VASCULAR ACCESS SITE BRUISING

RELIABILITY OF VASCULAR ACCESS SITE BRUISE MEASUREMENT AND PATIENT PERCEPTIONS: A MIXED METHODS STUDY

By

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ABSTRACT

Introduction

The most common complication following invasive cardiac procedures is the development of vascular access site (VAS) bruising. The extent and impact of VAS bruising is poorly understood and minimally reported in the literature. Research into this common post-procedure complication is hindered by the lack of a reliable bruise measurement tool, and the concept that VAS bruising is a minor complication. This mixed methods study examined the inter-rater reliability of two methods to measure VAS bruise size. The embedded qualitative descriptive study explored patient perceptions of VAS bruising.

Methods

Participants having femoral or radial artery puncture for invasive cardiac procedures were included in this study. Participants reporting VAS bruising completed self measurement of bruise size using two methods, linear measurement and planimetry. The principal investigator and research assistant completed bruise measurements at the same time, and were blinded to participant and each others' measurements. Following bruise measurement, the principal investigator conducted semi-structured interviews on a convenience sample of participants; including both sexes, a range of ages, and bruise sizes.

Results

Measurements were completed on 40 participants with VAS bruises. Analysis of inter-rater reliability was done using the intraclass correlation coefficient (ICC), two-way

random effects model. The inter-rater reliability for both linear measurement and planimetry between all three measurers was high (.929; .914 respectively). Analysis of participant narratives uncovered three major themes concerns, impact and mediating factors, with several sub-themes.

The findings of this study support the reliability of patient VAS bruise measurement using linear measurement and planimetry. The goals and available resources for VAS research may determine the choice of measurement approach. Qualitative descriptive results indicate that patients have concerns related to VAS bruising and that this bruising may impact activities of daily living. Future research examining VAS complications should include evaluation of VAS bruising as significant patient outcome.

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Chapter One – Background and Rationale

The primary purpose of this measurement-focused study was to investigate the reliability of two methods to determine vascular access site (VAS) bruise size seven to ten days following either femoral or radial arterial puncture for the purpose of cardiac catheterization (CATH) or percutaneous coronary intervention (PCI). The secondary purpose was to explore patients' concerns and their perceptions of the impact of post procedure bruising following CATH and/or PCI.

This chapter will provide the background and rationale for the study, including the limitations of current research and the need for a reliable bruise measurement tool for patients undergoing invasive cardiac procedures of CATH and/or PCI. The choice of study design will be described. The specific research questions will be presented and organization of the remainder of the thesis will be outlined.

Cardiovascular disease is the leading cause of death worldwide, with a predominance of coronary artery disease (CAD) (Gaziano, 2005; World Health Organization, 2004). Cardiac catheterization is the gold standard invasive diagnostic test for identification of luminal narrowing within the coronary arteries, also known as CAD. Identification of CAD can lead to further disease management options including coronary artery bypass surgery or PCI.

The use of invasive cardiac diagnostics and procedures has risen steadily in Canada over the past decade (Alter, Stukel, & Newman, 2006). In Canada, rates of CATH have increased from 359.9 to 471.5 per 100,000 between 1997/1998 and 2001/2002 (Farris, Grant, Galbraith, Gong, & Ghali, 2006). This represents a more than

30% increase in CATH over a period of four years. Percutaneous coronary intervention, a management option for patients with CAD, is also on the rise throughout Canada. In 2008 over 6,500 of these procedures (CATH or PCI) were performed every 3 months in Ontario (Cardiac Care network [CCN], 2008). Both CATH and PCI have a variety of complications associated with them; however, the most common complications are related to the arterial puncture required to perform the procedure (Applegate et al., 2008; Ohlow et al., 2009).

Femoral Access Site

Access to the coronary arteries is required to perform CATH and/or PCI. This is typically performed by accessing the arterial vasculature through either the femoral or radial artery. The femoral artery has been the dominant access site used for these procedures for the past 20 years (Jolly, Amlani, Hamon, Yusuf, & Mehta, 2008). Complications at the femoral VAS range from bruising and hematoma development to complications requiring external compression. These complications may require injection of thrombin (to control or stop bleeding), and possible surgical repair of the femoral artery (Samal & White, 2002). It is now widely understood that major bleeding following CATH and/or PCI is an independent predictor of morbidity and mortality (Hamon & Coutance, 2009; Jolly et al., 2008; Manoukian, 2009).

Many studies have examined various methods to reduce the risk of femoral VAS bleeding complications (Benson et al., 2005; Botti, Williamson, Steen, McTaggart, & Reid, 1998; Juran et al., 1998; Koreny, Riedmuller, Nikfardjam, Siostrzonek, & Mullner, 2004; Smith & Labriola, 2001). Research studies have also attempted to identify those

patients who are at increased risk of developing femoral VAS complications (Ammann et al., 2003; Andersen, Bregendahl, Kaestel, Skriver, & Ravkilde, 2005; Cox, et al., 2004; Dumont, Keeling, Bourguignon, Sarembock, & Turner, 2006; Sulzbach-Hoke, Ratcliffe, Kimmel, Kolansky, & Polomano, 2010; Yatskar et al., 2007). The majority of research on VAS complications to date has focused primarily on uncommon, albeit major, femoral VAS complications. The most commonly occurring VAS complication, significant bruising, has for the most part been unaddressed in the literature.

Previously completed studies examining femoral VAS complications as an outcome measure have examined the femoral site prior to patient discharge (Benson et al., 2005; Jones & McCutcheon, 2003; Sabo, Chlan, & Savik, 2008; Steffenino et al., 2006). Current practice patterns have resulted in the majority of patients being discharged home 6 to 24 hours following CATH and/or PCI. There is some evidence in the literature to suggest that this is too early to adequately assess for bruising at the femoral VAS (Botti et al., 1998; Cosman, Arthur, & Natarajan, 2011).

Radial Access Site

The use of the radial artery as a VAS for cardiac procedures was introduced in the late 1980's and has steadily gained popularity due to the low incidence of deleterious bleeding complications (e.g., avoidance of retroperitoneal bleeding). Two recent meta-analyses have demonstrated a reduction in major bleeding complications with radial access as compared to femoral access for CATH and PCI (Jolly et al., 2008; Vorobcsuk et al., 2009). Despite an increase in use of the radial artery as a site for CATH and PCI in some centers, internationally, the majority of these procedures continue to be done using

the femoral artery (Jolly et al., 2008; Nickolaus, Gilchris, & Ettinger, 2001; Ohlow et al., 2009). The decision about whether to use the radial or the femoral approach is made on an individual basis by the interventional cardiologist. Research examining complications related to the radial artery access site is sparse, as this is a relatively new clinical practice. Some case reports have described the rare development of compartment syndrome, as well as arteriovenous fistula, pseudoaneurysm and hematoma (Korn et al., 2008; Nickolaus et al., 2001; Tizon-Marcos & Barbeau, 2008). A longer term issue with radial artery access cited in the literature is the development of radial artery occlusion, resulting in an unsuitable conduit for future coronary bypass surgery (Burstein et al., 2007; Pancholy, Coppola, Patel, & Roke-Thomas, 2008). The development and extent of bruising following radial artery access has not been reported in the literature.

Rationale for Measurement Study

Studies examining VAS bruise size, at either the femoral or radial sites, are hampered by inconsistent definitions of hematoma and bruising and, more importantly, the lack of a standard, reliable method for determining bruise size (Havey & Quinlan, 1998). Bruise size has been reported in the following ways a) a continuous measure using square centimeters (Behan, Large, Patel, Lloyd, & Sulke, 2007; Botti et al., 1998; Robb & McLean, 2000), b) by ordered categories identified by familiar objects (quarter, golf ball etc.) (Cosman et al., 2011), and c) by having patients report bruising as local, moderate or extensive using line drawings as a guide (Botti et al., 1998). Only three studies had patients self report their bruise size following discharge (Botti et al., 1998; Cosman et al., 2011; Robb & McLean, 2000). In general, inconsistent descriptions,

definitions, and reporting of bruise size can limit the interpretation of study findings (Streiner & Norman, 2003). It is of critical importance that a common definition of bruising, and a reliable method of measuring VAS bruise size, is utilized in future research regarding VAS complications. The use of a reliable and cost effective method of VAS bruise measurement is essential if research into this common complication following CATH or PCI is to progress. As this complication often develops when patients are at home, a self administered method of measuring bruise size would be ideal.

