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Effects of Injection Duration on Site-Pain Intensity and Bruising Associated with Subcutaneous Administration of Lovenox (Enoxaparin Sodium)

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EFFECTS OF INJECTION DURATION ON SITE-PAIN INTENSITY AND
BRUISING ASSOCIATED WITH SUBCUTANEOUS ADMINISTRATION OF
LOVENOX (ENOXAPARIN SODIUM)

By

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Deep vein thrombosis (DVT) is a leading cause of preventable death in the United States. The possibility of developing a DVT is one major complication for the patient population with damaged blood vessels, decreased circulation problems or restricted mobility. DVTs can eventually lead to strokes, myocardial infarctions or pulmonary embolisms, often preventable complications that not only harm the patient but increase the resources needed to treat and rehabilitate the individual.

Lovenox (enoxaparin sodium), a low molecular weight heparin (LMWH), has been approved for prophylaxis prevention of DVTs. Research is demonstrating that LMWHs are becoming the drugs of choice in a range of clinical settings, due to their high bioavailability in the body, long half-life, and more predictable anticoagulation response. However, Lovenox can only be delivered as a subcutaneous injection, a potential cause of site-pain and bruising. Several local reactions, including mild irritation, pain, hematoma, ecchymosis, and erythema have been demonstrated at the injection site of Lovenox.

The purpose of the study was to explore the effects of two different injection techniques (10-second and 30-second) on pain and bruising associated with subcutaneous administration of Lovenox. Only after a review and analysis of these techniques can nurses conclude which promotes the best patient outcome.

Thirty-four patients received two injections of Lovenox, one over 10-seconds and the other over 30-seconds. The participants were asked to rate any perceived pain at the injection site for each injection. Additionally, any bruising noted with the injection site, if present, was measured and recorded.

The hypotheses examined whether or not the use of a 30-second subcutaneous injection technique with Lovenox would result in lower levels of perceived site-pain and bruising when compared with a 10-second injection technique on the same
hospitalized patient. Based on the data collected, there appeared to be no significant difference between the two techniques used and the patient’s perceived level of pain ($p = 0.941$) or measured bruising ($p = 0.549$). Therefore, the researcher’s hypotheses were not supported. These findings demonstrate the importance of conducting repeated research studies in the future to determine which technique to accept, or even reject, in clinical practice.
CHAPTER 1
INTRODUCTION

As the population in the United States ages, more and more individuals will become hospitalized for a wide range of acute illnesses and injuries. The need for hospital beds will continue to grow. This pressure will cause healthcare professionals to explore new, more creative ways to expedite a patient through the system while maintaining a safe environment.

Patients with higher acuity levels will require more skilled and knowledgeable staff, better medications, and more hospital bed care. These same individuals are often required to maintain bedrest, or have decreased mobility, as a result of their illness. Patients with impaired mobility or on prolonged bedrest due to trauma, surgery, or nursing interventions are often prescribed heparin subcutaneously to prevent embolic complications (McGowan & Wood, 1990). If appropriate interventions are not taken, this decrease in activity and mobility can lead to further complications such as thrombi formation (Agnelli & Sonaglia, 2000; Mozaffarian, 2002; Pavlovich-Danis, 2002).

The possibility of developing a deep venous thrombosis (DVT) is one major complication for the patient population with damaged blood vessels, decreased circulation problems, or restricted mobility (Agnelli & Sonaglia, 2000; Mozaffarian, 2002; Pavlovich-Danis, 2002). It can lead to strokes, myocardial infarctions, or pulmonary emboli (Pavlovich-Danis, 2002). These complications would not only cause harm to the patient but also increase the resources needed to treat and rehabilitate that individual.

Anticoagulation medications are available that can be delivered subcutaneously that reduce the morbidity and mortality associated with DVTs in the patient population (Agnelli & Sonaglia, 2000; Hovanessian, 1999; Pavlovich-Danis, 2002). Use of a low molecular weight heparin (LMWH), as part of the patients’ anticoagulation therapy, is
one intervention that can be implemented to prevent the formation of thrombi (clots) that
cause DVTs, pulmonary emboli, strokes and/or myocardial infarctions (Agnelli &
Sonaglia, 2000; Hovanessian, 1999; Pavlovich-Danis, 2002). As a result, research is
demonstrating that LMWHs are becoming the drugs of choice in a range of clinical
settings, due to the medications’ high bioavailability in the body, long half-life, and more
predictable anticoagulation response, compared to unfractionated heparin (Agnelli &
Sonaglia, 2000; Boccalon, Elias, Chale, Cadene & Gabriel, 2000; Braunwald, 1998;
Cohen et al., 1998; Hirsh, 1998; Hovanessian, 1999; Kalafut, Gandhi, Kidwell & Sauer,
2000; Levine et al., 1996; Rutschmann & Matchar, 2000; Venketasubramanian & Chua,

Nurses are advocates for patient safety. They must do what is in the patients’ best
interest while causing the least harm or distress. However, at times, and with the best
intentions of hospital personnel, varying degrees of discomfort and bruising are an
unavoidable side effect of patients’ medical treatment (Chan, 2001; Kuzu & Ucar, 2001;
Mitchell & Whitney, 2001; Ross & Soltes, 1995; Scarfone, Jasani & Gracely, 1998;
Venketasubramanian & Chua, 1998). Nurses are routinely at the bedside to provide care,
comfort, and information for the patient population. The nursing profession is the front-
line provider of health care. They admit, assess, monitor, and treat a broad range of
ailments. Patients see nurses as their caring hands in an unfamiliar environment. The
nursing profession is often caught in the middle of a never-ending struggle - providing
appropriate and prescribed care under the medical guidance of a physician, while
maintaining a safe, pain-free environment for the patient.

Statement of the Problem

Subcutaneous injections often cause pain and bruising (Chan, 2001; Kuzu &
Ucar, 2001; Ross & Soltes, 1995; Venketasubramanian & Chua, 1998). When nurses give
injections as part of the medical care, it can cause patients to become apprehensive about
receiving future subcutaneous medications, anxious about the nursing staff, or even
noncompliant with medical care. Kuzu and Ucar (2001) noted that site-pain causes the
patient physical and psychological discomfort and bruising limits possible sites for
subsequent injections (Kuzu & Ucar, 2001). It is imperative that techniques be explored
in nursing care delivery that reduce, or even eliminate, pain or bruising experienced by patients. These techniques must be tested on patients with care, compassion, and within the scope of knowledge and practice of the nursing profession. As patient care and satisfaction improve, so will the trust patients place in their healthcare providers.

**Significance of the Problem**

Advanced practice nurses must be leaders in their profession. They must expand their own knowledge and scope of practice while conducting research that develops or improves future techniques for use by all nurses. Current techniques need to be examined and tested to promote better patient comfort and outcomes and improve quality of life.

Lovenox (enoxaparin sodium), a low molecular weight heparin, has been a promising drug used in the treatment of venous thromboemboli in medical, coronary, and neurologically compromised patients (Bergqvist, 2002; Cohen et al., 1998; Hovanessian, 1999; Physicians’ Desk Reference, 2001; Warner & Perry, 2001; Zidar, 1998). Lovenox has been approved for prophylaxis treatment of deep vein thrombosis (DVT) and ischemic complications of unstable angina when used with aspirin (Physicians’ Desk Reference, 2001). Prophylactic use of low molecular weight heparin can help simplify the treatment and prevention of DVTs since it is administered subcutaneously and often does not require laboratory monitoring (Gould, Dembitzer, Ramona, Trevor & Garber, 1999; Hovanessian, 1999). This is different from prophylactic treatments involving the use of unfractionated heparin and/or warfarin which requires continual laboratory monitoring. Use of Lovenox carries certain risks and should be used with caution in patients with hemorrhages, thrombocytopenia, or prosthetic heart valves (Physicians’ Desk Reference, 2001). Several local reactions, including mild irritation, pain, hematoma, ecchymosis, and erythema have also been demonstrated at the injection site with the use of subcutaneous Lovenox (Physicians’ Desk Reference, 2001).

Pain and bruising are important concerns for many patients admitted to the hospital for treatment (Chan, 2001). Injections are one source of bruising and pain in hospitalized patients (Chan, 2001). It is the duty and obligation of the nursing community to explore ways to help alleviate patients’ fear and concerns. By conducting research on injection technique, nurses would develop increased awareness, knowledge, and skills
relating to subcutaneous injections in terms of site-pain and bruising. Nurses would then
be able to utilize newer, better supported techniques to provide better patient care in the
future. By developing techniques that promote patient comfort and safety, nurses help to
advance the profession and the trust patients have for their caregivers. Results obtained
from a study on Lovenox could help develop, or reinforce, other practical applications or
techniques for subcutaneous injections in the future. The patients, medical community,
and society would benefit from the knowledge gained, ultimately encouraging others who
will follow in current nurses’ footsteps, to develop and build even more creative ideas for
nursing care.

Statement of Purpose

The purpose of the proposed study is to explore the effects of two different
injection techniques on pain and bruising associated with subcutaneous administration of
Lovenox (enoxaparin sodium). Patients will be given two doses of Lovenox in the
abdomen using 10-second and 30-second injection durations. The outcomes to be
addressed are (a) perceived injection site-pain as measured with a Numerical Rating
Scale (NRS), and (b) measured bruising. The perception of site-pain and the potential
presence of bruising at the injection site warrant a review of the techniques currently
used. Only after a review and analysis of these techniques can nurses conclude which
promotes the best patient comfort and outcome.

Research Questions

This study will explore the following research questions:

1. What is the difference of site-pain perceived by the same hospitalized patient
receiving subcutaneous injections of Lovenox using two different injection techniques?

2. What is the difference in measurable size of bruising, if any, on the same
hospitalized patient receiving subcutaneous injections of Lovenox, measured 48 hours
after administration, using two different injection techniques?
Hypothesis

The researcher will examine the following two hypotheses:

Use of a 30-second subcutaneous injection technique with Lovenox (enoxaparin sodium) will result in lower levels of perceived site-pain when compared with a 10-second injection technique of Lovenox on the same person.

Use of a 30-second subcutaneous injection technique with Lovenox (enoxaparin sodium) will result in less measurable bruising at the injection site when compared with a 10-second injection technique of Lovenox on the same person.

Operational Definitions

Polit and Hungler (1999) defined operational definitions as a specification of the operations that the researcher must perform to collect the required information. “The definition must specify how the variable will be observed and measured in the actual research situation” (Polit & Hungler, 1999, p. 28). The following are pertinent definitions to the study and how each definition will be measured or examined in the context of this study.

Anticoagulation

A substance that prevents or delays coagulation of the blood (Glanze, 1990). For this study, it will refer to any medications that delay coagulation as listed on the patient’s medication administration record (MAR) or physician’s order sheet.

Bruising

An area of skin discoloration caused by the extravasation of blood into the subcutaneous tissues as a result of trauma to the underlying blood vessels or by fragility of the vessel walls (Glanze, 1990; McGowan & Wood, 1990). For this study, it is the measured diameter in millimeters at the bruise’s greatest width 48 hours after administration of the injection.

Deep Vein Thrombosis (DVT)

A blood clot in a deep vein of the body, usually in the thigh or leg (Mozaffarian, 2002). DVTs are caused by venous stasis, vascular damage, and hypercoagulability within the body (Pavlovich-Danis, 2002). For this study, it is the diagnosis documented in the patient’s progress notes or problem list of the medical chart.
**Injection technique**

The specific method used to deliver subcutaneous medications. Two different techniques, 10-second and 30-second injection durations, will be utilized in this study.

**Lovenox**

Trade name for enoxaparin sodium, a low molecular weight heparin with antithrombotic properties used to prevent venous thromboembolism (Physicians’ Desk Reference, 2001). For this study, it is the order for enoxaparin sodium as part of the patient’s anticoagulation therapy documented on the medication administration record (MAR) or physician orders.

**Site-pain**

Pain is an unpleasant sensory or emotional experience which is primarily associated with tissue damage or described in terms of tissue damage, or both. Pain is a complex perception that takes place only at higher levels of the central nervous system (Pain.com, 2002). Use of the Numerical Rating Scale (NRS) will allow the researcher to measure the patient’s perceived level of pain. The NRS is a horizontal or vertical line with numbers, usually 0 (no pain) to 10 (worst possible pain) indicating a patient’s perceived level of pain (Puntillo & Casella, 1998). For this study, it is the point on this scale indicated by the patient 30 seconds following the injection of Lovenox.

**Conceptual Framework**

The Neuman Systems Model will be the theoretical foundation for the current research study. It is a “system-based conceptual framework for nursing and other health care disciplines that is concerned with stressors, reactions to stressors, and the prevention interventions that address potential and actual reactions to stressors” (Neuman, 2002, pg. 13). There are basic components of Neuman’s Systems Model that must be summarized in order to understand how her framework could guide this and other future research studies.

According to Neuman, each patient is unique. However, within each system or patient, there are characteristics that allow for a certain range of normal or even predictable responses (Neuman, 2002). Patients are often placed in unfamiliar environments and find they must deal with their given situation. Neuman’s model (2002)
indicates that within this environment, many known and unknown environmental stressors exist. Each stressor, whether it is a subcutaneous injection or major surgery, disrupts the patient’s stability level or normal line of defense (Neuman, 2002). Each individual develops, over time, a normal range of responses to the environment (Neuman, 2002). This is often referred to as the normal line of defense or usual wellness/stability state (Neuman, 2002). When the patient’s flexible line of defense weakens and draws down to the normal line of defense, losing the protective space between them, the stressor can eventually penetrate the patient’s normal line of defense (Neuman, 2002). It is the interrelationship of the person’s physiological, psychological, sociocultural, developmental, and spiritual variables that determines how much the individual will react to the stressor (Neuman, 2002). The individual’s intrapersonal, interpersonal, and extrapersonal factors might help determine to what degree the individual will react to a painful or stressful situation. A person under little stress while in the hospital might have little to no reaction when approached about a subcutaneous injection. As a result, one patient might rate a level of pain quite differently from another individual undergoing extensive surgery or having numerous medical complications or health problems.

