difference in CES-D scores when considered by age group.

Sex

The contextual stimulus of sex partially was controlled by the study design. There were, however, more females (36) than males (14) in the study. This characteristic also is reflected in the primary diagnosis and surgical type data where 40% of the sample had problems that specifically were related to the female reproductive system.

When the bruise occurrence response was analyzed by sex alone, 30 of 36 females had a bruise at injection site 2, while only 5 of 14 males bruised with injection 2. This was a highly significant difference in bruise occurrence for injection 2, $\aleph^2$ (1, N = 50) = 10.88, p=.001. Injection 3 also resulted in a significant difference in bruise occurrence by sex, $\aleph^2$ (1, N = 50) = 4.64, p=.03. Women bruised more frequently than men.

Bruise occurrence was analyzed further by sex and age using a 2 x 4 table. Females 60 years or younger had 22 bruise sites out of 26; males in the younger category had 2 of 4

sites bruise; and females 61 or older had 8 of 10 sites bruise, while their male counterparts had 3 of 8 sites bruise. The 2 x 4 table for injection 2 indicated a statistically significant difference between the sexes and age groups for bruise occurrence, $\aleph^2$ (3, N=50) =10.98, p = .01. In this table, 50% of the cells had expected frequencies of less than 5, which cast some doubt on the results. The same table and statistic were generated for bruise occurrence at injection 3 site. For injection 3, the 60 or younger group showed that females bruised 20 of 26 times and males 2 of 4 times. In the 61 or older group, females bruised 7 of 10 times and males bruised 4 of 8 times. Injection 3 did not show a statistically significant difference between the sexes and age groups for bruise occurrence, $\aleph^2$ (3, N=50) =5.22, p = .15.

Collapse of the table for injection 2 was done because of the signicance level and the problem with expected frequencies. In this round of analysis, there was a significant difference in bruise occurrence between females and males who were 60 or younger, $\aleph^2$ (1, N=32) =6.83, p = .009. Of those subjects 60 years or younger (n=32), females had a 92% bruise occurrence compared with males who had an 8% occurrence. Again, the expected cell frequencies were less than 5 in 50% of the cells, indicating the need to perform a Fisher's exact test. The Fisher's exact test had a p=.02 for right and two tailed results. For those subjects 61 years or older, results indicated $\aleph^2$ (1, N=18) = 3.37, p = .06. The Fisher's exact test was p =.08 right tailed and p = .14 two tailed. The difference in bruise occurrence by sex remained significant for those 60 or younger but did not reach significance for subjects 61 years of age or older.

A GLM with sex as class and bruise surface area as model was performed during the second round of analysis (N=48). The results for injection 2 were F (1,47) = 2.95, p =.09, and F (1, 47) = .35, p =.55, for injection 3. No statistical significance was found in this analysis for either heparin injection.

When sex and pain of injection were considered, the analysis was done by GLM procedure (N=50). Injection 2 results were $F(1,49) = 2.14$, $p = .15$, and $F(1, 49) = 3.43$, $p = .07$, for injection 3. Because the difference was not significant for either injection, this analysis was not repeated on the second round of data analysis.

To assess whether the contextual stimulus of sex affected pain of injection site, measured 60-72 hours postinjection, a GLM procedure was performed using sex as class and MPQ-SF as model. The findings are reported for sex by the 5 components of the MPQ-SF for injection 2 and 3 in Table 9. There was no significant difference among MPQ-SF scores by sex for either injection 2 or 3. The difference between women and men on the CES-D Scale when grouped into the four levels of none, mild, moderate, and severe was χ^2 (3, N=50) = 5.02 and $p = .17$. Because some cells had a low expected frequency, a 2 x 2 table of low and high scores was constructed. This analysis was statisically significant at χ^2 (1, N=50) = 4.02 and $p = .04$.

Diagnosis and Surgery

The block design controlled for the contextual stimui of diagnosis and surgery. These stimuli had similar members. To avoid repetitive analysis, in most cases diagnosis and surgery were grouped as one stimulus for analysis. Most diagnosis and surgery cells were too small to analyze. Data, therefore, were collapsed into the three groups of gynecologic, gastrointestinal, and other diagnosis/surgery. Bruise occurrences by injection and diagnostic group were Injection 2: (a) gynecologic 15 (n = 20), (b) gastrointestinal 13 (n = 18), and (c) other 7 (n=12); and Injection 3: (a) gynecologic 13 (n = 20), (b) gastrointestinal 13 (n = 18), and (c) other 7 (n=12); χ^2 (1, N=48) =.35, $p = .55$. Injection 2 analysis showed χ^2 (2, N=50) =1.06, $p = .59$. For injection 3, analysis showed χ^2 (2, N=50) =0.63, $p = .73$.

Diagnosis and bruise surface area were performed using a GLM instead of the ANOVA procedure because of uneven group sizes. The data set used in this analysis had

been purged of outliers for bruise surface area. The model for the GLM was Bruise 2 surface area (M= 31.00 mm^2). Results were F (2,47) = 1.74, p = .19. This GLM procedure also was performed for injection 3, F (2,47) = 1.94, p = .15. There was no statistically significant difference among diagnostic groups and bruise surface area for either injections 2 or 3.

The amount of time between surgery and injection 2 was analyzed using the original data (N=50) for its effect on pain of injection. This analysis was done using 2 levels of surgery, gynecologic and other. The mean time period between surgery and injection 2 was 17 hours. The GLM revealed F (1, 49) =.64, p=.82. Injection 3 occurred 12 hours after injection 2. The difference in pain of injection 3 analyzed by time difference between surgery and injection was F (1, 49) =.90, p=.62. No significant difference occurred in pain of injection scores in relation to time difference from surgery to injection 2 or 3.

The contextual stimulus of diagnostic group (3 levels) was analyzed for effect on pain of injection (VAS) using the data set purged of the outlier (N=49). The GLM procedure resulted in F (2, 48) = .51, p =.60, for injection 2 and F (2, 48) = 3.96, p =.02, for injection 3. Because the variance was significant for injection 3, p <.05, a post hoc Tukey test was performed. The greatest variance lay between the gynecologic and other category. The lower confidence level was 0.111 and the upper confidence level was 2.623, with a difference between the means of 1.37.

To analyze the combined effect of diagnostic group and bruise occurrence on pain of injection site, a GLM was performed on the original data. In this analysis the diagnostic group was divided into gynecologic and other. Each diagnostic group class had the two levels of (a) bruise or (b) no bruise. These GLM class levels were used with the 5 components of the MPQ-SF as model. The analysis was performed for both injections 2 and 3. The results are reported in Table 10. There was no statistically significant difference on any segment except the affective portion for the other diagnostic group on injections 2

and 3, $F(1,29) = 99999.99$, $p = 0.0$. This unusual finding is reflective of a single subject. This subject reported affective pain and was a member of the gynecologic group. The mean affective pain score in the other group was zero. The outlier was not removed from the MPQ-SF data because the subject's ratings on injection sites 2 and 3 were essentially identical even though measured 12 hours apart.

Due to the spread of CES-D scores across diagnostic groups, a series of Chi square statistics were performed. First, a 3 X 4 table was created with the diagnostic groups being gynecologic (n=20), gastrointestinal (n=18), and other (n=12). The CES-D scores were none (28), mild (6), moderate (7), and severe (9). The results of this calculation were χ^2 (6, N=50) = 5.34, $p = .50$. Seventy-five percent of the cells had an expected frequency of less than 5; thus, the table was further collapsed. The final Chi square produced a 2 x 2 table of diagnosis (gyenocologic and other) and CES-D scores (≤ 15.5 and ≥ 16). The results were χ^2 (1, N=50) = 3.46, $p = .06$. The Fisher's exact test, two-tailed, results were $p = .09$. Thus, there was no significant difference among diagnostic group and CES-D scores.

Adipose Tissue

The amount of adipose tissue was controlled partially by the design because it is unlikely that a subject gained or lost a significant amount of fat stores between the two heparin injections. In addition, the inclusion criterion of at least 25 mm of adipose tissue at injection site served to control for those who might have too little fat stores to assure proper administration into subcutaneous tissue, thus posing an increased risk of accidental intramuscular injection.

The effect of amount of adipose tissue on bruise occurrence was analyzed by collapsing caliper measurements into two catagories of high (≥ 38 mm) and low (< 38mm). This division point was based on the mean caliper measurement of 37.26 mm. Those subjects with a caliper reading in the high range experienced 14 (78%) bruises with

injection 2 and 13 (72%) bruises with injection 3. Bruise occurrence was not significantly different between those with a high measure of adipose tissue and those with lower caliper measurements for injection 2, χ^2 (1, N = 50) =0.81, p=.36, and injection 3, χ^2 (1, N = 50) =0.48, p=.49.

In the anlysis of the original data there was a statistically significant difference among groups for caliper and bruise surface area for injection 2, F (22, 49) =7.93, p=0.0001. A Tukey post hoc analysis showed that the highest mean bruise surface area was 924.56 mm^2. This observation had one of the highest caliper measurements, 60 mm. The highest caliper measurement of 64+ mm, however, had a mean bruise surface area of only 34.09 mm. On the second round of analysis, where the two outlier observations were excluded, there was no significant difference among groups for injection 2, F (21, 47) = 0.92, p = .57, and injection 3, F (21, 47) = 0.65, p = .84.

Caliper measurements were considered as a continous variable when analyzed in the GLM with pain of injection (VAS) and pain of injection site post-injection (MPQ-SF). The caliper measurement and pain of injection 2 produced an F (22, 49) = 0.83, p=.67. For injection 3, the results were F (22, 49) = 0.93 p= .56.

