

School of Nursing

**Duration of Subcutaneous Heparin Injections:
Effect on Bruising and Pain**

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the award of the Degree of the Master of Science (Nursing)
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DECLARATION

I declare that the material contained in this thesis has not been submitted to any University in application for a Degree or Higher Education qualifications. Also, to the best of my knowledge and belief, the sources of information received in preparing this thesis have been fully acknowledged.

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ABSTRACT OF THESIS

Injection site-pain and bruising are common side effects of subcutaneous heparin injections. These adverse outcomes are problematic for both the patient and the nurse. Specifically, site-pain causes the patient discomfort and bruising limits possible sites for subsequent injections. It is important that nurses use an injection technique that minimises the incidence of adverse outcomes when administering subcutaneous heparin injections. This study examines the effect of duration of subcutaneous heparin injection on site-pain intensity and bruise size experienced by a group of patients being treated with heparin for ischaemic stroke or transient ischaemic attacks.

A quasiexperimental design with subjects serving as their own control was used to address the study objectives. The independent variable was the duration of the injection and the dependent variables were site-pain and bruise size. A convenience sample of 34 subjects receiving 5000 units of a subcutaneous Fragmin injection twice a day were recruited from a large teaching hospital. Subjects rated the level of perceived site-pain intensity during injection using the vertical Visual Analogue Scale. Injection-site bruising was measured at 48 and 60 hours after injection. Data were analysed using the Wilcoxon Sign-Rank test. Results indicated that injection technique B (30-second injection duration) resulted in significantly less intense site-pain during administering the injection and fewer and smaller bruises.

The findings of this study indicate that injecting subcutaneous heparin over a longer duration may reduce injection site-pain and bruising.

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CHAPTER ONE

INTRODUCTION

Injection site-pain and bruising associated with subcutaneous heparin injections are issues that cause patients concern. Most patients who have had a subcutaneous heparin injection are fearful of subsequent injections due to the site-pain and possible bruising experienced (Hadley, Chang, & Rogers, 1996; Ross & Soltes, 1995). These adverse outcomes of subcutaneous heparin injections are problematic for both the patient and the nurse. Specifically, site-pain causes the patient physical and psychological discomfort and bruising limits possible sites for subsequent injections. Thus, it is important that nurses use an injection technique that minimises the incidence of site-pain and bruising when administering subcutaneous heparin injections.

This chapter will discuss the background and rationale of the current project followed by the purpose and objectives of the study. The significance of this research will also be presented to illustrate clinical relevance. For clarity, terms used in this thesis are defined at the end of the chapter.

Background and Rationale

There is a high incidence of secondary thromboembolic diseases in medical patients. One commonly used treatment is anticoagulation therapy in the form of subcutaneous heparin. About 24% of patients following myocardial infarction and 42% following ischaemic

stroke will receive subcutaneous heparin injections during the acute in-hospital phase (Bergmann & Neuhart, 1996). In addition, most patients with primary thromboembolic diseases such as unstable angina, myocardial infarction and ischaemic stroke will require long-term anticoagulation therapy with subcutaneous low molecular weight heparin (LMWH). As a result, the clinical use of subcutaneous heparin has sharply increased in recent years.

Subcutaneous heparin is an effective anticoagulant therapy used in most clinical conditions associated with either venous or arterial thromboembolism (Braunwald, 1998; Frydman, 1996; Haas, 1996; Meschia & Biller, 1997; Samama, Desnoyers, Conard & Bousser, 1997). There are two types of heparin solutions; unfractionated heparin (UFH) and low molecular weight heparin (LMWH). Unfractionated heparin has been the drug of choice for decades. Recently, LMWH has superseded UFH due to its high bioavailability and predictable anticoagulant dose-response. Subcutaneous LMWH is believed to provide anticoagulation which is therapeutically equivalent or better than that of UFH (Boneu, 1994; Dahl, Friis & Abildgaard, 1997; Hirsh, 1998; Koopman, Prandoni, Piovella, et al., 1996; Levine, Gent, Hirsh, et al., 1996). This makes subcutaneous LMWH suitable for the therapeutic treatment of many actual or potential thromboembolic diseases including but not limited to, ischaemic stroke (Adams & Brott, 1995; Kay, Sing & Ling, 1995; Kay, Wong & Woo, 1994; Kong, 1997; Massey & Biller, 1997). Presently, the anticoagulant treatment for ischaemic stroke is subcutaneous LMWH administered twice daily from the time of stroke for up to 14 days.

Subcutaneous LMWH has similar adverse effects as subcutaneous UFH, such as pain and

bruising at the injection site (Eriksson, Söderberg, Widlund, et al., 1995; Frydman, 1996; Hillis, 1997; Nunnelee, 1997). The systemic anticoagulation effect of both UFH and LMWH is thought to cause local bleeding and bruising more than other drugs administered subcutaneously (McGowan & Wood, 1990; Vanbree, Hollerbach & Brooks, 1984). Furthermore, Hanson (1987) reported that bleeding and bruising occur more frequently at the injection sites of patients who have thicker subcutaneous fatty tissue with increased vasculature. This bruising undoubtedly creates a problem as it limits possible sites for subsequent injections. Depending on the extent of bruising over the abdomen, patients experience varying degree of psychological discomfort due to the unsightly bruising (Brenner, et al., 1981; Wooldridge & Jackson, 1988), see Figure 1.1. Site-pain and bruising cause additional stress for patients who are already coping with an existing illness or disease.

McGowan and Wood (1990) found that nurses use a variety of subcutaneous heparin injection techniques according to their education and experience. This variation in technique is compounded by the lack of consistent procedural guidelines for the nursing intervention (Brenner, et al., 1981; Hadley, et al., 1996; McGowan & Wood, 1990; Wooldridge & Jackson, 1988; Vanbree, et al., 1984). To date, there is no evidence supporting the use of a particular injection technique to minimise site-pain and bruising which are likely outcomes of any subcutaneous heparin injection technique (Brenner, et al., 1981; Coley, Butler, Beck & Mullane, 1987; Hadley, et al., 1996; Mitchell & Pauszek, 1987; Ross & Soltes, 1995; Wooldridge & Jackson, 1988).

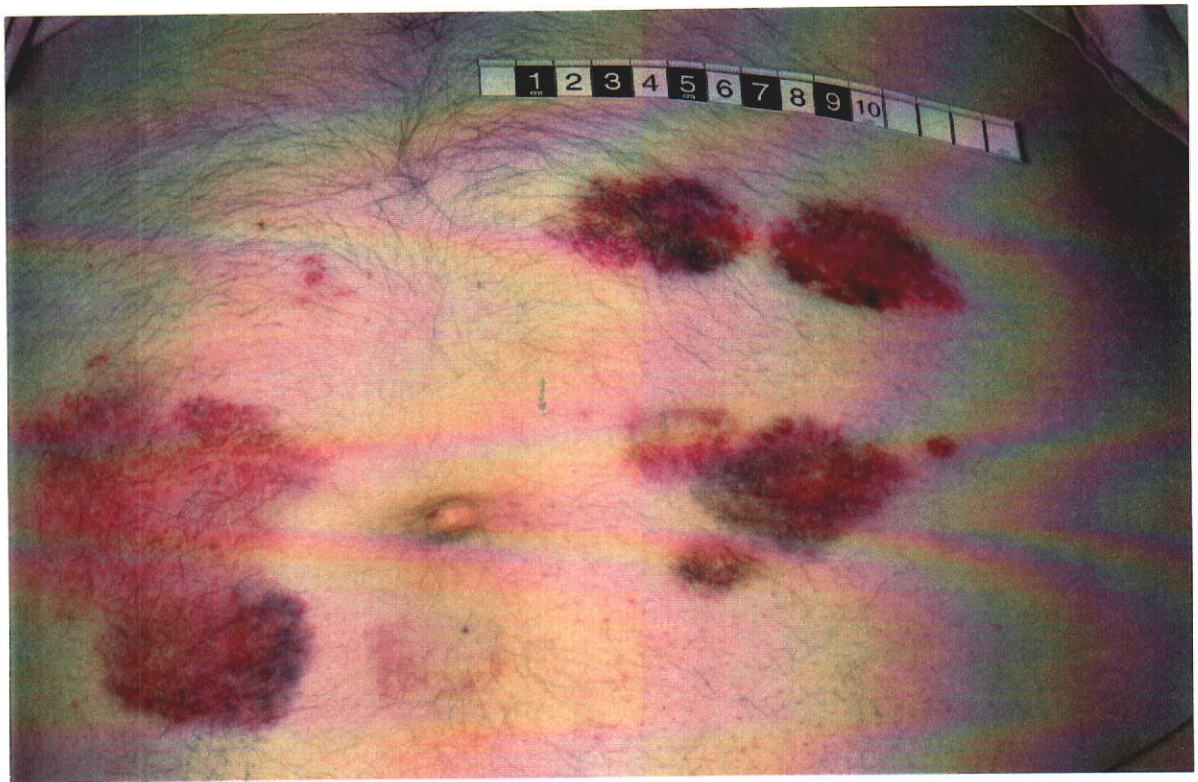


Figure 1.1. Abdominal Bruising associated with Subcutaneous Heparin Injections.

However, the literature indicates that site-pain and bruising might be affected by the injection technique used to administer subcutaneous heparin (Coley, et al., 1987; Hadley et al., 1996; McGowan & Wood, 1990; Mitchell & Pauszek, 1987; Wooldridge & Jackson, 1988). There are many injection variables of subcutaneous heparin administration discussed in the literature. These variables include, but are not limited to the injection site used, skin preparation at the injection site, needle gauge, syringe size and injectate volume. For the purpose of identifying an effective injection technique that would reduce site-pain and bruising, some of the injection variables have been manipulated and their effect evaluated. For example, administering subcutaneous heparin injections into the lower abdomen, lateral thigh and posterior upper arm resulted in similar bruising outcome (Fahs & Kinney, 1991); injecting the heparin via a wide bore, small gauge needle reduced site-pain (Coley, et al., 1987); decreasing the injectate volume resulted in decreased bruise size (Mitchell and Pauszek, 1987); and administering a subcutaneous heparin injection by a larger sized syringe reduced bruising (Wooldridge & Jackson, 1988; Hadley, et al., 1996).

Although the literature indicates that subcutaneous heparin injections should be given slowly, in most studies the actual duration of a subcutaneous heparin injection has not been specified (Brenner, et al., 1981; Coley, et al., 1987; Mitchell & Pauszek, 1987; Ross & Soltes, 1995; Vanbree, et al., 1984). However, many authors suggest that it is common practice to administer the subcutaneous heparin over a 10-second to 15-second period (Hadley, et al., 1996; McGowan & Wood, 1990; Wooldridge & Jackson, 1988). In the current research, the 10-second injection duration will be taken as a standard duration for administering a subcutaneous heparin injection.

There is anecdotal evidence that site-pain and bruising may be subsequent effects of local tissue trauma related to the administration technique used for subcutaneous heparin injections. The researcher's experience has indicated that increasing the duration of administering a subcutaneous heparin injection could reduce site-pain and bruising. It can be argued that a subcutaneous heparin injection technique is considered incorrect if it is administered rapidly or at a rate of less than 10 seconds as the heparin is injected under high pressure (Wooldridge & Jackson, 1988). However, the literature search reveals that this assumption has not as yet been scientifically tested in any clinical setting. In the current study, the *duration* of administering a subcutaneous heparin injection will be manipulated as the independent variable, and its effect on site-pain and bruising as the dependent variables will be evaluated.

Purpose of the Study

The literature indicates that site-pain and bruising are likely outcomes of subcutaneous heparin injections. The literature search reveals that there is no empirical evidence evaluating the relationship between the duration of a subcutaneous heparin injection, site-pain, and bruising. Therefore, the current study will evaluate the effect of the duration of administering a subcutaneous heparin injection on site-pain and bruise size. Specifically, duration of administration is an independent variable that has two levels, with site-pain and bruise size the dependent variables.

Study Objectives

The specific objectives of the current study are to compare the effect of duration of injection on site-pain intensity and bruise size experienced by a group of patients being treated with subcutaneous heparin for ischaemic stroke or transient ischaemic attacks (TIAs). Administering the subcutaneous heparin injection using the 10-second duration will be the standard duration (injection technique A) and the 30-second duration the treatment technique (injection technique B). The 30-second duration is an arbitrary injection time chosen for the treatment duration. The objectives of the current study are twofold.

1. To compare variation in perceived pain intensity at injection sites between two subcutaneous heparin injection techniques.
2. To compare the visible size of bruising at injection sites between two subcutaneous heparin injection techniques at 48 hours and 60 hours after injection.

Significance of the Study

The administration of subcutaneous heparin injections is a frequently used intervention for inpatients. Statistical estimation suggests that approximately 2,900 patients would require treatment for ischaemic strokes in Perth, Western Australia each year (Anderson, 1993; Goldswain, Macleod, Inglis & Alexander, 1998). Nurses are often required to administer the subcutaneous heparin injection and deal with any adverse outcomes.

Subcutaneous heparin injection technique has been a focus of concern for nursing research. However, studies have not identified an injection technique that reduces the adverse outcomes.

Currently, the incidence of bruising is approximately 14% to 90% with any subcutaneous heparin injection technique (Hadley, et al., 1996). Based on the frequency of site-pain and bruising, and the stroke incident rate (Anderson, 1993; Goldswain, et al., 1998), site-pain and bruising associated with subcutaneous heparin injections could be potentially avoided or minimised in approximately 406 to 2610 patients annually. In addition, patients receiving subcutaneous heparin injections for other types of thromboembolic disease may also benefit from an injection technique that has less adverse outcomes.