Assumptions
There are several assumptions by the researcher that warrant review:
1. Lovenox (enoxaparin sodium) will be given with the expected subcutaneous injection technique.
2. Patients will rate their pain accurately and truthfully.
3. The degree or level of pain experienced is whatever the patients reports it to be.
4. The research nurse will measure the bruising, if present, at the injection site accurately and truthfully.
5. The data collected by the researcher will be accurate and true.

Limitations
The following limitations will influence this study:
1. Pain is a subjective experience.
2. This study will be a smaller sized sample of convenience. The participants will be taken from only one geographical location. It will be limited to patients admitted only to the neurological intensive care unit (V-NICU), orthopedic/neurological (4N), cardiac intensive care unit (CICU), or cardiac (3N) treatment areas at a local hospital.

3. Use of the same patient to rate perceived pain at the injection site might bias the results.

Summary

As the population ages, more and more individuals will become hospitalized for a wide range of illnesses and injuries. As a result of these illnesses, injuries, or nursing interventions, patients will often have restricted mobility or be confined to bedrest (McGowan & Wood, 1990). The possibility of complications arises with a decrease in the individual’s mobility (Agnelli & Sonaglia, 2000; Mozaffarian, 2002; Pavlovich-Danis, 2002). Deep vein thrombosis (DVT) is one such complication (Agnelli & Sonaglia, 2000; Mozaffarian, 2002; Pavlovich-Danis, 2002). DVTs can eventually lead to strokes, pulmonary emboli, or myocardial infarctions if prophylactic treatments and interventions are not instituted early (Pavlovich-Danis, 2002).

Low molecular weight heparins (LMWH) are available as part of a patient’s anticoagulation therapy plan to prevent the formation of thrombi (clots; Agnelli & Sonaglia, 2000; Hovanessian, 1999 Pavlovich-Danis, 2002). The use of LMWHs are becoming the drugs of choice, due to the medications’ high bioavailability, long half-life and more predictable anticoagulation response, compared to unfractionated heparin (Agnelli & Sonaglia, 2000; Boccalon, Elias, Chale, Cadene & Gabriel, 2000; Braunwald, 1998; Cohen et al., 1998; Hirsh, 1998; Hovanessian, 1999; Kalafut, Gandhi, Kidwell & Sauer, 2000; Levine et al., 1996; Rutschmann & Matchar, 2000; Venketasubramanian & Chua, 1998; Warner & Perry, 2001; Zidar, 1998). Lovenox, a LMWH, is given as a subcutaneous injection (Physicians’ Desk Reference, 2001). Patients are often apprehensive about receiving subcutaneous injections since they are known to cause site-pain and bruising (Chan, 2001; Kuzu & Ucar, 2001; Ross & Soltes, 1995; Venketasubramanian & Chua, 1998). The researcher plans to explore two different
subcutaneous injection techniques and their effects on site-pain and bruising. Using the Neuman’s Systems Model (2002) as the theoretical framework, the goal of this study is to determine which technique can help validate current, or improve future, injection techniques for all nurses. Chapter 2 will explore the theory and practical applications of Neuman’s System Model as well as other pertinent research associated with pain, bruising, and Lovenox.
CHAPTER 2
REVIEW OF LITERATURE

This chapter will examine the Neuman Systems Model, the theoretical basis for this study, as well as review the literature supporting the purpose of this research study. A theoretical description and empirical review of literature relating to Betty Neuman’s Systems Model, anticoagulation, low molecular weight heparin, Lovenox (enoxaparin sodium), gate control theory of pain, site-pain, pain assessment, bruising, and future research will be presented.

Theoretical Review

The Neuman Systems Model

The Neuman Systems Model has been widely used in nursing education, practice, and research since its creation in the 1970’s by Betty Neuman. The model is dynamic. It is based on the patient’s relationship to environmental stress, which has the potential to cause a reaction, or could affect the patient’s reconstitution following treatment of a stress reaction. The goal of the nurse is to facilitate an environment of optimal wellness through retention, attainment, or maintenance of patient system stability. The Neuman Systems Model is discussed according to the model’s components: person, environment, health, and nursing (Neuman, 2002).

Person. Within the context of Betty Neuman’s model, the person can be an individual (i.e. hospitalized patient), a group, or family. Inside the client, there are five interacting variables: physiological (body structure and function), psychological (mental processes and interactive environmental effects), sociocultural, developmental (age-related developmental processes) and spiritual (spiritual beliefs and influences). These five variables are located within the client system, which includes the basic structure, the
flexible line of defense, the normal line of defense, and the lines of resistance (Neuman, 2002).

The basic structure is the core of the client system. Located inside the basic structure are the survival factors common to man such as normal temperature range, genetic structure, and organ strengths/weaknesses. The basic structure is protected by rings of concentric circles (flexible line of defense, normal line of defense, and lines of resistance) that preserve its integrity (Neuman, 2002).

The flexible line of defense is the outermost concentric circle, or boundary, that provides a buffer system for the person’s stable state. Its role is to provide a first line of defense from stressor invasions in order to help keep stability within the client system. The flexible line of defense is fluid, not static, moving away or towards the client’s normal line of defense. As the flexible line of defense moves away, more protection is provided to the system. However, as the flexible line of defense moves towards the normal line of defense, less protection is provided. Stressors can weaken this buffer system, ultimately leading to a reaction with the whole system. Large or repeated stressors can weaken the system. If the system is weakened beyond its capacity, or overwhelmed, the result is death (Neuman, 2002).

The normal line of defense signifies the client’s evolved state over time or usual wellness level. If a stressor overwhelms the client’s flexible line of defense, it can enter the normal line of defense, eventually reducing the systems’ resistance to additional stressors. However, the normal line of defense allows the client to deal with life stresses and remain stable, helping to keep the entire system intact. This type of client would experience changes with daily variations, or stressors, present in the environment. His/her baseline blood pressure, heart rate, and respiratory rate would change when stressed. Over time, the normal line of defense would either remain stable throughout the stress, and allow for the client’s vital signs to return to baseline, or weaken, leading to possible medical complications (Neuman, 2002).

Finally, if the normal line of defense is breached by an environmental stressor, the client system activates its lines of resistance. The client could enter a fight-or-flight response. Body functions such as blood pressure, heart rate, and respiratory rate would rapidly increase, while gastrointestinal motility would decrease, to provide oxygen and
blood to vital organs. The goal of the lines of resistance is to protect the system’s basic structure. Failure to do so would allow the stressor to enter the system’s basic structure and cause energy depletion and death. The hope is for the lines of resistance to resist or reverse the stressor, thus allowing the system to return to normal (Neuman, 2002).

The use of Neuman’s Systems Model fits well with the current research project. Neuman’s model explores a system, or person’s, reaction to stress and reconstitution following stress. A person may react quite differently to stress while being a patient in a hospital versus home. The reality of an illness may cause a patient to be overwhelmed more easily when compared to another point in time. As a result of stress placed on a hospitalized patient, an individual may have a weakened flexible line of defense, normal line of defense, and/or lines of resistance. The stress may ultimately affect the client’s basic structure leading to a reaction within the system. This reaction may affect present and future treatments, such as perception of site-pain following a subcutaneous injection.

Environment. Environment refers to any internal or external factors surrounding the client. The environment can be internal, forces within the client; external, forces outside the client; or created, an open system of exchanging energy with the internal and external environment (Neuman, 2002).

Neuman’s Systems Model defined stressors as “tension-producing stimuli with the potential for causing system instability” (Neuman, 2002, pg. 21). Depending on the client’s ability to handle the stressor, the client can have either a positive or negative outcome. Additionally, the client’s five variables help to protect the individual from instability caused by the stressors. A stressor can cause a reaction within the client system or affect the individual’s ability to return to a stable state after symptoms are treated (Neuman, 2002).

In terms of the current project, environment will refer to the hospital setting where a patient will receive any treatment. Additionally, environment will mean the internal structure and support the patient possesses. One patient could have a strong constitution and handle stress well while a similar type of patient may possess a weaker internal support system and handle stress poorly. As a result, each patient may have different reactions to a common medical procedure (i.e. subcutaneous injection).
Health. Wellness and illness are the two extremes of health as described by Neuman. Wellness refers to more energy being generated than used, versus illness, where more energy is used than generated. The health of the client is ever changing depending on how the system can adjust to environmental stressors (Neuman, 2002).

Each patient that is participating in this research study will be at some point on a wellness/illness continuum. The current degree of wellness, or illness, could affect the state and stability of the system. Ultimately, leading to varying degrees of patient reaction to treatments while hospitalized.

Nursing. The task for nurses is to maintain, or return, stability to the client system when it is exposed to environmental stressors. The nurse represents the common bond between the model’s four components: person, environment, health, and nursing. Their actions to provide optimal care and keep the system stable are achieved using interventions as prevention. There are three different levels of prevention as intervention: primary, secondary, and tertiary (Neuman, 2002).

Primary prevention as intervention, or wellness retention, is the beginning of the relationship between the client and the caregiver. It occurs before any reaction to stress has occurred. The function of the primary prevention as intervention is to protect the normal line of defense or strengthen the flexible line of defense of the client system. The goal is to provide wellness to the system by preventing stress or reducing its risk factors to stressors. This level of prevention is provided when the hazard is known but no reaction has occurred within the system. The nurse providing this level of prevention reduces the likelihood of a stress encounter with the client system or strengthens the flexible line of defense to decrease the likelihood of a reaction within the system (Neuman, 2002).

Advanced practice nurses can provide primary prevention as an intervention by conducting research studies that validate, or promote, various nursing techniques. The current study intends to explore the technique of administering a subcutaneous injection. By improving injection techniques, nurses may help to reduce the complications (i.e. site-pain and/or bruising) of subcutaneous injections.

Secondary prevention as intervention, or wellness attainment, occurs after a stressor reaction to the client system. Its function is to strengthen the lines of resistance,
thereby protecting the client’s basic structure. The goal of secondary prevention, as intervention, is to return the client to a level of wellness by treating the symptoms of the stressor. Nursing can aid the client by helping the individual focus on any internal and external resources. This will strengthen the internal lines of resistance and as a result reduce the reaction within the client system (Neuman, 2002).

Finally, tertiary prevention, as intervention, or wellness maintenance, follows a treatment of a stressor reaction. Its function is to return the client to wellness after treatment of symptoms. The goal is to maintain health and wellness by conserving energy and supporting strengths of the client system (Neuman, 2002).

Nursing can provide primary, secondary, or tertiary prevention, as intervention, for subcutaneous injection technique. If advanced practice nursing research could demonstrate which method of delivering subcutaneous injections was best for the hospitalized patient, the nurse could prepare the client for the injection. This would allow the client to prepare, make any needed internal adjustments, thereby strengthening the normal line of defense. If the client experienced symptoms such as pain, the nurse could help the client focus on internal resources to overcome the symptoms in order to reduce any reaction within the client system. Ideally, the client would have less reaction within the system or quicker reconstitution after the subcutaneous injection, allowing for wellness attainment or maintenance.

**Anticoagulation**

Anticoagulation is the process of introducing a substance into the body to prevent or delay coagulation of the blood (Glanze, 1990). It is an extremely important part of the treatment regimen for many hospitalized and non-hospitalized patients. There are medical conditions such as venous thromboembolism (VTE), a clot that forms in venous blood, that warrant the use of anticoagulant therapy (Pavlovich-Danis, 2002). These clots can remain stationary or move to another location in the body (Pavlovich-Danis, 2002). If a VTE breaks loose and becomes mobile in the body, known as a thromboembolism, it could lodge in a blood vessel and prevent blood flow to critical areas of the body. VTE is the most common cause of preventable death among hospitalized patients each year (Agnelli & Sonaglia, 2000). Deep vein thrombosis (DVT), one clinical manifestation of a
venous thromboembolism, are blood clots that typically develop in the deeper veins of the legs or thighs (Agnelli & Sonaglia, 2000; Mozaffarian, 2002). As a thrombus (clot) forms in a deeper vein, the flow of blood to the heart from the leg is blocked (Mozaffarian, 2002). As a result, the tissues do not drain properly, causing excess fluid accumulation, swelling, warmth, and discomfort in the leg (Mozaffarian, 2002). The thrombus can dislodge, travel from the leg towards the heart, lungs, or brain, and cause a myocardial infarction, pulmonary embolism, or embolic cerebral vascular accident, respectively (Mozaffarian, 2002). All these conditions are potentially life threatening and need to be treated with bedrest and anticoagulant drugs to prevent the further formation, or movement, of the thrombus (Glanze, 1990; Mozaffarian, 2002).

There are three factors, known as Virchow’s triad, that work together to determine the probability of developing a venous thromboembolism: venous stasis, vascular damage, and hypercoagulability (Pavlovich-Danis, 2002). The more risk factors or diseases an individual has present that contribute to Virchow’s triad, the greater the incidence of clot formation (Pavlovich-Danis, 2002). Risk factors, or susceptibility, for developing a DVT can be either inherited and/or acquired (Thompson-Ford, 1998). Inherited risk factors include deficiencies in antithrombin III, protein C, protein S, dysfibrinogenemia, and sickle cell anemia (Thompson-Ford, 1998). Acquired factors include heart disease, stroke, trauma, age, surgery of a lower extremity, pregnancy, estrogen use, obesity, paralysis, immobility, or malignancy (Agnelli & Sonaglia, 2000; Mozaffarian, 2002; Thompson-Ford, 1998). DVTs can occur in any individual, but are more evident in people who are inactive, have poor circulation, damaged blood vessels, or are on bedrest following trauma or surgery (Mozaffarian, 2002).

Prophylactic treatment of the patient population at risk is the most effective method to reduce their morbidity and mortality (Agnelli & Sonaglia, 2000). Prophylaxis can be either mechanical or pharmacological (Agnelli & Sonaglia, 2000). Mechanical methods promote venous return and include compression stockings, pneumatic compression devices, and increased hydration (Agnelli & Sonaglia, 2000; Pavlovich-Danis, 2002). Pharmacological agents, such as oral medications, unfractionated heparin, and low molecular weight heparin, interfere with the body’s normal coagulation process (Agnelli & Sonaglia, 2000). Overall, successful management of venous
thromboembolism must include a combination of bedrest, compression devices to promote venous return, pain control, and anticoagulation (Thompson-Ford, 1998).