The analysis revealed no statistically significant difference among caliper measurements and any of the scores on the MPQ-SF. The probability of rejecting the null hypothesis in this anlysis ranged from p=.33 to p=.99. None of the scores showed a statistically significant difference in relation to caliper measurement.

Side of Injection Site

The question of pain perception and laterality was controlled through randomization of the side of the abdomen that was injected first. Twenty-four injections were given in the left side and 26 in the right side for injection 2. These frequencies were reversed for injection 3. This method also allowed for control of injectate volume into site, either left or right.

In addition, a Chi square was computed to test the association of side of injection site and bruise occurrence. Neither injection 2 nor 3 showed a strong relationship between the groups of left or right abdomen and bruise occurrence, χ^2 (1, N =50) =.54, p=.45, for injection 2 and χ^2 (1, N = 50) =.009, p=.94, for injection 3.

A GLM analysis of variance was calculated for the independent variable of side of injection site and the dependent variable of bruise surface area. Side of injection site had two levels of class, left and right. Bruise surface area was an interval level, continuous variable. There was no difference in the mean bruise surface area and side of injection site for either injection 2 or 3. For injection 2, F (1, 49) = .37, and F (1,49) =.99 for injection 3, with the respective p values .54 and .32. Because the original data did not demonstrate a significant difference in bruise size by side of injection, round two analysis without the 2 outliers was not done for this contextual stimulus.

When the side of injection was added in a multifactorial GLM with volume as class and pain of injection (VAS) as model, the results were F (2, 49)= 0.76, p = .38, for injection 2 and F (2, 49)= 0.19, p = .66, for injection 3. The interaction of the two stimuli did not change the fact that research hypothesis 3 was rejected.

Time of Heparin Injection

The protocol at the data collection site required scheduling of the routine administration of low-dose heparin injections for 0800 and 2000 hours. These times could be changed, however. The most prevalent reasons to depart from the routine were the hour at which a medication prescription was written and time of surgery. The two injections in this study, therefore, were given at all hours depending on the scheduled medication times for the heparin. The question of whether time of day influenced the pain of injection was explored. Time was collapsed into an ordinal variable with three levels: days, evenings, and nights. There was no significant difference among groups for time and pain of injection, F (2, 49) =2.32, p=.10, for injection 2 and F (2, 49) =.80, p=.45, for injection 3.

Although the time of injection did not make a significant difference in pain of injection, a post hoc Tukey test was done to determine where the differences were for injection 2, which had the most variance in pain scores. Subjects who received injection 2 between 0700 and 1330 (n=26) had a mean pain score of 0.49 cm. Evening injections (n=15) produced a pain score of 1.27 cm, while nights (n=9) produced a pain level of 0.73 cm. Subjects who received heparin injection 2 between 1530 and 2300 had slightly more pain with injection, on the average, than those whose injection was given on days or nights.

Medications

This contextual stimulus was partially controlled through the use of a block design. Subjects, however, received varying types of medication that had the potential to affect either the response of pain or bruising.

Although all subjects received the same dose of heparin per injection and each had at least three injections, there was variance in the total number of heparin injections received by the time that the third injection site was inspected for bruising. The GLM analysis of variance performed on the total number of doses of heparin and bruise surface area produced F (7, 47)=.65, p=.73; thus, no significant difference existed. This analysis was not appropriate for injection 2 because some heparin injections calculated in the total dose class may have been administered after bruise 2 was measured.

Analgesics were administered to 46 of the 50 subjects during the time that data were collected for this study. It is obvious that the administration of medication to relieve the pain that occurs with disease process or surgical intervention could have an impact on the response of pain with either injection or bruising. The classification of medication used in this analysis was 28:08.08. To analyze the effect of this medication, a GLM was performed with the class being time of administration in relation to heparin injection and the model of pain of heparin injection.

In the first round analysis, GLM class was subdivided into five levels, with each level representing a time span of 60 minutes. Class 1 represented those analgesics that were given within 60 minutes of heparin injection and class 5 was for those analgesics given more than 240 minutes (4 hours) prior to the heparin injection in question. This division showed some variance in pain response of injection 2 as influenced by timing of analgesic medication, $F(4, 43) = 2.48$ $p = .059$. Although there was variance, it was not statistically significant with the alpha set at .05. The time frames were collapsed further and the GLM was recalculated. The second round of analysis used a two level class, those analgesics given within 4 hours and those given more than 4 hours prior to heparin injection 2. This analysis yielded $F(1, 43) = 8.00$, $p = .007$. This was a statistically significant finding. The division point of 4 hours was chosen because of the average expected efficacy time for opiate agonists (Spencer, 1989). A post hoc analysis, the Tukey test, revealed that 35 subjects received pain medication within 4 hours prior to heparin injection 2. These subjects had a mean VAS pain score of 0.48 cm. The 9 subjects who received analgesics more than 4 hours prior to injection 2 had a mean VAS pain score of 1.60 cm. Injection 3 did not show a statistically significant difference when timing of analgesic in relationship to heparin injection was analyzed, either on the first or on the second round analysis.

The potency of medications may varies within medication class 28:08.08. This difference was controlled with the creation of equipotency units that graded medications and doses with respect to the hallmark of the class, morphine. In addition, medications were leveled in regard to use for relief of three levels of pain severity. When these two contextual variables were created and analyzed in respect to the significant difference in pain of injection seen in injection 2, they served to control for the variance observed. A multifactorial ANOVA via GLM was performed. The equipotency units were classified either as 1, being less than equivalent to 10 mg of morphine, or 2, being equal to or more

than equivilant to 10 mg of morphine. The interactive effect of time of administration and equipotency units brought the F value of pain of injection 2 down to $F(2, 43) = 2.37$, $p=.13$. Adding severity level of analgesic to this equation produced $F(3, 43) = 1.33$, $p=.27$. Because injection 3 did not show a significant difference in pain of injection when analyzed by time of analgesic in relation to heparin injection, the multifactoral ANOVA was not carried out.

The total number of doses of those medications in the 28:08.08 classification were used as a continuous variable as class in the GLM performed with the five components of the MPQ-SF for injection site 3 as model. The results of this analysis were (a) sensory, $F(1,45) = 0.37$, $p = .54$; (b) affective, $F(1,45) = 1.09$, $p = .30$; (c) total pain $F(1,45) = 0.70$, $p = .40$; (d) VAS, $F(1,45) = 0.00$, $p = .96$; and (e) PPI, $F(1,45) = 0.74$, $p = .39$. The findings from this analysis suggest that the total number of doses of analgesics administered did not affect the pain of injection site measured postinjection via the MPQ-SF. This analysis was not appropriate for the pain of injection site 2 because data coded as total dose were based on dose received by the time of injection 3.

A similarly constucted GLM was performed for the time of administration of the class of medications labled miscellaneous anxiolytics, sedatives, and hypnotics (28:24.92) in relation to the pain of heparin injection. There was no difference in pain of injection for either injection 2, $F(1, 12) = .93$ $p=.35$, or injection 3, $F(1, 12) = .51$, $p=.49$, when analyzed in relation to time of administration of medication class 28:24.92. No other class of medication had a sufficiently large N to warrant statistical analysis of effect on subject response.

Summary

Because the correlation between the indpendent CES-D score and dependent VAS and MPQ-SF scores was below the requisite $r= 0.30$ level, an analysis of covariance (ANCOVA) could not be performed. In addition, because multiple regression procedures

require at least 30 subjects for each variable loaded into the regression (Waltz & Bausell, 1981), the multiple regression procedure was not considered appropriate for this study.

The analyses that were completed included descriptive statistics; analysis of variance procedures, including GLM and ANOVA; and measures of association such as Chi square, Fisher's exact test, and Pearson's correlation coefficient.

The tools used were sufficiently sensitive to measure the attibutes of the adaptive responses, viewed as dependent variables in this study. The analysis of data failed to reject null hypotheses 1 through 8.

CHAPTER 5

Discussion, Conclusions, and Recommendations

This chapter includes discussion of the findings related to the problem of patient response to the administration of subcutaneous heparin. In addition, the influence of contextual and residual stimuli, design, assumptions, subjects, and setting on patient responses is discussed. This discussion includes a comparison of the findings with the literature and the conceptual framework.

The focal stimulus of heparin injectate volume was manipulated and the responses of bruise occurrence, bruise size, pain of injection, and pain of injection site 60-72 hours postinjection were analyzed. None of the research hypotheses were supported for the manipulation of heparin injectate volumes .5 ml and 1 ml. Depressive symptoms were analyzed for relationship to pain of injection and pain of injection site 60-72 hours post - injection. The association between depression and pain measures was not strong enough to consider depression as a covariant with the independent variable of injectate volume. A cost analysis supported the research hypothesis of no difference between injectate volumes in terms of cost of administration.

Discussion

Research Question 1

When considering the effect of injectate volume of subcutaneous heparin on the physiologic response of bruise occurrence postinjection, a correlational analysis was done to test the null hyposthesis. The results supported null hypothesis 1.

In this study, overall bruise occurrence was 68% with 100 injection sites. The .5 ml injectate volume produced 72% (n= 50) bruises and the 1 ml injectate volume produced 64% (n=50) bruises. In the Stewart Fahs and Kinney (1991) study, 269 of 299 injection

sites bruised (89%) with a .5 ml injectate volume. VanBree et al. (1984) reported that the .5 ml injectate volume produced a 56% bruise occurrence, while the Wooldridge and Jackson (1988) study that used a 1 ml injectate volume produced an 88% bruise occurrence. In the Stewart Fahs and Kinney study, staff nurses gave all injections, while the researchers in both the VanBree et al. and Wooldridge and Jackson studies injected the subcutaneous heparin.