The clinical benefit that arises from reduced bruising relates to the accepted notion that subcutaneous heparin injections cannot be given within a 50-mm radius of the umbilicus or a bruise. For the usual course of 28 injections with smaller bruises, it would help preserve more sites over the lower abdomen. Additionally, potential psychological trauma related to the unsightly bruising could also be avoided.

Furthermore, a review of the literature reveals that no study has been conducted to evaluate the relationships between the duration of administering a subcutaneous heparin injection and site-pain and bruising. There is a gap in the nursing literature because the basis for current recommendations about injection duration has not been established. The current study will provide empirical data for future protocol recommendations to be based on evidence from research (Quality of Care and Health Outcomes Committee,

1995). The findings of the current study will add to evidence-based practice. Thus, the current study will address this gap in the nursing literature by evaluating the duration of subcutaneous heparin injection, as an independent variable, and its effect on site-pain and bruising as dependent variables.

Definition of Terms

Terms used in the current study are defined as follows:

A. Physiological Terms

Anti-IIa: Anticoagulation effect results from the binding and catalyses of heparin cofactor II (Hirsh & Fuster, 1994; Verstraete, 1990).

Anti-Xa: Inhibition of coagulation factor Xa by the heparin/Antithrombin complex (Hirsh & Fuster, 1994; Verstraete, 1990).

Antithrombotic: Inhibition of the blood clotting process.

Anticoagulation: Inhibition of the process by which the blood changes to a clot.

Antithrombin: Inhibition of the thrombin enzyme.

aPTT: Activated partial thromboplastin time is the thrombin clotting time measured in

seconds.

Bioavailability: The degree to which a drug or other substance becomes available to the target tissue after administration (Miller-Keane, 1998).

Cerebral infarction: Death of brain cells resulting from a sudden interruption of blood supply to a part of the brain. The synonym for cerebral infarction is **ischaemic stroke**.

Depolymerisation: Break down of a chemical into monomers or other smaller units.

Ischaemic stroke: Sudden onset of focal neurological deficits due to decreased blood supply to an area of brain tissue.

Low molecular weight heparin (LMWH): LMWH is derived from unfractionated heparin by depolymerisation and is approximately one third the size of heparin with molecular weight of 1000 Daltons to 10000 Daltons and a mean of 5000 Daltons.

Unfractionated heparin (UFH): Heparin that has not been separated into its lower molecular weight components.

B. Operational definitions

Bruising: An area of skin discolouration due to capillary bleeding into the tissues (McGowan & Wood, 1990). In the current study, 'a bruise' is defined as a skin discolouration that is equal to or greater than two mm².

'No bruise': A pinpoint haematoma at the site of needle entry less than two mm².

Duration of injection: The time for injecting a single dose of Fragmin 5000 unit in 0.2 ml after the needle is in the subcutaneous tissue. Using a watch with a second hand, the injection is timed such that a minute and equal amount (2 mm or 6 mm) of the volume in the syringe is injected at every 2 seconds until the whole dose is completed over 30 seconds or 10 seconds.

Heparin: A single dose of Fragmin 5000 unit in 0.2 ml.

Pain: In the current study, pain refers to site-pain at the time of injection and will be measured using a vertical 100-mm Visual Analogue Scale (VAS).

Planimetry: A surface-area measurement of the number of squares that lie within a bruise tracing when a metric graph is placed over the bruise. This is the manual millimeter square-paper count method of surface-area measurement. In the current study, digital planimetry refers to a surface-area measurement method aided by a mechanical device, the digital planimeter.

Size of bruise: the surface area of the bruise calculated by planimeter.

VAS: Visual Analogue Scale (VAS) is a vertical or horizontal 100-mm line with word anchors, 'no discomfort' or 'extreme discomfort' at either end (see Appendix C).

Overview of the Thesis

This thesis is presented in five chapters. Chapter One has introduced the background and rationale, purpose, objectives and significance of the current study. Chapter Two will provide the literature review. Chapter Three will describe the methodology of the study, and Chapter Four will present the study results. The findings in the context of the literature will be discussed in Chapter Five. The implications of the findings, recommendations for future research and implications for nursing practice will also be explored. Additionally, the limitations of the current study are also discussed in the final chapter.

CHAPTER TWO

LITERATURE REVIEW

Introduction

The purpose of this literature review is to consolidate and explore knowledge that forms the foundation of the current study. This chapter begins with a brief overview of ischaemic stroke and subcutaneous heparin injections and the benefits-risks of UFH and LMWH as anticoagulant agents in thromboembolic disease. The subject of site-pain and bruising associated with administration of subcutaneous heparin injections will be discussed in relation to various findings from the literature. A critical analysis of prior research will be undertaken noting what still needs to be investigated and making clear how this research will contribute to the current understanding of the relationship between the duration of subcutaneous heparin injections, site-pain, and bruising. Finally, a summary will follow including a conceptual model of the relationship between the subcutaneous heparin administration variables, site-pain and bruising (see Figure 2.1).

Ischaemic Stroke and Subcutaneous Heparin Injections

Ischaemic stroke is caused when a blood clot blocks a blood vessel in any part of the brain. Coagulation abnormalities may persist further after the primary cerebral thromboembolic event. Anticoagulant treatment is beneficial in preventing or limiting this condition. Subcutaneous heparin is a simple, practical anticoagulant treatment which is often given to patients with acute ischaemic stroke. (Adam & Brott, 1995; Dahl, et al.,

1997; Kay, et al., 1995; Kong, 1997; Meschia & Biller, 1997)

Goldswain and colleagues (1998) estimated that for each year, a minimum of 3,000 patients would require treatment for ischaemic strokes in Perth, Western Australia. Stroke accounts for 10% of all deaths and is the leading cause of serious chronic disability. Of 40,000 new stroke cases per year in Australia, 34,000 (85%) are ischaemic due to cerebral thromboembolic diseases (Australian National Stroke Foundation, 1998). Furthermore, the Australian National Stroke Foundation speculated that increase in the incidence of strokes would double by the year 2000 and beyond. Statistical estimation suggests that approximately 23,460 to 68,000 people will suffer strokes of an ischaemic nature by the year 2000.

Benefits-risks of Subcutaneous UFH and LMWH

The term thromboembolism refers to the formation of a clot or thrombus accompanying the rupture of an atherosclerotic plaque (Meschia & Biller, 1997). For decades, a wide range of thromboembolic diseases has been treated with unfractionated heparin (UFH). Unfractionated heparin has a mean molecular weight of 15000 Daltons, and a 1:1 ratio of anti-Xa to anti-IIa anticoagulation activity. The extent of anticoagulation is indicated by the test, activated thromboplastin time (aPTT) commonly known as clotting time. Unfractionated heparin inhibits blood clot formation by catalysing a plasma cofactor AT-III from a slow to rapid coagulation inhibitor and by inactivation of factors IX, X, XI, and XII. This interaction forms a chemical molecular complex that exerts anticoagulation: antithrombin III (anti-IIa) and anti-Xa activity (Frydman, 1996; Hillis, 1997). The activity

of anti-IIa and anti-Xa inactivates free thrombin generated in the vicinity of the ruptured plaque. Although UFH cannot dissolve the thrombus, its ability to neutralise factor Xa via the AT-III is beneficial to prevent further extension of the thrombus (Cohen, 1998; Meschia & Biller, 1997).

However, UFH has pharmacokinetic limitations. Specifically, its short half-life and high affinity to plasma proteins, endothelial cells and platelets often result in inadequate anticoagulation. A high risk of treatment failure is reported with intravenous UFH due to unstable aPTT. Continuous laboratory monitoring of aPTT is, therefore, necessary to ensure an effective anticoagulant dose-response (Camerlingo, et al., 1994; Chamorro, et al., 1994; Lutomski, Bottorff & Sangha, 1995; Street & McPherson, 1996; Turpie, 1998). The risk of treatment failures with subcutaneous UFH is also remarkably high (Cohen, 1997; Hirsh & Fuster, 1994). Additionally, thrombocytopenia with thrombosis associated with UFH is about 1.1% to 2.9%. This condition is usually known as the white clot syndrome, which is untreatable and carries a 100% mortality rate (Meschia & Biller, 1997).

Recent literature supports use of LMWH to circumvent the problems of UFH (Biller, Love & Gordon, 1991; Boneu, 1994; Chesterman & Chong, 1993; Hirsh & Levine, 1992; Howard, 1997). Depending on the preparation, each LMWH has fewer than 18 saccharides, with a mean molecular weight of 5000 Daltons. All LMWH are produced by chemical or enzymatic depolymerisation of UFH. They have a higher anti-Xa activity than anti-IIa with 4:1 ratio. When administered by subcutaneous route, LMWH is less likely to be neutralised by platelet factors and plasma proteins. It has a longer half-life with 90%

bioavailability compared to 30% for UFH. Thus, LMWH provides a more predictable anticoagulant response than UFH (Bergmann & Neuhart, 1996; Cohen, 1998; Dahl, et al., 1997; Hirsh, 1998; Turpie, 1998).

Although LMWH appears to cause less bleeding complications, this assumption remains unconfirmed. If both UFH and LMWH exert similar anticoagulant activity, there seems no reason on biochemical grounds to expect LMWH to cause less bleeding than UFH (Thomas, 1997). Furthermore, Thomas (1997) found that the published clinical trials identify no significant difference in major bleeding complications between patients given either UFH or LMWH. Similar incidence of minor bleeding such as injection site bleeding and bruising occurs in both drug types (Eriksson, et al., 1995; Frydman, 1996; Hillis, 1997; Hirsh & Levine, 1992; Nunnelee, 1997). However, the nursing literature only reports bruise incidence of UFH which ranges from approximately 14% to 90% (Hadley, et al., 1996).

Site-Pain associated with Subcutaneous Heparin Injection

Site-pain is a problem patients experience during subcutaneous heparin injections. This pain can be distressing and unpleasant for patients. Although site-pain is often reported by patients during subcutaneous heparin injection, there is a paucity of research into this problem. There were only two formal studies identified, one study investigated the analgesic effect of applying ice to the injection sites (Ross & Soltes, 1995) and the other study evaluated the effect of needle gauge on site-pain during administering the subcutaneous heparin injection (Coley, et al., 1987).

Ross and Soltes (1995) hypothesised that subjects who had ice applied to the injection site, two minutes pre and post subcutaneous heparin injection, would experience less discomfort than when ice was not used. Immediately following each injection, the subjects used a Visual Analogue Scale to rate the severity of site-pain at the time of injection. The difference in site-pain perception for injections with the use and non-use of ice was reported to be statistically significant ($p = .01$). However, the application of ice to the skin only modifies the perception of site-pain and can be impractical in the clinical setting. Therefore, an injection technique that prevents the cause of the site-pain, rather than merely the perception of site-pain, needs further investigation.

It has been postulated that the gauge of the needle used for subcutaneous heparin injections may affect pain experienced during administration of the injection. Coley and colleagues (1987) evaluated the effect of needle gauge on site-pain during administering the subcutaneous heparin injection. The 28-gauge needle, which was finer than the 25-gauge needle, resulted in less intense site-pain than the 25-gauge needle. Using a chi-square test, this difference was statistically significant [(3 N = 73), $p < .01$].

Gauge is a standard measure of the actual size of a hypodermic needle. Technically, gauge refers to the outer diameter of a hypodermic needle, the higher the gauge the finer is the hypodermic needle. The internal diameter (lumen) of the hypodermic needle varies according to the thickness of the needle wall. Needles may have a thin wall or a regular wall. A 28-gauge needle has a thin wall which results in a finer outer diameter and wider internal diameter. By comparison, a 25-gauge needle has a regular wall which results in a thicker outer diameter and narrower internal diameter. It is possible that a decreased level

of site-pain may result from injecting the heparin through the larger lumen as the heparin exists the 28-gauge needle.

Under normal circumstances, the finer gauge (28-gauge) needle would be expected to cause more site-pain due to increased pressure on the tissues during administering the injection (Hanson, 1987; Lundin, 1978). This raised a question as to why the finer gauge (28-gauge) of the two needles resulted in less site-pain. However, it is uncertain whether it is the finer gauge needle or the slower injection time that lead to less injection pain. Slower administration of the injection may prevent the cause of site-pain.

From a physiological perspective, injection pressure can cause tissue trauma resulting in site-pain. Murphy (1991) reported that site-pain from an intramuscular injection could be reduced by slowly injecting at a rate of 20 seconds per millimeter of volume. In case of volumes of more than one millimeter, extending the injection time was necessary for pain reduction. Hahn (1990) and Travell (1955) also argued that a link might exist between administering the injection slowly and a reduction in the level of site-pain. This assumption has not been applied to subcutaneous heparin injection technique in a clinical setting. Therefore, a purpose of the current research is to evaluate whether there is a correlation between increased duration of injection and decreased level of pain during the injection.

Bruising from Subcutaneous Heparin Injection

A bruise is an area of discoloured skin (Moore, 1997). Bruising is a sign of tissue injury where there is capillary bleeding in the dermal and hypodermal (subcutaneous) layer of the skin. Bruising associated with subcutaneous heparin injections is defined as any skin discolouration due to capillary bleeding into the tissues (McGowan & Wood, 1990). Bruising usually peaks at 48 hours and begins to resolve at 72 hours after injection (Vanbree, et al., 1984). It is noted that most investigators obtain bruise size data at a single time-point between 48 to 72 hours after the injection (Fahs & Kinney, 1991; Hadley, et al., 1996; McGowan & Wood, 1990; Ross & Soltes, 1995; Wooldridge & Jackson, 1988). In keeping with previous research, bruise size data in the current study will be obtained at both 48 and 60 hours after administering the injection.