Rationale for Qualitative Study

To date there have been no identified studies which examined patients' perspectives of VAS complications following invasive cardiac procedures. Understanding the concerns of patients, and the impact of VAS bruising on their lives, may promote insight and empathy among health care providers who care for these individuals (Kearney, 2001). Health care providers frequently make comments such as "it's only a bruise", which tends to minimize the importance of this complication without the necessary information to support or refute such a statement. Creswell and Plano Clark (2007) also suggest that qualitative methods can "enrich and explain the quantitative results in the words of participants" (p. 34). The use of qualitative research to gain understanding of the patient perspective regarding VAS bruising will enhance the overall understanding of this complication following invasive cardiac procedures.

Rationale for Mixed Methods Design

This study employed an embedded, mixed-method design as described by Creswell and Plano Clark (2007). Using taxonomy introduced by Morse (2003), the

design is written QUAN + qual. The capital letters indicate the priority of the quantitative portion of the study and the plus sign (+) indicates the concurrent nature of two methods. The embedded, mixed-methods design acknowledges the primary goal of the quantitative component as well as the complementary value of the qualitative component (Creswell & Plano Clark, 2007).

Reliability Study

The quantitative component of this study evaluated the inter-rater reliability of two different methods of bruise measurement. Raters were a) the principal investigator (PI), an advanced practice nurse, b) a research assistant (RA), and c) study participants who developed VAS bruising following CATH or PCI. This portion of the study endeavored to meet the key criteria for reliability studies as described by Karanicolas et al. (2009). Specifically, the raters and participants were representative of those who would be likely to use measurement tools in either clinical or research settings.

Qualitative Description

The qualitative component of this study explored the impact of VAS bruising as well as the concerns of patients who developed VAS bruising following CATH and/or PCI. Qualitative description, as described by Sandelowski (2000; 2010), was the study method used. The aim of qualitative description is exploratory, and the goal of this study was to enhance our understanding and awareness of VAS bruising through identification of themes in patients' narratives (Dobbins, Jack, Thomas, & Kothari, 2007; Sandelowski, 2000). As little is known about patients' perceptions related to VAS bruising, qualitative description is the appropriate qualitative method for this study.

The quantitative and qualitative components of this mixed methods study address different questions about the phenomenon of VAS bruising. Performing either study alone would lack the richness of the mixed methods design. A stand alone study assessing the reliability of VAS bruise measurement fails to acknowledge the individual's perspective; a qualitative study alone would fail to identify the optimal method for measuring VAS bruising. The rationale for mixed methods in this study was to "initiate new modes of thinking by attending to paradoxes that emerge from two data sources" (Johnson, Onwuegbuzie & Turner, 2007, p. 115). The results of this mixed methods study provide a deeper understanding of VAS bruising and will guide future research examining this phenomenon.

In summary, the most commonly occurring complications following invasive cardiac procedures are related to the VAS. Bruising at the VAS is the most common complication following CATH or PCI. The number of patients having these procedures is increasing, with the majority of patients discharged home within 24 hours of their procedure. Evidence suggests that VAS bruising becomes apparent several days after the CATH and/or PCI and will therefore not normally be observed prior to hospital discharge. Previous studies of VAS bruising are limited by the absence of a reliable method of bruise measurement and a lack of understanding about the concerns and impact of post-procedure bruising on patients. A reliable, patient-friendly method of measuring VAS bruise size is required. Quantitative methods are inadequate to describe the concerns of patients who develop VAS bruising. The combination of quantitative and qualitative research methods will provide a better understanding of the phenomenon of

VAS bruising. Using a mixed methods approach to examine these questions will enhance our understanding of this phenomenon (Creswell & Plano Clark, 2007).

The primary purpose of this study was to determine the reliability of two different methods of VAS bruise measurement. A further objective was to determine which method would be easiest for patients to use. The overall goal was to develop a measurement tool that is both reliable and easy for patient and clinician use in order to measure and report the extent of VAS bruising that occurs following CATH and/or PCI.

The secondary purpose was to explore the concerns of patients related to VAS bruising and the impact of VAS bruising on patients following CATH and/or PCI.

Research Questions

Quantitative Questions

1. What is the inter-rater reliability of two different methods for measuring VAS bruise size? Inter-rater reliability involved comparison of measurements taken by; a) the PI, an experienced advanced practice nurse; b) the research assistant (RA); and c) the patient participant.

2. What factors do participants identify as affecting their ability to measure VAS bruise size (with each measurement method)?

Qualitative Questions

3. What are the concerns of individuals who develop VAS bruising following CATH or PCI at either radial or femoral sites?

4. What are the patients' perceptions regarding the impact of VAS bruising following CATH or PCI, at either the radial or femoral sites, on patients' activities of daily living?

Mixed Methods Question

5. Does the impact of VAS bruising and related concerns vary according to the size of VAS bruises?

Organization of Thesis

The thesis is organized into five chapters. This chapter has provided background information regarding VAS bruising, rationale for the mixed methods study, and briefly described why a reliable tool is needed for research into VAS bruising.

Chapter two reviews, in detail, the literature regarding VAS bruising and the need for a reliable tool for VAS bruise measurement. The incidence and impact of VAS bruising, in terms of utilization of health care resources and effect on patients, will be addressed. The potential for using currently available measurement tools from the wound care literature will be examined, including an evaluation of the reliability of these tools. The requirements for a suitable VAS bruise measurement tool will be addressed and two potential methods for measurement of VAS bruise size will be put forward.

Chapter three describes the research methods including study design, setting, population, data collection, and plan for data analysis. The methods for both the measurement study and the embedded qualitative study are addressed throughout the chapter.

Chapter four presents the results of the study and is divided into four sections. The first two sections address the quantitative study results including; description of study participants, results of the reliability study, and participant questionnaire results. The third section reviews the results of the embedded qualitative descriptive study. The

major themes identified from the participants' narrative data are described and exemplars are used to illustrate the major themes. The fourth section addresses the mixed methods research question.

The study results, both quantitative and qualitative, are discussed in Chapter five. How the current study results relate to prior studies and how the current study findings might be used in future research are examined. Strengths and limitations of the current study and implications for future research and nursing practice are also considered.

Chapter Two - Literature Review

This chapter reviews the literature related to VAS bruising, as well as literature related to wound size measurement, which was used to support the development of the VAS bruise measurement tools. The first section of this chapter provides an overview of key literature on VAS bruising related to its importance to nursing practice, definitions, timing, incidence and patient impact of VAS bruising on patients.

The second section of this chapter focuses on the wound care literature; specifically, a review of wound measurement tools and a critique of reliability studies conducted on wound measurement tools that are potentially applicable to VAS bruise measurement.

The chapter concludes by reviewing the requirements for VAS bruise measurement and proposing two alternatives for VAS bruise measurement.

Importance of Vascular Access Site Bruising

As stated previously, VAS complications are the most common complication following CATH or PCI and continue to contribute to patient mortality and morbidity. There has been a large amount of research conducted by both nurses and physicians with the aim to identify patients at risk for developing major VAS complications, and strategies to decrease the incidence of such events. Major vascular complications have traditionally been defined as a significant drop in hemoglobin requiring transfusion (e.g., retroperitoneal bleeding), pseudoaneurysm, arteriovenous fistula, peripheral embolization, and arterial thrombosis (Konstance et al., 2004; Ohlow et al., 2009). Technological and clinical advances have resulted in a decrease in the incidence of these

major vascular complications (Applegate et al., 2008; Doyle et al., 2008; Ohlow et al., 2009). At their institution, Applegate et al., (2008) reported a major vascular complication rate including retroperitoneal bleeding, major bleeding, vascular occlusion, loss of distal pulse, vascular surgery, and vascular death, of < 1% from 2000 onward. Development of pseudoaneurysm, arteriovenous fistula and hematoma > 10 cm were reported as minor complications, occurring < 1.1% of the time over the past ten years. Ohlow et al., (2009) reported the incidence of pseudoaneurysm and arteriovenous fistula of 1.2% and 0.6% respectively. While the incidence of these complications is relatively low, there are limitations to the current body of research regarding VAS complications.

The development of bruising is by far the most common VAS complication following CATH or PCI, yet has been neglected in the research literature. There are many potential explanations for this including a) VAS bruising is considered by some to be a minor complication and an acceptable outcome of CATH or PCI, b) VAS bruising is not a life threatening complication, c) VAS bruising may not prolong hospital stay and therefore may not have an obvious impact on human and financial resources of the hospital, and d) there is currently no reliable method for measuring the extent or impact of VAS bruising. The lack of a reliable method for measuring VAS bruising can be traced to two significant issues; a) absence of a clear definition of bruising, as distinct from hematoma; and b) identification of the optimal timing for assessment of VAS bruising.