Bruise occurrence in the current study did not match findings that were reported in the literature. The .5 ml injectate volume produced 16% more bruises than those reported by VanBree et al.(1984) who used .5 ml injectate volume, and 21% less than the Stewart Fahs and Kinney (1991) study. The 1 ml injectate volume used in this study produced 24% fewer bruises than those reported by Wooldridge and Jackson (1988), who used the 1 ml injectate volume. Both Van Bree et al. and Wooldridge and Jackson manipulated injection technique while holding the injectate volume constant for their respective studies. This study held technique constant and manipulated injectate volume.

Mitchell and Pauszek (1987) also held technique constant, and manipulated injectate volume, finding a large difference between the two injectate volumes and bruise occurrence. The volumes manipulated were .25 ml (20,000 u: 1 ml) and .5 ml (10,000 u: 1 ml). The authors reported a bruise occurrence of 12% for the .25 ml injectate volume and 33% for the .5 ml volume. This study used multiple staff nurses to administer the injections. One investigator, blinded to injectate volume, measured bruise occurrence and size. The bruise occurrence rate for the Mitchell and Pauszek study was much lower than for any other reported study, including the current study.

Stewart Fahs and Kinney (1991) and VanBree et al. (1984) measured bruise occurrence at 48 hours after the third injection, thus making measurements at 48, 60, and 72 hours postinjection. Wooldridge and Jackson (1988) measured bruise occurrence 52 hours after each injection. Mitchell and Pauszek's report (1987) did not include the exact time frame for measuring bruise occurrence. The authors stated "Each patient received an

injection every 12 h and was examined after receiving four injections by a physician . . . " (p. 88). Bruise occurrence rates in the current study were between those reported in the VanBree et al. and Wooldridge and Jackson studies and below that reported by Stewart Fahs and Kinney. All four of these studies had a much higher bruise occurrence rate than that reported for the Mitchell and Pauszek study.

In addition to the issue of when bruise occurrence was measured, other questions are raised. Mitchell and Pauszek (1987) reported a difference between bruise occurrence for injectate volume .25 ml (12% bruising) and .5 ml (33% bruising). It is not possible to tell whether the significant difference stated as $\aleph^2 = 5.88$, $p < .02$, was for bruise occurrence, bruise size, or both. The difference in bruise occurrence (21% overall) would be clinically significant, but given the gaps in information provided, doubt is cast upon the generalizability of the data from the study. Unlike Mitchell and Pauszek's study, the current study did not show a significant difference for bruise occurrence when injectate volume was manipulated.

The issue of magnitude of focal stimulus is addressed by Roy and Roberts (1981) in their theoretical propostions. They speculate that manipulation of the magnitude of stimuli should bring about changes in response seen in the appropriate adaptive mode. In the case of the current study, an attempt was made to manipulate the focal stimulus of heparin injectate volume. Results indicated that the response of bruise occurrence not only was not significant but also was not in the expected direction. It is difficult to compare the results of this study with those from Mitchell and Pauszek's (1987) study because of the previously raised questions regarding time frame for measurement and detail of reporting. The Mitchell and Pauszek study, however, is the only one found in the literature that manipulated the injectate volume of subcutaneous heparin. Mitchell and Pauszek manipulated a .25 volume and a .5 ml volume. This investigator manipulated .5 ml and 1 ml volumes. It may be that the focal stimulus in the current study was not manipulated to the extreme needed to produce a change in the adaptive physiologic mode for bruise

occurrence. The question of differences in bruise occurrence in relation to concentrations of heparin not used in this study remains open.

The cross-over design of this study should have been sufficient to control for several contextual variables in relation to bruise occurrence. The analysis revealed that age, diagnosis, type of surgery, adipose tissue, and side of injection did not affect the response of bruise occurrence. Sex, however, did produce a difference in bruise occurrence at a statistically significant level, $p < .05$. Women bruised more often than men in this study. In addition, when sex and age group of younger or older were considered, injection 2 showed a statistically significant response, $p = .01$. The same analysis for injection 3 did not produce a statistically significant difference in bruise occurrence. A further collapsing of data to control small cell sizes indicated that females, 60 and younger, bruised more often than males in the same age group, $p = .009$. The difference was not statistically significant for females and males who were 61 years or older. In this study (N= 50), those 60 years old or younger (n=32, 64%) outnumbered those 61 years or older (n=18, 36%). Females (72%) also outnumbered males (28%).

Van Bree et al. (1984) reported that females older than 60 years bruised more often than males who were older than 60 years at a statistically significant level. A significant difference in bruise occurrence between females and males under the age of 60 did not occur. The sample in the Van Bree et al. study contained 27 subjects who were 60 years or younger (62%) and 16 subjects over 60 years of age (37%) . The total sample consisted of 44% females and 55% males. Wooldridge and Jackson (1988) reported that women over 60 not only had more bruises than men over 60 but also had more than women or men under the age of 60 years. They did not, however, report whether the results were statistically significant for their sample of 64% women and 36% men. These authors neither indicated how many subjects were over the age of 60 nor provided a mean age. The Stewart Fahs and Kinney (1991) research did not find a significant difference between men and women (N=101) on bruise occurrence at any age. They had a 62% female and

39% male sample. Excluding anyone with less than 25 cm of adipose tissue may explain why women over the age of 60 did not have a significant variance in bruise occurrence. This exclusionary factor prevented the emaciated frail elder from participating in the study. VanBree et al. (1984) and Wooldridge and Jackson (1988) did not mention similar controls in their study, but Stewart Fahs and Kinney (1991) did use this control. The finding of more females under the age of 60 having a bruise occur at the injection site needs further exploration.

Because of the multiple measurement time frames for bruise occurrence in the literature, it is not realistic to draw any specific conclusions as to the difference in bruise occurrence when considering the contextual stimuli of sex and age together. It does seem realistic, however, to consider that females bruise as a result of subcutaneous heparin injections more frequently than males.

Time of day of heparin injection was not analyzed for this research question because of the assumption that time of day would not affect bruise response. The residual stimulus of skin color was not considered in the issue of bruise occurrence because of the limitation of access to subjects and the lack of literature on validity for measurement in non-Caucasian populations. Although there was a difference in bruise occurrence between men and women in the current study, the cross-over design offers some protection of validity because subjects served as their own control. In addition, the power level of .80 offers some protection against a type II error of accepting a false null hyposthesis for the first research question. The finding of sex effect on bruise occurrence does, however, cast doubt on the generalizability of the findings.

In conclusion, findings from the current study supported null hyposthesis 1. The literature is confusing as to bruise occurrence because the time frames used for measurement are inconsistent. There remains a question as to whether further manipulation of the magnitude of the focal stimulus of sodium heparin injectate volume can produce an increase in adaptive response of fewer bruises at injection site. In addition, the sample

differed in bruise occurrence by sex even when age was controlled with at least one of the injections.

Research Question 2

The question of the effect of injectate volume of subcutaneous heparin on the physiologic response of bruise size measured 60 -72 hours postinjection was explored via analysis of variance procedures. The first round of analysis (N=50) indicated no significant difference between injectate volumes relative to bruise size as measured for surface area in mm^2 units for either injection site 2 or 3. The data were analyzed on a second round (N = 48) because 2 outliers had been identified that had a difference of more than 900 mm^2 between injection site 2 and injection site 3 bruises.

Two primary ways of measuring bruise size have been reported in the literature. These techiques include (a) measuring the diameter of the bruise at its widest point or (b) tracing the bruise outline and calculating the surface area either by hand calculation or by computer scanning and anaylsis. Stewart Fahs and Kinney (1991) used both methods and reported correlations of r= .86 to r=.91 but used the surface area measurement in statistical analysis because it more accurately reflected the size of any irregularly shaped bruises. The surface area in that study was hand calculated. These authors also reported that bruise surface area was less when measured at the 48 hour versus 60 or 72 hour mark post-injection. This difference in bruise surface area was statistically significant ($p < .05$, $N = 101$) on a repeated time ANOVA.

Barbaccia et al. (1984), VanBree et al. (1984), and Wooldridge and Jackson (1988) all reported using surface area in the analysis of bruise size. VanBree et al. used a computer to scan and calculate bruise surface area, but the other researchers did not mention their method of calculating surface area. Mitchell and Pauszek (1987) measured bruise size by taking the largest diameter to explore the relationship between injectate volume and bruise size through a Chi square analysis. Barbaccia et al. compared sodium heparin and calcium heparin with bruise occurrence and bruise size. They made bruise size

a discrete variable of ≤.5 cm or ≥ .5 cm and reported no statistically significant difference in bruise size by heparin salt. VanBree et al. also grouped bruise measurements and used a Chi square to analyze difference in bruise size by technique. Neither Barbaccia et al. nor VanBree et al. reported a mean bruise size. Mitchell and Pauszek reported that diameter of bruises ranged from 3 to 33 mm but did not give a mean bruise size.