Clinical research has used many techniques to measure bruise size. For example, Fahs and Kinney (1991) and Hadley et al. (1996) multiplied the length by width of each bruise. Coley et al. (1987) and Wooldridge and Jackson (1988) used manual planimetry (graph-paper count). Vanbree et al., (1984) applied computer-assisted planimetry whereas digital planimetry was used by McGowan and Wood (1990). The longest diameter of the bruise was the measurement utilised by Brenner et al. (1981), Mitchell and Pauszek (1987) and Ross and Soltes (1995). As expected, the inconsistency in bruise size measurement techniques led to inconsistent findings. In the current study, bruise size measurement will be undertaken using digital planimetry because it provides accurate measurement and is less time-consuming.

Several investigators attempt to describe bruise sizes in terms of four categories of none (0 mm^2), small ($1-10 \text{ mm}^2$), medium ($11-100 \text{ mm}^2$), and large ($>101 \text{ mm}^2$) (Hadley, et al., 1996; Ross & Soltes, 1995; Wooldridge & Jackson, 1988). In addition, 'a bruise' is defined as a skin discolouration that is equal to or greater than 2 mm^2 , and 'no bruise' refers to a pinpoint haematoma at the site of needle entry that is less than 2 mm^2 (Fahs & Kinney, 1991; McGowan & Wood, 1990).

The injection administration process affects the formation of bruises following subcutaneous heparin injections. Although inconclusive, the literature indicates that manipulation of one or more variables of administration may result in fewer and/or smaller bruises. These variables of administration include injection site used (Fahs & Kinney, 1991), needle gauge (Coley, et al., 1987), syringe size (Hadley, et al., 1996; Wooldridge & Jackson, 1988), injectate tonicity (Mitchell & Pauszek, 1987), and techniques of injection (McGowan & Wood, 1990; Vanbree et al., 1984). Each variable will be discussed within the context of current literature on techniques used to administer subcutaneous heparin.

Injection Administration Variables

Injection Sites

Subcutaneous injection is a convenient route of administration for certain types of medication such as apomorphine, epinephrene, heparin, hyoscine, insulin, maxalon, midazalem, morphine or isotonic fluid. The drug mixture or fluid is driven into the

adipose tissue beneath the skin either by manual syringe and needle, syringe driver, infusion or jet injection. Thus, subcutaneous injections permit infiltration and absorption to promote systemic drug action. (Craddock, 1989)

Subcutaneous absorption of the drug is by means of slow diffusion into the capillaries at a rate of one to two millimeters per hour per injection site (Newton, Newton & Fudin, 1992). There are many factors that influence the rate of absorption by subcutaneous route. These include the cardiovascular and hydration status, drug tonicity (pH) and volume, site of injection, skin fold thickness, and the injection technique (Craddock, 1989; Kroon, De Boer, Kroon, et al., 1991; Newton, et al., 1992). For example, insulin is absorbed faster during exercises (Craddock, 1989); and LMWH diffuses into the capillaries quicker than UFH (Kroon, et al., 1991). As a general rule, the quickest subcutaneous absorption of the drug occurs at the abdominal wall as against absorption at the arm and thigh (Newton, et al., 1992).

There are at least three reasons for using the lower abdominal wall for subcutaneous heparin injections. Firstly, Craddock (1989), Hahn (1990) and Viele (1994) argued that subcutaneous heparin injections should be given into a skin fold of minimum 25 mm thickness. This minimises the risk of extravasation of the injected heparin into the superficial tissue plane. As the lower abdominal wall usually has the thickest subcutaneous tissue, it is an optimal site for subcutaneous heparin injections (Kroon, et al., 1991; McGowan & Wood, 1990). Secondly, the rate of drug absorption is reported to occur faster at the lower abdominal wall. Finally, subcutaneous heparin injections are not to be administered within a 50 mm radius of a scar, bruise, broken skin lesion, and the

umbilicus/navel (Coley, et al., 1987; Fahs & Kinney, 1995; McGowan & Wood, 1990). With the larger surface area of the lower abdominal wall, more injections and/or bruises can be accommodated. Thus, it is common practice to use the alternate sites (posterior upper arms and lateral thighs) only when the lower abdominal area cannot be used (Vanbree, et al., 1984; Wooldridge & Jackson, 1988).

However, Fahs and Kinney (1991) questioned the practice of using the lower abdomen as the *only* acceptable site for subcutaneous heparin injection. They systematically evaluated the efficacy of subcutaneous heparin injections using the abdomen, thigh, and arm. The outcome variables were plasma activated thromboplastin time (aPTT) and bruise size. Each subject received three injections per anatomic site with a total of nine injections. Plasma aPTT levels were obtained prior to commencement of subcutaneous heparin and four hours after the first injection. Surface areas of bruising were measured at 72 hours after the first injection, 60 hours after the second injection, and 48 hours after the third injection. While there were no mention of the actual statistical results of the repeated measure of Analysis of Variance tests, the author reported that the aPTT levels were maintained and bruise sizes were similar among all three anatomic sites. These findings provide empirical support in the clinical utilisation of the arm and thigh as sites for subcutaneous heparin injections but no clear direction in relation to bruise reduction.

However, from the patient's perspective, several possible concerns are raised. Firstly, the surface areas of the upper arm and lateral thigh may not accommodate many injections when bruising occurs (up to 90% of the time). Secondly, bruises on thigh and arm are generally more visible and may elicit possible psychological discomfort (Chamberlain,

1980; Hanson, 1987). Thirdly, as normal mobility requires arm and leg movements, multiple injections to the arm and/or thigh might cause more pain than injections in the abdomen. This pain, added to the illness, can cause a patient emotional distress that may affect his or her functional recovery. Therefore, conservative use of arm and thigh sites is recommended for subcutaneous heparin injections, although the patient should be consulted on the site of choice for this nursing intervention (Chamberlain, 1980; Hanson, 1987).

Needle Gauge

The magnitude of injection pressure is related to the outlet orifice diameter of the needle. Logically, when the drug is forced out of a small gauge needle (25-gauge or less) the tissue is subjected to increased pressure. Injecting the drug under high pressure damages tissue resulting in capillary bleeding and bruising. For example, the jet injection system generates a high velocity jet stream that pierces the skin, and the drug disperses into the subcutaneous tissue. Thus, jet injection always produces bleeding and bruising (Baer, Bennett, Folwick & Erickson, 1996).

With the advent of shorter needles (13 mm x 25-gauge) a full depth perpendicular injection into a raised skin fold is recommended for subcutaneous injection (Hahn, 1990; Newton, et al., 1992; Viele, 1994). A 25-gauge needle is recommended for subcutaneous heparin injections. The rationale for the use of the short fine gauge needle is to avoid leakage of drug to the superficial layer of the skin on withdrawing the needle after injecting the drug (Wooldridge & Jackson, 1988). On the other hand, based on anecdotal evidence, it is thought that the use of the 25-gauge needle could be causing increased

pressure tissue damage and bruise formation.

By contrast, a study by Coley et al. (1987) revealed conflicting findings. The researchers evaluated the effect of two needles (a 28-gauge and a 25-gauge) on site-pain and bruising. Results showed that bruising developed at 56 of the injection sites in the 28-gauge needle group (n = 390) compared with 46 of the injection sites in the 25-gauge needle group (n = 340). Although the mean bruise size of the 28-gauge needle group (1.79 mm²) was slightly larger than that of the 25-gauge needle group (1.47 mm²), bruise size difference between the two groups were reported to be statistically nonsignificant. It was concluded that needle gauge did not significantly affect the frequency and size of bruising associated with subcutaneous heparin injections.

However, Coley et al.'s study has at least one limitation. For example, the analysis only included those bruises formed within the first 24 hours. Nineteen bruises (8 in the 28-gauge needle group and 11 in the 25-gauge needle group) appeared after the 24-hour time frame; these were omitted in the data analysis. As bruising often peaks at 48 hours after injection the timing of bruise measurement was not deemed to be totally appropriate. For this reason, bruise size data will be obtained at two time series, 48 and 60 hours after injection, in the current study.

Syringe Size

Wooldridge and Jackson (1988) evaluated the relationship between bruise outcome and syringe size (1-ml and 3-ml). Two techniques with different combinations of four

independent variables were used for subcutaneous heparin injections. Technique A consisted of using a 3-ml syringe, an air bubble in the syringe, changing the needle before injection, and pressing the site with a dry sponge. Technique B consisted of a 1-ml syringe with no air bubble in the syringe, using the same needle, and pressing the site with a sterile alcohol swab. Each of the 50 subjects received two subcutaneous heparin injections by technique A and B. Bruise data was obtained at 52 hours after each injection. Bruising developed at 41 (82%) technique A sites when compared to 47 (94%) technique B sites. Using a chi-square test, the difference in bruise incidence was significant [(3, $N = 50$), $p = .0458$]. Furthermore, the Mann-Whitney U-Wilcoxon rank sum test yielded significant difference in bruise sizes between the two techniques ($z = -2.78$, $p = .03$). That is, injection technique A (3-ml syringe) yielded significantly fewer and smaller bruises. However, due to the simultaneous influence of three co-independent variables (presence or absence of an air bubble in the syringe, use of the same or a new needle before administering the injection, and pressing the injection site with a dry or alcohol sponge), the effect of syringe size on bruising remained unconfirmed. Interestingly, the authors reported that some subjects stated that injections given by the nurse researchers to be slower (over a 10-second period) than those given by other nurses, and that they experienced increased discomfort from the faster injections. This comment appears to support the link between injection duration and tissue trauma, and indicates a need for the current study to clarify the issue.

In a recent study, Hadley et al. (1996) evaluated the effect of two syringe sizes (3-ml and 1-ml) on bruising after subcutaneous heparin injection. Each of the 29 subjects received two of their regular scheduled subcutaneous heparin injections with a 3-ml and 1-ml

syringe in a randomised sequence. Bruise data were obtained at 24, 48 and 72 hours after the injection. Results revealed that injection sites by the 1-ml syringe yielded larger bruises (mean = 51 mm²) compared to sites by the 3-ml syringe (mean = 19.54 mm²). Using the Wilcoxon Matched-Pairs Signed-Ranks test, the findings were statistically significant in that the 1-ml syringe group had more medium and large bruises at 48 hours ($z = -1.99$, $p = .45$) and 72 hours ($z = -2.63$, $p = .008$) than the 3-ml syringe group. As the syringe size was the only independent variable under study, it was possible to conclude that a 1-ml syringe is associated with bigger bruise formation than was the 3-ml syringe. The results demonstrate that syringe size is a variable that can impact on injection site bruising.

Injectate Volume

A link between injectate volume and bruising may exist. One study has indicated that injecting the subcutaneous heparin dose in smaller volumes reduces tissue trauma and bruising. Mitchell and Pauszek (1987) demonstrated the need to consider injectate volume in subcutaneous heparin injections. Subjects received their subcutaneous heparin injections, either as 5 000 unit/0.25 ml concentration or 5 000 unit/0.5 ml concentration. Bruise data were obtained at 48 hours after injections. The 0.25-ml group and the 0.5-ml group resulted in 8 (32%) and 16 (66.6%) bruises respectively. This difference was reported to be statistically significant ($p = .02$) but the test used for data analysis was not reported. The authors suggested that injecting the subcutaneous heparin dose in smaller volumes might reduce bruising.

However, the research design had at least one limitation. The extraneous variable of individual variability in coagulation and tissue bruisability was not controlled by a between-subjects design. This raises problem for the internal validity of the study findings. Given this, the injectate volume as a variable that may affect bruising needs to be validated in future studies, which use a within-subjects design. Results would have to be replicated before the application of these findings in clinical practice.

Techniques of Injection

The literature suggests a wide range of variations in the technique for administering subcutaneous heparin injections. The following lists the variables with amplification of the technique.

Preparing the skin. The site is cleansed gently using an alcohol wipe. Rubbing and pinching the skin tissue during preparation are discouraged. The needle is then inserted after the site is dry (Brenner et al., 1981; Hadley et al., 1996; McGowan & Wood, 1990; Schumann & Bruya, 1988; Vanbree et al., 1984). One reference suggests that applying ice to cool the skin be included in the skin preparation for subcutaneous heparin injection (Ross & Soltes, 1995).

Using an air bubble in the syringe. An air bubble is used to expel the dead space volume in the needle (Vanbree et al., 1984; Wooldridge & Jackson, 1988). This ensures accurate dosing, and minimises leakage of the heparin that may damage the tissue, on removing the needle after the injection.

Changing needle after drawing heparin into the syringe. When the tissue is in contact with the heparin on the surface of the needle, bleeding or bruising results. The literature suggests that changing the needle or removing the heparin from the surface of the drawing up needle prevents the heparin coming in contact with the patient's subcutaneous tissue during needle insertion (Brenner, et al., 1981; McGowan & Wood, 1990; Vanbree, et al., 1984).

Inserting the needle into a raised skin fold and at right (90 degree) angle. Injecting the heparin into the superficial layer of the skin results in tissue damage and bruising. This problem is minimised when the needle is inserted at 90 degree angle into a raised skin fold (Coley, et al., 1987; Hadley, et al., 1996; McGowan & Wood, 1990; Mitchell & Pauszek, 1987; Wooldridge & Jackson, 1988).

Aspirating for blood. It is thought that aspiration can lead to tissue damage and bruising (Coley, et al., 1987; Fahs & Kinney, 1991; Mitchell & Pauszek, 1987). Although some studies show no significant effect of aspiration on bruise size (Brenner, et al., 1981; McGowan & Wood, 1990; Vanbre, et al., 1984), it is generally discouraged.

Wiping and pressing the site after administering the injection. Wiping the injection site with an alcohol swab and massaging the site after injection are discouraged. To prevent oozing or bleeding light pressure is applied to the site after injection using a dry, cotton sponge (Brenner, et al., 1981; Fahs & Kinney, 1991; Wooldridge & Jackson, 1988).

By keeping several of these variables constant and manipulating the independent variable(s) under study, researchers were able to compare the effect of combinations of the above various injection techniques on bruise size. The following are discussions on the research findings.