Lack of Consistent Definition

Most published research reporting VAS bruising has neglected to provide clear definitions of bruising and hematoma; when definitions have been offered, there is inconsistency among studies (Havey & Quinlan, 1998). A recent randomized controlled trial (RCT) with a focus on the development and size of bruising following CATH did not define the difference between bruising and hematoma (Behan et al., 2007). Two studies examining nursing care and predictors of VAS complications included hematoma as a minor complication, but used inconsistent definitions of hematoma, and did not include bruising as an outcome measure (Anderson et al., 2005; Steffenino et al., 2006). The study by Steffenino et al., (2006) reported hematoma size as < 4 cm, 4 to 8 cm, and > 8 cm, but gives no indication of how the size was measured. Anderson et al., (2005) reported hematoma size as > 5 to 10 cm, and > 10 cm and describes hematoma assessment completed by either two experienced nurses or a nurse and a doctor, however bruising was not included as an outcome measure. In a more recent study of same day discharge following PCI, 60% of patients self-reported a femoral hematoma; however there was no definition or description of how patients determined the difference between hematoma and bruising (Lauck, Johnson, & Ratner, 2009). Bruising at the sheath site was well defined by Jones and McCutcheon (2003); however there was no definition of hematoma. There was also no measurement of bruise size, the authors simply reported the development of bruising during the sheath removal process as a 'yes' or 'no' outcome. When patients in this study were telephoned five days following CATH, 50% reported bruising and 14% reported swelling (Jones & McCutcheon, 2003). The study by

Botti et al., (1998) focused on the development of bleeding and bruising with the use of pressure dressings following CATH. The paper describes how nurses measured local complications, defined as "bruising or swelling at the groin site" (Botti et al., 1998, p. 362). The inclusion of swelling is not consistent with accepted definitions of bruising. In contrast, a study by Sabo, Chlan and Savik (2008) clearly defined the VAS complications of:

> oozing (presence of any leakage of blood from the puncture site), ecchymosis (presence of any skin discoloration without a mass), hematoma (presence of a nonpulsatile mass > 4 cm, or pulsatile mass (presence of a palpable mass with movement corresponding to systole and diastole) (p. 192).

Robb and McLean (2000) also defined hematoma as "a swelling containing clotted blood" and bruising as "abnormal discoloration of skin around the puncture site" (p. 371). It is clear that a clinically accurate and universal definition of VAS bruising is a priority if it is to be considered an important outcome measure in research designed to minimize this complication.

Timing and Incidence of Vascular Access Site Bruising

A second limitation of studies examining VAS bruising has been the timing of VAS assessment. Decreased length of hospital stay has resulted in the majority of patients being discharged home within 6 to 24 hours of their CATH and/or PCI. Previously completed studies using VAS complications as an outcome measure have examined the femoral VAS site prior to patient discharge (Benson et al., 2005; Jones & McCutcheon, 2003; Steffenino et al., 2006; Sulzbach-Hoke et al., 2010; Walker, Jen, McCosker, & Cleary, 2008). There is some evidence to suggest that this is too early to adequately assess for bruising at the VAS.

Botti et al. (1998) found the overall incidence of VAS bruising prior to discharge was 14.6%. In contrast, 41.9% of patients in this study reported persistent or new bruising when contacted 6 to 28 days following CATH (Botti et al., 1998). In a RCT comparing manual compression to vascular closure devices Behan et al., (2007) reported sequential mean bruise size following CATH. They found an increase in the mean bruise size from the two hours post-CATH assessment to the one week follow up visit. Mean bruise size increased from 3.2 cm^2 to 82.5 cm^2 in patients who had manual compression and from 0.7 cm^2 to 28.5 cm^2 in patients who had closure devices. A recent study specifically examining VAS complications reported an incidence of 6.3% of hematoma (smaller than 5 cm^2) and no bruising at the time of discharge, based on nursing VAS assessment. However, at the time of telephone follow up, five to seven days following CATH or PCI, 68.6% of participants reported bruising, with 47% of patients reporting bruising of 7.5 cm or greater (roughly equivalent to the size of a tennis ball) (Cosman et al., 2011). In summary, it is reasonable to conclude that VAS bruising is a frequent and emerging process that occurs over several days to weeks following CATH or PCI. Bruising at the VAS will not be captured as an outcome of interest if studies continue to report VAS bruising at the time of hospital discharge, 6 to 24 hours following CATH and/or PCI.

Three studies in the literature specifically examining the incidence of VAS bruising found between 41% and 68% of patients reported bruising 3 to 28 days following CATH or PCI (Cosman et al., 2011; Botti et al., 1998; Robb & Mclean, 2000).

Impact of VAS Bruising – Resources and Patients

It has been suggested in the literature that complications that "do not require medical attention or affect length of stay" (Sulzbach-Hoke et al., 2010. p. E6), such as bruising, are not clinically significant. This comment raises questions regarding the definition of clinical significance in the hospital setting, and from whose perspective clinical significance is being considered. It would appear that Sulzbach-Hoke et al. (2010), define a clinically significant event as one that increases length of hospital stay or requires increased medical or nursing care; the significance of VAS bruising to the patient has been disregarded. In contrast Amoroso (2005) notes that cardiology nurses should worry about arterial access complications as nurses are taking an active role in arterial sheath removal and arterial compression. Amoroso (2005) acknowledges that "vascular complications, whenever they occur, still have significant impact on morbidity, mortality and hospital costs" (p. 3). Two studies have recently demonstrated that approximately 4% of patients with concerns related to VAS, following CATH or PCI, return to either the emergency department or their family physician for medical follow up (Cosman et al., 2011; Lauck et al., 2009). In Ontario, this translates to 2,800 health care visits/year related to patient concerns regarding their VAS following CATH or PCI. The majority of CATH and PCI procedures are performed at quaternary health care hospitals and patients may not return to the hospital where the procedure was completed for follow up. Consequently, staff at the quaternary hospitals may not have a true sense of the volume of patients presenting for follow up regarding VAS concerns. When patients present to the family physician or emergency department over VAS concerns, regardless

of the perceived clinical significance of those concerns, there is an increased cost to the overall health care system. Given the volume of these procedures completed nationally and internationally, this cost is not insignificant. Bruising at the VAS following invasive procedures may indeed be a hidden cost of health care utilization following CATH or PCI.

There is growing acknowledgement that bruising, although not life threatening, can have an impact upon long term patient outcomes. In the study by Cosman et al. (2011), it was noted that 41.5% of patients reported pain or discomfort at their VAS but only 13.4% of patients reported taking any medication for their discomfort. Roy et al. (2008), recently found that 11% of patients who developed "nuisance bleeding" following PCI, with a drug eluting stent, discontinued dual antiplatelet therapy without medical consultation. Nuisance bleeding was defined by the authors as "easy bruising, bleeding from small cuts, petechia, and ecchymosis" (Roy et al., 2008, p. 1616). The decision by patients to discontinue antiplatelet medications may have clinical consequences as short-term studies have shown that early withdrawal of antiplatelet therapy has been linked to stent thrombosis (Iakovou et al., 2005).

A literature search regarding the impact of VAS complications, specifically bruising, did not uncover any findings with this patient population. Although not specifically examined in studies to date, it has been proposed that VAS bruising may be painful, decrease patient mobility, create increased patient distress, and increase nursing care time (Behan et al., 2007; Jones & McCutcheon, 2003; Sabo et al., 2008). The results of a study exploring the experience of day surgery patients' discharge and recovery found

that some patients were not prepared for the shock of skin discoloration with post operative bruising. It was suggested that this may have been stressful and perceived as a threat to body image and appearance for these patients (Gilmartin, 2007).

VAS Bruise Measurement Tool

The use of a reliable measurement tool is of paramount importance when conducting clinical research (Karanicolas et al., 2009; Streiner & Norman, 2003). Karanicolas et al. (2009) list seven questions to consider when assessing a reliability study:

1. Was the research question appropriate?
2. Were the raters representative of the individuals who will apply the instrument in practice?
3. Were the patients or subjects representative of the population that will be rated in practice?
4. Did raters assign the ratings in a clinically relevant manner?
5. Were the data analyzed with use of appropriate reliability statistics?
6. How was the sample size (of raters and subjects) determined?
7. How can the results be interpreted? (p. 100).

A reliable measurement tool strengthens the results of research findings, and provides support for clinicians as they translate study results to the practice setting (Gethin & Cowman, 2006; Streiner & Norman, 2003). There is no current standard for measurement of VAS bruising following invasive cardiac procedures in either the clinical or research setting. A reliable tool for the measurement of VAS bruise size is required for research into this common complication following CATH or PCI. Prior to beginning

this study a literature search was conducted to determine if there was a reliable tool used in clinical research to measure VAS bruising.