Wooldridge and Jackson (1988) reported a mean bruise surface area of 27.70 mm^2 (88 bruises), while Stewart Fahs and Kinney (1991) reported a mean bruise surface area of 231.00 mm^2 (269 bruises). There was a high degree of variability in bruise surface area reported by Stewart Fahs and Kinney. The authors speculated that the variance in surface area may have been due to individual bruisability and variability in injection technique used by staff nurses. In the current study, the mean bruise surface area for all bruises was 48.42 mm^2 (68 bruises, n=100), standard deviation 68.12 mm^2, on the original anlaysis and M=30.40 mm^2 (66 bruises, n=100), a standard deviation of 67.83 mm^2 after the 2 outlier observations were removed from the data set. The reported means and standard deviations for bruise surface area from the current study are more in line with the literature than those reported by Stewart Fahs and Kinney. The rationale of the regression toward the mean in the current study may lie in the fact that only the investigator gave injections and the cross-over design controlled for bruisability. The reported mean bruise surface area for this study and that reported by Wooldridge and Jackson were similar.

The contextual stimuli that included age, sex, diagnosis, type of surgery, and side of injection did not affect the response of bruise size. In addition, caliper measurements were not related to bruise size after the 2 outliers were removed from the data set on the second round analysis. Analysis of the total number of heparin doses and effect on bruise surface area was not appropriate for injection 2 but was performed for injection 3. No significance was found for bruise 3 surface area in relation to total number of subcutaneous heparin doses. Medications that might have affected the bruise surface area were largely controlled by the exclusionary criteria. Those remaining classes of medications were in small

numbers and could not be analyzed, i.e., there were 3 subjects who received at least two doses of very dilute heparin (100 u : 1 ml) in the form of Intravenous heparin lock flushes. This extremely small dose of no more than 200u : 1 ml for each of the 3 subjects was unlikely to affect bruise size or occurrence.

When considering the conceptual framework in relation to this second research question, the same issue of magnitude of stimulus needs to be considered as was the case in research question 1. The injectate volumes manipulated in this study may not have covered a wide enough range or may not have been sufficiently concentrated to produce a significant difference in bruise surface area. Certainly, the injectate volumes manipulated by Mitchell and Pauszek (1987) should be included in any futher analysis of effect of injectate volume on the response of bruise surface area. There are multiple concentrations of sodium heparin available that deliver a prescribed dose of heparin in a variety of injectate volumes. The range of concentrations should be assessed for effect on bruise response in low-dose heparin administration. Adaptation level also needs to be considered for the Roy adaptation model to be of assistance in guiding future research in the nursing intervention of administration of low-dose heparin injections. At what point does the size of a bruise become an ineffective response? A very large bruise would limit the space for subsequent heparin injections. Also, if an injection were given closely enough to a surgical incision, a hematoma could result at the surgical site (De Lange, 1982). One adaptive mode not evaluated in this study was the self-concept portion of the model in relation to bruise formation and size. The assumption was made that the Roy Adaptation Model could be used to guide research and thus suggest areas that need further exploration in regard to the focal stimulus of heparin injectate volume. The stimulus that resulted in a large difference between bruise surface area for injections 2 and 3 in two subjects needs further exploration. In addition, the model could be used to identify other potential focal stimuli for testing in relation to response of bruise surface area, including time frame for surface area measurement.

In conclusion, the bruise surface area mean and standard deviation were somewhat controlled in this study by the cross-over design and using only the researcher to administer all injections. Two outliers for surface area differences between injections 2 and 3 were identified and controlled in the data analysis. Findings indicated the need to accept null hypothesis 2.

Research Question 3

Research question 3 concerned the effect of injectate volume of subcutaneous heparin on the response of pain of injection as measured on the vertical VAS scale. This question was explored via analysis of variance procedures. The first round of analysis (N=50) indicated no significant difference between injectate volumes relative to pain of injection for either injection site 2 or 3. Injection 3, however, did exhibit more variance than injection 2 on the GLM. The data were analyzed on round 2 (N = 49) because 1 outlier had been identified as having rated the pain of injection 3 as 10 cm on the VAS. This outlier did not mark as extreme a score for pain of injection 2. No other score on this measure was higher than 6.5 cm. When the outlier was removed, the VAS score means on injections 2 and 3 were less diverse.

The question of whether subcutaneous injections are painful has received very little attention in the literature. Stewart Fahs and Kinney (1991), in exploring alternate sites for heparin injections, and Wooldridge and Jackson (1988), in studying injection techniques, speculated that these injections might induce momentary pain. They used the possible pain argument as partial rationale in studying response to heparin injections. Neither of these studies, however, measured pain responses. Only one study has examined pain of injection site as a dependent variable in a study of subcutaneous heparin administration (Coley et al., 1987). The authors manipulated needle size and measured pain of injection and bruise occurrence. They used a four-level, forced choice pain scale to measure pain of injection. Pain severity ranged from none (n=541), mild (n=119), moderate (n=20), and severe (n=0) for the total number of injections (N=680). Coley et al. did find a significant

difference in pain of injection when the focal stiumulus for their study, needle size, was manipulated, $p = < .001$. They did not report further analysis by sex or age.

Levin (1982) studied the perception of momentary pain of intramuscular (IM) injections in relation to patient choice of injection site and locus of control. This author reported using two pain scales, a forced choice and a continous VAS, and found a high correlation between the scales (r=.84). Age and sex were shown to affect pain ratings of injection. Younger subjects and females experienced more pain of injection. In addition, pain ratings were analyzed for differences considering the two nurses who gave injections in the study. A statistically significant difference was reported for pain perception and person administering the injection, even though technique was held constant. In the current study, only one person administered all injections, thus controlling for differences in person administering the injection. In addition, the technique was held constant.

Contextual stimuli analyzed in this study for research question 3 were age, sex, diagnosis and surgery, adipose tissue, side of injection, time of injection, and medications. Age and medications were shown to influence the response of pain of injection as measured by the vertical VAS. Levin's (1982) findings of more pain with IM injections for subjects under 60 years of age and women of all ages were similar to the findings in this study. In the current study, age did make a significant difference in the VAS scores for injection 3 but not injection 2. The post hoc analysis of variance indicated that those 60 years of age or under reported higher pain scores than their older counterparts. Sex alone did not significantly affect VAS scores, but there was a larger variance for injection 3 ($p = .07$). Because the gynecologic group membership is exclusively female and because subjects in this group were mainly under the age of 60, it seems likely that the significant variance in the analysis by diagnostic group was partially a reflection of sex and age differences on pain of injection experienced.

The analgesic agonists of class 28:08.08 were administered to patients with the expected effect of pain relief. It was not surprising that the time of administration of these

medications in relation to the heparin injections affected the pain levels reported by subjects for pain of heparin injection. This response is consistent with the assumptions of Roy's (1989) adaptation model. According to assumption 6" . . . adaptation is a function of the stimulus a person is exposed to and his or her adaptation level" (p. 107) is discussed. Roy (1989) points out that stimuli other than those immediately affecting the response play a part in the individual's adaptation, which is the goal of the organism. In light of Roy's (1989) sixth assumption, it is evident that while receiving medications to relieve the pain of disease or surgery, an individual's response to the pain of heparin injection could be mediated by the analgesia produced for other stimuli.

The Roy model supports the concept of the VAS for measuring pain when one considers that the model defines pain in mainly a subjective manner. The assumption that the model would lend guidance to reseach was justified when contextual stimuli were identified as affecting variance of pain of injection. Magnitude of injectate volume may need further manipulation in order to identify any existing differences in pain of subcutaneous heparin injections. The identified focal stimulus of injectate volume resulted in acceptance of null hyposthesis 3.

Research Question 4

The question of the relationship of bruise occurrence and pain of injection site 60 - 72 hours postinjection was analyzed using total pain portion of the MPQ-SF and the discrete catagories of bruise occurrence. The literature has little information on the pain of bruises produced by subcutaneous sodium heparin. Nurse researchers (Stewart Fahs & Kinney,1991; VanBree et al., 1984; Wooldridge & Jackson, 1988) have speculated that injection sites that bruise postinjection may be painful. Indeed, some pain was reported in each segment of the MPQ-SF, although the numbers of those reporting pain of bruising were small. One interesting finding for this research question was that, despite the lack of significance on the Fisher's exact test, only subjects with bruises postinjection reported pain on the total pain portion of the MPQ-SF. It is likely that the effect size is large for this

previously unexplored response of pain of injection site postinjection. The power analysis projected for this study was for the effect of bruise occurrence and size. The possibility of a type II error in the analysis of hypothesis 4 needs to be considered.

Although the VAS and the PPI are two parts of the evaluative portion of the MPQ-SF, they were considered separately in most analyses for pain of injection site post - injection. A few subjects (n=7, injection 2, and n=3, injection 3) reported pain on the horizontal VAS and not the forced choice PPI. These particular measurements on the VAS were never any larger than 0.03 cm. This may reflect the difficulty that some subjects had marking the horizontal VAS that was located toward the lower part of the page. There is the possibility that the horizontal VAS was not as reliable as the PPI in reflecting pain of injection site post injection. However, the two scales correlated at r = .89 for injection 2 and r = .86 for injection 3. The correlations were significant and indicate a strong positive relationship.

The contextual stimuli of age, sex, adipose tissue, side of injection, and medications did not affect the response of pain of injection site postinjection. Bruise occurrence by diagnostic grouping did generate an unusual result for affective pain. This finding was explained when the outlier, who had the highest pain scores, was the only subject to experience pain sensation measured in the affective realm of the MPQ-SF, and was a member of the gynecologic diagnostic and surgery group. The MPQ-SF score for this subject was not deleted from the data set because the conceptual framework clearly affirms the belief that pain is what the patient says it is (Roy, 1984). In addition, the subject reported almost identical pain on all components of the MPQ-SF; thus, the design did control for individual pain perception that remains in the residual stimulus pool.