Brenner et al. (1981) investigated the effect of a modified and a standard subcutaneous injection technique on bruise outcome. Each of the 33 subjects received two injections of subcutaneous heparin by the standard and the modified injection technique. There were seven variables studied in the two techniques. The modified injection technique included changing the needle after drawing heparin into the syringe, allowing the skin to dry after swabbing with an alcohol wipe before inserting the needle, inserting the needle vertically or at 45 degree into the skin fold, releasing the skin fold before injecting heparin slowly, withdrawing the needle quickly and pressing lightly on the site with a dry sponge for a few seconds. Bruise data were obtained at 48 hours after the second injection. Of all injection sites, 33 (50%) resulted in some observable bruising. There were 15 (45%) injection site bruises by the modified technique and 19 (57%) by the standard technique although no finding was statistically significant. However, as it was one of the earliest studies to be done, interest was generated in the issue of subcutaneous heparin injection technique.

Vanbree et al. (1984) evaluated the effect of three subcutaneous heparin injection techniques on bruising. The techniques included (A) releasing the skin fold and aspirating the syringe before injecting the drug, (B) injecting the drug without releasing the skin fold and aspirating the syringe, and (C) performing the injection as per technique B plus using

an air bubble in the syringe to clear the needle of any medication. Each subject ($N = 43$) received three injections in a randomised sequence. Bruise data were obtained at 48 hours after the third injection. Only 37 (29%) injection sites ($N = 129$) resulted in definite bruises; 11 were by technique A, 15 by technique B, and 11 by technique C. The authors reported that using the Friedman test, differences in bruise sizes among the three techniques were not statistically significant. However, the number of variables manipulated simultaneously might have confounded the results.

McGowan and Wood (1990) studied four modified techniques by manipulating two independent variables. These were aspirating for blood before injecting and applying pressure to the site after injection. Each subject received injections under four different techniques in a randomised sequence. Overall, 122 (31%) injection sites ($N = 380$) developed bruising. From the analysis of the first injection data the technique requiring pressure and no aspiration resulted in the lowest incidence of bruising. Aspiration was found to have minimal effect on bruising outcome regardless of whether pressure was applied. Manipulating two variables simultaneously to evaluate four different injection techniques might have confounded the results. However, another finding of interest was that using logistic regression test, females had a significantly higher probability of bruising than males with all injection techniques ($p < .05$).

Duration of Subcutaneous Heparin Injection

The literature suggests that subcutaneous heparin injection should be administered slowly. Previously, slow subcutaneous injection referred to 'injecting the heparin solution over 10

seconds' (Hadley, et al., 1996; McGowan & Wood, 1990; Wooldridge & Jackson, 1988). Thus, the standard duration of a subcutaneous heparin injection is defined as the 10-second duration. The rationale for this is that slow subcutaneous heparin injections reduces tissue pressure trauma and minimises the risk of bruising. From a physiological perspective, the explanation would be that a slow subcutaneous injection allows time for the tissue to expand to accommodate the injectate volume (Murphy, 1991). It is possible that when the subcutaneous tissue is subjected to a sudden increase in volume-pressure, stretch injury occurs. This results in tissue and capillary damage, which causes site-pain and bruising. Dickenson (1992) and Hahn (1990) have indicated that injecting a medication over a short duration of less than 10 seconds constitutes an incorrect injection technique. Thus, it is postulated that the duration of a subcutaneous injection may be a contributing factor in site-pain and bruise formation. This is a major variable in the current study.

Conceptual Framework

The review of the literature focused on the concept of subcutaneous heparin injection technique and its effect on site-pain and bruising. This is conceptualised in Figure 2.1. In this model, a number of administration variables affect site-pain and bruise size after subcutaneous heparin injections. Specifically, given the limitations of the reported studies, syringe size and injectate volume affect bruise formation and needle gauge reduces site-pain. Although these findings are encouraging, more research should be performed to further confirm the significance and efficacy of these variables. The current study will investigate the effects of the variable, *injection duration*, on site-pain and bruising.

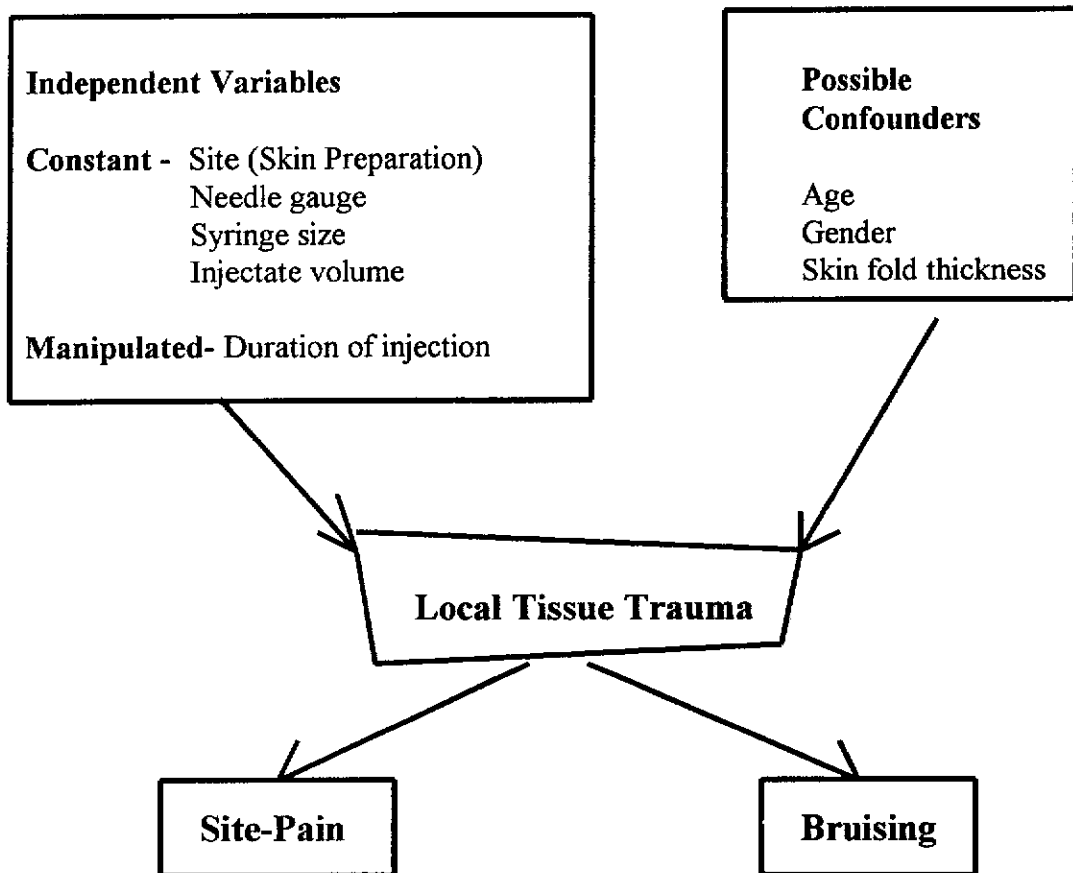


Figure 2.1. Conceptual framework of variables contributing to Site-Pain and Bruising from Subcutaneous Heparin Injection.

Summary

If site-pain and bruising are obvious effects of local tissue trauma, factors causing tissue trauma need to be considered when administering subcutaneous heparin injections. Pain related to needle insertion is unavoidable. However, strategies such as holding the needle perpendicular on the skin fold and inserting it smoothly and rapidly, and stabilising the needle while in position can prevent tissue trauma and pain. Furthermore, tissue irritation due to heparin can be minimised by changing the needle before insertion or using a prefilled syringe with an air bubble as an air lock. These aspects of administration will be considered as constant variables for the subcutaneous injection techniques in the current study. Details of injection technique are described on page 40.

Injection duration is another factor to consider. Administration of a subcutaneous injection for a duration of less than 10 seconds constitutes incorrect injection technique, because the subcutaneous heparin is injected under increased pressure causing tissue trauma. There are a number of ways which may ensure the subcutaneous heparin is injected under low pressure to reduce tissue trauma. For example, use of a larger syringe (2-ml or 3-ml), use of a small gauge needle with larger inner bore (insulin syringe), and/or use of a smaller volume injectate (ie. 5000 unit/0.25 ml concentration of heparin). Nevertheless, it is simpler to achieve low injection pressure by injecting the heparin slowly, that is, increasing the duration of administering a subcutaneous heparin injection.

Since the duration of a subcutaneous heparin injection has not been a focus in previous research the current study will seek to determine the effect of the duration of

administering a subcutaneous heparin injection on site-pain and bruising. As there are a considerable number of patients requiring subcutaneous heparin injections, this field warrants investigation. The current research has taken this investigation up as a challenge to provide data for evidence-based practice.

CHAPTER THREE

METHOD

Introduction

The purpose of the current study was to evaluate the effect of two subcutaneous heparin injection techniques on site-pain and bruising. Specifically, it sought to compare the effect of the 10-second and 30-second injection duration on site-pain and bruise size in a group of patients treated with subcutaneous heparin for acute ischaemic stroke or transient ischaemic attacks.

This chapter provides the reader with the method of the current study detailing the research design, sample, method of data collection, study procedure, measurement of dependent variables, and data analysis. Ethical considerations are also included at the end of the chapter.

Research Design

A quasiexperimental design was used to address the study objectives. Specifically, this design involves manipulation of the independent variable (treatment condition) and controlling other study variables to enhance the internal validity of the findings (Polit & Hungler, 1989; Woods & Catanzaro, 1988). The independent variable, duration of the subcutaneous heparin injection, had two levels: 10-second duration (injection technique A) and 30-second duration (injection technique B). Site-pain and bruise size were the two

outcome variables studied. Site-pain data had one level with two data cells and bruise size data had two levels where bruises were measured 48 hours and 60 hours after injection. Figure 3.1 illustrates the study design of the dependent and independent variables, where each subject was injected using both technique A and B.

Each subject, as stated, was given a subcutaneous heparin injection using injection technique A and B. In this way each subject acted as his/her own control. Thus, a within-subjects design was used to manage individual differences between subjects. These individual differences were mainly related to inter-subject variations in pain perception and coagulation parameters that might influence the outcome variables, site-pain and bruise size. Wood and Catanzaro (1988) stated that a within-subject design occurs when the subject is exposed to the treatment and control variables simultaneously. The use of a within-subject design would yield more convincing causal inferences, owing to the assumption that pain perception and physiological factors affecting coagulation vary less in the same subject than in two comparable subjects.

	Injection Technique A (Standard = 10 seconds)	Injection Technique B (Treatment = 30 seconds)
Site Pain Intensity	VAS	VAS
Bruise Size	48 hours	48 hours
Bruise Size	60 hours	60 hours

Figure 3.1. Research Design.

KEY:

VAS = pain scores

48 hours = measurement of bruise size at 48 hours post injection

60 hours = measurement of bruise size at 60 hours post injection

Sample

In the current study, a sample of 34 subjects was recruited to investigate the effect of the single independent variable, *injection duration*, in the administration of a subcutaneous heparin injection.

Sampling Technique

A convenience sample was chosen for the current study because of the need to achieve the desired sample size within the time frame (six months) scheduled for data collection. Convenience sampling entails the use of most readily available subjects who meet the study requirements (Polit and Hungler, 1989, p.171; Woods and Catanzaro, 1988, p.107). The source for the convenience sample of 34 subjects was an acute stroke-care unit of a major teaching hospital located in Perth, Western Australia.

Subjects

Subjects comprised volunteers from a group of adult inpatients with ischaemic stroke or transient ischaemic attacks who met the study requirements.

Inclusion Criteria: Subjects who were prescribed twice daily subcutaneous injections of Fragmin 5000 units as part of their medical treatment regimen, were adults of 18 years or older, and able to provide written informed consent. Non-English speaking patients were, however, only included if the interpreter was available to fully explain the study to allow

informed consent and to assist with VAS measure. Subjects who received daily dose of aspirin as part of the stroke treatment were eligible to be included.

Exclusion Criteria: Patients who had liver dysfunction, coagulation or haematological diseases, and were taking Warfarin (an oral anticoagulant medication) were not suitable. The study also excluded patients who were pregnant, patients who had difficulty understanding the nature of the study and were unable to give informed consent, and patients who displayed distress or expressed anxiety when being asked to take part in the study.

Subcutaneous Heparin Injection Technique

Based on the review of the literature and the researcher's experience, two injection techniques for subcutaneous heparin were designed for the current study. All injection variables were held constant for the two injection techniques except the duration of injection. The purpose of this approach was to isolate the effect of the independent variable, duration of injection, on the two dependent variables, site-pain and bruising.

Injection Protocol

1. A site on the right or left lower abdomen was chosen for each injection.
2. The site was cleansed with an alcohol wipe, and the alcohol was allowed to dry before needle insertion.
3. The prefilled single-dose Fragmin syringe (5000 unit in 0.2ml, with needle cap removed) was held vertically downward, with air bubble above the fluid level.
4. A roll of skin at the site was gently pinched to create a skin fold.
5. The needle of the Fragmin syringe was placed at a right angle on the skin fold and pushed through to its full depth.
6. Duration of injection - The single dose of Fragmin was injected over 10 seconds (technique A) or 30 seconds (technique B). The injection was timed, using a watch with a second hand, such that a minute an equal amount (2 mm or 6 mm) of the volume in the syringe was injected at every two seconds until the whole dose of Fragmin and air bubble was completed over 10 seconds or 30 seconds.
7. The needle was withdrawn at the same right angle.

8. The skin fold was released, and a cotton wool sponge was placed over the injection site for 10 seconds or until bleeding stopped.

9. The injection site was circled with a felt-tip pen for a diameter of 50 mm using a circular template, and labelled A or B respective to the technique used. This was necessary as subjects had multiple subcutaneous heparin injections in their normal treatment, and only two injections formed part of the current study.