The following definition for bruise was used when searching for an appropriate tool to measure bruise size; a bruise is an accumulation of blood in the subcutaneous tissues as a result of tissue injury. This is evident by the typical discoloration of the skin surrounding the injured tissue in the absence of a palpable mass. This definition is based on prior research of VAS complications (Akpinar & Celebioglu, 2008; Robb & McLean, 2000; Sabo et al., 2008). The literature search confirmed the lack of a consistently used or reliable tool for the purpose of measuring VAS bruising. Two studies were found which did examine bruise size related to subcutaneous needle puncture. These studies used wound surface area (WSA) measurement techniques to quantify bruise size (Chan, 2001; Zaybak & Khorshid, 2007). The lack of existing literature related to the measurement of VAS bruise size demonstrates the perceived lack of significance of VAS bruising in the health care community.

Following the literature review, it became clear there was no standard reliable method for measuring VAS bruise size. Examination of the wound care literature lead to the idea that perhaps modification of existing wound measurement tools would meet the specific requirement for VAS bruise measurement. Based on clinical experience, the following attributes of a measurement tool were considered essential to measure VAS bruising a) ability to measure the surface area of tissue discoloration, b) ability to measure irregular shapes, and c) ability to measure around body contours. Considerations for the utility of a bruise measurement tool included the financial costs of

implementing the tool in research. Given the large number of patients undergoing CATH or PCI, and the clinical practice of discharge within 6 to 24 hours of these procedures, it would pose a large financial and human resource burden to have patients return to the hospital for bruise measurement following CATH and/or PCI. It would be ideal if a reliable VAS bruise measurement tool could be developed for use by patients at home following discharge. With the above requirements in mind, techniques of WSA measurement from the wound care literature were considered.

Wound Care Literature Review

To determine the reliability of wound measurement tools, a literature search from January 1990 to January 2009 was conducted. The Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Medline databases were searched using the search terms wound measurement, validity, and reliability, with limits to the English language. Hand searching the reference lists of all retrieved articles was also done. Research papers examining the reliability and validity of various wound measurement tools were reviewed.

Within the wound care literature there exist an abundance of research papers examining the reliability of various measurement tools. Accurate wound measurement is essential for researchers in this field because change in wound size is an indicator of treatment success (Bolton, 2008; Flanagan, 2003; Krouskop, Baker & Wilson, 2002). Tools exist which measure the two dimensional size of the wound, also known as the surface area. Three dimensional measures also exist, which incorporate the depth of the wound. Bruises, as defined in this study, are visualized as two dimensional skin

discolorations apparent at the VAS. A hematoma results when there is a collection of blood under the skin with the development of a palpable mass. A hematoma is by definition three dimensional. For the purpose of measuring VAS bruising, as defined in this study, measurement tool which examined the two dimensional wound size, or surface area were reviewed. Wound measurement tools which measured the depth of a wound (three dimensions), or the rate of wound healing were not reviewed.

Wound Measurement Tools

There are a large number of techniques and tools used to assess WSA. Each technique involves either; a) linear wound measurement, using a ruler; or b) surface area measurement, based on wound perimeter, referred to as planimetry. Identification of the wound border can range from the straightforward use of transparent film and a fine tipped marker to trace the wound perimeter, to sophisticated techniques involving photography, image processing technology and computer software programs (Ahn, & Salicido, 2008; Li, 2006). Keeping in mind that one of the attributes of a VAS bruise measurement tool is ease of use for the patient in the home environment, measurement methods employing photography and/or computer scanning were not considered viable options. The two methods of WSA measurement considered reasonable options for VAS bruise measurement were linear measurement and planimetry. A pictorial representation that summarizes these two techniques of WSA measurement is provided in Appendix A. The following is a detailed description of these measurement techniques, including a review of the reliability of these methods.

Linear measurement.

Linear measurement, also referred to as diameter product, is reported as the most commonly used WSA measurement in clinical practice (Bryant, Brooks, Schmidt & Mostow, 2001; Langemo, Anderson, Hanson, Hunter & Thompson, 2008). Using a paper or plastic ruler, the length and width of the wound is directly measured and the wound size is reported in either square millimeters (mm^2) or centimeters (cm^2). With irregularly shaped wounds the appropriate line of measurement may not be clear. Determining the axis for measuring length and width has been examined by several authors (Bryant et al., 2001; Langemo et al., 2008). Four options for length and width measurement of the wound are outlined:

- perpendicular method – irrespective of axis, measure the maximum wound length, measure width as the widest, perpendicular to length;
- clockwise method – along the head-to-toe axis, measure the maximum wound length, measure width at its widest, perpendicular to the head-to-toe axis;
- along the head-to-toe axis, measure maximum wound length, measure width at its widest point, regardless of angle to each other; and
- irrespective of axis, measure maximum wound length and maximum wound width regardless of angle to each other (Bryant et al., 2001; Langemo et al., 2008).

Once the length and width of the wound are determined, the area can be calculated using one of two formulas. Using the formula, area = length x width, assumes a rectangular or square shape to the wound and will result in overestimation of wound

size (Ahn & Salcido, 2008; Keast et al., 2004; Majeski, 1992). In many wounds the surface area has an elliptical shape, and a formula exists for calculating the area of an ellipse (Langemo, et al., 2008). This method of calculating surface area was rejected for VAS bruise measurement as clinical experience did not support the notion that the majority of VAS bruises are elliptical in shape.

Planimetry.

Planimetry is described as the precise measurement of the plane, or flat surface area, contained within a wound tracing or outline of a wound image (Ahn & Salcido, 2008; Flanagan, 2003). This broad definition has resulted in a number of diverse wound measurement methods which fall under the umbrella term planimetry. Measurement of the WSA using planimetry involves two phases.

Phase one involves the delineation of the wound perimeter; this can be done either directly or indirectly. Direct measurement is often described as the tracing method. This involves placing an acetate sheet or flexible transparent film directly on the wound. A fine-tipped indelible marker is then used to outline the wound edge. This fairly straightforward approach has been used in practice for many years. Wunderlich, Peters, Armstrong and Lavery (2000) state that this technique was first identified in 1916. Disadvantages of placing a film over the wound bed include; potential for contamination of the wound, disruption of granulation tissue and potential distortion of the wound perimeter with transparency contact and pressure exerted during tracing (Keast et al., 2004; Krouskop et al., 2002). While measurement of a bruise, where the skin is intact, will not present the same concerns of contamination and wound disruption, there may be

potential for distortion of bruise perimeter as the bruises often cover curved body surfaces.

Indirect measurement involves the use of cameras or video equipment (Langemo et al., 1998; Thawer, Houghton, Woodbury, Keast, & Campbell, 2002). Due to the complexity and cost involved in these techniques this method was not considered a viable alternative to direct measurement of the bruise perimeter.

Phase two of planimetry involves calculation of the WSA. Manual calculation involves placing the wound tracing over graph paper and counting the number of squares contained within the wound perimeter. Using smaller grid squares, millimeters versus centimeters, will produce a more precise measure of WSA and would be useful in small wounds (Langemo et al., 1998). Discrepancies in WSA calculations were found when observers differed in their decisions about whether to include or exclude squares that were only partially within the tracing field (Bryant et al., 2001; Richard, Daures, Parer-Richard, Vannereau, & Boulot, 2000). Richard et al., (2000) suggest including all partial squares at a rate of 45% (0.45) of the full square area. The manual counting technique has been described by some as tedious and time consuming (Majeski, 1992; Richard et al., 2000).

Handheld devices, sometimes referred to as digitizers, or digital planimetry, automatically calculates surface area of a traced area and has partially eliminated the need for manual calculation of surface area. Unfortunately the use of digital planimetry, with the automatic calculation of surface area, is limited by the size of the digital pad (14 cm x 14 cm) (Flanagan, 2003; Goldman & Salcido, 2002; Sugama et al., 2007). Clinical

experience and pilot study data by the author indicated that the size of some VAS bruises would not be accommodated by the upper size limit of the digital planimetry device.