For years, the common method for prevention of a VTE, or treatment of a DVT, has been unfractionated heparin (Thompson-Ford, 1998). Heparin does not dissolve a clot; it only facilitates the body’s own mechanism to dissolve the clot (Pavlovich-Danis, 2002). Heparin’s anticoagulant effect is achieved by combining with antithrombin III, which is already present in the body (Hovanessian, 1999; Pavlovich-Danis, 2002). The result is a state of increased anticoagulation. If a DVT is suspected, physicians in the past have treated the patient with an intravenous bolus of unfractionated heparin followed by a continuous infusion (Thompson-Ford, 1998). During the hospitalization, patients would be concurrently treated with an oral anticoagulant (i.e. Coumadin, Plavix, Ticlid, aspirin, etc.) to allow the patient to be discharged (Thompson-Ford, 1998). This process is time consuming for the patient, requires extensive monitoring (vital signs, laboratory results, etc.) and results in high medical costs (Thompson-Ford, 1998).

Low Molecular Weight Heparin

More recently, low molecular weight heparins (LMWH) have given physicians another treatment option for their clients. As Hovanessian (1999) explained, low molecular weight heparins have been evaluated in both medical and surgical settings and are safe, efficacious, cost-effective, and easier to monitor than standard unfractionated heparin (Hovanessian, 1999). LMWH is chemically derived from unfractionated heparin (Agnelli & Sonaglia, 2000). However, the chemical change allows LMWH to have a more predictable anticoagulation response, longer half-life, and better bioavailability within the body when compared to standard heparin (Agnelli & Sonaglia, 2000; Boccalon, Elias, Chale, Cadene & Gabriel, 2000; Braunwald, 1998; Cohen et al., 1998; Hirsh, 1998; Hovanessian, 1999; Kalafut, Gandhi, Kidwell & Sauer, 2000; Levine et al., 1996; Rutschmann & Matchar, 2000; Venketasubramanian & Chua, 1998; Warner & Perry, 2001; Zidar, 1998). The enhanced bioavailability of LMWH is achieved through its engineered properties. LMWH has a decreased affinity for plasma proteins in the body, allowing more “free” LMWH to be available to exert its anticoagulant effects (Hovanessian, 1999; Pavlovich-Danis, 2002). Subcutaneous bioavailability of LMWH
approaches 100% in most patients whereas unfractionated heparin is only 30% on average (Thompson-Ford, 1998). Additionally, side effects seen with unfractionated heparin (bleeding, thrombocytopenia, and osteoporosis) may be less common with LMWH (Hauer, 1998). Unfractionated heparin is believed to inhibit thrombin to a greater extent than LMWHs leading to increased bleeding, increased effects on platelet function, and increased vascular permeability (Thompson-Ford, 1998). In general, the most common side effect associated with the subcutaneous administration of LMWH is hematoma at the injection site due to an increase in anti-Xa activity in the body (Thompson-Ford, 1998). Factor Xa is one of many clotting factors present in the bloodstream (Thompson-Ford, 1998). Physicians can now use LMWH, instead of unfractionated heparin, to treat conditions such as unstable angina, non-Q-wave myocardial infarctions, and/or thromboembolic disease (DVT, PE, acute ischemic CVA, etc.; Hovanessian, 1999).

Traditionally, unfractionated heparin levels are monitored using partial thromboplastin time (PTT) when given intravenously (Hovanessian, 1999). However, PTT monitoring is an insensitive measure of the anticoagulant effect produced by LMWH (Hovanessian, 1999). LMWHs have more anti-Xa, than antithrombin, activity (Thompson-Ford, 1998). As a result, there is less effect on a patient’s partial thromboplastin time (Thompson-Ford, 1998). LMWHs bind less to plasma proteins and to cell surfaces making its response more predictable (Thompson-Ford, 1998). With the more predictable dose response of LMWH, routine monitoring of PTT is unnecessary (Hovanessian, 1999; Thompson-Ford, 1998). Only laboratory monitoring that test for anti-Xa activity in plasma would be beneficial (Thompson-Ford, 1998). Thompson-Ford (1998) noted that only periodic complete blood counts (CBC) would be useful to detect heparin-induced thrombocytopenia. As a result, this could help to reduce some costs associated with treating patients with unstable angina, non-Q-wave myocardial infarctions, and/or thromboembolic disease.

Research studies have indicated that further savings can be achieved by treating selected individuals (i.e., DVTs without signs of pulmonary embolism, cerebral ischemia) in an outpatient versus inpatient setting (Boccalon, Elias, Chale, Cadene & Gabriel, 2000; Dunn & Coller, 1999; Hirsh, 1998; Kalafut, Gandhi, Kidwell, & Sauer, 2000; Levine et
al., 1996; Lindmarker, 1999; Rutschmann & Matchar, 2000; Venketasubramanian & Chua, 1998). Not all affected patients would qualify for this method of treatment. Individuals with symptomatic pulmonary embolism, active bleeding, marked renal insufficiency, severe liver disease, obesity, severe leg pain/swelling, pregnancy, or medical compliance issues would need to be treated in a hospital setting (Dunn & Coller, 1999). However, outpatient treatment with LMWH could allow physicians to treat some patients in the comfort of their homes while reducing healthcare costs (Dunn & Coller, 1999).

**Lovenox (enoxaparin sodium)**

There are several different brands of low molecular weight heparin available on the market, including Lovenox (enoxaparin sodium), Fragmin (dalteparin sodium), and Innohep (tinzaparin sodium; Physicians’ Desk Reference, 2001). However, for the purpose of this study, Lovenox (enoxaparin sodium) will be the focus. Lovenox was approved by the Food and Drug Administration for thromboembolism prophylaxis for selected orthopedic and abdominal surgical procedures, inpatient treatment of DVT’s, with or without PE, outpatient treatment of DVT without PE, and anticoagulation in patients with unstable angina or non-Q-wave myocardial infarctions (Hauer, 1998; Hovanessian, 1999; Physicians’ Desk Reference, 2001). Complications include hemorrhage, heparin-induced thrombocytopenia, and osteoporosis, but are less frequent when compared to unfractionated heparin (Hovanessian, 1999; Physicians’ Desk Reference, 2001). Lovenox is delivered to the patient as a subcutaneous injection, typically in the abdominal area (Physicians’ Desk Reference, 2001) Common complaints with subcutaneous administration of Lovenox, as well as unfractionated heparin, include local reactions: mild irritation, pain, hematoma, ecchymosis, and erythema at the injection site (Physicians’ Desk Reference, 2001; Warner & Perry, 2001).

**The Gate Control Theory of Pain**

Patients are often subjected to painful diagnostic and treatment procedures (Puntillo & Casella, 1998). Pain is a sensation derived from nerve receptors, known as nociceptors, in tissues and organs (Puntillo & Casella, 1998). These peripheral receptors,
which originate in the skin, subcutaneous tissue, muscles, joints, and ligaments, transmit
the noxious stimuli from the injured site to the brain (Puntillo & Casella, 1998).

Within the spinal cord dorsal horn, primary nociceptive fibers relate with other
larger sensory fibers transmitting non-noxious information such as touch, pressure, and
vibration. “The relationship between nociceptive fibers and nonnociceptive sensory fibers
can be explained by the gate control theory” (Puntillo & Casella, 1998, p. 62).

Puntillo and Casella (1998) explained the following:

The hypothesis of this theory is that both nociceptive and nonnociceptive
sensory fibers synapse on the same cells that transmit pain sensations to
the brain. Inhibitory interneurons in the spinal cord influence these central
transmission cells by interrupting the balance between smaller (pain)
fibers and larger (non-pain) fibers. When larger, non-pain fibers are less
active, compared with pain fibers, pain transmission cells are stimulated.
When larger, non-pain fibers are stimulated, inhibitory interneurons block
pain transmission to higher centers. Higher CNS central control processes
can influence the spinal cord gate by delivering descending inhibitory
messages to the spinal cord (p. 62).

This spinal cord activity, stimulation of nociceptors leading to pain, can be
interrupted by the body’s inhibitory nerve fibers. Endorphins, serotonin, norepinephrine,
gamma-aminobutyric acid (GABA) and thyrotropin-releasing hormone all act as
inhibitory neurotransmitters. These neurotransmitters help prevent neural excitation,
causing cell firing to be inhibited. The end result is nociceptive impulses are blocked

It is vital that pain, as well as site-pain, are controlled for physiologic reasons.
Stress associated with pain has been shown to alter respiratory mechanisms, increase
cardiac demands, cause skeletal muscles to contract/become rigid, decrease immune
function, lead to hyperglycemia, and increase certain hormone levels (catecholamine,
cortisol & ADH) within the body. Nurses need to reduce sources of stress to promote
patient well being (Puntillo & Casella, 1998).
Site-pain

So what is the problem? When heparin, both unfractionated and LMWH, are administered via the subcutaneous route, they have been shown to cause pain and bruising at the injection site (Chan, 2001; Davis, Lagattolla & Scholey, 2001; Kuzu & Ucar, 2001; Nunnelee, 1997; Thomas, 1997). Injection pain is often the result of injury to the nerve fiber endings located in the skin and tissue from mechanical trauma caused by the needle puncture. Injections are a basic nursing skill often seen as an invasive procedure, causing discomfort and fear to some individuals who receive them (Mitchell & Whitney, 2001). Nurses are expected to be advocates for patients while in the health care system. Therefore it is the duty of advanced practice nurses to explore which subcutaneous injection technique should be used in clinical settings that produce the least adverse outcomes.

Pain is defined as an unpleasant sensory or emotional experience which is primarily associated with tissue damage or described in terms of tissue damage, or both. It is a complex perception that takes place only at higher levels of the central nervous system (Pain.com, 2002). Site-pain and bruising are often the result of local tissue damage that occurs during the administration of the heparin solution (Chan, 2001). Pain can mean different things to different people. However, the degree or level of pain experienced is whatever the patient reports it to be (McCaffery & Pasero, 1999).

Pain Assessment

There are several instruments available to rate individuals’ pain. The Numerical Rating Scale (NRS) and the Visual Analog Scale (VAS) both use a horizontal (or vertical) line and measure a patient’s perceived level of pain. The Simple Descriptor Scale (SDS) uses a list of adjectives to describe different levels of pain intensity (i.e. no pain, mild, moderate or severe pain; McCaffery & Pasero, 1999). The VAS has the patient draw a mark along a line to indicate the individual’s pain level. The NRS numerically rates the patient’s pain on a 0 (no pain) to 10 (worst possible pain) scale (Puntillo & Casella, 1998). For the purpose of this study, participants will be asked to rate their pain using the Numerical Rating Scale (NRS).
With the NRS, the patient is asked to rate the pain stimulus either verbally or in writing from 0 (no pain) to 10 (worst possible pain; McCaffery & Pasero, 1999). The NRS is easy for patients to understand and score and will measure any changes in pain intensity (McCaffery & Pasero, 1999). The validity, whether the scale accurately measures pain intensity, and reliability, how consistently it measures pain from one time to the next, of the NRS has been well-established (Jensen, Karoly & Braver, 1986; Jensen & Karoly, 1992; McCaffery & Pasero, 1999; Paice & Cohen, 1997). The NRS is available in English, Chinese, French, German, Greek, Italian, Japanese, Korean, Russian & Spanish (McCaffery & Pasero, 1999).

**Bruising**

A commonly encountered response to subcutaneous heparin injections is the formation of a hematoma or bruise at the injection site (Ross & Soltes, 1995). A hematoma is a mass of clotted blood confined to space, such as subcutaneous tissue, caused by a break in a blood vessel (Thomas, 1993). A bruise is a discoloration of the skin caused by the extravasation of blood into the subcutaneous tissue as a result of trauma to the underlying blood vessels or by fragility of the vessel walls (Glanze, 1990; McGowan & Wood, 1990). Heparins, in general, are known to interfere with the body’s clotting mechanisms and can lead to a bruise at the injection site (McGowan & Wood, 1990). Since patients can receive any number of subcutaneous injections, any method that can be shown to reduce bruising caused by Lovenox will give nurses more potential sites for future injections and promote patient confidence for their caregivers.

Hadley, Chang, and Rogers (1996) reported in their review of literature that up to 90% of individuals develop a bruise or hematoma from subcutaneous administration of heparin. Venkatasubramanian and Chua (1998) noted during their clinical study that two patients developed bruises after receiving subcutaneous injections of a LMWH. Injection technique could play a large role in the presence or development of a bruise at the injection site (Chan, 2001). Also, Chan (2001) noted that patients who were given Fragmin (dalteprin sodium) as part of their anticoagulation therapy developed far fewer bruises using a longer injection duration (Chan, 2001). The frequency of bruising using the 10-second injection technique was nearly twice that of the 30-second technique.
Additionally, the bruises present were significantly larger in size in the patient population that received the 10-second duration injection technique (Chan, 2001). However, Chan’s (2001) research was limited by the fact that her study included only Caucasians admitted with ischemic cerebral vascular accidents (Chan, 2001). Studies that demonstrated a decrease in site-pain with the application of ice after injection showed no benefit in reducing the probability of developing a bruise or its size (Kuzu & Ucar, 2001). During the ESSENCE trial (1998), subjects who received Lovenox, compared to unfractionated heparin, were noted to have higher levels of bruising at the injection site (Cohen, et al., 1998). Vanbree, Hollerbach and Brooks (1984) noted that bruises caused by subcutaneous heparin peak in their development at 48 hours and begin to resolve around 72 hours after injection (Vanbree, Hollerbach & Brooks, 1984). The overall goal for advanced practice nurses is to explore which method would reduce the number and size of bruises associated with subcutaneous injections to preserve skin sites for subsequent injections.

Research

The Neuman Systems Model

The Neuman systems model has been utilized for nursing research, administration, and clinical practice. The model focuses on a patient’s response to environmental stress, the use of prevention interventions for retention, attainment, and maintenance of client system wellness. The purpose of the nurse is to provide assistance to patients in order to maintain optimal system stability. Individuals, families, groups, and communities, in a range of diverse settings, facing environmental stressors are all potential recipients of nursing care based on the Neuman systems model (Neuman, 1995).