Data Collection

Equipment

The data collection equipment consisted of a skin-fold calliper for measuring thickness of skin fold at the waist, a watch with a second hand for timing the duration of injection, a 50-mm diameter plastic circular template, a felt-tipped pen for marking and labelling the injection sites and tracing of bruises onto transparent plastic sheets, a digital planimeter for measuring the surface area of bruises, and the vertical VAS .

Documentation

A set of 50 folders was prepared for documentation, each containing an informed consent form (Appendix A), a demographic data form (Appendix B), data collection charts (Appendixes C, and D) and four transparent plastic sheets (10 cm²).

Demographic Data Form

Demographic data collected included the subject's gender, age, medical diagnosis, presenting neurological deficits, current medications, admission and discharge date (Appendix B). If aspirin was used, it was noted for analysis. The subject's skin fold thickness was also recorded as part of the data. These data allowed identification of covariates that might confound the study findings.

Data Collection Charts

The Data collection charts were designed to record pain intensity and injection details.

Chart One - Pain. Chart One consisted of two slips, each having a vertical Visual Analogue Scale (VAS) for measuring site-pain intensity on injection (Appendix C). Each VAS had a 100-mm vertical line with end anchors, 'zero' representing no discomfort (the lowest anchor) and 'hundred' representing extreme discomfort (the top anchor).

Chart Two - Injection details. Chart two (Appendix D) consisted of a schematic drawing of the abdomen for recording the selected injection technique and the site used. This chart also included date and time for site assessment, and time that the site was actually assessed. If no bruising was identified at the time of assessment, it was recorded on this chart as " no bruise" or "pinpoint bruise". If bruising was identified at the time of assessment, it was recorded as "bruise present".

Bruise Tracings

Bruises were traced onto transparent plastic sheets at 48 hours and 60 hours respectively, and then photocopied onto A4 size paper. Both the plastic sheet and the photocopied tracings were then filed as study data.

Study Procedure

Prior to the commencement of the current study the researcher held regular meetings with nurses in the designated clinical setting to inform them about the study. They were given a short written piece of information about the study (Appendix E). The nurses were encouraged to contact the researcher if they had any questions. They were also asked to administer the remaining subcutaneous Fragmin injections outside the marks encircling the two injection sites in each subject. These meetings were repeated for new nurses and nurses who returned from annual leave during the six month data collection period between mid September 1998 and April 1999.

The prepared folders, labelled 1 to 50, contained all the charts and forms for documentation (as mentioned previously in Data Collection). Each potential subject was allocated a folder. After initiation of the prescribed subcutaneous Fragmin therapy, potential subjects who met the study requirements were approached and asked to participate in the study. They were initially given a verbal explanation of the study purpose and procedure. Then, upon agreeing to participate, subjects were asked to read and sign the informed consent form (Appendix A). Subjects were given a photocopy of

the signed informed consent form and were reminded that they were free to withdraw from the study at any time.

The researcher obtained measurements of subjects' skin fold thickness at the waist using the skin fold calliper. The data were recorded in the demographic data form. Then, the researcher administered all the subcutaneous injections according to the protocol outlined earlier. This approach ensured the use of a consistent injection technique. Thus bias due to individual judgment and technique would be reduced to a minimum. For each subject, one of the two injection techniques was used as the first injection and twelve hours later the researcher used the other injection technique as the second injection. A circle of 50-mm diameter was drawn around each injection site and labelled A or B respectively, in accordance with the technique used. The subjects were instructed not to rub or scratch the injection sites. Injection details were accordingly recorded on chart two.

The two injections were administered to each subject within 48 hours after the initial prescription of subcutaneous Fragmin therapy. After the second injection, the subjects were instructed to remind nurses to administer the remaining subcutaneous Fragmin injections outside the marks encircling the two injection sites. To minimise the influence of informal information on the subjects' understanding of the current study, information as to the meaning of the A and B marking was withheld from the subjects and the nurses in the ward.

Measurement of Dependent Variables

Site-Pain at time of administering the injection (VAS Pain Scores)

Immediately following each of the two injections, the subject was seated upright in bed and given a VAS slip to rate the intensity of site-pain experienced at time of injection. The subject was instructed to report any sensation of burning, stinging, aching, soreness, or hurting by placing a mark at a point along the vertical line of the VAS. Both the injection time and injection technique were then recorded on the VAS slip before it was filed in the subject's folder.

Each subject had two VAS slips, one after injection A and one after injection B respectively. For the sample, a total of 68 VAS slips was obtained. A number system was used to code the VAS slips before measurement. The VAS pain scores were obtained by measuring the distance in millimeters from the lowest edge (zero) to the subject's mark. The researcher and a rater who was blind to the study performed the measurements. Interrater reliability was assessed using the Pearson's product moment correlation test.

Bruise Size

Based on all previous research on subcutaneous heparin injection technique, the development of bruises is shown to peak at 48 hours and resolve at or beyond 72 hours. Therefore, the time frame for assessing injection site bruising was 48 hours and 60 hours after each injection.

(a) *Pilot testing of bruise measurement technique.* The measurement technique of bruise size was piloted with three patients prior to the commencement of the study. The researcher assessed each injection site for bruising at 48 and 60 hours after injection. The perimeter of each bruise was traced onto a transparent plastic sheet with a fine felt-tipped pen. This plastic tracing was placed onto a millimeter square grid, and the bruise surface area was measured by counting the number of squares within the bruise tracing. Bruise surface area was recorded in square millimeters. An experienced researcher who had expertise in this area was approached to validate the researcher's measurement technique. The feedback was that surface-area measurement by graph-paper (planimetry) was accurate; however, it was time-consuming. As bruises were often irregular in shape and could assume many configurations, surface-area measurements could more accurately be determined by digital planimetry. Digital planimetry is generally accurate when used on flat wounds or bruising. Also, reliability of digital planimetry has been established in previous wound care research (Cooper in Bryant, 1992; van Rijswijk in Krasner & Kane, 1997). This adjustment to bruise measurement technique was duly made prior to commencement of the current study.

(b) *Bruise measurements for the study.* At 48 hours and 60 hours after each injection, the researcher assessed the injection site for bruising. Presence or absence of bruising was recorded on chart two. Any bruise, including "pinpoint bruise", was carefully and precisely traced onto a piece of transparent plastic sheet. The plastic bruise tracing was photocopied before being labelled with the subject's study number, injection site label (A or B), date and time of injection site assessment. The plastic bruise tracing was filed in the subject's folder. The photocopied bruise tracing was coded and filed in a separate folder.

Prior to formally measuring the bruise tracings, the researcher piloted the use of a digital planimeter. Subsequently, the same digital planimeter was used to measure bruise tracings in the current study. A second nurse-researcher, who was blind to the study but an expert in the use of digital planimetry, assisted in the reliability check of the bruise measurements using digital planimetry.

Data Analysis

Variables included in data analysis included VAS pain scores of injection A and injection B, bruise size at 48 hours post injection A and B, and bruise size at 60 hours post injection A and B. Demographic data included age, gender, and skin fold thickness. Descriptive statistics were used to describe the data. The Statistical Packages of Social Sciences (Microsoft, 1998) were used for data analysis.

There was one independent variable, the duration of a subcutaneous heparin injection, which had two levels of measurements, a 10-second duration (A) and a 30-second duration (B). Appropriate parametric or nonparametric tests, such as Paired *t* tests or Wilcoxon Signed-Rank tests, were used to test the effects caused by the independent variable on the dependent variables. Specifically, site-pain intensity from injection A and B and variations in visible bruise size with the two injection techniques at 48 hours and 60 hours were assessed and compared to identify any significant differences. The level of statistical significance was determined at $p < .05$.

The final data set for analysis of the sample of 34 subjects consisted of a total of 68 VAS

pain scores and 132 bruise sizes. Age, gender and skin fold thickness were identified as covariates that might have an influence on bruise outcome. The degree of influence of each of the three covariates or their interactions was also explored using a backward elimination procedure of logistic regression analysis.

Reliability and Validity

Methods used for gathering information from subjects in a study are fundamental in the evaluation of findings in a research project. It is important, therefore, that the data and conclusions that form part of the research project are reliable and valid. Polit and Hungler (1989) describe validity as the measurement that actually measures what it is supposed to measure, whereas reliability refers to the stability of the measurement or result or its reproducibility.

Although every measurement involves some error, and error can never be totally eliminated, it can, however, be reduced. For this reason, care was taken to maximise the quality (reliability and validity) of measuring instruments and procedures.

Bias, Confounders and Chance

The convenience sample of the current study consisted of adult inpatients of 18 years or older with ischaemic strokes or transient ischaemic attacks from an acute stroke-care unit of a major urban teaching hospital. As convenience sampling carries the risk of sample bias, it is necessary to consider this bias when interpreting the findings of the current study.

Confounding occurs when a third factor becomes associated with the variables of interest. In the current study, the effects of inter-subject variations in pain perception and physiological factors affecting coagulation were minimised using a within-subjects quasiexperimental design.

Chance may also affect the findings of any study if sample size is insufficient. To quantify the degree, of which chance may account for the results, a test of statistical significance such as the *t* test or chi-square test may be performed. The critical significance level (*p* value) is usually specified to be 0.05, indicating the result as significant if the probability of obtaining the result by chance alone was 5% or less. By further employing confidence intervals, a wide interval range may suggest that sample size was not adequate for one to conclude that chance was not a likely explanation of the findings.

Validity and Reliability of the Visual Analogue Scale

The Visual Analogue Scale (VAS) is a recognised clinical measure for pain intensity. A typical VAS is composed of a horizontal 100-mm line, with right angle “stops” and word anchors at either end. These word anchors should be bipolar antonyms representing the extreme boundaries of the feeling such as best to worst. Precision is required for the construction of the VAS. To ensure accuracy of the length of the line the VAS should be reproduced by printing rather than photocopying. Photocopying has been found to distort the length of the line (Lee & Kieckhefer, 1989; McQuire, 1984; Mottola, 1993). However, in the current study, the vertical Visual Analogue Scales were constructed by tracing from an original. The researcher used a designated ruler to construct each 100-mm vertical Visual Analogue Scale.

To use the VAS, subjects are asked to place a mark on the vertical or horizontal line at the point, which corresponds to the intensity of the pain they experience. Scoring the VAS is accomplished by measuring the distance between the subject’s mark and the lowest (zero) point in millimeters. Scores can range from 0 to 100 representing continuous interval/ratio data that can be subjected to statistical tests. This makes the VAS a valuable clinical measure of pain amenable to statistical analysis (Cline, Herman, Shaw, & Morton, 1992; Flaherty, 1996; Gift, 1989; McQuire, 1984; Mottola, 1993).

Acceptable validity data of the VAS is reported in the literature (Cline, et al., 1992; Flaherty, 1996; Gift, 1989; Wewers & Lowe, 1990). Furthermore, the VAS has demonstrated its high correlation with the McGill Pain Questionnaire (Flaherty, 1996).

Reliability has also been established by its stability across time (Flaherty, 1996; Lee & Kieckhefer, 1989). That is, comparison of ratings over time has shown that ratings made by the same individual are consistent if they are repeated within a close time frame, for example, after one to twenty-four hours. In addition, the VAS produces more sensitive measurements than other verbal descriptor scales because it avoids the categorisation of pain (Flaherty, 1996; Gift, 1989).

The VAS is simple to construct. It uses few words so that pitfalls of language generally do not occur and vocabulary limitation is not a problem. Although most people find the VAS easy to use, some people have difficulty in converting the sensation to a mark on a straight line (Scott & Huskisson, 1979). This problem can be overcome when instructions regarding how to use the scale are given carefully. To ensure validity of data and avoid error resulting from visual perspective, Mottola (1993) advised the subjects to be seated upright to view and use the scale. Traditionally, the VAS is a horizontally oriented scale. Recently, it has been used as a vertical scale. Two studies showed that the vertical scale and horizontal scale correlate extremely well to each other ($r = 0.99$, $p < .001$) (Gift, 1986; Scott & Huskisson, 1979). Other studies recommend the use of the vertical VAS for clinical phenomena requiring increased sensitivity (Cline, et al., 1992; Gift, 1989; McGuire, 1984). Thus, the vertical VAS was used in the current study.

Reliability of Measurements

Measurement error may be random or constant. Random errors limit the degree of precision in estimating the true scores from observed scores and therefore lead to ambiguous measurement and decreased reliability of the measure (see discussion in Polit & Hungler, 1989).

In the current study, the VAS pain scores were obtained by measuring the distance in millimeters from the lowest edge to the subject's mark. To ensure measurement reliability, the ruler used in the construction of the VAS was used to assess this score. Each VAS pain score obtained by the researcher was subjected to reliability check by a rater who was blind to the study. The results of the Pearson product-moment correlation test confirmed a strong interrater agreement ($r = .96$, $p = .00$) indicating that the measurements were reliable.

Reliability of each bruise measurement by digital planimetry was also ensured by interrater reliability check. That is, digital planimetry was used to obtain bruise measurements by the researcher and a rater who was blind to the study. The results of the Pearson product-moment correlation test also confirmed a strong agreement ($r = .98$, $p = .00$) between the two raters, indicating that the measurements were reliable.

Finally, having the researcher administer all the injections that formed part of the study eliminated the problem of technique variability; thus the reliability of observational data was maximised.

Ethical Considerations

Written approval was sought and granted from the Ethics Committees of Curtin University of Technology and the hospital where the study was undertaken. Patients who met the study requirements were approached by the researcher. First, they were given a verbal explanation of the study purpose and procedure. Upon agreeing to participate, subjects were asked to read and sign an informed consent form (Appendix A). All subjects were volunteers. They were given a photocopy of the signed informed consent form and reminded that they could withdraw from the study at any time without their nursing and medical care being affected. Subjects were also assured that all data generated from the study would remain strictly confidential, and that their identity would remain anonymous in written reports and publications. A number system was used for data coding, and the list of subjects' names would be destroyed on completion of the study. Additionally, data access was to be limited only to the researcher and the supervisors. In accordance with university regulations, the data would be kept in a secure place at Curtin University of Technology, School of Nursing and would be destroyed five years after the study was completed.