Reliability of Measurement Tools

Streiner and Norman (2003) refer to reliability as a "fundamental way to reflect the amount of error, random and systematic, inherent in any measurement" (p. 126). Random error is a reflection of 'noise' within the measurement, whereas systematic error refers to the accuracy or precision of the measurement tool (DeVon et al., 2007; McDowell, 2006). One component of reliability is how consistently the tool performs across patients, observers and time (McDowell, 2006). Measures of reliability reported in the wound measurement literature include; a) inter-rater reliability, the level of agreement between different observers using the same measurement tool; b) intra-rater reliability, the level of agreement within the same observer when the tool is used at least twice; and c) test-retest reliability, the level of agreement when the tool is used at two different times (McDowell, 2006; Streiner & Norman, 2003). The inter-rater reliability of the WSA measurement tools was the focus for consideration when searching for a VAS bruise measurement tool. The intraclass correlation coefficient (ICC) and Pearson's correlation are the two most commonly reported statistics in reliability studies of wound measurement tools.

The Pearson's correlation coefficient represents the level of association between two measurements; it does not reflect absolute agreement between two measures. For example, with inter-rater reliability one rater may consistently over estimate WSA. If the raters are consistent in their measures, the Pearson's correlation between raters (inter-

rater reliability) will be high; however, this does not necessarily reflect agreement between the raters. The statistical calculation of the ICC accounts for differences between raters and is therefore the preferred statistic to measure reliability of this type of tool (Karanicolas et al., 2009; McDowell, 2006; Streiner & Norman, 2008). Thawer et al., (2002) are very clear in stating that the ICC "reflects both the degree of correspondence and agreement among two measurement techniques, assessors, or ratings" (p. 49). The inter-rater reliability of a measurement tool for wound surface area needs to reflect both consistency and agreement between raters; therefore, the preferred measure of reliability is the ICC. There is no standard regarding the required reliability level of a measurement tool, although some authors suggest that an ICC of .75 – 1.00 be considered excellent, .40 – .74 modest, and .00 – .39 poor (Sugama et al., 2007; Thawer et al., 2002). Given that the WSA measurement is an objective measure, one would expect the reliability measures to be excellent.

Reliability of linear measurement.

One study was found which exclusively examined inter-rater reliability of WSA using the linear measurement technique. Bryant et al., (2001) examined the inter-rater reliability of 16 raters by having them measure 6 different imitation wounds on a prosthetic leg, using three different linear methods 1) clockwise, 2) perpendicular, and 3) their usual method. The largest wound size was $12cm^2$ (3 cm x 4 cm). Each measurement was taken two weeks apart by raters who were considered experts in wound care. The ICC for the clockwise method (.682) and the raters' usual method (.699) were both considered acceptable. However the ICC for the perpendicular method was superior

with an ICC of .962. This indicates that the perpendicular method of linear measurement is more reliable, with 4% of the variance between raters explained by error. The authors concluded the preferred method of linear measurement was the perpendicular method.

Reliability - linear measurement and planimetry.

Some reliability studies of wound measurement examined multiple measurement techniques simultaneously. Langemo et al. (1998) had 66 non-expert raters measure three uniquely shaped plaster of Paris wound models using four different methods including linear measurement (perpendicular method), and three types of planimetry. Planimetry included direct measurement with tracing and manual area calculation (full squares only) and two forms of digital planimetry. Each model was measured twice and the average measurement was used for reliability calculations. Langemo et al. (1998) examined inter-rater reliability and reported high inter-rater reliability (ICC .98 – .99) for all methods when the mean rating was used. However when a single rating was used the inter-rater reliability decreased for both linear planimetry and planimetry (ICC .30), as compared to the inter-rater reliability for the two forms of digital planimetry (ICC .53 - .87). Multiple measures using the same tool should result in improved reliability as the degree of error is minimized when a tool is administered multiple times (Streiner & Norman, 2003). The authors concluded that computerized digital planimetry is the most reliable method when a single measurement is used. While these results do not support the reliability of linear measurement or basic planimetry, Langemo et al., (1998) comment that some raters did not follow specific instructions regarding either planimetry or linear measurement. Raters did not consistently follow written instruction regarding

determining length and width measures specific to the perpendicular method of linear measurement. As well, some raters counted partial as well as full squares and either deliberately or randomly placed the transparency grid over the wound which would impact the calculated surface area. Langemo et al., (1998) comment that "grid placement can lead to about a 5 square difference in area" (p. 342). The authors also examined intra-rater reliability using Pearson's correlations and found that intra-rater correlation with linear measurement also varied widely (.48 – .68) based on wound shape, the lowest correlations occurring in the wound that was L shaped. The authors concluded that wound shape could significantly affect the reliability of measurement tools (Langemo et al., 1998).

A similar study testing the reliability of both linear measurement and planimetry had three raters create two tracings of venous stasis ulcers on the lower leg that were no larger than 4 x 5 cm^2 (Majeske, 1992). One rater traced 34 wounds and the remaining two raters each traced 18 wounds. All tracings occurred on the same day and each rater calculated wound area using a) linear measurement (method not defined), b) planimetry with manual calculation (full squares), and c) two different types of digital planimetry. The authors reported high inter-rater and intra-rater reliabilities with ICC of .97 – .99 across all methods. These findings suggest that each of the four techniques is equally reliable in wound area calculation.

Limitations.

Overall, the reliability studies of wound measurement tools describe excellent intra and inter-rater reliabilities for various methods of WSA calculation (Bryant et al.,

2001; Sugama et al., 2007; Majeski, 1992). There are however, limitations to these reliability studies. As pointed out by Wunderlich et al. (2000), the overall reliability of tracing and digital planimetry has been confirmed, however "the methods by which these techniques have been studied are quite inconsistent" (p. 92). Inconsistent definitions and descriptions of the measurement techniques result in limitations in the interpretation of reliability as well as reproducibility of these results in research and clinical practice.

There exist a variety of approaches to statistical measurement and reporting of reliability. Although ICC is the preferred method of analysis and reporting, some authors report Pearson's correlation coefficient; others give inadequate description of the statistical analysis (Haghpanah et al., 2006; Majeski, 1992; Oien et al., 2002; Streiner & Norman, 2003; Sugama et al., 2007; Thomas & Wysocki, 1990). This creates difficulty when comparing results across studies.

Lastly, none of the reliability studies examined included a sample size calculation or considerations when determining the number of raters or the number of wounds to be measured. Finally, a clear limitation is the scarcity of reliability studies which examine linear measurement as a technique. Although there are deficiencies in the psychometric properties of WSA measurement tools, the research that has been done can be informative when choosing a measurement technique for VAS bruise size.

VAS Bruise Measurement Tool Development

There is no standard method for measuring bruise size as a VAS complication. In order to perform research related to VAS bruising a reliable measurement tool is required. A review of the wound care literature has identified two general methods of

surface area measurement which may be applicable to VAS bruise measurement; linear measurement and planimetry. Streiner and Norman (2008) emphasize that a measurement tool needs to be assessed for reliability when it is used on a population other than those for whom it was originally developed.

Requirements for VAS Bruise Measurement Tool

As stated previously, a tool for measuring VAS bruise size would need to be practical for use, given the size and location of bruising (femoral or radial artery site). The tool would need to measure an irregularly shaped surface area of tissue discoloration around body contours. Acknowledging the number of patients undergoing these procedures and the timing of VAS bruise development, a tool that is reliable for patient use without excessive training would be ideal. Two methods of measuring surface area from the wound care literature were considered viable for patient self measurement of VAS bruise size.

Bruise Measurement Tools – Two Alternatives

Linear measurement and planimetry, with tracing and manual counting of squares, are both feasible VAS bruise measurement options, each method having unique strengths and limitations.

Linear measurement calculates surface area based on maximal length and width measurements. The resulting surface area assumes the shape of a rectangle. This estimation has been shown to overestimate wound surface area in comparison to planimetry (Keast et al., 2004; Oien et al., 2002). Specific instructions regarding the preferred method of linear measurement, the perpendicular method, are essential if linear

measurement is used. Linear measurement however has clear advantages in terms of time and technology requirements to complete the assessment. Linear measurement should be considered a potential technique for bruise measurement in clinical research.

Planimetry can range from simple and cost efficient with manual counting, to complex and expensive, with digital calculations and computer requirements. Digital planimetry with direct measurement (tracing) and the use of a hand-held digital planimetry device would be ideal as it performs automatic calculation of area, decreasing the time and subjectivity associated with manual counting of squares (Shaw, Hughes, Lagan, Bell, & Stevenson, 2007; Majeski, 1992). However, the use of hand-held devices for calculating surface area is hindered by the size of the tracing pad. Specific instructions regarding the placement of the tracing over the grid paper, and the inclusion or exclusion of partial squares, are essential if manual counting of squares is used. Planimetry with manual calculation, or counting of squares, is a viable option for the calculation of VAS bruise surface area. Regardless which of these two methods of measurement is utilized, the measurement tool will need to be assessed for reliability for use in VAS bruise size measurement (Streiner & Norman, 2008).