Betty Neuman’s model has been used in over 100 different research-based publications including journal articles, books, doctoral dissertations, and master’s theses. It has been used to guide various study designs such as qualitative descriptions and quantitative experiments. Examples of experimental studies mentioned by Betty Neuman include, the incidence of safety restraint use by, and alcohol use of, motor vehicle crash victims, perceptions of mechanical ventilation during hospitalization in a critical care unit, and the needs of family members of critically ill clients (Neuman, 1995). However,
a recent Internet search revealed various ways the Neuman systems model could be used to promote research in the nursing profession.

May and Hu (2000) conducted a descriptive study that described perceptions of infant health, caregiving at home, and help seeking by mothers of low birthweight (LBW), and normal birthweight, infants. The authors used Betty Neuman’s model for the conceptual framework of the project. For this study, interaction among system components occurred as mothers gave infant care and sought help within the network of resources. Maternal perception of infant health, maternal perception of caregiving (preparation for caregiving, confidence in caregiving, and caregiver burden) were measured via questionnaires. Infant health status can weaken the parents’ flexible line of defense and threaten the normal line of defense. The parent may respond to this threat by seeking help from others. May and Hu (2000) measured 60 mothers’ perceptions of help seeking with a questionnaire. Several research questions guided data analysis to determine if there were any relationships between infant health, caregiving, and help seeking. There was a statistically significant relationship ($R^2 = 0.18, p < 0.001$) between mothers’ perception of infant health and perception of confidence in caregiving. Perception of a healthier infant was related to more confidence in caregiving. There was a statistically significant relationship ($R^2 = 0.10, p < 0.05$) between mothers’ perception of preparation for caregiving and perception of confidence in caregiving. Finally, there was significant relationship between preparation ($R^2 = 0.18, p < 0.001$) and confidence ($R^2 = 0.12, p < 0.01$) in caregiving and caregiver burden. The authors concluded there were significant relationships between infant health and confidence in caregiving ($p < 0.001$), preparation for caregiving and confidence in caregiving ($p < 0.05$), and confidence in caregiving and caregiver burden ($p < 0.01$). Additionally, mothers of LBW infants perceived poorer infant health and increased caregiver burden compared to normal birthweight infants. The questionnaires indicated that serious health questions were often directed toward physicians or other healthcare personnel. This study, directed under Neuman’s conceptual framework, suggested that nurses could use mothers’ perceptions of infant health, caregiving, and help seeking to facilitate caregiving and use of available resources (May & Hu, 2000).
Shamsudin (2002) conducted research on whether or not the Neuman’s Systems Model could be adapted to Malaysian nursing. Currently, it is the medical model for patient care that is predominately practiced in Malaysia. As of 2002, conceptual models of nursing have not been used in Malaysia to guide nursing practice. The majority of nurses in Malaysia are hospital-trained, where emphasis is placed on practice, not theory. It was not until recently that university programs were developed for nursing. Nursing models provide nursing practice with information on how to understand practice and nursing practice provides information that will provide content to conceptual models (Shamsudin, 2002).

Since many nursing models have their origins in North America, criticism exists on how these models can be applied to nursing care in other cultures. Shamsudin conducted an exploratory study in Malaysia with two aims. First, to explore patients’ spiritual needs and how nurses could fulfill these roles. Second, to develop a conceptual model of the nurse-patient interaction and determine if it fit into Neuman’s Systems Model. Fifty-eight participants were interviewed. From analysis of the interviews, Shamsudin theorized about a conceptual model of the nurse-patient interaction for Malaysian culture using the framework of Betty Neuman (Shamsudin, 2002).

Shamsudin noted that before a North American based model (i.e. Neuman’s Systems Model) is imported to Malaysian culture, factors must be considered. Factors, such as preparation of nurses, practice of nursing, culture, and the healthcare system, would determine if the model could be used and how effective it would be if implemented. In Malaysia, the family plays an important part in the care of the patient. Before a conceptual model could be implemented in Malaysia, based on Neuman, the patient system must fit to include the patient as well as the family. Nursing, within the context of the Neuman systems model, involves the patient and nurse. For this conceptual model to be effective in Malaysia, it must include the role of the nurse, patient as well as family. However, in Malaysia this idea is in its infancy. Much more empirical research would need to be conducted to support this expanded model in order to fit Malaysian nursing (Shamsudin, 2002).

Stepans and Knight (2002) examined how Neuman’s model could be applied to nursing practice by studying infant exposure to environmental tobacco smoke (ETS). The
authors operationalized Neuman’s framework and discussed a research-based theory investigating the interaction between the infant and the environment. The flexible line of defense was the epithelial lining that protects the lungs when exposed to ETS. However, nicotine and carbon monoxide pass through and are able to threaten the normal line of defense. The respiratory, cardiovascular, hepatic, and renal systems begin to make up the normal line of defense. If the normal line of defense is overwhelmed, the lines of resistance attempts to protect the patient’s basic structure. For this study, competition of carbon monoxide with oxygen for heme binding sites lead to decreased oxygen levels for tissues and increases in respiratory rates. If the lines of resistance failed, the energy levels were depleted, the result is illness or death of the system (Stepans & Knight, 2002). The theoretical basis of this and other studies helps to demonstrate that Neuman’s systems model can be utilized to fit a wide range of nursing research.

**Lovenox**

Lovenox is being used in an array of medical, cardiac, and neurological settings (Agnelli & Sonaglia, 2000; Cohen, Demers, Gurfinkel, Turpie, Fromell, Goodman et al., 1998; Gould, Dembitzer, Doyle, Hastie & Garber, 1999; Kalafut, Gandhi, Kidwell & Sauer, 2000; Venketasubramanian & Chua, 1998; Warner & Perry, 2001; Zidar, 1998). Neurosurgeons, for example, are often concerned with bleeding complications after surgery, particularly intracranial hemorrhages (Agnelli & Sonaglia, 2000). According to Agnelli & Sonaglia (2000), Lovenox has been supported as useful in decreasing the risk of DVT formation for neurological and neurosurgical patients (i.e. spinal cord injuries, trauma, elective neurosurgery) without excessive bleeding complications (Agnelli & Sonaglia, 2000). Both Venketasubramanian & Chua’s (1998) and Kalafut’s, et al. (2000) research studies demonstrated that Lovenox was safer to use and reduced hospital lengths of stay in patients with subacute cerebral ischemia when compared to intravenous unfractionated heparin use (Kalafut, Gandhi, Kidwell & Sauer, 2000; Venketasubramanian & Chua, 1998).

The purpose of Kalafut’s, et al. (2000) study was to explore the safety and cost of using Lovenox, versus intravenous unfractionated heparin (IVUH), as a bridging anticoagulant from the acute inpatient setting to long-term outpatient setting for cerebral...
ischemic attack or cerebral infarction were included in the study (Kalafut et al., 2000).

Twenty-four patients were studied starting Lovenox and warfarin on the same day, as well as another 24 patients using IVUH and warfarin. Warfarin dosing was left to the discretion of the attending physician. Most physicians in the study accepted an INR (international normalized ratio) between 2.0 to 3.0 as therapeutic and therefore adequate for discontinuation of Lovenox or IVUH to warfarin alone. Data were collected between the two groups and compared with nonparametric tests using the $\chi^2$ test (Kalafut et al., 2000).

Kalafut (2000) noted that no patients in either group had hemorrhagic transformation of infarction, or death, while participating in the study. Patients receiving Lovenox had fewer declines in neurological status, or complications, compared to the IVUH group (2/24 versus 8/24; $p = 0.033$). Adverse events (i.e. guaiac-positive stools, gross hematuria, phlebitis, thrombocytopenia or bleeding) were less frequent in the Lovenox, versus the IVUH, group (3/24 versus 20/24; $p = 0.002$) In this study of patients with subacute cerebral ischemia, the authors concluded that bridging with LMWH appeared safer than bridging with IVUH (Kalafut et al., 2000).

Cost savings were higher in the Lovenox group, an average of $865 per patient, compared to the IVUH group. This savings was due to the fact that Lovenox could be administered at home for selected patients while the bridging to warfarin was still in progress. This study demonstrated promising research with one type of LMWH. There were no serious hemorrhagic events (cerebral or systemic) with the Lovenox group when compared to the IVUH group. The benefits of Lovenox appear to outweigh the risks when compared to IVUH use in cerebral ischemia patients. Fewer medical complications were noted, some patients could potentially be discharged home earlier and cost savings could be larger. These are all advantages in the current climate of medicine today (Kalafut et al., 2000).

Venketasubramanian and Chua (1998) studied patients admitted to a stroke unit in Singapore from 1995 to 1997. Potential subjects were excluded if the CT scan of the brain revealed an intracranial hemorrhage or mass lesion. Fifteen patients were taken off intravenous unfractionated heparin, started on a LMWH and warfarin after agreeing to be
participants in the research study. The participants were then discharged home once medically stable. The LMWH was discontinued once the subject’s INR reached 2.0. Each subject was interviewed twice a week to monitor for symptoms suggestive of cerebral ischemia. No major hemorrhages, recurrent strokes, or deaths were reported. However, two participants reported bruising at the injection site as the only side effect of taking the LMWH subcutaneously. Because of the small sample size, this study did not conduct any detailed statistical analysis or relationships. However, this study did help further demonstrate that select patients may benefit from utilizing LMWH at home. However, readers must be aware that the sample size was too small to generalize to a larger population (Venketasubramanian & Chua, 1998).

The ESSENCE trial (1998), conducted on cardiac patients, demonstrated a lower risk of death, myocardial infarction, or recurrent angina when placed on Lovenox (Cohen et al., 1998). When Lovenox was used in conjunction with aspirin, it was more effective than standard heparin at reducing ischemic events for patients with unstable angina or non-Q-wave myocardial infarctions (Cohen et al., 1998).

The ESSENCE trial (1998) randomly assigned 3,171 patients with unstable angina or non-Q-wave myocardial infarction to receive Lovenox subcutaneously or unfractionated heparin intravenously. The study used a double blind, placebo-controlled approach for medication administration. After 14 days, patients receiving Lovenox had a lower risk of death, myocardial infarction, or recurrent angina than individuals receiving unfractionated heparin (16.6% versus 19.8%; \( p = 0.019 \)). This difference was greater after 30 days (19.8% versus 23.3%; \( p = 0.016 \)). Additionally, the incidence of a major bleeding complication after 30 days was 6.5% for the Lovenox group versus 7.0% (\( p = \) not significant) for the unfractionated heparin group. However, incidence of minor bleeding was higher in the Lovenox group than unfractionated heparin group due to injection site bruising (13.8% versus 8.8%; \( p < 0.001 \)). Cohen’s trial (1998) supports the use of Lovenox in select cardiac patients. However, the study does indicate that subcutaneous bruising could be a significant problem for individuals who receive Lovenox (Cohen et al., 1998).

Finally, Zidar (1998) noted during the ENTICES trial that Lovenox, used with aspirin and Ticlid, produced significantly fewer clinical events and vascular
complications than conventional warfarin anticoagulant treatment after coronary stenting. One hundred twenty-three patients were enrolled for the study. Inclusion criteria were stent implantation, evidence of chest pain, and a candidate for bypass surgery. However, patients were excluded if actively bleeding, recent history of stroke, major surgery, or acute myocardial infarction with the past 48 hours. Patients were randomized into two groups; either receiving a Lovenox/Ticlid/aspirin, or traditional heparin/warfarin regimen. Blood samples were taken on several occasions from each participant to compare thrombin activity and platelet activation. Participants received either Lovenox for 10 days with Ticlid/aspirin for 30 days or intravenous unfractionated heparin until the INR was 2.0 to 3.0 with warfarin for 30 days. After 30 days, the Lovenox/Ticlid/aspirin group experienced lower rates of myocardial infarctions (4%) with no bypass surgery or stent thrombosis noted. The heparin/warfarin group experienced more myocardial infarctions (11%), bypass surgery (9%) and stent thrombosis (7%). The authors concluded from these numbers that there was a significantly higher clinical event rate in patients treated with heparin/warfarin versus Lovenox/Ticlid/aspirin (20% versus 5%; \( p = 0.01 \)). When participants were reevaluated 6 months later, clinical events (i.e. myocardial infarction, bypass surgery, stent thrombosis, pseudoaneurysm, atrioventricular fistula, retroperitoneal hematoma, or vascular groin repair) were noted more in the heparin/warfarin, versus Lovenox/Ticlid/aspirin, group (27% versus 14%; \( p = 0.07 \)). A combination of Lovenox, Ticlid and aspirin was well tolerated with fewer complications after elective stenting in the ENTICES trial (Zidar, 1998).

The ESSENCE and ENTICES trials, along with other research, continues to provide support that Lovenox will likely be more widely used in the future. Further studies are needed which explore what injection technique may deliver these increasingly popular medications with less pain and bruising.

**Site-pain**

Kuzu and Ucar (2001) noted that the pain resulting from subcutaneous injections caused patients both physical and psychological distress (Kuzu & Ucar, 2001). This could cause patients to avoid future injections or fuel any distrust the individual may have for the medical community. Ideally, this is a result that needs to be reduced or even
eliminated. In the past, researchers have explored methods that might achieve this goal. Kuzu and Ucar (2001) applied ice prior to and after subcutaneous injections of heparin. They discovered that patients had far fewer complaints of site-pain with subcutaneous injections of heparin when ice was applied (Kuzu & Ucar, 2001).

The purpose of Kuzu’s and Ucar’s (2001) research was to study the effect of cold application at the injection site on bruising and site-pain from Lovenox. Sixty-three patients were utilized and divided into four sample groups of convenience. Group 1 (27%) received no cold application before or after the subcutaneous injection of Lovenox. Group 2 (25%) received cold application for 5 minutes before injection only and group 3 (24%) for 5 minutes after injection only. Finally, group 4 (24%) received cold application for five minutes before and after the subcutaneous Lovenox injection. Bruising was evaluated and measured by Kuzu and Ucar after 48 and 72 hours, while site-pain noted immediately after injection (Kuzu & Ucar, 2001).