CHAPTER FOUR

RESULTS

Introduction

The purpose of the current study was to examine the effect of duration of administering a subcutaneous heparin injection on site-pain and bruising. For this purpose, each subject was given two subcutaneous heparin injections of 10-second and 30-second duration. Site- pain on administering the injections and bruise size at injection sites were assessed and compared. The results of the current study are discussed under the headings of sample description, site-pain of injection, and injection-site bruising.

Sample Description

The convenience adult sample consisted of 14 female (41.1%) and 20 male (59.9%) subjects. All 34 subjects were caucasian, alert, responsive and English-speaking. Their ages ranged from 40 to 85 years (Table 4.1). Skin fold thickness ranged from 7 mm to 36 mm with a mean of 15.7 mm ($SD = 6.38$). Female had a higher mean skin fold thickness (18.8 mm) compared to male (13.5 mm). Nonparametric bivariate correlation of age and skin fold thickness indicated almost zero correlation ($r_s = - .003$).

Twenty-two subjects (64.7%; 7 female and 15 male) were diagnosed with ischaemic stroke and 12 subjects (35.3%; 7 female and 5 male) with transient ischaemic attacks. Of the 34 subjects, only 11 (32.3%; 4 female and 7 male) suffered some residual neurological

deficits. These deficits were mild and included left leg weakness (17.6%; 2 female and 4 male), slight right-hand weakness (8.7%; 2 female and 1 male), dysphagia (2.9%; 1 male), and right facial numbness (2.9%; 1 male). These deficits did not pose any problem for the subjects to rate the feeling of pain on the vertical VAS slips. Although all subjects were rest-in-bed, they were able to move freely and could change their position in bed.

Table 4.1

Demographic Data of the Sample (N = 34)

	<u>n</u>	Age (years)	Mean Age
Female	14	40 - 85	65.7 (<u>SD</u> = 13.17)
Male	20	41 - 78	63.1 (<u>SD</u> = 9.82)

Eleven of the 34 subjects had a stroke condition only. However, twenty-three subjects (66.7%; 9 female and 14 male) had one or more secondary medical conditions. For example, the secondary conditions included hypertension, hyperlipidaemia, cardiac disease, type 2 diabetes mellitus, old transient ischaemic attacks, gout, gastric disease, breast cancer, hypothyroidism and sleep apnoea. None of these co-existing conditions had any influence on coagulation. Seventeen subjects (49.3%; 6 female and 11 male) were on

aspirin before hospitalisation and continued to have aspirin throughout their hospitalisation; 15 subjects (43.5%; 8 female and 7 male) started aspirin with heparin therapy, and only 2 subjects (5.8%; 2 male) did not take aspirin at all. None of the subjects developed complications attributed to changes in plasma coagulation during or after the course of subcutaneous heparin therapy. The average length of subcutaneous heparin therapy for this sample was 7.9 days ($SD = 3.58$).

Site-Pain during administering the injection

Objective 1 - To compare variation in perceived site-pain intensity between two subcutaneous heparin injection techniques.

Injection technique A was the standard injection rate (10-second duration) whereas injection technique B was designated as the treatment (30-second duration). The presence of some form of discomfort was noted for 34 of the injections by technique A (100%) and 32 of the injections by technique B (94.1%). Although both injection techniques resulted in similar incidence of discomfort of varying intensity, results to follow indicate one technique was perceived to be less painful.

The VAS pain scores by the two injection techniques are detailed in Table 4.2. The difference in the mean VAS pain scores between two injection techniques was 12.1 mm. It was found that injection technique A yielded higher ratings of VAS pain scores than injection technique B.

Table 4.2

VAS Pain Scores by Injection Technique (N = 68)

	VAS Pain Scores		
	Range	Mean	<u>SD</u>
Injection Techniques:			
Standard = 10 seconds (A)	1 - 99 mm	22.8 mm	24.75
Treatment = 30 seconds (B)	0 - 59.5 mm	10.7 mm	15.28
Difference in mean VAS Pain Scores (A - B) 12.1 mm			

The VAS pain scores were checked for normality prior to data analysis. As the criteria for normal distribution were not met, transformations were attempted but without success. Therefore, rank analysis using the Wilcoxon Signed-Rank test was used to address the research question in regard to pain scores.

The results of the Wilcoxon Signed-Rank test revealed a difference that was statistically significant ($Z = -4.000$, $p = .000$) (Table 4.3). That is, site-pain was significantly less intense for injection technique B when compared to injection technique A.

Table 4.3

Wilcoxon Signed-Rank Test for Site-Pain Intensity related to Injection Technique

A and B

		RANKS		
		<u>N</u>	Mean Rank	Sum of Ranks
Site-Pain Intensity :				
VAS pain scores injection B -	Negative Ranks	28 ^a	16.14	452.00
VAS pain scores injection A (mm)	Positive Ranks	3 ^b	14.67	44.00
	Ties	3 ^c		
	Total	34		
a	VAS pain scores injection B < VAS pain scores injection A (mm)			
b	VAS pain scores injection B > VAS pain scores injection A (mm)			
c	VAS pain scores injection B = VAS pain scores injection A (mm)			

Test Statistics: Wilcoxon Signed-Rank Test

		VAS pain scores injection B – VAS pain scores injection A (mm)
<u>Z</u>		-4.000 ^d
Asymp. Sign. (2-tailed)		.000
d	Based on positive ranks	

Injection-Site Bruising

Objective 2 - To compare the visible size of bruising between two subcutaneous heparin injection techniques at 48 hours and 60 hours after injection.

Injection sites were inspected for bruising at 48 hours and 60 hours post injection. In keeping with previous research, a definite bruise was deemed to be present if its surface-area size was equal to or greater than 2 mm². Results are in Table 4.4. The data indicated frequency of bruising at injection A sites were approximately double that of injection B sites.

Size of injection site bruising was assessed using descriptive statistics (Table 4.5). At 48 hours, bruise size of injection A sites ranged from 0 to 177.66 mm² with mean size of 24.14 mm² (SD = 41.47). Bruise size of injection B sites ranged from 0 to 5 mm² with mean size of 0.98 mm² (SD = 1.28). Mean bruise size of injection A sites was larger than injection B sites; the difference was 23.16 mm². At 60 hours, bruise size of injection A sites ranged from 0 to 188 mm² with mean size of 26.03 mm² (SD = 44.35). Bruise size of injection B sites ranged from 0 to 6.66 mm² with mean size of 1.36 mm² (SD = 1.87). Again, at 60 hours injection A sites had larger bruise size than injection B sites; the difference was 24.67 mm².

Bruise data were analysed using the Wilcoxon Signed-Rank test. The difference between bruise sizes from injection technique A and B was statistically significant at 48 hours (Z = -4.542, p = .000) and 60 hours (Z = -4.569, p = .000) (Table 4.6 - 4.7). The results

demonstrated that injection technique B yielded significantly smaller bruises than injection technique A at both 48 hours and 60 hours after injection.

Table 4.4

Frequency and Percentage of Bruising at 48 hours and 60 hours by Injection Technique (N = 136)

	Technique A		Technique B	
	48 hours	60 hours	48 hours	60 hours
Frequency & Percentage of sites that:				
developed bruise	16 (47.0%)	18 (53.0%)	7 (20.6%)	10 (29.4%)
did not bruise (< 2 mm ²)	18 (53.0%)	16 (47.0%)	27 (79.4%)	24 (70.6%)

Table 4.5

Bruise Size by Injection Technique (N = 136)

	Bruise Size (mm²)		
	Range	Mean	<u>SD</u>
Injection Techniques:			
48 hours after Standard = 10 seconds (A)	0 - 177.66	24.14	41.47
48 hours after Treatment = 30 seconds (B)	0 - 5	0.98	1.28
Difference in mean bruise size		23.16	
60 hours after Standard = 10 seconds (A)	0 - 188	26.03	44.35
60 hours after Treatment = 30 seconds (B)	0 - 6.66	1.36	1.87
Difference in mean bruise size		24.67	

Table 4.6

Wilcoxon Signed-Rank Test for Bruise Sizes related to Injection Technique A and B at 48 hours after injection

RANKS				
		<u>N</u>	Mean Rank	Sum of Ranks
Bruise Size (mm²) at 48 hours:				
Injection Technique B Bruise -	Negative Ranks	28 ^a	15.27	427.50
Injection Technique A Bruise	Positive Ranks	1 ^b	7.50	7.50
	Ties	5 ^c		
	Total	34		

- a Injection Technique B Bruise < Injection Technique A Bruise (mm²)
- b Injection Technique B Bruise > Injection Technique A Bruise (mm²)
- c Injection Technique B Bruise = Injection Technique A Bruise (mm²)

Test Statistics: Wilcoxon Signed-Rank Test

Injection Technique B Bruise – Injection Technique A Bruise	
<u>Z</u>	-4.000 ^d
Asymp. Sign. (2-tailed)	.000

d Based on positive ranks

Table 4.7

Wilcoxon Signed-Rank Test for Bruise Sizes related to Injection Technique A and B at 60 hours after injection

RANKS				
		<u>N</u>	Mean Rank	Sum of Ranks
Bruise Size (mm²) at 60 hours:				
Injection Technique B Bruise -	Negative Ranks	28 ^a	16.23	454.50
Injection Technique A Bruise	Positive Ranks	2 ^b	5.25	10.50
	Ties	4 ^c		
	Total	34		
a	Injection Technique B Bruise < Injection Technique A Bruise (mm ²)			
b	Injection Technique B Bruise > Injection Technique A Bruise (mm ²)			
c	Injection Technique B Bruise = Injection Technique A Bruise (mm ²)			

Test Statistics: Wilcoxon Signed-Rank Test

Injection Technique B Bruise – Injection Technique A Bruise	
<u>Z</u>	-4.569 ^d
Asymp. Sign. (2-tailed)	.000

d Based on positive ranks

Interestingly, when data were collapsed into three categories based on previous studies (Hadley, et al., 1996; Ross & Soltes, 1995; Wooldridge & Jackson, 1988): no bruise (< 2 mm²), small bruise (2 - 5 mm²), and larger bruise (> 5 mm²), it was found that injection B sites had a greater number of small bruises (25%) than injection A sites (16.29%). Larger bruises (67.5%) were only found at injection A sites (Table 4.8).

Table 4.8

Frequency and Percentage of Bruise Categories at 48 hours and 60 hours by Injection Technique (N = 136)

	Technique A		Technique B	
	48 hours	60 hours	48 hours	60 hours
Bruise Category:				
No bruise (< 2 mm ²)	18 (53.0%)	16 (47%)	27 (79.4%)	24 (70.6%)
Small bruise (2 - 5 mm ²)	5 (14.7%)	6 (17.8%)	7 (20.6%)	10 (29.4%)
Larger bruise (> 5 mm ²)	11 (32.3%)	12 (35.2%)	0	0
Total	16 (47.0%)	18 (53.0%)	7 (20.6%)	10 (29.4%)

Effect of Covariates on Injection-Site Bruising

The frequency and percentage of bruising by injection technique A and B with gender and age group are summarised in Tables 4.9 - 4.12. Specifically, for injection technique A, at 48 hours after injection male subjects had three larger bruises and two small bruises while female subjects had eight larger bruises and three small bruises; and at 60 hours after injection, male subjects had three larger bruises and three small bruises whereas female subjects had eight larger bruises and four small bruises. For injection B, at 48 hours after injection, male subjects had only one small bruise while female subjects had six small bruises; and at 60 hours after injection, males had two small bruises whereas females had eight small bruises. Overall, the data indicated that fewer and/or smaller bruises were found in males when compared to females for both injection techniques.

The degree of influence of covariates (age, gender and skin fold thickness) on bruise outcome was explored using a “backward elimination” procedure of the logistic regression analysis as normality of the data could not be met, and transformations did not improve the normality assumption. Backward elimination started with all the covariates and interactions in the model and were tested for removal one by one. Evaluation for removal was based on the significance of the Wald statistic. Variables removed if Wald statistics was nonsignificant. The final model only contained gender, which was significant for bruising at both 48 hours and 60 hours after injection technique A. None of the covariates were deemed to have an impact on bruising at either 48 hours or 60 hours after injection technique B.

Testing for multicollinearity and outliers that might have influenced the model was carried out with all variables in the operation. Nonparametric bivariate correlation testing indicated all correlations were less than .7. Standardised residual for the three covariates were within the expected normal range (+3 to -3 standard deviation) indicating that there were no outliers that might have influenced the result.

The results of the logistic regression analysis are shown in Table 4.13 and 4.14. For injection technique A, the influence of age and skin fold thickness on bruise outcome were nonsignificant. Gender was identified as the only covariate to have an impact on bruising with significant results at both 48 hours ($p = .0145$ at 95% confidence interval) and 60 hours post injection ($p = .0056$ at 95% confidence interval). The proportion of variance in the dependent variable (bruise size) accounted for by gender was 75% with 17 out of 22 bruises at 48 hours and 60 hours predicted correctly. Similarly, 8 out of 11 bruises at 48 hours or 9 out of 12 bruises at 60 hours were predicted inaccurately.

In addition, the odds ratio coefficient indicated that females were seven and half times to ten times more likely to bruise than males (see Tables 4.13 and 4.14). Subsequent frequency analyses also revealed that the percentage of females (78.6% to 85%) that bruise at both 48 hours and 60 hours after injection technique A was higher than that of males (25%) (see Tables 4.15 and 4.16).