In conclusion, VAS bruising is a common occurrence that generally appears several days following CATH or PCI. Minimal research has been done examining VAS bruising and the impact and related concerns of patients related to VAS bruising is unknown. There is some evidence to suggest that VAS bruising may lead to increased use of health care resources and possible early discontinuation of proven medical therapy, and therefore may not be as innocuous as thought by health care professionals. Lack of a

reliable VAS bruise measurement tool and standardized definitions of bruising and hematoma in the literature has hindered clinical research into VAS bruising. Linear measurement and planimetry, two reliable methods of WSA measurement may be useful in the measurement of VAS bruise size. Chapter three will provide the details of both the reliability study and the qualitative descriptive study examining VAS bruising.

Chapter Three - Methods

Study Design

As previously described, this study used an embedded mixed methods design in order to address the proposed research questions (Creswell & Plano Clark, 2007). The primary study was a measurement study, examining the inter-rater reliability to two different VAS bruise measurement tools. Embedded within the measurement study was a qualitative descriptive study which examined the impact and concerns of participants who developed VAS bruising. Participant selection and data collection for both components of this study occurred simultaneously. Data analysis for the measurement study occurred following participant recruitment and VAS bruise measurement was completed. Analysis of the qualitative data commenced following the first patient interview and progressed in an iterative fashion, in keeping with conventional content analysis (Hsieh & Shannon, 2005). These methods will be described in detail in this chapter.

Setting

Hamilton Health Sciences Corporation (HHSC) is a major tertiary care center which provides invasive cardiovascular testing (CATH and PCI) for persons living within the Hamilton Niagara Haldimand Brant Local Health Integration Network (LHIN 4). The Heart Investigation Unit (HIU) provides CATH and PCI services to patients from 16 referring hospitals within LHIN 4. Over 7,000 procedures were completed in the HIU in 2008/2009.

Participants were recruited either prior to or following their procedure. All bruise measurement appointments were conducted following CATH or PCI in either a private outpatient examination room, or in one case, an inpatient hospital room. Participant interviews were conducted following completion of bruise measurements.

Population

Inclusion/Exclusion Criteria

All patients undergoing CATH or PCI using either the femoral or radial artery were potential participants for this study. However, due to the study requirement of a return hospital visit, only patients living within Hamilton and the surrounding communities were approached for participation in the study.

Participants were excluded if they a) were not clinically stable following the procedure (e.g., requiring inotropic support), b) were booked for urgent coronary artery bypass surgery, c) were expected to remain in hospital for an extended period, d) did not speak and read English, e) had language or mental impairments (e.g., aphasia), f) did not have access to a telephone, or g) were unable to return to the hospital for VAS bruise measurement.

Ethics Approval

Study protocols were submitted and approved by the Joint Research Ethics Board of McMaster University and Hamilton Health Sciences. The study approval letters are included (Appendix B) as is the participant consent form for this study (Appendix C).

Participant Recruitment

In a previous pilot study at HHS, 68% of patients developed some degree of bruising at their VAS five to seven days following CATH or PCI (Cosman et al., 2011). With over 500 CATH or PCI procedures carried out per month in the HIU, it was estimated that recruitment could be completed within 15 to 20 weeks. However a large number of patients were either not eligible, or were unwilling to participate in the study due to the required return visit for bruise measurement. The initial strategy for participant recruitment involved recruiting patients either prior to or following their procedure in the HIU. Following REB amendment and approval participants were recruited to take part in this study through three different avenues, described as follows.

Heart investigation unit.

i) Participants living within the Hamilton region were recruited in the HIU either prior to or following their cardiac procedure. Nurses within the patients' circle of care, but at arms length from the study, obtained permission from the patient to have either the RA or PI speak to the patient to a) determine study eligibility and b) fully explain the study. If acceptable to the patient, the RA or PI obtained consent for study participation (Appendix C). Consenting participants were contacted by telephone two to four days following their procedure. Participants who reported a bruise at their VAS returned to the hospital 3 to 11 days after their procedure for bruise measurement. Participant interviews, if conducted, were completed following bruise measurement.

ii) It was postulated that potential participants who initially declined participation in the study may later choose to participate if they developed a VAS bruise following

discharge from the HIU. A flyer describing the study and providing the name of the PI and telephone contact number was given to eligible patients who declined study enrollment while in the HIU (Appendix D). If an individual was interested in participating in the study after he/she returned home they could contact the PI to arrange outpatient bruise measurement.

Percutaneous coronary intervention follow-up clinic.

iii) A post-PCI clinic was created at HHSC following the initiation of this research study. Conversations with the Nurse Clinicians working in the clinic revealed that the majority of this population presented with VAS bruising when seen in clinic seven to ten days following PCI. These potential participants were not being captured in the HIU as they may have been clinically unstable pre-procedure, and post procedure would have been taken directly to the Coronary Care Unit. Standard practice was for the Nurse Clinicians to see these patients in hospital and book a post-PCI clinic appointment prior to discharge from the hospital. The Nurse Clinicians provided participants with a study information sheet (Appendix D) prior to discharge and obtained permission from the patient to have either the RA or PI speak to the patient to a) determine study eligibility and b) explain the study. If acceptable to the patient, the RA or PI fully explained the study and obtained consent for study participation following post-PCI clinic visit. Bruise measurement and participant interview, as appropriate, were completed following post-PCI clinic visit.

All participants consenting to this study were made aware that they would be required to return to the hospital for follow up VAS bruise measurement. All participants

enrolled were also aware that they may be asked to take part in a patient interview following bruise measurement. Participants had the right to decline to be interviewed, even if they took part in the bruise measurement component of the study.

Remuneration

From the time of initial recruitment into this study all participants received a parking voucher to cover the cost of parking for the return visit to the hospital. Due to slower than expected recruitment, and subsequent to REB amendment and approval, participants also received remuneration in the sum of $50 to cover the approximate expense of driving up to 50 kilometers for participation in this study.

Management of Adverse Clinical Events

In the previously completed pilot study of 172 patients following CATH or PCI no participants reported complications requiring medical attention (Cosman et al., 2011). In the event that a participant arrived for bruise measurement and had a) clinical signs indicating loss of femoral/pedal pulses, b) numbness or pain in the affected extremity (leg or hand), or c) worrisome signs and symptoms at the VAS, the PI would escort the participant to the Emergency Department for further assessment.

Data Collection

Reliability Study

Sample size.

This reliability study assessed the inter-rater reliability of two VAS bruise measurement tools. The sample size is reflective of the number of bruises measured, not the number of participants enrolled in the study. Some participants had more than one

VAS (e.g., femoral and radial) and therefore more than one bruise measurement. When assessing the reliability of a measurement tool it is important that there is variability in the measured outcome (Streiner & Norman, 2008). In this study the cardiac procedure and location of the bruise were less important for the sample size calculation than variability in bruise size. Pilot work completed in 2005 demonstrated a range of bruise sizes as reported by the participants of the study; from < 2.5 cm^2 to >7.5 cm^2 (Cosman et al., 2011).

The calculation of sample size for reliability studies is based on an estimate of the reliability coefficient of the measurement tool (Streiner & Norman, 2008). The planned statistical analysis, and sample size calculation, was based on using the ICC to determine the reliability of each measurement tool. To compute the required sample size an estimate of the likely ICC was hypothesized as well as the likely standard error (or confidence interval). Sample size calculation was dependent upon three factors the hypothesized reliability, the standard error, and the number of raters (Streiner & Norman, 2008). The number of raters for this study was based on generalizability and feasibility as outlined by Karanicolas et al. (2009). Having raters that were representative of those who would use the instrument in research and practice required at least one professional rater along with the participant rater. The feasibility of performing multiple measures on human subjects also limits the number of raters and negates the option of performing test-retest reliability in this study. For these reasons three raters were used in this study.

The primary objective of this study was to determine the most reliable measurement tool for nurses or other health professionals to use in measuring VAS

bruises. A secondary objective was to determine which measurement tool was most reliable when patients themselves, or family members, measure VAS bruise size. In regard to the primary objective, there were two professional raters, the PI and RA. It was hypothesized that there would be high agreement between these two raters. An estimated reliability of .90 with a standard error of 0.05 was used in calculating sample size. Using these data, the required sample size was approximately 30 bruise measurements to assess reliability between the professional raters (Streiner & Norman, 2008). In regard to the secondary objective, there were three raters; two professionals (PI and RA) and one participant. It was hypothesized that the reliability between participants and professional raters would be lower than between professional raters alone. Therefore a reliability coefficient of .80 and a standard error of 0.05 were hypothesized when measurement involved the participant. Using these data, the required sample size was approximately 42 bruise measurements. In order to have sufficient numbers for determination of reliability related to both study objectives, a target of 42 bruise measurements was set for the reliability study. Based on literature reporting post procedure bruising rates between 41% and 68%, it was estimated that approximately 100 participants would need to be enrolled in the study (Cosman et al., 2011; Botti et al., 1998; Robb & Mclean, 2000).