Nonparametric tests (i.e. $\chi^2$ and Fisher exact tests) were used for statistical analysis. Bruising was noted after 48 ($\chi^2 = 0.895, df = 3, p > 0.05$) and 72 ($\chi^2 = 3.686, df = 3, p > 0.05$) hours at the injection site for all participants. Group 1 (no ice) had the highest levels of bruising at 72 hours, but there was no statistically significant difference between the four groups ($p > 0.05$). Therefore, cold application did not appear to be effective in reducing bruising for this study (Kuzu & Ucar, 2001).

However, pain intensity was significantly different between the four groups ($\chi^2 = 37.229, df = 12, p < 0.05$). The decrease in site-pain intensity perception was noted with all three groups that received cold application treatment. Kuzu and Ucar demonstrated that altering even one aspect of injection technique could have an effect on clinical outcomes. Therefore, the authors provide evidence that further research is still needed to help nurses master simple, routine tasks to improve patient care (Kuzu & Ucar, 2001).

Both Chan’s (2001) and Scarfone’s, Jasani’s, and Gracely’s (1998) clinical research on subcutaneous injections clearly demonstrated that by simply lengthening the injection duration, measured site-pain and bruising were significantly reduced. Chan (2001) evaluated the effects on site-pain and bruising using a 10-second, versus 30-second, injection duration technique. Thirty-four participants were studied from 1998 to 1999 in Australia. Each subject received a subcutaneous injection of Fragmin (dalteparin.
sodium), a low molecular weight heparin, twice as participants. Each participant received the 10-second and 30-second injection duration technique. Immediately following each injection, site-pain intensity was measured using the visual analogue scale (VAS). Bruising was measured at 48 and 60 hours after injection (Chan, 2001).

Chan (2001) utilized the Wilcoxon Signed-Rank tests (nonparametric $t$-tests) to determine if injection duration had any effect on site-pain and bruising ($p < 0.05$). The 10-second injection duration yielded higher pain scores than the 30-second technique ($p = 0.000; Z = -4.000$). The mean VAS pain score for the 10-second injection technique was 22.8 mm (SD ± 24.75 mm) and 10.7 mm (SD ± 15.28 mm) for the 30-second injection technique. Additionally, the 10-second technique revealed significantly larger bruises after 48 hours ($p = 0.000; Z = -4.542$) and 60 hours ($p = 0.000; Z = -4.569$) than the 30-second technique. Out of all the measurements for bruising ($n = 136$), 18 individuals developed a bruise >2 mm$^2$ 60 hours after using the 10-second injection technique. However, only 10 individuals developed a bruise 60 hours after using the 30-second injection technique. The difference in mean bruise size between the two groups was 24.67 mm$^2$. This study did not randomize its sample, but helped reinforce the idea that injection duration may affect site-pain perception and bruising at the injection site of a low molecular weight heparin (Chan, 2001).

The objective of Scarfone’s, Jasani’s, and Gracely’s (1998) project was to study how administration rate was associated with pain, using subcutaneous infiltration of lidocaine. Forty-two volunteers receiving lidocaine as a local anesthetic in the emergency department agreed to participate in the study. Each participant received an injection over 5 seconds and 30 seconds. Whether or not the injectate was delivered over 5 or 30 seconds, the needle was left in the patient’s forearm for the entire 30 seconds in an effort to reduce any bias from the participants. The patients rated the level of pain at the injection site using the VAS after the needle was withdrawn (Scarfone, Jasani & Gracely, 1998).

Statistical analysis was conducted using the Friedman analysis of variance and the Bonferroni-corrected Wilcoxon test. A sample size of 42 was needed to detect 25% difference in mean pain scores with a power of 80%. The 30-second rate of administration showed lower site-pain scores when compared to the 5-second injection.
duration technique (1.49 ± .29 versus 3.11 ± .33) on a 10-cm visual analog pain scale. Therefore, the rate of administration on site-pain intensity was highly significant ($p < 0.001$). Again, this study supports the idea that rate of administration significantly affected perception of site-pain (Scarfone, Jasani & Gracely, 1998).

However, Mitchell and Whitney (2001) found no correlation between pain perceived by study participants and injection speed duration used to deliver hepatitis B vaccinations. The study explored whether or not intramuscular injections delivered over 30-seconds, or 10-seconds, would have more or less pain. Participants were their own control, both injection speeds were used on each one. Pain was rated immediately after injection, 12 hours and 24 hours later (Mitchell & Whitney, 2001).

A sample of 50 adults receiving the hepatitis B vaccine were enrolled in this study. Each participant received the 10-second and 30-second injection technique with a brief massage following the injection at the site with a cotton ball. Three separate Wilcoxon matched-pairs signed-rank tests compared the pain perception at the 0, 12, and 24-hour interval ($p < 0.05$). Immediate (0 hour) pain scores revealed that 50% reported 10 or less for site-pain intensity on the 0 to 100 visual analogue pain scale (10-second mean = 11.98, SD = 10.29; 30-second mean = 13.4, SD = 11.11). The 12 (10-second mean = 8.7, SD = 15.74; 30-second mean = 11.26, SD = 15.58) and 24 (10-second mean = 7.52, SD = 13.61; 30-second mean = 6.86, SD = 10.59) hours results showed that 80% reported pain 10 or less on the VAS. The $z$ score for pain at 0 hour between the 10-second and 30-second injection speed was –1.08; $z$ score for 12 hour was –1.42; $z$ score for 24 hour was 0.0 (critical $z = \pm 1.96$ for $p < 0.05$). Mitchell’s and Whitney’s (2001) study showed that slowing injection speed down to 30 seconds did not decrease pain perception for intramuscular injections of hepatitis B (Mitchell & Whitney, 2001). The study did not support the current authors’ research hypothesis. However, the difference could be due to the fact that Mitchell and Whitney examined intramuscular, not subcutaneous, site-pain. More research is needed before one method can be generally accepted, or rejected, into nursing practice for the diverse patient population.
**Future Research**

Chan’s study (2001) demonstrated that the 30-second injection technique did reduce the reported level of site-pain and measurable size of bruising (Chan, 2001). However, additional studies are needed to determine whether or not any one finding or technique can be generalized to a larger patient population. The goal of this study is to determine if a standard subcutaneous injection technique can be developed that will help reduce perceived pain and bruising at the injection sites.

**Summary**

The Neuman Systems Model (2002), the theoretical basis for the current study, has been widely used in nursing education, practice, and research since its creation in the 1970’s by Betty Neuman. The model is dynamic. It is based on the patient’s relationship to environmental stress, which has the potential to cause a reaction or could affect the patient’s reconstitution following treatment of a stress reaction. The goal of the nurse is to facilitate an environment of optimal wellness through retention, attainment or maintenance of patient system stability. The Neuman Systems Model is discussed according to the model’s components: person, environment, health and nursing (Neuman, 2002).

Anticoagulation is the process of introducing a substance into the body to prevent or delay coagulation of the blood (Glanze, 1990). There are medical conditions such as venous thromboemboli (VTE), clots that form in venous blood, that warrant the use of anticoagulant therapy (Pavlovich-Danis, 2002). As a thrombus (clot) forms in a deeper vein, it can dislodge and travel toward the heart, lungs, or brain and cause a myocardial infarction, pulmonary embolism, or cerebral vascular accident (Mozaffarian, 2002). These conditions can be life threatening. Successful management of a VTE must include a combination of bedrest, compression devices to promote venous return, pain control, and anticoagulation (Thompson-Ford, 1998).

For years, the common method for prevention of a VTE has been unfractionated heparin (Thompson-Ford, 1998). Low molecular weight heparins (LMWH), derived from unfractionated heparin, have allowed for a more predictable anticoagulant response, longer half-life, and better bioavailability within the body when compared to standard

Several studies demonstrating the use of Neuman’s Systems Model in nursing research and practice were discussed (May & Hu, 2000; Shamsudin, 2002; Stepans & Knight, 2002). Topics ranging from caregiving and help seeking by mothers of low birthweight infants to adapting Neuman’s model in Malaysian nursing were described. Additionally, studies on site-pain were presented that manipulated a variable (i.e. cold application, lengthening injection duration) with the goal of decreasing the reported level of pain at the injection site.

In this chapter, studies were discussed that support the use of Lovenox (enoxaparin sodium) for cost and effectiveness over other anticoagulation therapies (Kalafut et al., 2000; Venketasubramanian & Chua, 1998). The ESSENCE trial (1998) demonstrated a lower risk of death, myocardial infarction or recurrent angina for patients placed on Lovenox (Cohen et al., 1998). The ENTICES trial (1998) showed that patients on Lovenox, Ticlid, and aspirin had significantly fewer clinical events and vascular complications than conventional warfarin anticoagulant treatment after coronary stenting (Zidar, 1998).

Injections are a basic nursing skill often seen as an invasive procedure, causing discomfort and fear in some individuals (Mitchell & Whitney, 2001). Injection pain is often the result of injury to the nerve fibers in the skin from mechanical trauma caused by the needle puncture (Mitchell & Whitney, 2001). Additionally, individuals that receive heparin subcutaneously are at risk of developing a bruise at the injection site (Hadley, Chang & Rogers, 1996). Injection technique could play a large role in the presence or development of a bruise at the injection site. A number of research studies have indicated
that by simply increasing the injection duration, patients had far fewer complaints of site-pain or measurable bruising (Chan, 2001; Cohen, et al., 1998; Hadley, Chang & Rogers, 1996; Kuzu & Ucar, 2001; Scarfone, Jasani & Gracely, 1998; Venketasubramanian & Chua, 1998). The goal of this study was to determine if a standard subcutaneous injection technique could be developed that would help reduce perceived pain and bruising at the injection site. In chapter 3, the reader will learn how the research questions were investigated, human subjects will be protected, the procedure involved and how the data was analyzed.
CHAPTER 3
METHODOLOGY

This chapter explored the methodology used to collect and analyze data relating to site-pain and bruising associated with subcutaneous administration of Lovenox (enoxaparin sodium). The research design, setting, sample, protection of human subjects, instruments, procedure, and data analysis are discussed. The goal was to seek results for the following research questions:

1. What is the difference of site-pain perceived by the same hospitalized patient receiving subcutaneous injections of Lovenox using two different injection techniques?
2. What is the measurable size of bruising, if any, on the same hospitalized patient receiving subcutaneous injections of Lovenox 48 hours after administration using two different injection techniques?

Research Design

A quasi-experimental, comparative design was used in this study to investigate what differences, if any, exist between the two subcutaneous injection techniques on perceived site-pain and measured bruising. It was the plan to compare a single group of individuals who are under different circumstances or experiences. Patients who were receiving Lovenox (enoxaparin sodium) as part of their medical treatment plan were used for this study. The independent, or manipulated, variable in this study was the injection duration, while the dependent variables were perceived levels of pain and measured bruising at the injection site. In order to limit the number of extraneous variables present in the study, each participant received both injection techniques. Each participant received Lovenox (enoxaparin sodium) subcutaneously using a 10-second and 30-second injection duration for the next two prescribed injections and then was asked to rate his/her
perceived level of pain at the injection site immediately after each injection. Forty-eight hours after the second injection, both sites were examined for bruises and, if present, measured. This amount of time lapse between injection and measurement was appropriate. Chan’s (2001) research study demonstrated that most bruising that did develop occurred by 48 hours after injection (Chan, 2001). Additionally, Vanbree et al. (1984) noted that bruising from subcutaneous injections usually peaks at 48 hours and begins to resolve by 72 hours after injection (Vanbree, Hollerbach & Brooks, 1984).

**Setting**

The setting for this study was at a moderately large regional hospital located in north Florida. Patients admitted only to the neurological or cardiac intensive care units, or orthopedic, neurological, or cardiac treatment areas of the hospital were utilized in this study. A hospital setting was chosen since most patients are often started on Lovenox (enoxaparin sodium) as part of an anticoagulation therapy while in a hospital setting. Use of one setting will allow the researcher to maintain constancy of conditions. Use of multiple units within the same hospital helped ensure a more diverse sample and possibly allowed the study to be generalized to a larger patient population.

**Sample**

The target population for this study was patients who were receiving Lovenox (enoxaparin sodium) as a subcutaneous injection. However, the accessible population was patients located on selected units within a hospital located in the North Florida region.

Inclusion criteria for this study were patients receiving Lovenox (enoxaparin sodium) as a subcutaneous injection. These patients had to be located within the neurological or cardiac intensive care units, or the orthopedic, neurological, or cardiac treatment areas of a local hospital. Patients selected had to be 18 years of age or older, oriented to person/place/time/situation, and able to rate the pain perceived at the injection site. Exclusion criteria included patients unable to rate their pain, those having injuries or trauma affecting sensation to the injection site, and individuals with cognitive impairments.
Chan’s (2001) study used 34 stroke patients and allowed for an 80% or more chance of detecting a 50% change in site-pain and bruising due to an injection technique (alpha = 0.05; Chan, 2001). The plan for this current research was to have an alpha of 0.05, power of 0.80, and effect size of 0.5σ. As a result, a sample size of at least 34 participants would be needed to determine if the longer injection duration had any effect on reported site-pain or measured bruising.

**Protection of Human Subjects**

Before any subjects were approached, or data collected, the student nurse researcher sought approval from the Institutional Review Boards at both Florida State University and the selected hospital. Once approved, the researcher looked for patients admitted to the identified units in the hospital that were receiving Lovenox (enoxaparin sodium) subcutaneously as part of their anticoagulation therapy. After a potential participant was located, the nurse researcher approached the potential subject, explained the purpose and goals of the study, and determined if the potential subject was interested in participating. All subjects were assured that their names and responses were confidential, to the extent allowed by law. All confidential information was treated and respected according to the guidelines of Florida State University and the selected hospital. Subjects were made aware that they had the right to decide whether or not they would be in the study without risk of penalty or prejudicial treatment. Additionally, they were informed that they could terminate participation at any time throughout the study.