Table 4.9

Frequency and Percentage of Bruising at 48 hours by Injection Technique A according to Gender and Age Group by Bruise Size (N = 34)

	Male (<u>n</u> = 20)		Female (<u>n</u> = 14)	
	60 years or younger	> 60 years	60 years or younger	> 60 years
No Bruise (< 2 mm ²)	5 (14.7%)	10 (29.4%)	2 (5.9%)	1 (2.9%)
Small Bruise (2 - 5 mm ²)	1 (2.9%)	1 (2.9%)	0	3 (8.9%)
Larger Bruise (> 5 mm ²)	2 (5.9%)	1 (2.9%)	2 (5.9%)	6 (17.6%)
Total	8%	12%	4%	10%

Table 4.10

Frequency and Percentage of Bruising at 48 hours by Injection Technique B according to Gender and Age Group by Bruise Size (N = 34)

	Male (<u>n</u> = 20)		Female (<u>n</u> = 14)	
	60 years or younger	> 60 years	60 years or younger	> 60 years
No Bruise (< 2 mm ²)	7 (20.6%)	12 (35.3%)	5 (14.7%)	3 (8.9%)
Small Bruise (2 - 5 mm ²)	0	1 (2.9%)	0	6 (17.6%)
Larger Bruise (> 5 mm ²)	0	0	0	0
Total	7%	13%	5%	9%

Table 4.11

Frequency and Percentage of Bruising at 60 hours by Injection Technique A according to Gender and Age Group by Bruise Size (N = 34)

	Male (<u>n</u> = 20)		Female (<u>n</u> = 14)	
	60 years or younger	> 60 years	60 years or younger	> 60 years
No Bruise (< 2 mm ²)	5 (14.7%)	9 (26.5%)	2 (5.9%)	0
Small Bruise (2 - 5 mm ²)	1 (2.9%)	2 (5.9%)	0	4 (11.8%)
Larger Bruise (> 5 mm ²)	1 (2.9%)	2 (5.9%)	2 (5.9%)	6 (17.6%)
Total	7%	13%	4%	10%

Table 4.12

Frequency and Percentage of Bruising at 60 hours by Injection Technique B according to Gender and Age Group by Bruise Size (N = 34)

	Male (<u>n</u> = 20)		Female (<u>n</u> = 14)	
	60 years or younger	> 60 years	60 years or younger	> 60 years
No Bruise (< 2 mm ²)	7 (20.6%)	11 (32.4%)	4 (11.8%)	2 (5.9%)
Small Bruise (2 - 5 mm ²)	1 (2.9%)	1 (2.9%)	0	8 (23.5%)
Larger Bruise (> 5 mm ²)	0	0	0	0
Total	8%	12%	4%	10%

Table 4.13

Significance of Gender Effect on Bruise Size at 48 hours by Injection Technique A using Logistic Regression.

Injection Technique A Bruise Size at 48 hours (N = 34)					
Step	Variable Entered	Regression Coefficient	Standard Error	Wald	Significance (p)
1	Age	.0164	.0368	.1992	.6554
	Skin fold	.0362	.0676	.2864	.5925
	Gender	1.8144	.8880	4.1746	.0410
2	Age	.0141	.0362	.1526	.6960
	Gender	1.9934	.8304	5.7621	.0164
3	Gender	2.0219	.8269	5.9792	.0145

Significant Variable	Expected Regression	95% Confidence Interval	
	Coefficient	Lower	Upper
Gender	7.5527	1.4937	38.1888

Table 4.14

Significance of Gender Effect on Bruise Size at 60 hours by Injection Technique A using Logistic Regression.

Injection Technique A Bruise Size at 60 hours (N = 34)					
Step	Variable Entered	Regression Coefficient	Standard Error	Wald	Significance (p)
1	Age	.0298	.0391	.5819	.4456
	Skin fold	.0714	.0722	.9766	.3230
	Gender	1.9863	.8886	4.9963	.0254
2	Age	.0248	.0375	.4369	.5086
	Gender	2.2900	.8444	7.3544	.0067
3	Gender	2.3220	.8385	7.6678	.0056

Significant Variable	Expected Regression Coefficient	95% Confidence Interval	
		Lower	Upper
Gender	10.1961	1.9709	52.7483

Table 4.15

Frequency and Percentage of Subjects that bruise at 48 hours by Injection Technique A (Female =14, Male = 20).

		Bruise Size at 48 hours			Total
		< 2 mm²	2- 5 mm²	> 5 mm²	
Gender	Count	3	3	8	14
Female	% within gender	21.4%	21.5%	57.1%	100%
	% within bruise	13.0%	13.1%	72.7%	41.2%
Male	Count	15	2	3	20
	% within gender	75.0%	10.0%	15.0%	100%
	% within bruise	65.2%	8.7%	27.3%	58.8%
Total	Count	18	5	11	34
	% within gender	52.9%	14.7%	32.4%	100%
	% within bruise	78.2%	21.7%	100%	100%

Table 4.16

Frequency and Percentage of Subjects that bruise at 60 hours by Injection Technique A (Female =14, Male = 20).

		Bruise Size at 60 hours			Total
		< 2 mm²	2- 5 mm²	> 5 mm²	
Gender	Count	2	3	9	14
Female	% within gender	14.3%	21.4%	64.3%	100%
	% within bruise	9.7%	13.0%	75.0%	41.2%
Male	Count	15	2	3	20
	% within gender	75.0%	10.0%	15.0%	100%
	% within bruise	68.2%	9.1%	25.0%	58.8%
Total	Count	17	5	11	34
	% within gender	50.0%	14.7%	32.4%	100%
	% within bruise	77.9%	22.1%	100%	100%

The Correlation between VAS Scores and Bruise Size

The possibility of an association between site-pain and bruise size was explored. Given that the two covariates have non-normal distributions, the Spearman's Rank correlation coefficient was used to measure the degree of linear association between the ranks of pain VAS scores and bruise size. The results were nonsignificant. Within the limitation of the current study, it can be concluded that these two variables are independent. In the current study, the degree of site-pain felt is independent of bruise size.

Summary

The study sought to determine if there was a difference in (1) site-pain intensity experienced by patients at the time of administering injection using techniques A and B, and (2) bruise size between injection techniques A and B at 48 hours and 60 hours postinjection. It was found that injection technique B resulted in significantly less intense site-pain and fewer and smaller bruises in comparison with injection technique A. Thus, for this sample, the administration of subcutaneous heparin injections over 30 seconds (injection technique B) significantly reduced both site pain and bruise size. Furthermore, it was also found that age and skin fold thickness were not predictors for bruise outcome. However, gender did have significant impact on bruise outcome.

CHAPTER FIVE

DISCUSSION AND CONCLUSION

The current study examined the effect of duration of administering a subcutaneous heparin injection on site-pain and bruising. More specifically, it sought to determine if there was a difference in (1) site-pain intensity between two subcutaneous heparin injection techniques, and (2) bruise sizes at injection sites between two subcutaneous heparin injection techniques at 48 hours and 60 hours after injection. In addition, the relationship between bruise size and the covariates (age group, gender and skin fold thickness) was examined. The findings of the current study are discussed with reference to literature and the related variables of administration of subcutaneous heparin injections as depicted in the conceptual model (Figure 2.1).

Impact of Injection Technique on Site-Pain

Analysis of the data revealed that site-pain was perceived to be significantly less intense with the 30-second duration injection technique than the 10-second duration injection technique. One explanation for this is that administering the injection slowly over 30 seconds allows time for the subcutaneous tissue to accommodate the injectate volume, thereby reducing tissue pressure and the intensity of site-pain experienced. By contrast, administering the injection over a shorter duration increases pressure on the tissues and causes more site-pain. The findings of the current study provide empirical support for Murphy (1991) and Travell's (1955) claims that administering an injection slowly

minimises site-pain. Both Murphy (1991) and Travell (1955) asserted that pain at injection sites occurs as a result of trauma due to the sudden distension of tissue caused by rapid introduction of the injectate.

Coley et al. (1987) have demonstrated a reduction in pain when administering subcutaneous heparin injection using a finer gauge needle, a 28-gauge needle, that has a larger lumen than the 25-gauge needle. The pain data in the current study is difficult to compare with that reported by Coley et al. (1987) because of differences in pain measurement techniques and research design used in the two studies. The current study measured site-pain using the VAS which yielded continuous data compared to Coley et al.'s (1987) study which used categorical data. The between-subjects design used in Coley et al.'s (1987) study was not able to consider the effect of inter-subject variability on pain perception. One could argue that the pain data obtained from Coley et al.'s two non-matched groups of subjects were not comparable.

On a practical level, merely increasing the duration of subcutaneous heparin injection administration has some appeal when compared to some other strategies to reduce site-pain. For example, applying ice has been found to reduce site-pain (Ross & Soltes, 1995). While applying ice before and after an injection offers an alternative technique, it can be more labour intense and costly. The current study demonstrates that the treatment variable (30-second duration injection) is more practical than the use of ice for a similar reduction in pain perception.

Impact of Injection Technique on Bruise Size

In the current study, the incidence of bruising with 10-second and 30-second injection duration was 47.0% and 20.6% at 48 hours postinjection, and 52.9% and 29.4% at 60 hours post injection, respectively. The findings were at the lower end of the range (approximately 14% to 90%) reported by previous research (Coley et al., 1987; McGowan & Wood, 1990; Mitchell & Pauszek, 1987; Wooldridge & Jackson, 1988; Vanbree et al., 1984). As expected, the percentage of bruising at the 10-second injection technique sites was approximately double that of the 30-second injection technique sites, clearly indicating that slow administration of subcutaneous heparin injections had lesser impact on bruising.

To reiterate, sizes of the bruises were significantly smaller with slow administration of subcutaneous heparin injections over 30 seconds, while the 10-second duration injection technique resulted in larger bruises. Given these findings, one could argue that bruising is a likely outcome of injections that are administered over a short duration. One possible cause is that administering the injection over 10 seconds or less increases pressure tissue damage and capillary bleeding. The findings of the current study thus provide empirical support for Baer et al.'s (1996) claim that administering subcutaneous heparin injections under high pressure causes tissue bleeding and bruising.

Higher pressures are also associated with syringe size. Administering the subcutaneous

heparin injection with a larger syringe has been shown to reduce tissue trauma and bruising (Hadley et al., 1996). One explanation may be that the larger surface area of the 3-ml syringe decreases by two thirds the injecting force of the pressure created by the 1-ml syringe. Consequently, the decreased tissue pressure causes reduced tissue trauma and bruising. A similar reduction of tissue pressure results from the 30-second duration injection technique when compared with the 10-second duration injection technique. The findings of the current study support the use of a subcutaneous heparin injection technique that decreases the injection pressure on tissue to reduce tissue trauma and bruising. Longer injection duration and larger syringe use are equally practical. However, the longer injection duration tested in the current study would appear to have resulted in more 'no bruise' and 'small bruise' categories than was achieved by using a larger syringe.

Another approach to reducing the injection pressure on the tissues is by injecting a smaller volume of the heparin. Mitchell and Pauszek (1987) found that injecting the subcutaneous heparin in half the usual volume (5000 unit in 0.25 ml) significantly reduced the frequency and size of bruising, indicating that injectate volume impacts on injection-site bruising. Injecting the 0.25-ml heparin solution over 10 seconds reduces the pressure on the tissues by half that produced by injecting the 0.5-ml heparin solution over the same duration. This pressure reduction effect is similar to the effect caused by administering the 0.5-ml heparin solution over a longer duration. That is, longer injection duration is required for more injectate volume. Thus, both injection variables, the injection duration and the injectate volume, have similar impact on bruising. Again, the use of such a subcutaneous heparin injection technique that reduces injection pressure on the tissues to

reduce bruising is supported by findings of Mitchell and Pauszek (1987) and the current study.

Travell (1955) indicated that trauma to skin tissue may occur when a needle pierces through the skin or when the tissues at the site are distended by rapid introduction of the injectate. Although piercing the skin by the smallest needle may reduce tissue trauma, the small inner bore of the needle would create increased pressure on the tissues, and in turn cause tissue trauma and bruising. Based on this knowledge, one would expect that administering the injection with a small gauge needle that has a wide inner bore should reduce tissue trauma and bruising. However, Coley et al. (1987) found no significant differences in bruise outcome when using the 28-gauge needle, which has a wider inner bore than the 25-gauge needle, for subcutaneous heparin injections. The nonsignificant findings may, however, be attributable to the inappropriate timing of bruise data collection at 24 hours postinjection. The findings of the current study and those of previous research (Hadley et al., 1996; McGowan & Wood, 1990; Mitchell & Pauszek, 1987; Vanbree et al., 1984; Wooldridge & Jackson, 1988) suggest that bruises should be assessed at 48 hours postinjection and beyond as the development of bruises may extend past 24 hours. As a result of this inconclusiveness, needle gauge as a variable that reduces bruising should be further investigated.

Impact of Study Design

The current study sought to explore one independent variable which was manipulated to evaluate two injection techniques in a small sample. The study also used a within-subjects design where the subject was exposed to the treatment and the control variables. This design reduces the impact of inter-subject factors owing to the assumption that pain perception and coagulation physiology vary less in the same subject than in two comparable subjects. For example, each subject reported a VAS pain score by the standard injection and a VAS pain score by the treatment injection at two injection time series. The difference between the two VAS pain scores was significant.

However, other studies appeared to have manipulated several variables simultaneously and included a small sample. For example, McGowan and Wood's (1990) study in where two variables were manipulated to study four injection techniques, also had difficulty obtaining an adequate sample size due to the high attrition rate of participants during the study. Other studies that investigated two or more independent variables included Brenner et al. (1981) who studied seven variables between two subcutaneous injection techniques and Vanbree et al. (1984) investigated three variables in three subcutaneous heparin injection techniques. Like McGowan and Wood (1990), these studies found no significant differences in bruising attributable to various mechanical aspects of injection administration. In light of these design limitations, it would seem advisable to consider designing nursing studies using simple designs rather than using more complex designs that require larger sample sizes.