Demographics and Procedural Details

Participant demographics and procedural details were obtained either directly from the participants at the time of consent or from the participant's chart following the procedure. Demographic and procedural details were collected on a case record form created for each participant (Appendix E).

Instruments

Linear measurement and planimetry were the two methods used to measure VAS bruise size in this study. Each of these methods was modified to accommodate the unique characteristics of VAS bruise measurement. Written instructions, specific for femoral and radial VAS, provided to the participants instructed them to a) remove any bandages at the VAS, b) measure purple/blue discoloration only, and c) place a towel or sheet in line with their inner thigh to provide privacy during femoral VAS bruise measurement (Appendix F, G). Bruising that was concealed by the towel with femoral VAS, was not to be measured. The decision to discount bruising occurring in the pubic region may hamper the accuracy of bruise measurement; however it was deemed necessary in order to maintain participant privacy, minimize potential embarrassment for participants and enhance ease of bruise measurement for both participant and professional raters.

Linear measurement.

Linear measurement involved using a measuring tape and directly measuring the length and width of the bruise. Research has demonstrated the perpendicular method of linear measurement as the most reliable (Bryant, Brooks, Schmidt, & Mostow, 2001). The perpendicular method involves measuring the maximum bruise length, irrespective of axis, and measuring the bruise width at its widest point, perpendicular to length (Langemo et al., 2008). Therefore the instructions provided to the participants were written such that the participant would measure bruise length and width using the

perpendicular method. The perpendicular method of bruise measurement was used by both APN and RA when completing linear measurement.

Planimetry.

The second bruise measurement method involved placing a sheet of acetate directly over the VAS bruise. A permanent black marker was used to trace the outline of the bruised area. As with linear measurement, bruising concealed by towel placement was not included in the tracing and therefore was not part of the bruise measurement. If participants were unable to trace the full extent of their VAS bruise on a single transparency sheet, two transparency sheets were taped together. Participants were not asked to calculate bruise surface area using either measurement method.

In order to calculate the surface area of the tracings generated by the three raters it was necessary to manually count the number of square centimeters contained within the perimeter of each tracing (Richard et al., 2000). Manual counting was completed independently by both the PI and RA for all tracings. The graph paper used for manual counting of squares was the same size as the acetate (8.5 inches x 11inches) with a grid in square centimeters on the paper. In order to minimize subjectivity with placement of the graph paper, it was consistently placed in line with the corners of the acetate tracing prior to counting. The number of complete square centimeters within the tracing perimeter was recorded as FULL. In addition, any squares that were more than 50% within the tracing perimeter were counted as a partial square. The number of FULL and PARTIAL squares counted for each tracing was entered into the database and used in the final calculation of the bruise surface area.

Bruise Measurement

Participants who returned to hospital for bruise measurement were met by the PI and RA and taken to a private examination room for bruise measurement. If the participant arrived with a family member or individual to assist with bruise measurement they were encouraged to assist as needed. Assistance was recorded on the case record form (Appendix E). Written instructions with diagrams, specific for femoral or radial VAS, were given to the participant (Appendix F, G). Participants were supplied with all necessary equipment to complete both methods of bruise measurement including; instruction sheet, pen, one to two sheets of 8.5 inches x 11 inches acetate for tracing, permanent black marker, flexible plastic measuring tape (centimeters and inches on opposite sides), towel or sheet to ensure modesty with bruise measurement, bruise measurement questionnaire and opaque envelope. The instruction sheet, tracing acetate, bruise measurement questionnaire and envelope were all labeled with the participant identification number (ID) and the letters PT. Participants were asked to write the linear measurement results on the instruction sheet and insert the tracing and instruction sheet into the opaque letter size envelope once completed. Participants were asked to complete the bruise measurement questionnaire following bruise measurement (Appendix H). Bruise measurements were completed without the assistance of the PI or RA. The PI and RA left the examination room to allow the participant, with or without assistance from family member, to complete the bruise measurement in privacy.

Once the participant completed the measurements the PI and RA returned to the examination room. The RA then completed both methods of bruise measurement.

Linear measurement results and tracings were recorded independent of participant results and were placed in an opaque envelope identified by the participant ID number and the letters RA (research assistant).

Following RA measurements the PI then completed VAS bruise measurements using both methods. Linear measurement results and tracings were recorded independent of participant and RA results and were placed in an opaque envelope identified by the participant ID number and the letters PI (principal investigator). The PI and RA remained blinded to both the participant and each other's measurements.

Following all bruise measurements the PI examined the VAS for any indication of vascular compromise. Peripheral arterial circulation was assessed and femoral VAS was assessed for the presence of a bruit.

All demographic and procedural data entry were completed by the RA. A third, independent research coordinator, not directly involved with this study, entered the measurement data for both linear measurement and planimetry. A data audit was performed by the RA following all demographic, procedural and measurement data entry. All measurement data (100%) were checked for accuracy of data entry. Random selections of 20% of the participants' demographic and procedural data were checked for accuracy of data entry.

Bruise Measurement Questionnaire

In order to determine the ease of use of each of these methods of bruise measurement by the participants, a short questionnaire was developed (Appendix H). This short two page questionnaire used a five point Likert scale to examine a) participant

understanding of the measurement instructions and b) ease of each method of bruise measurement. Participants were also asked their preference for either linear measurement or planimetry as a method of measuring VAS bruise size.

Qualitative Description

Sample size.

The participants in the qualitative study were purposively selected from those who took part in the measurement study. Sandelowski (2000) recommends maximum variation sampling to gather narrative data from a range of participants. In order to attain maximum variation in the sample of participants interviewed, the PI kept a log which identified interview participants in terms of their demographics, VAS and extent of bruising (Appendix I). Participants in the measurement study were asked to take part in the qualitative study following bruise measurement if the PI felt they met the following criteria a) would be able to provide a rich description of their experience; b) provided some variability in terms of the range of participants related to age, gender, VAS and bruise size; and c) there was adequate time to properly engage the participant in a meaningful dialogue regarding their VAS bruise.

Sample size for the qualitative descriptive study was not specified a priori, however it was estimated that between 10 and 15 interviews would be conducted. Participant interviews continued until it was determined that data saturation had been reached (Guest, Bunce & Johnson, 2006).

Data collection - Interview guide.

All interviews were conducted by the PI in a private examination room following bruise measurement. Interviews were audio-taped and were conducted using a semi-structured interview guide (Appendix J). The focus of the interview questions was related to participant concerns related to VAS bruising and impact of VAS bruising on functional abilities or physical activities (e.g., return to work, driving). The data collection and analysis process was iterative; that is data analysis began following the first participant interview and that analysis was used to inform subsequent interview questions and probes. The interview questions evolved following analysis and discussions with one of the PI's supervisory committee members, an experienced qualitative researcher (PS) (Appendix J).

Prior to transcription, the PI reviewed all audio-tapes and erased any names or comments considered to be direct identifiers of the participants. The audio-files of participant interviews were identified only by the study ID number assigned to the participant. These files were sent to the transcriptionist via email. No one except the transcriptionist and the PI listened to the audio-taped interviews. The transcribed interview files were returned to the PI and the transcriptionist was instructed to delete any audio-tape files of the interviews. Before beginning data analysis all transcriptions were checked against the original audio-tape for accuracy by the PI. Any required corrections to the transcriptions were made by the PI.

Following each interview the PI listened thoughtfully to each interview and completed a contact summary sheet (Appendix K). The aim of this exercise was

threefold, to assist the investigator to identify particularly meaningful comments or interactions within the interview, identifying new or persistent areas of investigation, and to enrich the interview skills of the PI as a novice qualitative researcher.

An audit trail was kept by the PI. Thoughts and reflections regarding the data collection process, discussions with supervisory committee members, and decisions regarding interview questions, data analysis and coding were recorded in the audit trail. Support and guidance with the participant interviews, data analysis, and coding was provided by an experienced qualitative researcher (PS). Data collection and analysis did not bring to light any new themes following the eighth interview. Discussion with the qualitative methods expert resulted in the suggestion that concentration be placed on completing interviews that increased the variation of the sample, specifically to interview male participants and those having radial access sites. Data collection was concluded following the tenth participant interview.