In order to protect human subjects, full disclosure was necessary. All individuals involved had the full nature of the study explained, including researcher responsibilities, benefits, and risks participants could incur. Participants were informed that they would receive only two injections of Lovenox (enoxaparin sodium) as study subjects using two different injection techniques. The subjects were asked to rate the level of pain experienced at the site after each injection. It was explained that 48 hours after the injections, the research nurse would return to measure bruising, if any, at the injection sites. The human subjects were informed that they were approached as potential participants because they were receiving Lovenox as part of their medical treatment. The researcher explained that there might be no direct benefits to the participant and that
foreseeable risks might include pain and bruising at the injection site. However, the risks were no greater than receiving Lovenox as the physician prescribed it. Participants were informed that information obtained from this study may one day improve the technique used to administer Lovenox (enoxaparin sodium) to patients in the future. After this was completed and the subject agreed to participate, informed consent (Appendix C) was obtained and a copy was provided to the participant. All future reports and presentations will contain only the aggregate data. No names or other personal information will be used. The raw data and informed consents will be kept separately at the researcher’s residence in a secured cabinet for a period of three years. On December 31st, 2006, all records will be destroyed.

**Instruments**

For the purpose of this study, participants were asked to rate their pain using the Numerical Rating Scale (NRS). With the NRS, the patient was asked to rate the pain, either verbally or in writing, from 0 (no pain) to 10 (worst possible pain; McCaffery & Pasero, 1999). The NRS is simple to administer, score, and measures any changes in pain intensity (McCaffery & Pasero, 1999). The validity, meaning the scale accurately measures pain intensity, and reliability, how consistently it measures pain from one time to the next, of the NRS has been well-established (Jensen, Karoly & Braver, 1986; Jensen & Karoly, 1992; McCaffery & Pasero, 1999; Paice & Cohen, 1997).

Jensen, Karoly and Braver (1986) studied six pain rating instruments to determine which was the most precise, replicable, and valid measure of pain. Five criteria for judging pain scales were used: ease of administration, relative rates of incorrect responding, number of available response categories, statistical power, and the magnitude of the relationship between each scale. Seventy-five patients with chronic pain were asked to rate pain using all six pain scales. The scales were: the Visual Analogue Scale (VAS), the 101-point Numerical Rating Scale (NRS-101), the 11-point Box Scale (BS-11), the 6-point Behavioral Rating Scale (BRS-6), the 4-point Verbal Rating Scale (VRS-4), and the 5-point Verbal Rating Scale (VRS-5). According to Jensen, Karoly & Braver, there was no significant difference between any of the six scales for subjects who gave incorrect responses (range: 2.7% to 8.0%; $\chi^2 = 3.33, p > 0.05$); indicating that subjects
did not show more incorrect responses to one pain scale over another. “The strength of
the relationship between each individual scale and the shared variance of all of the scales
was determined by intercorrelating responses to the six measures and performing a series
of principal axis factor analysis on these correlations” (Jensen, Karoly & Braver, 1986,
pg. 123). The degree of consistency in the results of the factor analysis can be seen, the
average loading of the intensity measures to the factors were all high (range: BRS-6
(0.72) to BS-11 (0.90)) and showed little variation. According to the authors, this factor
analysis indicated that all six pain scales are valid and reliable for measuring subjective
pain. Therefore, it could be left up to the researcher on which pain scale to use in the
future (Jensen, Karoly & Braver, 1986).

Paice and Cohen (1997) examined the validity of a verbally administered numeric
ingrating scale to measure pain intensity. Fifty patients with cancer pain were asked to rate
their pain using three pain scales; the Simple Descriptor Scale (SDS), Visual Analogue
Scale (VAS), and Numerical Rating Scale (NRS). A Spearman correlation coefficient
was obtained and showed a strong positive correlation between the VAS and NRS ($r =
0.847, p < 0.001$). The VAS has been generally accepted as a measure of pain intensity.
Since the VAS is highly correlated to the NRS in Paice and Cohen’s study, the validity of
using the NRS to measure pain is supported. Additionally, 25 of the 50 patients sampled
preferred the NRS over the VAS or SDS (Paice & Cohen, 1997).

In order to measure any bruising, a disposable measuring tape with millimeter
markings was utilized. If a bruise was noted at the injection site, the researcher measured
the diameter in millimeters at its greatest width. Once the information was collected, the
measuring tape was discarded to reduce any risk of spreading infection to other study
participants. Both the NRS and measuring tape are effective tools to measure the research
questions.

Procedure

The student researcher approached patients who met the criteria to enter this study
as early as possible into their hospital stay. After a brief introduction, the researcher
explained the details of the study. The researcher and potential subject discussed the
study’s purpose, goals, benefits, and potential risks. The potential participant was given
time to ask questions, read/sign the informed consent, and provided a phone number if further questions or concerns needed to be discussed. A copy of the informed consent was provided to the study subject. Once consent was obtained, the researcher reviewed the patient’s chart. The patient was assigned a subject number. From this point, only the individual’s comorbidities, anticoagulation history, and present pain management treatments, along with the assigned subject number, were used by the research nurse on a simple Data Collection Tool. This allowed the research nurse to keep accurate records of information without completely identifying which individual subject provided the information. No detailed personal information (i.e. name, address, date of birth, or social security number) was present on the subjects’ Data Collection Tool. A separate sheet of paper, or link, included the patient’s name and subject number to allow the researcher to identify the subject during the subcutaneous injections. The link, that connected the patient’s name and subject number, was permanently destroyed 48 hours after the second injection of Lovenox (enoxaparin sodium) was delivered. These measures helped to guarantee confidentiality, to the extent allowed by law.

Data collection began at the time of the patient’s next scheduled injection on the Medication Administration Record (MAR). Prior to entering the patients’ room, the researcher tossed a coin to determine if the first injection was to be administered over 10-seconds (heads) or 30-seconds (tails). The injection site was cleaned with an alcohol prep pad. The researcher then administered the first dose of Lovenox (enoxaparin sodium) as determined by the toss of the coin. The researcher used the second hand on the clock located in each hospital room to measure time. Regardless of the injection duration, the needle was left in the abdomen for a full 30-seconds to reduce the potential for participant bias. Thirty seconds after the first injection was complete, the participant was asked to rate the perceived level of pain at the injection site from 0 (no pain) to 10 (worst possible pain). The next time the participant was scheduled to receive Lovenox (enoxaparin sodium); a subcutaneous injection was delivered in the abdomen, with the 10-second or 30-second technique, whichever was not previously used. For example, if the coin toss determined the first injection has to be delivered over 30-seconds, the participant automatically received the next injection over 10-seconds, or vice versa. Again, the participant was asked to rate the pain at the injection site using a 0 (no pain) to
10 (worst possible pain) scale thirty seconds after injection. After each injection, the nurse placed a small circle around the injection site and labeled it either A (10-second injection duration) or B (30-second injection duration) with a Sharpie® marker. Both the subject and staff were informed not to erase the markings on the abdomen for at least 2 days or until the student researcher gave approval.

Forty-eight hours after the second injection was complete, the student researcher met with each study participant and examined his or her abdomen for bruising. Any bruise was measured using a disposable measuring tape. If a bruise was present, the diameter was measured in millimeters and recorded. Once all data were collected, each subject was thanked for participating in the study.

**Data Analysis**

The two research questions being studied addressed if there is any difference in site-pain and bruising on the same hospitalized patient receiving subcutaneous injections of Lovenox using two different injection techniques. Descriptive statistics were utilized for data analysis to either support, or reject, the researchers’ hypothesis. Following completion of the data collection, the data were tabulated to provide the following summaries: distributional properties (i.e. graphs, charts), central location measures (i.e. mean, median), and dispersion measures (i.e. standard deviations). This allowed the research nurse to illustrate and compare data between the 10-second and 30-second injection technique in the results section. These data provided the reader information on which injection technique may produce the least pain and bruising at the injection site. The analytical design for the two research questions was the paired samples t-test. Assumptions for the paired samples t-test include continuity of the underlying variables, interval scale, normality, intrasample independence, and random selection. As neither of these dependent variables (pain and bruising) can be thought of as discrete and categorical, it is reasonable that they be continuous in nature. The paired samples t-test requires at least a minimum of an interval scale, but the investigator can reasonably defend a ratio scale. The researcher assumed a ratio scale. A zero indicated that either bruising was absent or the patient perceived no pain. Finally, normality was an assumption pertaining to the population distribution of bruising and pain perception.
differences. The investigator felt confident with the assumptions of normality due to the nature of the variables and how they were measured. Due to constraints on resources available to the researcher, the participants came from a sample of convenience. Therefore the sample was not randomly selected from the whole population. These assumptions will be discussed in detail in Chapter 4.

Summary

This chapter explored the methodology that was used to collect and analyze data relating to site-pain and bruising associated with subcutaneous administration of Lovenox (enoxaparin sodium). A quasi-experimental, comparative design was used in this study to investigate what differences, if any, existed between the two subcutaneous injection techniques on perceived site-pain and measured bruising. The setting for this study was at a larger hospital located in north Florida. Patients admitted only to the neurological or cardiac intensive care units, or orthopedic, neurological, or cardiac treatment areas of the hospital were utilized in this study. Use of one setting allowed the researcher to maintain constancy of conditions. The target population was patients who were receiving Lovenox (enoxaparin sodium) as a subcutaneous injection, 18 years of age or older, oriented to person/place/time/situation, and able to rate pain at the injection site using the Numerical Rating Scale. The plan for this current research project was to have an alpha of 0.05, power of 0.80, and effect size of 0.5σ. As a result, a sample size of at least 34 participants was needed to determine if longer injection duration had any significant effect on reported site-pain or measured bruising. All individuals involved had the full nature of the study explained, including researcher responsibilities, benefits, and risks participants could incur. Finally, a detailed description of the instruments and procedure to be used in this study were discussed. In Chapter 4, results from the raw data will be presented.
CHAPTER 4
RESULTS

This chapter will present the findings obtained during data collection as related to the two research questions. Tables and figures of the data, from simple frequencies to more in-depth analysis, will be provided. All necessary data, interpretation and conclusions will be provided to the reader. The study explored the effects of injection duration on site-pain and bruising utilizing two different injection techniques with subcutaneous Lovenox (enoxaparin sodium). All available data relating to the sample population and research questions will be provided.

Description of the Sample

Approval was received from the Institutional Review Boards of Florida State University and the participating research hospital, along with the primary physicians caring for the patient. Once formal approval was obtained from the governing bodies, patients were screened based on the inclusion/exclusion criteria, approached, selected, and given two subcutaneous injections of Lovenox (after informed consent) by Todd Chenicek RN, BSN.

The sample consisted of 34 patients admitted to a neurological intensive care unit, cardiac intensive care unit, orthopedic/neurology, or cardiac, treatment floors at a hospital in the north Florida area. The study participants were admitted to the hospital primarily for traumatic and/or surgical events relating only to orthopedic, neurological or cardiac disease processes. Patients ranged from causalities of motor vehicle accidents, strokes, subdural hematomas, elective knee surgery and myocardial infarctions. It is worth exploring how the research study population compared with the overall hospital population at the facility. The research hospital has a total of 597 acute care beds serving approximately 600,000 people in 16 counties in north Florida, southwest Georgia, and
southeast Alabama (Tallahassee Memorial HealthCare, 2002). Of the 597 acute care beds, nearly 100 are located in the treatment areas from which data was collected. Inpatient services are diverse ranging from pediatrics, oncology, cardiology, gynecology, urology, orthopedics, neurology and obstetrics (Tallahassee Memorial HealthCare, 2002). Specialized intensive care units range from medical, surgical, coronary, neurological, pediatric and neonatal (Tallahassee Memorial HealthCare, 2002). Analysis of the hospital population showed that 92% of total hospital discharges were patients treated for cancer (5.7%), diabetes (13.3%), emphysema (4.5%), dyslipidemia (2.0%), HIV/AIDS (6.2%), hypertension (24.9%), ischemic heart disease (1.3%), stroke (2.2%), arthritis (6.1%), asthma (4.3%), gallbladder disease (2.1%), stomach ulcers (5.2%), back problems (2.2%), Alzheimer’s (4.2%), and depression/anxiety (7.8%; (Tallahassee Memorial HealthCare, 2002). Data were collected from October, 2003, to January, 2004. The sample that agreed to participate in this research study were examined via frequencies of sex, race, highest level of education completed, how long the participant had been on Lovenox during the current hospitalization, whether or not the participant was on any other anticoagulant therapy and, finally, comorbidities.

**Descriptive Statistics:**

The 34 participants consisted of 14 males (41.2%) and 20 females (58.8%), comprised of 23 non-Hispanic white (67.6%), 9 black (26.5%), and 2 Hispanic (5.9%) individuals (Figure 1). During the interview process, patients were asked about the highest level of education completed prior to entering the study. Each category was associated with a numerical rating: 1) Elementary school ($n = 0$), 2) Middle School ($n = 1$), 3) High School ($n = 8$), 4) Associate degree ($n = 9$), 5) Bachelor’s degree ($n = 11$), 6) Master’s degree ($n = 5$), and 7) PhD ($n = 0$). The average participant possessed an Associate’s or Bachelor’s degree accounting for 59% of the participants (Figure 2).

Subjects ranged from $<1$ day to $\geq 11$ days on Lovenox during the current hospitalization. The categories [1: $<1$ day ($n = 7$), 2: 1-2 days ($n = 14$), 3: 3-4 days ($n = 10$), 4: 5-6 days ($n = 2$), 5: 7-8 days ($n = 0$), 6: 9-10 days ($n = 0$), & 7: $\geq 11$ days ($n = 1$)] demonstrated that most participants had been on Lovenox between 1-4 days (Figure 3). Of the 34 participants, 76.5% ($n = 26$) were not currently on any other anticoagulant
therapy other than Lovenox. The other 23.5% \((n = 8)\) were also taking aspirin \((n = 6)\), Plavix \((n = 2)\), Coumadin \((n = 2)\), or a combination of these medications. Finally, the patients had a wide range of comorbidities. Hypertension (41.2%), diabetes (17.6%), and obesity (14.7%) were the three leading comorbidities identified when the chart was reviewed. However, seven of the subjects had no comorbidities listed in the medical chart or records (Figure 4).