Effect of Covariates on Bruising

Gender effect on bruising associated with the 10-second duration injection technique was significant. Female subjects appeared to have a higher probability of bruising than male subjects. One could speculate that given the age group of female subjects (40 years to 85 years) in the current study, it is possible that skin tissue physiology may account for the bruising. The gender difference in tissue bruisability may be related to differences in oestrogen level, capillary strength, percentage of body fat, or fat distribution. For example, in females, decreased oestrogen level can result in skin tissue changes including decrease in collagen and elasticity, and increased fragility of blood capillaries (Burke & Walsh, 1997; Carnevali & Patrick, 1993; Matheson & McConnell, 1988). It is understood that these changes can affect the rate of absorption of subcutaneous drugs and make the skin susceptible to bleeding and bruising even after a slight trauma such as that caused by subcutaneous heparin injections. However, for the current study, the small sample size is too small to draw any conclusions. Furthermore, the possibility that age and skin fold thickness might be related to gender was also explored as an interaction term within the logistic regression model and the impact was nonsignificant. Thus, age and skin fold thickness did not have any influence on bruise outcome for this sample.

The Correlation Between Site-Pain Intensity and Bruise Size

The analysis of the data revealed that administering the injection over a 10-second duration resulted in greater site-pain intensity and bruise size when compared to injection over a 30-second duration. It follows that the severity of tissue trauma associated with

the bruise may also impact on the intensity of site-pain. However, in the current study, the lack of a statistically significant association between site-pain and bruise size may be related to study limitations. Nevertheless, the association is clinically important in that both site-pain and bruising are adverse effects of subcutaneous heparin injections. Any technique that can alleviate either or both is clinically important. Thus, the findings of the current study suggest a need to consider increasing the duration time for administering subcutaneous heparin injection to decrease both site-pain intensity and bruise size.

Analysis of the Conceptual Framework

The current study examined two techniques of subcutaneous heparin injections. The conceptual framework that guided it was based on the injection administration factors identified in the literature that influenced the adverse outcomes of site-pain and bruising (see Figure 2.1). Site-pain and bruising are consequences of local tissue trauma that occur during administration of subcutaneous heparin injections. The cause of local tissue trauma may be related to the magnitude of injection pressure on tissue. Less tissue trauma results from injecting the volume of the heparin under low pressure. The literature suggested a number of ways that tissue trauma may be reduced, including use of a larger syringe, use of a fine gauge needle with a wide inner bore, or injecting a smaller volume (more concentrated solution) of the heparin.

Keeping the administration variables of injection site, syringe size, needle gauge and injectate volume constant, the current study demonstrated that administering a subcutaneous heparin injection over a longer duration (30 seconds) significantly reduces

site-pain intensity and bruising. The findings of the current study support the conceptual framework outlined in Figure 2.1. In the light of the current study's findings, the importance of injection duration on site-pain and bruising should be considered in the clinical practice of subcutaneous heparin injection administration.

Furthermore, age, skin fold thickness and gender are recognised possible confounders on bruise outcome (Wooldridge & Jackson, 1988). Although only the covariate gender has been identified as a predictor for bruise outcome in this sample, the possible confounding effect of age and skin fold thickness should not be overlooked in the administration of subcutaneous heparin injections. Considering the small sample size of the current study, gender, age and skin fold thickness may be considered as confounders on bruise outcome until proven otherwise.

Limitations of the Study

There are limitations associated with this research. First, the subjects in the current study were all caucasian and affected by ischaemic strokes. Therefore generalisability of the study findings are limited to similar groups. A second reason for the lack of generalisability of the findings is the small sample. A larger sample with equal number of male and female subjects is suggested for future research. This would help to identify impact of other covariates. Finally, one person, the researcher, performed data collection and measurements of dependent variables. Although this was strength as it increased reliability, some biases may have occurred. A double-blind technique where the measurer is not the person administering the injections would control potential bias. Also, the

administration sequence of injection techniques might have affected pain ratings. The sequence in which injection technique A and B are administered should be randomised for each subject to avoid potential bias.

Recommendations for Research and Practice

The current study can be considered to be well designed. The within-subjects design and manipulation of one independent variable, with all other variables held constant for the two subcutaneous heparin injection techniques, strengthened the causal inferences of the study findings.

As a result of the current study the following suggestions for future research and practice are made.

1. That future studies use a larger sample that includes non-caucasian subjects and random sampling.
2. That given the increased probability of bruising with subcutaneous heparin injections in females, the interaction effect of gender, age and bruising should be further investigated using a sample with an equal number of female and male subjects.
3. That, given the current anticoagulant treatment consists of the combined use of

aspirin, warfarin and subcutaneous heparin, the current study should be replicated on patients who are receiving this combined therapy.

4. That, given the results of the current study, which is based on 5000 units heparin in 0.2 ml, a future study could examine the possibility of a sliding scale that considers injection duration per volume of injectate.
5. That clinical practice guidelines recommend that subcutaneous heparin injections be administered slowly over a minimum of 30 seconds, using the injection technique B described in the current study.

Implications for Nursing Practice

Injection technique used for subcutaneous heparin injections may account for the adverse outcomes of site-pain and bruising. Identified variables that affect injection administration are of concern and raise interest for inquiry. The current study has demonstrated clearly that administering the subcutaneous heparin injection slowly over 30 seconds reduces site-pain intensity and bruising. The findings are not only statistically significant; they are also clinically important. A major implication of the current study is that reduced site-pain and bruising preserves more potential abdominal skin sites for subsequent injections, with the added potential to minimise psychological discomfort for patients who require multiple subcutaneous heparin injections over an extended period of time. Specifically, those have ischaemic strokes or other types of thromboembolic diseases, benefit most

from this improved subcutaneous heparin injection technique.

The findings of the current study provide empirical support for using a longer subcutaneous heparin injection technique that may eliminate the potential cause of site-pain and bruising. The technique provides a guide for nurses with regards to injection practice of this nature. Also, the scientific data may be used for establishing guidelines for subcutaneous heparin injection practice, thus adding to the repertoire of evidence-based practice. The findings of the current study hold important clinical implications for nursing practice.

Conclusion

The current study examined two subcutaneous heparin injection techniques to determine the effects of different injection duration on site-pain and bruising. As the variable, duration of injection has not been the focus in previous research, the current study provides quantitative data to support the clinical utilisation of a longer (30 seconds rather than 10 seconds) duration of injection in administering subcutaneous heparin injections.

Considering the investigative findings within the limitations of the current study, the following conclusions can be drawn. The 30-second duration injection significantly reduces site-pain during injection and results in fewer and smaller bruises. This technique, therefore, is worth considering in developing nursing practice guidelines.

Given the strength of the study design and findings of the current study, one could argue

that results obtained from the current study matches level III evidence-based practice (as identified in the Guidelines for development and implementation of clinical practice guidelines, National Health & Medical Research Council, 1995). Level III evidence refers to evidence obtained from well designed controlled studies without randomisation. On the strength of this, the recommendations are worthy of consideration. The 30-second duration injection technique should be used for subcutaneous heparin injections in clinical practice.

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APPENDIX A

INFORMED CONSENT FORM

RESEARCH TITLE: A comparative study evaluating two subcutaneous heparin injection techniques.

RESEARCHER: Harriet Chan RN

I am a registered nurse enrolled in the Master of Science (Nursing) program at Curtin University of Technology. As part of my commitment to this program, I am undertaking this study to evaluate two methods of giving an injection. This research is important as it will provide nurses with information necessary to improve injection techniques.

As part of your medical treatment you have been prescribed Fragmin injection twice each day for approximately 10 days. I am evaluating whether the length of time taken to give the injection affects bruising and discomfort. If you agree to participate in this study, I will vary the time taken to give two of your prescribed injections. I will need to note the size of any bruising 48 and 60 hours later. I will also ask you to rate, on a scale, the level of pain you experienced while each injection was given.

The information you give will only be used for this study. You are assured that all information will be kept strictly confidential. Your participation in this study is entirely voluntary. There are no risks with this research and you may withdraw at any time without care being affected. If you have any questions or concerns regarding this study please contact: Harriet Chan on xxxxxxxx or Dr. Bev O'Connell, on xxxxxxxx at the Nursing Research Unit, XXXXXXXXX Hospital.

THIS IS TO CERTIFY THAT I, _____, have read the above information and I understand the nature and purpose of the study. I have been given the opportunity to ask any questions and I have had all my questions answered to my satisfaction. I freely agree to participate in this study and understand that I am free to withdraw at any time without being disadvantaged.

Signature: _____ Date: _____

Researcher: Print Name: _____ Date: _____

Signature: _____

APPENDIX B

DEMOGRAPHIC DATA FORM

Subject Name: _____ Age: _____ Sex: _____

Current Diagnosis: Ischaemic stroke _____ TIA _____

Neurological deficits: _____

Current medications: _____

Aspirin: Yes _____ Date commenced: _____
Dose/Frequency: _____

Analgesics: Yes _____ Name of analgesics: _____
Time of analgesics: _____
Route: _____
Dosage: _____
Reason: _____

Abdominal skin fold measurement (mm): _____

The subject	Answer yes or no
Is able to provide informed consent:	_____
Is not pregnant:	_____
Has not taken any drugs with anticoagulant effect during the last 7 days	_____
Is given Fragmin as the only anticoagulant:	_____
Is on twice daily Fragmin injection:	_____
Is able to comprehend English:	_____
Requires an interpreter to obtain informed consent:	_____

Subject Study No. _____

This number will be assigned to the subject when all inclusion criteria have been met and the subject has voluntarily agreed to participate in the study by signing an informed consent.

*This Chart used for Technique A and B.

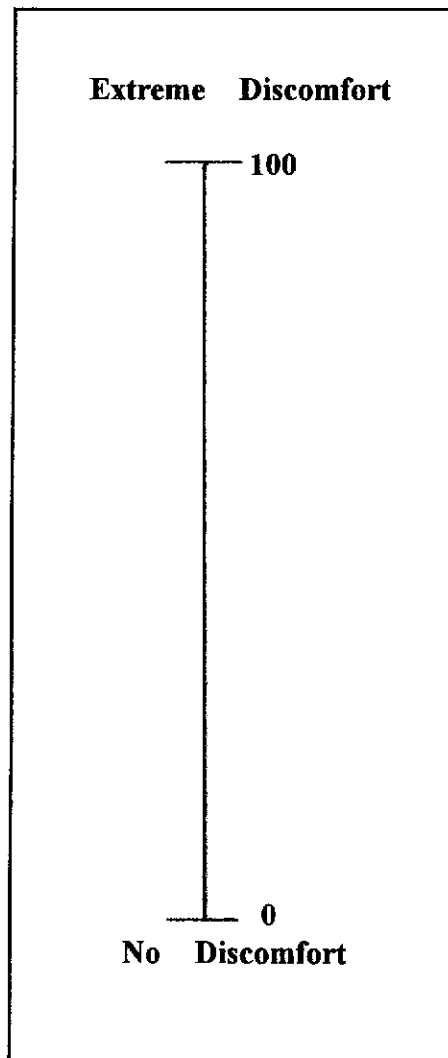
APPENDIX C

DATA COLLECTION CHART

PAIN (VAS SCALE)

Subject name: _____ Sex: ____ Age: ____ Study No. _____

VAS SCALE:



Fragmin injection Technique	Time/date of injection	Code Number for VAS score
* A		

APPENDIX D

DATA COLLECTION CHART

INJECTION DETAILS

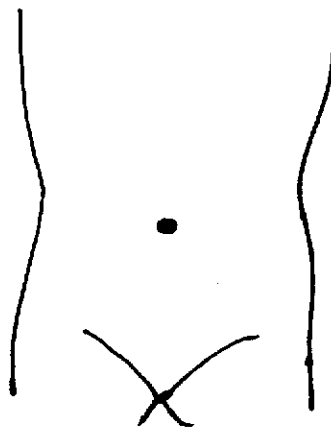
Subject Name: _____ **Sex:** ____ **Age:** ____ **Study No.** _____

Medical Diagnosis: _____

Fragmin dose: _____

**In the diagram, mark the injection site used for technique A and B respectively,
ie A = site used for technique A**

B = site used for technique B



Date/time of injection technique A: _____ **Bleeding** yes / no

Date/time of injection technique B: _____ **Bleeding** yes / no

Injection Site	Time/date due for assessment	Time/date site is actually assessed	Bruise, No Bruise or Pinpoint Bruise
Technique A injection site	48 hours		
	60 hours		
Technique B injection site	48 hours		
	60 hours		

APPENDIX E

NURSES INFORMATION SHEET

To: Nursing Staff

Subject: A Comparative study evaluating two subcutaneous injection techniques.

Date: 21 September 1998

Dear Colleague,

I am undertaking the above research project for the Master of Science (Nursing) study program. This study has the approval of Ethics Committees at Curtin University and at the Hospital.

During the next six months I will enrol approximately 50 subjects/patients with ischaemic stroke or TIAs to participate in the study. Subjects will be enrolled in this study if they meet the designated inclusion criteria.

I will administer two of the prescribed subcutaneous Fragmin injections within the first 48 hours of each patient's hospitalisation. These two injection times will be marked on the medication chart for me to give.

All other subcutaneous Fragmin injections should be administered outside and well away from the circles marked on the subject's (patient's) abdomen.

Each of the two injection sites administered by the researcher will be assessed at 48 hours and 60 hours after injection.

Any queries, please contact the researcher on XXXXXXXX.

Thank you for your cooperation.

Yours sincerely,

Harriet Chan RN