In summary, null hypothesis 4 was supported and the reseach question could not be answered in the affirmative. There are questions of a type II error and effect size for the attribute of pain of injection site postinjection.

Research Question 5

The question of the effect of bruise size on the physiologic response of pain at injection site 60 - 72 hours postinjection, measured by the MPQ-SF, was analyzed via the Pearson correlation coeffiecent. The results did support the fifth null hypothesis and again the research question was answered in the negative.

The discussion for Research Question 4 regarding literature, contextual stimuli, and conceptual framework also applies for this research question. There is little in the way of descriptive or higher level information on the pain of bruising. This observation, coupled with lack of a power level for this analysis with the sample of 50 subjects (n=100 injection sites), leads to the suggestion that a type II error may have been made.

Research Question 6

The analysis of data regarding the effect of level of depression on intensity of pain of injection led to the acceptance of the null hypothesis for this question. The correlation of CES-D scores with pain of injection (VAS) was weak and prohibited the use of CES-D as a covariant with pain scores.

No examples were found in the literature that linked depression and pain of injection. Levin (1982) examined the link of locus of control with choice or no choice of injection site and pain of injection. The findings of the Levin study did not support a significant link between either of the psychologic variables and pain of injection. Roy (1984) would place contextual stimuli such as locus of control, choice, and depression in the cognator coping mechanism. The cognator processes stimuli through cognitive-emotive channels. Roy and Roberts (1981) speculated about a regulator cognator cross-over point where stimuli from the physiologic mode could cross over to the more psychologic modes or vice versa.. This study failed to support that particular theoretical proposition in the adaptive response of subjects to the focal stimulus of subcutaneous heparin.

There are reports in the literature of a fairly strong link between depressive symptoms and chronic pain (Hagglund et al., 1989; Keefe et al.,1986; Summers et al., 1988).

Whether subjects in this study experienced chronic pain remains in the residual stimuli pool.

There is little information about the association between depression and acute pain. Otto et al. (1989) examined the association between depression and experimentally induced pain and found a weak negative correlation. In contrast, this study showed a weak but positive relationship between CES-D scores and pain of injection.

Fifty-three percent of subjects 60 years of age or younger scored above 15.5 on the CES-D scale, while only 28% scored above that level in the over 60 group, but the difference was not significant. The results of this study are inconsistent with Comstock and Helsing's (1976) report of field testing of the CES-D tool in terms of significant differences between age groups on the CES-D. Hagglund (1990) also failed to find a difference in CES-D scores between two groups of subjects who did differ significantly on age.

In the current study, there was a difference on the CES-D for sex, with women scoring higher than men on the tool. This finding is consistent with the literature (Devins & Orme, 1985). The cross-over design offered some protection for validity in this study because subjects acted as their own control. The generalizability of findings regarding effect of depression on responses to heparin injections is questionable because the sample differed significantly on this measure.

Although it is conceivable that the amount of adipose tissue an individual has could affect that individual's feelings of depression, this combination was not analyzed. Thus, it is not known whether the CES-D scores differed by caliper measurement.

Depression and laterality issues have been raised in the literature (Otto et al., 1987, 1989). The effect of depression and side of injection together were not analyzed in this study. The absence of analysis for this combination of stimuli was due to the lack of significant effects found for side of injection alone. The Roy model (1984) stipulates that when the effect of a stimulus on adaptive response is considered but not measured or

identified, the stimulus is classified as residual. Thus, the effect of adipose tissue on depression levels and the effect of depression combined with side of injection were classified as residual stimuli in the current study. Medications in the 28:16 class of psychotherapeutic agents also were considered residual stimuli because the number of subjects who received these drugs and the number of total doses were too small to analyze in relation to depression levels.

The intervention afforded to those who scored high on the CES-D prior to the injections in this study may have affected the correlation between CES-D and the responses of pain of injection or pain of injection site postinjection. These subjects may not have been identified as exhibiting depressive symptoms without the use of this tool. The literature (Nielsen & Williams, 1980) suggested that depression is often overlooked in a non-psychotic population. The potential effect of early intervention for subjects scoring high on the CES-D limits the generalizabiltiy of the findings of this study and increases the likelihood of a type II error regarding correlation of depression and pain. Thus, the research question of the relationship between depressive symptoms and pain still remains open for further exploration.

Research Question 7

The question of the effect of level of depression on pain of injection site, measured 60-72 hours postinjection was explored in this study. The correlation analysis failed to support the link between depression and pain of injection site as measured on the MPQ-SF. The discussion of literature, conceptual framework, tools, and concerns with analysis for this research question have been addressed under question 6 for the CES-D. Questions 4 and 5 address the same components in regard to pain of injection site. In summary, there was no strong link established between self-reported depresive symptoms (CES-D) and pain of injection site as measured by the MPQ-SF. The lack of support for the hypothesis derived from research question 7 led to abondonment of the plan to use depression scores as a covariate with pain of injection site.

Research Question 8

The question of effect of injectate volume on the cost of preparation of subcutaneous heparin injections was analyzed by means of the GLM procedure. The analysis, based on N=10, failed to reject null hypothesis 8. No references regarding the cost effectiveness of the various concentrations of sodium heparin available were found in the literature. Although cost in relation to health care delivery is an issue in this country, there is little evidence in the literature that specific nursing interventions have been examined for cost effectiveness (Shortridge et al., 1989). The possibility of a type II error, falsely accepting the null hypothesis when an alternative hypothesis is true, is high for this question. The use of 10 timed incidents only to test this hypothesis should be considered as pilot data to bring the cost of preparation of heparin from the residual into the contextual stimulus pool in the nursing administration of subcutaneous heparin. The issue of cost to prepare sodium heparin injections deserves further attention. The incidental observation of preparation of the 1 ml injectate volume taking longer than the .5 ml volume in all comparisons (n=5) should be explored further. Some of the registered nurses who prepared these two volumes during the timed trails commented afterward that it was awkward to draw up the 1 ml volume in the 1 ml tuberculin syringe used in this study.

Limitations

The following limitations were identified:

1) Only Caucasian subjects were used in this study due to the lack of information regarding accurate assessment of bruise formation in non-Caucasian populations. This exclusion limits the generalizability of the findings.

2) The dependent variables of pain of injection, pain of bruise, and the contextual stimulus of depression were measured via self-report scales which may be confounded by subjects' desire and ability to complete the tools properly.

3) The researcher assisted subjects to complete the CES-D and total pain portion of the MPQ-SF by reading possible responses and marking responses made by subjects. This

assistance may have influenced subject responses. No assistance was provided for the VAS or the evaluative portion of the MPQ-SF.

4) The researcher was not blind to injectate volumes of heparin during injections. Thus, bias toward a particular volume may have been introduced.

5) Power B=.80 was established a priori for bruise occurrence and bruise size but not for pain of injection, pain of injection site postinjection; or cost of preparation of subcutaneous heparin injections. Thus, there is less protection against a type II error for those responses where power level was not calculated prior to the study.

6) Pain scores on the MPQ-SF and VAS were very low in this sample. This skewed distribution may have led to an inability to detect the true relationships in questions that addressed these variables.

Recommendations

Research

Several recommendations for future research were identified as a result of this study. Although the cross-over design was a definite strength in this research, the contextual stimuli of sex and age pointed out differences in the sample on the responses studied. Age affected pain injection scores when analyzed by younger and older groups of subjects. Sex was found to affect bruise occurrence at a significant level. Female subjects also scored higher on the CES-D than males in this sample. Diagnostic group was found to affect pain of injection 3. This finding may have been a reflection of the demographic makeup of the subjects in the gynecologic group, again reflecting variance in pain of injection by sex. Future research designs could be strengthened when subjects are grouped by sex. Cross-over treatment within each group would protect for many other residual stimuli, including pain perception and bruisability. The power analysis in future research should take into consideration the smaller effect size for bruise occurrence and pain seen in men in this study. The cross-over design also would offer protection against sample differences if the CES-D tool were used to explore further the relationship between depression and pain

response. Another potential sample difference in CES-D scores is effect of body size as measured by caliper. The relationship between caliper measurement and CES-D scores was not explored in this study and thus remains in the residual stimulus pool.

Due to the posssibility of a type II error in hypostheses 4 and 5, further exploration of the corresponding research questions is suggested. If these areas are included in future studies of the nursing intervention of administration of subcutaneous heparin injections, a power analysis should be calculated for the specific hypothesis. This study indicated that the effect size of pain of injection site measured postinjection, may be very small and thus would require a much larger sample size.

The Roy adaptation model guided this researcher to suggest future research regarding the residual stimuli identified in this study. The stimuli to be explored further include the effect of bruising at injection site on the self-concept mode of the model and the effect of race on bruise occurrence. Tools for measuring attributes of both these residual stimuli need to be located or developed and tested.

The magnitude of the focal stimulus of injectate volume can be manipulated further in future research by exploring a wider range of concentrations. This recommendation is made based on Roy's (1989) seventh assumption of variance in the adaption level depending on the range and magnitude of stimuli. The time frame for measurement of bruise occurrence and surface area also warrant further study.

Practice

The findings of this study failed to dispute current nursing practice of using two injectate volumes (.5 ml and 1 ml) for the administration of subcutaneous heparin. Nurses in practice, however, should be alert to clinical variance in patient responses in the areas of bruise occurrence, bruise surface area, pain of injection, and pain of injection site post - injection. If clinical evidence of a range of injectate volumes affecting the responses is noted, then further clinical research on this problem is indicated.