![Frequencies of Gender and Ethnicity](image)

**Figure 1: Frequencies of Gender and Ethnicity**

![Highest Level of Education Completed](image)

**Figure 2: Highest Level of Education Completed**
Research question #1 explored the difference of site-pain perceived by the same hospitalized patient receiving subcutaneous injections of Lovenox using two different injection techniques (10-second versus 30-second duration). The reported level of pain was measured on a 0 (no pain) to 10 (worst possible pain) scale. Utilizing the 10-second injection technique, the pain ratings ranged from 0 to 8 (mean: 1.62, median: 1, $SD$: 1.859; Figure 5). Thirty of these participants (88.2%) did not receive any pain medication within 4 hours prior to the 10-second injection. Next, the pain ratings after the 30-second injection duration ranged from 0 to 6 (mean: 1.59, median: 1, $SD$: 1.844; Figure 5). Twenty-seven of the participants (79.4%) did not receive pain medications within 4 hours prior to the 30-second injection technique. The results show that neither the reported level...
of pain data nor the measured bruising data appeared symmetrical (i.e. bell-curve) after completion of the study (Figure 5, Figure 6).

Research question #2 examined the difference in measurable size of bruising on the same hospitalized patient receiving subcutaneous injections of Lovenox, measured 48 hours after administration, using a 10-second and 30-second injection technique. Forty-eight hours after the 10-second technique, bruising ranged from 0 mm to 3 mm (mean: 0.41 mm, median: 0, SD: 0.743 mm; Figure 6). Finally, after the 30-second injection technique, bruising ranged from 0 mm to 6 mm (mean: 0.56 mm, median: 0, SD: 1.160 mm; Figure 6).

<table>
<thead>
<tr>
<th>Reported level of pain (10-second)</th>
<th>Reported level of pain (30-second)</th>
</tr>
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<tbody>
<tr>
<td>10 (n=0) 0%</td>
<td>10 (n=0) 0%</td>
</tr>
<tr>
<td>9 (n=0) 0%</td>
<td>9 (n=0) 0%</td>
</tr>
<tr>
<td>8 (n=1) 2.90%</td>
<td>8 (n=0) 0%</td>
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<tr>
<td>7 (n=0) 0%</td>
<td>7 (n=0) 0%</td>
</tr>
<tr>
<td>6 (n=1) 2.90%</td>
<td>6 (n=1) 2.80%</td>
</tr>
<tr>
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</tr>
<tr>
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<tr>
<td>3 (n=2) 5.90%</td>
<td>3 (n=2) 2.90%</td>
</tr>
<tr>
<td>2 (n=7) 20.60%</td>
<td>2 (n=5) 14.70%</td>
</tr>
<tr>
<td>1 (n=9) 26.50%</td>
<td>1 (n=8) 23.50%</td>
</tr>
<tr>
<td>0 (n=11) 32.40%</td>
<td>0 (n=13) 38.20%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Measured bruising (10-second)</th>
<th>Measured bruising (30-second)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3mm (n=1)</td>
<td>6mm (n=1)</td>
</tr>
<tr>
<td>2mm (n=5)</td>
<td>2mm (n=3)</td>
</tr>
<tr>
<td>5mm (n=7)</td>
<td>1mm (n=7)</td>
</tr>
<tr>
<td>0mm (n=24)</td>
<td>0mm (n=23)</td>
</tr>
</tbody>
</table>

Figure 5: Reported level of pain

Figure 6: Measured bruising

**Statistical Analysis**

The purpose of the proposed study was to explore the effects of two different injection techniques on pain and bruising associated with subcutaneous administration of Lovenox. The perception of site-pain and the potential presence of bruising at the injection site warranted a review of the techniques currently used. Only after a review and analysis of these techniques can nurses conclude which promotes the best patient
comfort and outcome. The data in this study were collected and analyzed using a paired samples t-test.

Research question #1 sought to determine whether or not a significant difference existed between site-pain perceived by the same hospitalized patient using two different injection techniques. The average 10-second (mean: 1.62; SD: 1.859) and 30-second (mean: 1.59; SD: 1.844) pain rating score differed by a score of 0.03. The calculated standard error of the difference, or amount of difference the researcher can attribute to pure chance, was 0.395. Therefore, the data indicated that the difference in 10-second and 30-second technique pain scores needed to differ by more than a mean of 0.395. The mean pain score difference observed with this sample was only 0.03. Therefore, the difference in mean pain scores could be attributed to pure chance (Table 1).

Research question #2 explored whether or not a significant difference existed between measurable bruising on the same hospitalized patient using two different injection techniques. The average 10-second (mean: 0.41 mm; SD: 0.743 mm) and 30-second (mean: 0.56 mm; SD: 1.16 mm) bruise differed by a score of 0.15 mm. The calculated standard error of the difference for bruising was 0.243 mm. Therefore, the data indicated that the difference in 10-second and 30-second technique bruising measurements needed to differ by more than a mean of 0.243 mm. The observed bruises that were measurable had a difference in mean size of 0.15 mm. The difference in mean values could be attributable to nothing more than pure chance. Based on the available data, there appeared to be no significant difference between which technique was used versus the patient’s perceived level of pain ($p = 0.941$) or measured bruising ($p = 0.549$; Table 1).

<table>
<thead>
<tr>
<th>Table 1: Paired Samples $t$-test</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pair #1</strong></td>
</tr>
<tr>
<td>Reported level of pain (10-second)</td>
</tr>
<tr>
<td>Reported level of pain (30-second)</td>
</tr>
<tr>
<td><strong>Pair #2</strong></td>
</tr>
<tr>
<td>Measured bruising in mm (10-second)</td>
</tr>
<tr>
<td>Measured bruising in mm (30-second)</td>
</tr>
</tbody>
</table>
Conclusions

The following conclusions were derived from the research analysis:

1. There was no statistically significant difference in site-pain among hospitalized patients receiving subcutaneous injections of Lovenox using two different injection techniques. Therefore, the researcher’s hypothesis was not supported. Use of the 30-second injection technique did not result in statistically lower levels of perceived pain when compared to the 10-second injection technique on the same hospitalized patient.

2. There was no statistically significant difference in measurable bruising on hospitalized patients receiving subcutaneous injections of Lovenox using two different injection techniques. Therefore, the researcher’s hypothesis was not supported. Use of the 30-second injection technique did not result in statistically lower levels of measurable bruising when compared to the 10-second injection technique of Lovenox on the same hospitalized patient.

Summary

This chapter provided both descriptive and statistical analyses addressing the two research questions posed by this study. The descriptive statistics focused on the demographics of the participant population, describing factors such as sex, race, number of days on Lovenox, highest level of education completed, and comorbidities. Two research questions were presented and examined according to level of pain reported and measurable bruising utilizing two different injection techniques on the same hospitalized patient.

Using the 10-second versus 30-second injection technique of Lovenox did not show any statistically significant differences in terms of pain reports ($p = 0.941$) or bruising ($p = 0.549$) at the injection site. However, there were two correlations worth noting among the participants. The longer the patient was on Lovenox, the less bruising that was noted at the 10-second injection site 48 hours later. Also, the data supported that as reported pain scores go higher, bruising may go up on the same individual with the 10-second injection technique. However, based on the overall data collected for this study, the researcher’s two hypotheses were not accepted.
CHAPTER 5
DISCUSSION

This chapter provides a summary discussion of the research findings, how they relate to the conceptual framework and whether this study supports, or differs, from previous literature. Limitations and assumptions postulated prior to the study will be discussed. Conclusions based on the research findings will be provided, as well as how these findings can improve advanced nursing practice and recommendations for future research.

Discussion of the Study/Findings

The purpose of this study was to explore the effects of two different injection techniques on pain and bruising associated with subcutaneous administration of Lovenox (enoxaparin sodium). Patients were given two doses of Lovenox in the abdomen using 10-second and 30-second injection durations. The study explored two research questions. The first question studied the difference of site-pain perceived by the same hospitalized patient receiving subcutaneous injections of Lovenox using these two injection techniques. The second research question studied the difference in measurable bruising, if any, on the same hospitalized patient 48 hours after injection using these two injection techniques. The researcher proposed two hypotheses; use of a 30-second injection technique of Lovenox would result in lower levels of perceived site-pain and less measurable bruising at the injection site compared to the 10-second injection technique on the same hospitalized patient.

After approval was obtained from the Institutional Review Boards of Florida State University and a north Florida area hospital, study participants were selected based on inclusion/exclusion criteria. Thirty-four patients agreed to participate in the proposed study. The patients were randomly assigned to receive either the 10-second or 30-second
injection first, but always received the opposite technique on the second injection. The result was that the patient was not aware which technique was first, but all participants did receive both injection techniques. This method helped to minimize any potential for bias that may have existed among the participants. Using the same patient for both injections also helped to reduce any potential bias associated with confounding variables.

The average participant was white (68%) and female (59%), with at least an Associate’s degree of education, and on Lovenox between 1-4 days during the current hospital stay. After the pain rating and bruising data were compiled from both injection techniques, examination of the results revealed that there was not a statistically significant difference between the two techniques in relation to site-pain ($p = 0.941$) and bruising ($p = 0.549$). As a result, the researcher’s hypotheses were not supported. Possible reasons why significant findings were not found could include the fact that the same patient was utilized for both injections. Even though the participant did not know if he/she was receiving the 10 or 30-second injection, the patient could have unconsciously concluded which injection should be more painful. Not including pain ratings within 4 hours of receiving pain medication, may help to eliminate any bias caused by reduced pain scores. Also, excluding individuals on other forms of anticoagulation could have eliminated the possibility that bruising was enhanced, or even reduced, in these participants. It must be noted that a larger effect size (0.5$\sigma$) was used to allow for a smaller sample size. As a result of this tradeoff, the difference between the two techniques would have to be large for a significant difference to appear in the results. These are some of the possible explanations why there were not significant findings between the two injection techniques.

**Relationship of the Results to Previous Empirical Work**

As in this study, Chan (2001) evaluated two subcutaneous heparin injection techniques on site-pain and bruising. However, Fragmin (dalteparin sodium), another low molecular weight heparin, was used. Chan’s (2001) methods were similar to this study; 34 patients were studied using similar techniques, inclusion/exclusion criteria and analysis. However, only stroke patients were evaluated using a vertical visual analogue scale (VAS) for pain ratings and digital planimetry to measure surface area of bruises.
VAS pain scores ranged from 1-99 mm (mean: 22.8 mm, SD: 24.75 mm) for the 10-second technique and 0-59.5 mm (mean: 10.7 mm, SD: 15.28 mm) for the 30-second technique. The mean difference in Chan’s pain scores was 12.1 mm ($p < 0.000$).

Measured bruising was also smaller the greater the injection duration. The 10-second technique ranged from 0-177.66 mm$^2$ (mean: 24.14 mm$^2$, SD: 41.47 mm$^2$) and ranged 0-5 mm$^2$ (mean: 0.98 mm$^2$, SD: 1.28 mm$^2$) for the 30-second technique. Given the fact that Chan used a VAS (0-100 mm) to rate pain, participants had more of a range of values to select from in order to rate pain. This small difference in data collection could possibly explain the fact that a significant difference existed when compared to the present study that used the NRS pain scale (0-10). Chan’s (2001) study also showed an increased bruise presence and size. The fact that only one research nurse gave all the subcutaneous injections in the current study using the technique previously described in Chapter 3, his meticulous technique and attention to detail could possibly explain why so few bruises were noted in these results. Results of Chan’s (2001) study demonstrated that the 30-second duration technique resulted in significantly less intense site-pain and smaller bruises ($p < 0.05$). The conclusion was that by administering the LMWH injection over a longer duration, site-pain and measurable bruising would also be reduced.

Similar to the current study, Mitchell and Whitney (2001) found no correlation between pain perceived by the study participants and injection speed duration used when delivering hepatitis B vaccinations. One important difference between Mitchell and Whitney’s (2001) study and the current project is that the hepatitis B injections were intramuscular, not subcutaneous. Mitchell and Whitney (2001) did not examine the injections effects on bruising. It is important that all research, whether supporting the researcher’s hypothesis or not, be made available to the scientific community. It is up to the advanced practice nurse or other practitioner to research which techniques should be adopted or rejected.

**Relationship of the Results to the Conceptual Framework**

Neuman’s model (2002) is based on the patient’s relationship to environmental stress, which has the potential to cause a reaction, or affect the patient’s reconstitution following treatment of a stress reaction. Using Neuman’s Model as the framework for
this study allowed the researcher the ability to examine a routine, but often stressful, procedure performed daily at hospitals around the country. It was important to understand this theory, helping the researcher understand how a person might perceive and react to a stressful situation as a hospitalized patient. Using the terminology of Neuman, the following narrative will attempt to connect this study with the model.

The four components of Neuman’s model (person, environment, health, and nursing) are all pertinent in relation to pain and bruising. Pain and potentially unsightly bruising can be considered stressful events. These events will likely cause changes within the client’s basic structure and shifts between the flexible line of defense, normal line of defense, and lines of resistance. The degree to which it affects each individual can vary greatly. A subcutaneous injection of medication will likely not evoke a fight-or-flight response, but, rather, alter the individual’s perception of the moment. The result could affect a pain rating either artificially high or low. How well the individual reorganizes after the stress response will likely determine how he/she will respond to future injections.

The environment plays a vital role in the responses obtained. Neuman described the environment as both internal and external. Patients often have preconceived ideas and biases about hospitals, a place to recover from illness while potentially being exposed to varying degrees of discomfort. This potential innate bias may prejudice any results obtained by any research study performed in a hospital setting.

In terms of health, all patients are at some point on the wellness/illness continuum. A patient with more severe medical problems may perceive any pain or bruising as more significant and alter the responses accordingly. Also, those subjects on anticoagulants other than Lovenox for countless reasons may bruise more easily. It would be impossible to pinpoint exactly where each individual falls on the continuum and scale the results accordingly.

Nursing is the common bond for many individuals in the hospital setting. Nurses are often perceived as caring hands in an unfamiliar environment. As a result, nurses are often looked at favorably by patients within the hospital system. It will be viewed positively if a nurse can provide a more comfortable way to deliver an injection or study techniques to determine which method bruises less in the future. This internal view of
nursing, whether positive or negative, could alter the recorded outcomes for some individuals and affect the results.