The tools used in this study also may be of interest to nurses in clinical practice. The finding of some level of depression in 44% of the sample and severe depression in 18% of the sample, measured on the CES-D, indicated that there is a need to screen for depression in the population that requires hospitalization for medical-surgical problems. The CES-D tool requires little time for administration, is simple to administer, and is easy to score. This type of tool seems to be of benefit in the assessment of depression in non-psychotic populations.

The vertical VAS scale also was easy to administer and has validity and reliability for measuring pain. This scale can be used to measure pain responses to a variety of focal stimuli, including the pain of disease, surgery, or a given intervention. Funk et al. (1989) commented on the National Institutes of Health report regarding the under-treatment of acute pain. The VAS tool could be useful to nurses in the clinical setting to obtain data about the intensity of pain experienced by clients and amount of relief that they obtain post-intervention. The MPQ-SF also could be useful in the clinical setting, particularly when information is needed on the sensory and affective components of pain as well as intensity. This abbreviated form of the McGill Pain Questionnaire can be administered in a short period of time and is easy for clients to use. The information produced by these tools may enable nurses to intervene more effectively to relieve pain.

Summary

The effect of subcutaneous sodium heparin injectate volume on pain and bruising was explored in this study using the Roy adaptation model. The focal stimulus of injectate volume manipulated included .5 ml and 1 ml of sodium heparin. The design controlled for several contextual and residual stimuli because subjects served as their own control. The effect of contextual stimuli on responses of pain of injection, bruise occurrence and size, and pain of injection site postinjection also was explored. In addition, the relationship between depression and pain was addressed. Variance within several contextual stimuli identified in the sample was explored.

Null hypotheses 1 through 7 were supported based on findings from data analysis (N=50). Null hypothesis 8 was supported based on a small sample (n=5) of timed trials in the preparation of 10 doses of subcutaneous heparin.

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APPENDIX A

Instrumentation

CES-D Tool for Measuring Depression Symptoms

Circle the number for each statement which best describes how often you felt or behaved this way - DURING THE PAST WEEK.

		Rarely or None of the Time (Less than 1 Day)	Some or a Little of the Time (1-2Days)	Occasionally or a Moderate Amount of the Time (3-4Days)	Most or All of the Time (5-7Days)
	DURING THE PAST WEEK:				
1.	I was bothered by things that usually don't bother me	0	1	2	3
2.	I did not feel like eating: my appetite was poor	0	1	2	3
3.	I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4.	I felt that I was just as good as other people	0	1	2	3
5.	I had trouble keeping my mind on what I was doing	0	1	2	3
6.	I felt depressed	0	1	2	3
7.	I felt that everything I did was an effort	0	1	2	3
8.	I felt hopeful about the future	0	1	2	3
9.	I thought my life had been a failure	0	1	2	3
10.	I felt fearful	0	1	2	3
11.	My sleep was restless	0	1	2	3
12.	I was happy	0	1	2	3
13.	I talked less than usual	0	1	2	3
14.	I felt lonely	0	1	2	3
15.	People were unfriendly	0	1	2	3
16.	I enjoyed life	0	1	2	3
17.	I had crying spells	0	1	2	3
18.	I felt sad	0	1	2	3
19.	I felt that people disliked me	0	1	2	3
20.	I could not get "going"	0	1	2	3

PSF:bg
Facl.44

VAS for Measuring Pain of Injection

Injection #_____
Subject #_____ Visual Analogue Scale

Instructions: This line is used to show how much the shot you just recieved hurts. The bottom of the line indicates "no pain" and the top indicates the "worst possible pain". Mark the spot on the line that you think indicates how much pain the shot caused. When you finish put the paper in the envelope provided and seal the envelope. The person giving the shot will not know how you rated the pain until after all shots in this study are given.

MPQ-SF for Measuring Pain of Injection Site

Short-Form McGill Pain Questionnaire
Ronald Melzack

Subject Number:_____ Date:_____
Injection Site Number:_____

INSTRUCTIONS: MARK ONE SPOT FOR EACH WORD ON THIS LIST AS IT DESCRIBES THE SENSATION OF THE THE SPOT YOU RECIEVED THE HEPARIN SHOT IN QUESTION. THE RESEARCHER WILL INDICATE WHICH BRUISE YOU ARE RATING.

	NONE	MILD	MODERATE	SEVERE
THROBBING	0)___	1)___	2)___	3)___
SHOOTING	0)___	1)___	2)___	3)___
STABBING	0)___	1)___	2)___	3)___
SHARP	0)___	1)___	2)___	3)___
CRAMPING	0)___	1)___	2)___	3)___
GNAWING	0)___	1)___	2)___	3)___
HOT-BURNING	0)___	1)___	2)___	3)___
ACHING	0)___	1)___	2)___	3)___
HEAVY	0)___	1)___	2)___	3)___
TENDER	0)___	1)___	2)___	3)___
SPLITTING	0)___	1)___	2)___	3)___
TIRING-EXHAUSTING	0)___	1)___	2)___	3)___
SICKENING	0)___	1)___	2)___	3)___
FEARFUL	0)___	1)___	2)___	3)___
PUNISHING-CRUEL	0)___	1)___	2)___	3)___

INSTRUCTIONS: MARK THE SPOT ON THIS LINE THAT BEST INDICATES HOW MUCH PAIN YOU ARE HAVING FROM THE SPOT WHERE YOUR RECIEVED THE HEPARIN SHOT IN QUESTION.

No Pain _____ Worst Possible Pain

PRESENT PAIN INTENSITY
INSTRUCTIONS: MARK THE NUMBER OR WORD THAT BEST INDICATES HOW MUCH PAIN YOU ARE HAVING FROM THE SPOT WHERE YOUR RECIEVED THE HEPARIN SHOT IN QUESTION.

0 NO PAIN ____
1 MILD ____
2 DISCOMFORTING ____
3 DISTRESSING ____
4 HORRIBLE ____
5 EXCRUCIATING ____

©

APPENDIX B

Tables

Table 1

Stimuli and Responses Explored

STIMULI		
FOCAL:	CONTEXTUAL:	RESIDUAL: *
Injectate volume	Depression symptoms	Trauma
	Age	Previous pain
	Sex	Pain perception
	Diagnosis	Pain threshold
	Surgery	Pain tolerence
	Side of injection site	Feelings
	Adipose tissue	Medications (other)
	Total doses of heparin	Ease of bruising
	Time of heparin injection	Cultural beliefs
	Medications in class 28:08.08 and 28:24.92	Fear of injection

RESPONSES:		
PAIN OF INJECTION:	BRUISE:	PAIN OF SITE:
VAS	Count	MPQ - SF
	Tracing and Scan	

*Residual Stimuli includes but is not limited to those stimuli listed.

Table 2

AHFS Classification of Medications

CLASS	NAME	NUMBER OF SUBJECTS
20:00	BLOOD FORMATION AND COAGULATION:	
20:12.04	Anticoagulants	3*
20:40	Thrombolytic Agents	2
28:00	CENTRAL NERVOUS SYSTEM AGENTS:	
28:08.04	Non-steroidal anti-inflammatory agents	1
28:08.08	Opiate Agonists	46
28:08.92	Miscellaneous analgesics and antipyretics	4
28:16.04	Antidepressants	2
28:16.08	Tranquilizers	2
28:24.92	Miscellaneous Anxiolytics, Sedatives, and Hypnotics	13

* 50 subjects received at least 2 doses subcutaneous of heparin (20:12.04).

The number in this table represents those subjects who received heparin lock flushes.

Table 3

Pearson Correlation Coefficients for
CES-D Scores and Pain Responses

Pain of Injection

	Injection 2	Injection 3
VAS:		
	r=0.08 (p=.60)	r=0.19 (p=.18)

Pain of Injection Site

	Injection Site 2	Injection Site 3
MPQ-SF:		
Sensory	r=0.17 (p=.24)	r=0.17 (p=.23)
Affective	r=0.26 (p=.11)	r=0.23 (p=.11)
Total	r=0.20 (p=.16)	r=0.20 (p=.15)
VAS	r=0.15 (p=.29)	r=0.07 (p=.58)
PPI	r=0.16 (p=.26)	r=0.14 (p=.34)

Table 4

Bruise Occurrence by Pain of Injection Site 2

	Pain		
	No	Yes	Total
BruOcc			
No	15	0	15
Yes	30	5	35
Total	45	5	50

Statistic	DF	Value	Prob
Chi square	1	2.38	.12
Fisher's exact	(Left)		1.0
	(Right)		.15
	(2 tailed)		.30

Table 5

Bruise Occurrence by Pain of Injection Site 3

	Pain		
	No	Yes	Total
BruOcc			
No	17	0	17
Yes	27	6	33
Total	44	6	50

Statistic	DF	Value	Prob
Chi square	1	3.51	.06
Fisher's exact	(Left)		1.0
	(Right)		.06
	(2 tailed)		.08

Table 6

Pearson Correlation Coefficient
Bruise Surface Area Relative to the MPQ-SF

Pain of Injection Site

	Injection Site 2		Injection Site 3	
MPQ-SF:	2-tailed	1-tailed	2-tailed	1-tailed
Sensory	r= -0.06 (p=.62)	(p=.31)	r= 0.03 (p=.79)	(p=.40)
Affective	r= -0.03 (p=.79)	(p=.39)	r= -0.02 (p= .88)	(p=.23)
Total	r= -0.05 (p=.68)	(p=.34)	r= 0.20 (p=.15)	(p=.23)
VAS	r= -0.06 (p=.67)	(p=.33)	r= 0.07 (p=.58)	(p=.23)
PPI	r= -0.07 (p=.62)	(p=.31)	r= 0.14 (p=.34)	(p=.23)