Inside the person, there are five interacting variables: physiological, psychological, sociocultural, developmental, and spiritual. Many of the patients in the study were female and white. The backgrounds, beliefs, and reactions to stressful situations for these participants might have been similar based on the demographics of the sample. If more of the participants have similar backgrounds, the body structure, mental processes, age-related developmental processes, and spiritual influences may allow for less variability in stressful situations. This potential common ground between the participants (i.e. sex, race, being confined to a hospital, repeatedly being injected with medications), might allow for a stronger or more similar flexible line of defense. The fact of being a patient in a hospital might push the flexible line of defense out away from the client’s normal line of defense and basic structure. As a result, the responses to perceived levels of pain after a minor stressful situation and measurable bruising could be nearly the same. This might be one possible explanation why there were no statistically significant differences between the techniques with these study participants. This may not hold true the more serious the therapy or the greater the potential it has for altering the individual’s life. Most patients in a hospital setting have experienced repeated intravenous catheter placements, blood draws or other more painful and invasive procedures. As a result, many patients would likely agree that receiving a daily subcutaneous injection of Lovenox in the abdomen is not as stressful as these other procedures.

**Limitations**

Although the subjects were selected at random, the patients were chosen from a sample of convenience since only one researcher was able to give injections and collect all the data. Patients were only approached if admitted to the neurological intensive care unit, cardiac intensive care unit, neurological, or cardiac treatment floors at a local hospital in north Florida. As a result, participants were taken from only one geographical region in the hospital (i.e. cardiac and neurological, and orthopedic patients), thereby reducing the ability to generalize the study’s results to the entire hospitalized population.
Pain is a subjective experience. The researcher must record whatever the patient reports the pain to be. These subjective data do allow for the potential bias in the results. The subject could relate to the researcher in some incalculable way and as a result provide a rating that he/she believes the researcher would want to hear. Additionally, using the same patient for both injections allows the participant to anticipate and possibly determine ahead of time a pain rating for the second injection. Although many confounding variables are reduced, using the same patient for both injections allows bias still to enter the study.

One of the assumptions of the current study was normality as mentioned in Data Analysis of Chapter 3. However, as noted in Figure 5 (Reported Levels of Pain) and Figure 6 (Measured Bruising), the curves are not symmetrical or bell-shaped, but rather skewed to one side. This could affect the study’s findings as to whether one could have confidence in their accuracy.

The NRS scale has only 11 possible data points to record, compared to the VAS which has 101 data points. Using the NRS as a pain rating tool may limit the sensitivity of the pain recordings. The hospital chosen for this study routinely uses the NRS scale to rate pain. It would have been difficult or impossible for the research nurse to implement the use of an entirely new pain rating tool (i.e. VAS) in the facility for the purposes of this study.

Finally, Chan’s (2001) study used a different LMWH (Fragmin) to research site-pain and bruising. The use of different drugs (Lovenox versus Fragmin) could also explain the variation in results. Student researchers are limited in the medications which are available to provide to patients in order to study a medication’s effect on the human body.

Assumptions

The current project made a number of assumptions that the reader must examine when drawing any conclusion on its results. Patients were expected to rate any perceived pain accurately and truthfully. The researcher assumed that any pain rating reported by the patient after the injection was accurate and equal to future pain ratings. Also, all recordings for bruises were measured to the nearest millimeter at the bruise’s greatest
diameter. It was assumed that any bruises present would essentially be circular, versus linear, in nature.

**Implications for Advanced Nursing Practice**

The results of this study support the fact that practice cannot be based solely on a single study. Chan’s (2001) study clearly demonstrated the positive difference in patient outcomes when longer injection duration was utilized on the same patient. However, the current study, using the same sample size and technique as Chan (2001), showed completely different results. One possible explanation for the difference in the outcomes of these two studies may be the use of the VAS versus NRS as the pain rating tool. The VAS has 101 potential data points versus only 11 data points with the NRS. This fact alone could allow for a statistical difference to exist. Therefore, it may be possible to consider the VAS a more sensitive measure of pain when compared to the NRS. If this were ever proved factual with future studies, APNs should push for the VAS scale to determine perceived pain among all hospital patients. It would be interesting to replicate this project in the future using all the same techniques and methods, only substituting the VAS to rate the pain, to determine whether or not a significant difference existed.

Advanced practice nurses are leaders in the field of nursing in terms of research and education. The burden must fall on individual nursing departments, under the guidance of advanced practice nurses, to take the information that is provided in this and future studies and formulate a method of practice. It is vital that more advanced practice nurses replicate this type of study to promote ideal nursing research and practice, using larger, random sample sizes from a variety of geographical and hospital locations.

**Recommendations for Future Research**

One recommendation for future research would be to obtain repeated measurements from the same patient. Instead of limiting the subject to only two encounters, one 10-second and one 30-second, ask the patient to agree to four injections. This would provide the researcher opportunity to collect more data to determine whether or not a difference existed over a longer period of time. If the participant was not aware if
the four injections would all be 10-second, 30-second, or a combination of the two techniques, less bias might result.

Additionally, the current study used an effect size of $0.5\sigma$. A future study might want to use a smaller effect size. As a result, smaller differences would be required for the results to be statistically significant. However, a smaller effect size would require a larger sample. The current project was completed with a single research nurse; a larger sample was a luxury the researcher could not afford. Based on this study, any sample greater than 34 patients would likely require another research nurse to assist in collecting the data.

Finally, future research might benefit from the analysis of more than one low molecular weight heparin (LMWH). If patients in the same geographical region were all evaluated using the same methods, but with different subcutaneous anticoagulation medications, the results might show which drugs are best at either the 10-second or 30-second injection duration. It is one hope that readers of the current project will be drawn into the objectives/goals of this study and pursue future research for the advancement of the nursing profession.

**Summary**

This chapter discussed the findings provided in Chapter 4 and how the results related to the researcher’s hypothesis. The researcher explained what relationships could be made between the current study and previous empirical works. As well as how Neuman’s model guided and related to the project. Finally, various limitations and assumptions taken by the researcher were analyzed and how the present research project could be advanced in the future.
APPENDIX A

FLORIDA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD
APPROVAL LETTER
APPROVAL MEMORANDUM
from the Human Subjects Committee

Date:       June 2, 2003
From:      David Quadagno, Chair
To:        Todd Chenicek
            1533 Copperfield Circle
            Tallahassee, FL 32312
Dept:      Nursing
Re:        Use of Human subjects in Research
            Project entitled: Effects of Injection Duration of Site-Pain and
            Bruising Associated with Subcutaneous Administration of
            Lovenox (Enoxaparin Sodium)

The forms that you submitted to this office in regard to the use of human subjects in the
proposal referenced above have been reviewed by the Human Subjects Committee at its
meeting on May 14, 2003. Your project was approved by the Committee.

The Human Subjects Committee has not evaluated your proposal for scientific merit,
except to weigh the risk to the human participants and the aspects of the proposal
related to potential risk and benefit. This approval does not replace any departmental
or other approvals which may be required.

If the project has not been completed by May 13, 2004, you must request renewed approval
for continuation of the project.

You are advised that any change in protocol in this project must be approved by
resubmission of the project to the Committee for approval. Also, the principal investigator
must promptly report, in writing, any unexpected problems causing risks to research subjects
or others.

By copy of this memorandum, the chairman of your department and/or your major professor
is reminded that he/she is responsible for being informed concerning research projects
involving human subjects in the department, and should review protocols of such
investigations as often as needed to insure that the project is being conducted in compliance
with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Protection from Research Risks.
The Assurance Number is IRB00000446.

APPLICATION NO. 03.264
Co: J. Flannery
APPENDIX B

TALLAHASSEE MEMORIAL HOSPITAL PERMISSION LETTER
August 18, 2003

Todd Chenicek, RN, BSN
1533 Copperfield Circle
Tallahassee, FL 32312

Dear Mr. Chenicek:

I have reviewed your research proposal, “Effects of Injection Duration on Site-pain Intensity and Bruising Associated with Subcutaneous Administration of Lovenox (enoxaparin sodium)”. I find that your research project meets the requirements for an Expedited Review and you may proceed with your evaluation as soon as it is practical for you to do so.

The Institutional Review Board would like to receive a copy of your findings at the completion of your research project.

Sincerely,

[Signature]

Richard J. MacArthur, M.D.
SVP/Chief Medical Officer
APPENDIX C

INFORMED CONSENT
Todd Chenicek, research student, is a registered nurse currently enrolled in the Graduate Nursing program at Florida State University conducting a study on subcutaneous administration of Lovenox (enoxaparin sodium). The purpose of this study is to explore the effects of two injection techniques on pain and bruising associated with subcutaneous administration of Lovenox (enoxaparin sodium).

My participation will involve receiving two injections of Lovenox (enoxaparin sodium) using two different injection techniques. I will be asked to rate my perceived level of pain at the injection site. Forty-eight hours after the injections, the research student will measure any bruising, if present, at the injection site. The goal is to be able to determine which technique might cause the least discomfort and bruising for patients receiving subcutaneous Lovenox injections. Once I give consent to participate in this study, I understand that I will receive only two injections as a study participant. The researcher will label each injection site. I will try, to the best of my ability, to avoid removing the labeling or markings for a period of forty-eight hours after the second injection to allow for data collection. After the researcher has examined the injection sites for bruising, I understand that my obligation as a study participant will be completed.

I understand that Todd Chenicek is obtaining these data for a research study being conducted as part of his degree requirements at Florida State University’s School of Nursing. I understand that I was chosen for this study since I am receiving Lovenox (enoxaparin sodium) as a patient on either the cardiac intensive care unit (CICU), cardiac treatment floor (3N), neurological intensive care unit (VNICU), or orthopedic-neurological treatment floor (4N) at Tallahassee Memorial Hospital.

Although there may be no direct benefits to me, the possible benefits of my participation are that I may assist the researcher in understanding which injection technique causes the least amount of site-pain and bruising for patients receiving Lovenox (enoxaparin sodium) in the future. There are minimal foreseeable risks or discomforts to me if I agree to participate in this study. Possible discomforts include pain and bruising at the injection site, but no differently than would have occurred with the usual administration of Lovenox. Participating in this study does not alter when or what medications I will receive now or in the future from my physician.

I understand that my privacy will be protected at all times. Information obtained during the course of the study will remain confidential, to the extent allowed by law. The results of this research may be published but my name or identity will not be revealed. The researcher will do the following to maintain confidentiality of my records, Todd Chenicek will not label any data with my name. The use of a subject code on all data will be used to maintain confidentiality.

In case of injury I expect to receive the following treatment or care which will be provided at my expense: my physician will be notified of any injury and resulting care will be directed at the discretion of that physician. I will not be paid for my participation. I understand that participating in this study is strictly voluntary and failure to comply with the study will not result in any penalties or loss of benefits during my hospital stay. The research student has informed me that even after consenting to cooperate in this study, I have the right to withdraw and/or refuse to provide any specific piece of information at any time.

Any questions I have concerning the research study or my participation in it, before or after my consent, will be answered by Dr. Jeanne Flannery or Todd Chenicek. I can reach Dr. Jeanne Flannery at Florida State University’s School of Nursing at (850) 644-5626 or Todd Chenicek at (850) 894-3757.

In case of injury or in the event I have questions about my rights as a participant in this research study, or if I feel I have been placed at risk, I can contact the Chair of the Human Subjects Committee, Institutional Review Board, through the office of the Vice President for Research at (850) 644-8633. The nature, demands, benefits and any risk of the project have been explained to me. I knowingly assume any risks involved.

I have read the above informed consent form. I understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I may otherwise be entitled. In signing this consent form, I am not waiving any legal claims, rights or remedies. A copy of this consent will be offered to me.

Subject’s Signature: ___________________________________________________

Date: ______________________________
APPENDIX D

DEMOGRAPHIC DATA COLLECTION FORM
Data Collection Tool

Subject Number: ____________________

Sex:

A) Male  
B) Female

Race:

A) White (non-Hispanic)  
B) Black  
C) Hispanic  
D) Asian  
E) Indian  
F) Other

Highest level of education completed:

A) Elementary (K-5th)  
B) Middle school (6th to 8th grades)  
C) High school (9th to 12th)  
D) Associates degree  
E) Bachelor’s degree  
F) Master’s degree  
G) Doctorate of Philosophy  
H) Other

How long has the participant been on Lovenox during the current hospitalization?

A) < 1 day  
B) 1-2 days  
C) 3-4 days  
D) 5-6 days  
E) 7-8 days  
F) 9-10 days  
G) > 11 days

Is the participant currently on any other anticoagulant therapy (other than Lovenox)?

A) No  
B) Yes (If so, list below)

Comorbidities:

Intervention/Results

Reported level of pain after the 10-second injection duration: 0 1 2 3 4 5 6 7 8 9 10

Did the participant receive any pain medications within the past 4 hours? (If so, list the medication and dose)

Reported level of pain after the 30-second injection duration: 0 1 2 3 4 5 6 7 8 9 10

Did the participant receive any pain medications within the past 4 hours? (If so, list the medication and dose)

Measured bruising in millimeters noted to the 10-second injection site (if any): ____________________

Measured bruising in millimeters noted to the 30-second injection site (if any): ____________________

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REFERENCES


acute deep venous thrombosis: A meta-analysis of randomized, controlled trials. 
*Annals of Internal Medicine, 130*(10), 800-809.


BIOGRAPHICAL SKETCH

Todd E. Chenicek was born on March 31st, 1971 in Chicago, Illinois, to Don and Sharon Chenicek. He is married to Jolynda B. Chenicek and has two sons, Brock and Logan. He is a Registered Nurse and employed by Tallahassee Memorial Hospital.

Mr. Chenicek has previously worked in the areas of medical/telemetry while employed as a staff nurse at Bethesda Memorial Hospital in Boynton Beach, Florida. He now currently works, as he has for the past 8 years, full-time as charge/staff nurse for the Vogter-Neurological Intensive Care Unit at Tallahassee Memorial Hospital. His critical care experiences with neurology and neurosurgery have been vital in his desire to pursue his advanced nursing education. The current study provided an opportunity to explore how nursing care was provided and how it could possibly be improved.

Mr. Chenicek returned to Florida State University in the Spring, 2000, after being formally accepted into the School of Nursing Graduate Program. On August 7th, 2004, he received his Master’s Degree in Nursing, specializing as a Family Nurse Practitioner in a primary care setting.