Table 7

Reports of Pain of Injection Site (n subjects) in Each Section of MPQ-SF by Injection

(N=50)

	Injection 2	Injection 3
Sensory	n = 4	n = 5
Affective	n = 1	n = 1
Total Pain	n = 4	n = 5
VAS	n =12	n = 9
PPI	n = 5	n = 6

Visual Analogue Scale (VAS)

Present Pain Index (PPI)

Table 8

Analysis of Variance (GLM) of Age Group and Pain of Injection Site Postinjection

	F Value	Two-Tailed
INJECTION 2 (N=50)		
SENSORY	$F(1,19) = 2.02$,	$p = .16$
AFFECTIVE	$F(1,19) = 0.56$,	$p = .46$
TOTAL PAIN	$F(1,19) = 1.41$,	$p = .24$
VAS	$F(1,19) = 3.06$,	$p = .08$
PPI	$F(1,19) = 2.31$,	$p = .13$
INJECTION 3 (N=50)		
SENSORY	$F(1,19) = 2.06$,	$p = .16$
AFFECTIVE	$F(1,19) = 0.56$,	$p = .46$
TOTAL PAIN	$F(1,19) = 1.42$,	$p = .24$
VAS	$F(1,19) = 2.10$,	$p = .15$
PPI	$F(1,19) = 2.31$,	$p = .13$

Table 9

Analysis of Variance (GLM) of Sex and Pain of Injection Site Postinjection

	F Value	Two-Tailed
INJECTION 2 (N=50)		
SENSORY	$F(1,19) = 1.38$,	$p = .25$
AFFECTIVE	$F(1,19) = 0.38$,	$p = .53$
TOTAL PAIN	$F(1,19) = 0.97$,	$p = .33$
VAS	$F(1,19) = 2.69$,	$p = .11$
PPI	$F(1,19) = 1.57$,	$p = .22$
INJECTION 3 (N=50)		
SENSORY	$F(1,19) = 1.41$,	$p = .24$
AFFECTIVE	$F(1,19) = 0.38$,	$p = .54$
TOTAL PAIN	$F(1,19) = 0.98$,	$p = .33$
VAS	$F(1,19) = 1.49$,	$p = .23$
PPI	$F(1,19) = 2.05$,	$p = .16$

Table 10

Analysis of Variance (GLM) of Diagnosis Group and Pain of Injection Site Postinjection

INJECTION 2 (N=50)

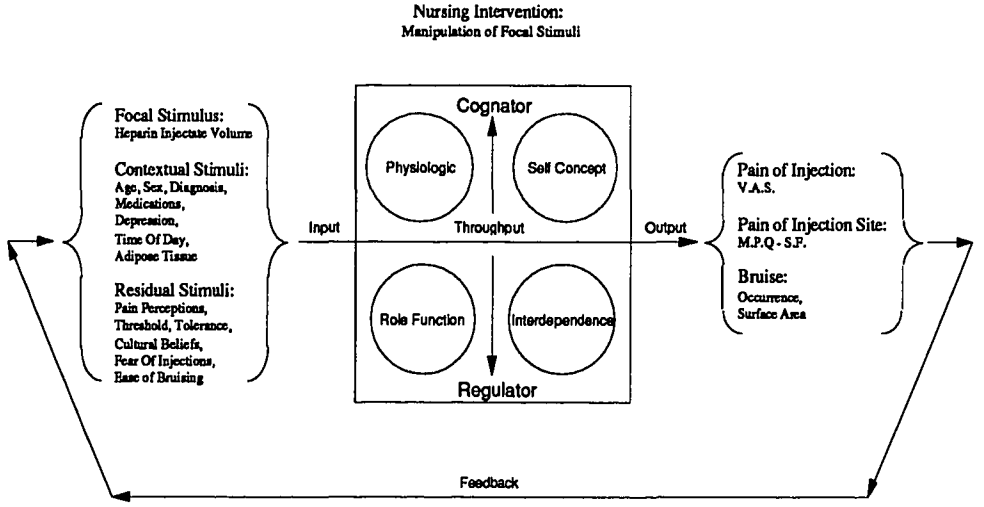
	GYNECOLOGIC(n=20)	OTHER (n=30)
SENSORY	$F(1,19) = 0.88$, $p = .36$	$F(1,29) = 1.04$, $p = .31$
AFFECTIVE	$F(1,19) = 0.32$, $p = .57$	$F(1,29) = 99.99$, $p = .00$
TOTAL PAIN	$F(1,19) = 0.66$, $p = .43$	$F(1,29) = 1.04$, $p = .31$
VAS	$F(1,19) = 1.35$, $p = .26$	$F(1,29) = 1.18$, $p = .29$
PPI	$F(1,19) = 0.80$, $p = .38$	$F(1,29) = 1.04$, $p = .32$

INJECTION 3 (N=50)

	GYNECOLOGIC(n=20)	OTHER (n=30)
SENSORY	$F(1,19) = 1.85$, $p = .19$	$F(1,29) = 0.49$, $p = .49$
AFFECTIVE	$F(1,19) = 0.53$, $p = .48$	$F(1,29) = 99.99$, $p = .00$
TOTAL PAIN	$F(1,19) = 1.27$, $p = .43$	$F(1,29) = 0.49$, $p = .49$
VAS	$F(1,19) = 1.91$, $p = .18$	$F(1,29) = 0.31$, $p = .58$
PPI	$F(1,19) = 2.80$, $p = .11$	$F(1,29) = 0.49$, $p = .49$

APPENDIX C

Figures



Adapted From:
Andrews, H.A. & Roy, C. (1986). Essentials of the Roy adaptation model , Norwalk, CT: Appleton-Century-Crofts.

Figure 1. Problem in View of Conceptual Framework

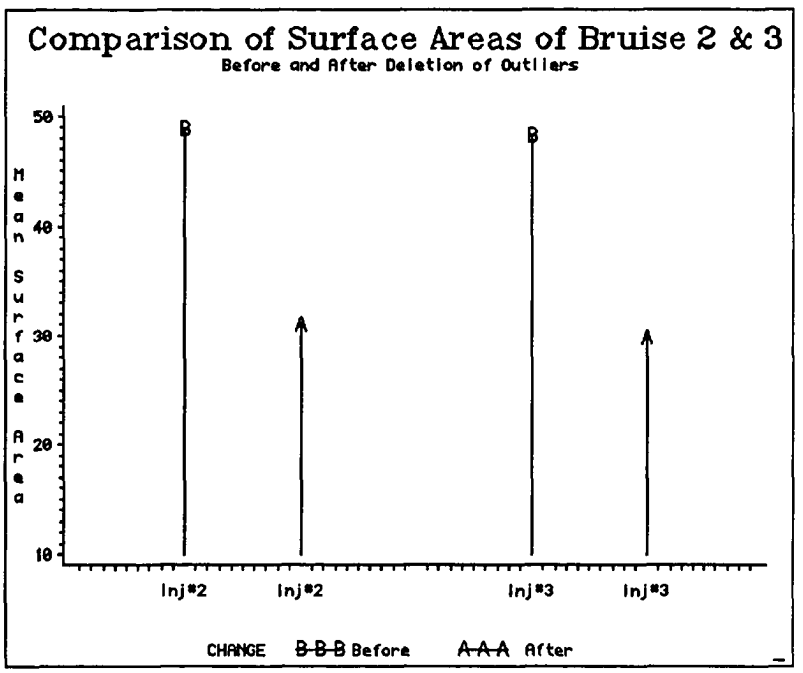


Figure 2. Mean Surface Area for Each Injection on Rounds 1 and 2 of Data Analysis

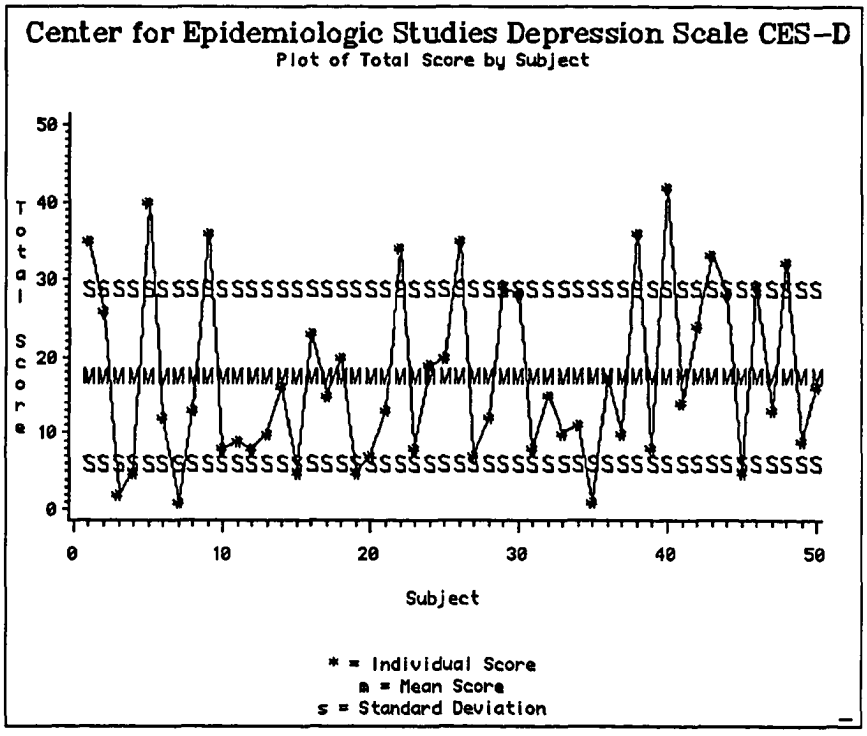


Figure 3. CES-D Total Score, Mean, and Standard Deviation by Subject.

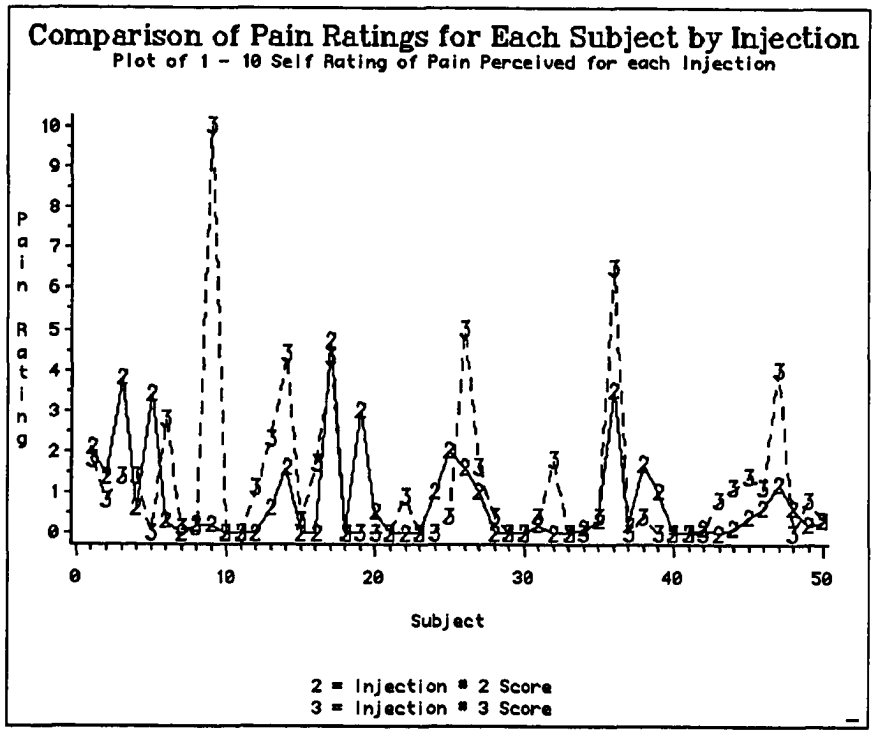


Figure 4. Relationship of VAS Scores for Injections 2 and 3.

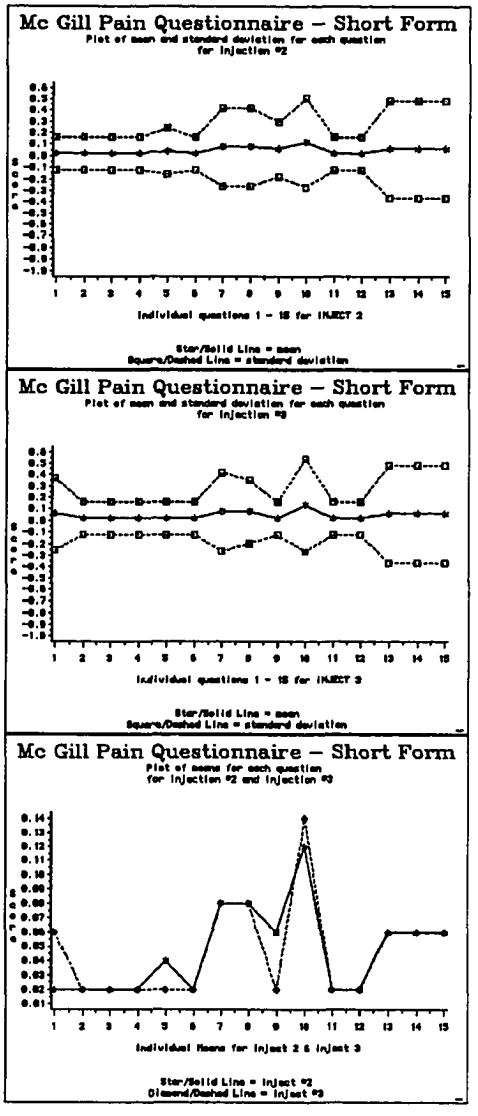


Figure 5. MPQ-SF Scores for Injection 2, Injection 3, and a Superimposed Graph of Injection 2 and 3.

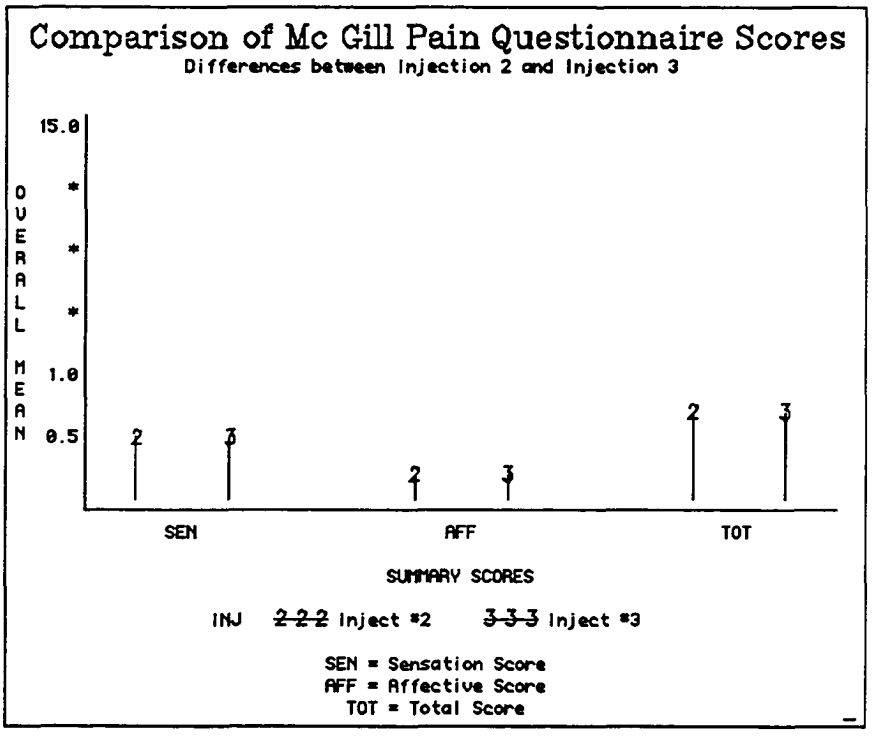


Figure 6. Mean Scores for Sensory, Affective, and Total Pain MPQ-SF Scores for Injections 2 and 3.

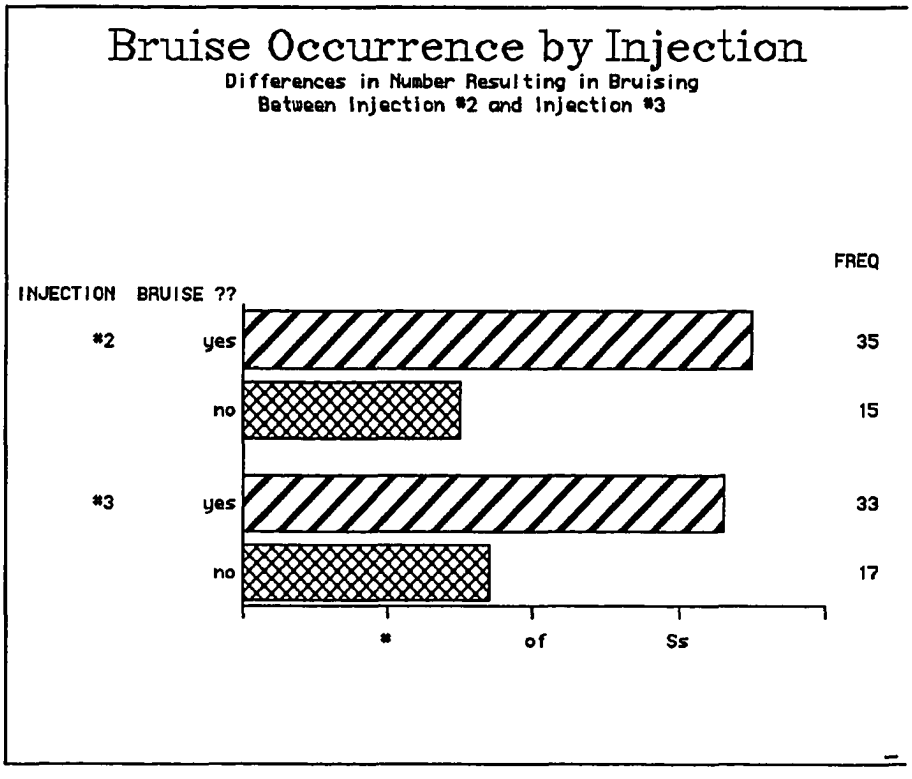


Figure 7. Frequency of Bruise Occurrence Regardless of Volume for Injections 2 and 3

GRADUATE SCHOOL
UNIVERSITY OF ALABAMA AT BIRMINGHAM
DISSERTATION APPROVAL FORM

Name of Candidate Pamela Stewart Fahs

Major Subject Adult Health Nursing

Title of Dissertation The Effect of Subcutaneous Heparin on Pain and Bruising Using the Roy Model

Dissertation Committee:

[redacted] Chairman [redacted]

Director of Graduate Program [redacted]

Dean, UAB Graduate School [redacted]

Date

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