Data Analysis

This section will provide a brief overview of the data analysis procedures utilized in this study. Detailed description of the analysis procedures and their rationale will be provided along with the study results in chapter four.

Measurement Study

Demographics and Procedural Details

All data analyses were conducted using SPSS statistical software (17.0). Descriptive analysis, including means, standard deviations and frequency distributions, as appropriate, were conducted on demographic and procedural data (e.g., age, sex,

procedure completed, access site, sheath size), of the entire sample. In addition, a comparison between participants who developed bruising versus those who did not report bruising was undertaken. Demographic and procedural details were compared between groups using the t-test and Chi square statistic as appropriate. Details specific to the bruise measurement group were also assessed.

Reliability Statistics

Calculation of bruise surface area for both linear measurement and planimetry was completed using SPSS software. Bruise surface area of linear measurement was calculated by creating a new variable in SPSS and using the formula length multiplied by width (L x W) (Appendix A). Bruise surface area of planimetry was calculated by creating a new variable in SPSS, and using the formula FULL squares plus PARTIAL squares multiplied by 0.5 (FULL + (PARTIAL x 0.5)) (Appendix A).

Analysis of inter-rater reliability for linear measurement and planimetry was done using the ICC, two way random effects model looking for absolute agreement (Karanicolas et al., 2009; McGraw & Wong, 1996; Streiner & Norman, 2008). This statistical analysis of inter-rater reliability looks not only at correlation between measures but also at agreement between raters (Karanicolas et al., 2009; McGraw & Wong, 1996; Streiner & Norman, 2008). Calculation of the ICC for planimetry involved a two step process. Step one involved calculating the ICC between PI and RA for planimetry measures for each individual tracing. It was hypothesized that there would be a high correlation (ICC > .90) between PI and RA planimetry measures. In step two, given a

high correlation between professional raters, the calculation of ICC between participant, PI and RA planimetry measures was undertaken using the PI planimetry measures.

Two participants were unable to complete linear measurement and three participants were unable to complete the bruise tracings (planimetry), these data were excluded from the original analysis. Secondary analysis of the ICC was undertaken following imputation for the missing data. Missing data were imputed with the mean bruise size for participants matched for sex, vascular access site (femoral or radial), procedure completed, and age (mean ± SD).

Bruise Measurement Questionnaire

Descriptive statistics including; mean, standard deviation and range for each item on the questionnaire was conducted. Narrative comments by participants relating to difficulties with each particular method, and preference for measurement method, were categorized by similar related themes for reporting. Direct quotes of participant comments were used to highlight the strengths and limitations of each method of measuring VAS bruising.

Qualitative Description

Conventional content analysis, as described by Hsieh and Shannon (2005) was the specific method of content analysis used to examine the interview data in this study. Content analysis takes a large volume of narrative data and condenses it to a manageable number of themes and exemplars from the actual data. This is the least interpretive of the many techniques available for qualitative analysis and is grounded in the data. Content analysis is the method of choice for analysis when little known about the phenomenon of

interest; there are no predefined codes and the codes and themes are developed from, and grounded in, the data (Hsieh & Shannon, 2005; Sandelowski, 2000). There were no predetermined codes identified prior to the first interview in this study.

Following transcription of the interviews and checking for accuracy of transcription, the coding of the narrative data was begun by the PI. Coding of interviews was completed as described by Hsieh & Shannon (2005) and Miles and Huberman (1994). Initial codes were developed following the first participant interview. The transcripts were read a second, third and occasionally a fourth time to identify general topics within the narrative data. Narrative segments of the transcripts that identified a specific idea or concept were highlighted, and a code (word or phrase) was developed to identify the idea or concept. Initial codes were reviewed and discussed with the experienced qualitative researcher (PS). Consensus was obtained regarding the initial codes before proceeding with further data analysis. Subsequent to the first interview and discussion with PS, contact summaries (Appendix K), as described by Miles and Huberman (1994) were completed following each interview. Word files were created for each code developed in the process of qualitative data analysis. Coded segments from within the narrative data were copied and pasted into word files specific for that code. It was possible for narrative data elements to be given more than one code.

Subsequent interviews and ongoing data analysis utilized the constant comparison method of data analysis (Hsieh & Shannon, 2005; Thorne, 2000). Interviews were coded and compared to the initial codes for new ideas/thoughts within the transcripts. New codes were developed as new themes emerged from the data. Four further meetings were

held between the PI and PS to discuss and come to consensus on a) the interview guide questions and prompts, b) code development and definitions of the coded segments, c) combining, splitting and deleting codes, d) data saturation, and e) themes emerging from the data.

Chapter Four – Results

This chapter presents the results of the study in four distinct sections. The first section focuses on the results of the reliability study. Descriptive statistics regarding the participants and procedural details, including details related to timing and assistance with bruise measurement, are described. Comparison of the demographic and procedural details between participants who developed VAS bruising, versus those who did not, is also reported. The results of the reliability analysis, including all secondary analyses, are reviewed.

The second section of this chapter summarizes the results of the participant questionnaire that was administered following bruise measurement. Descriptive statistics were used to illustrate participant ease of use of both methods of bruise measurement. Participant comments are discussed further in chapter five.

The third section of this chapter provides the results of the embedded qualitative, descriptive study. Major themes and sub-themes emerging from the data are outlined, along with participant narratives as exemplars.

The final section of this chapter will addresses the mixed methods question which focused on the relationship between VAS bruise size, its impact, and the concerns of participants related to bruising.

Reliability Study

Study Enrollment

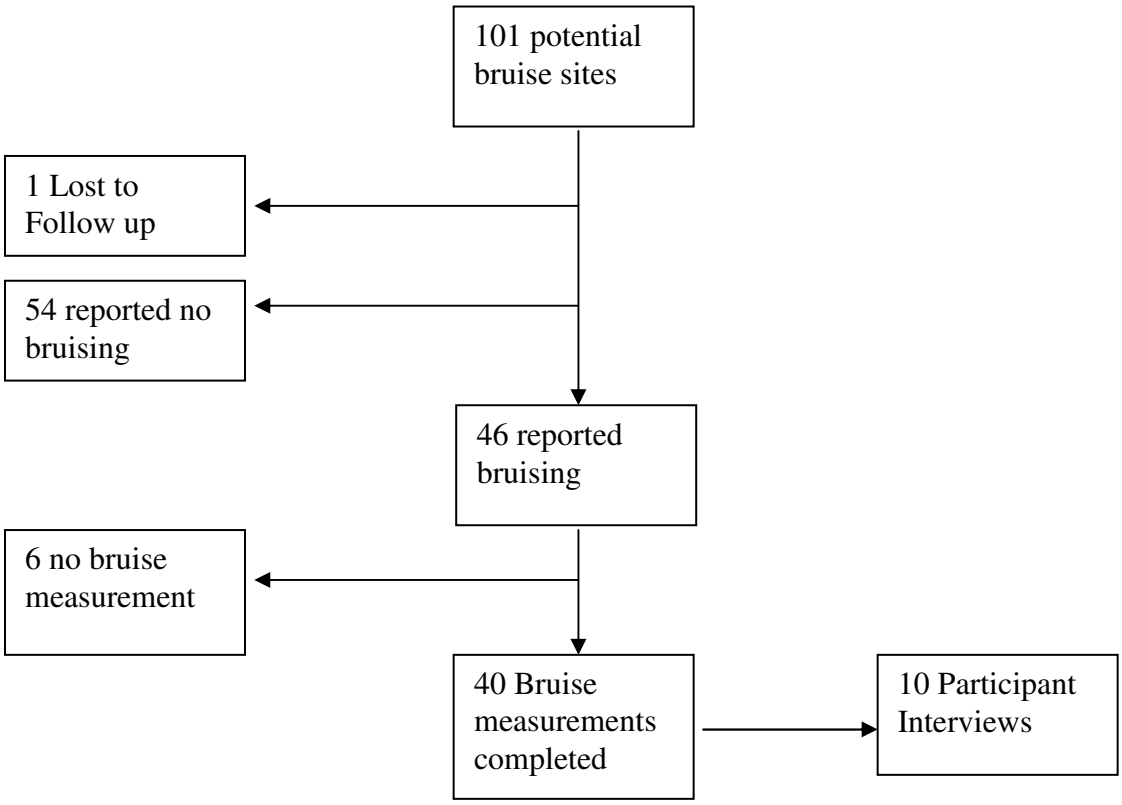
A convenience sample of participants was recruited and followed up between November 2009 and June 2010. Participants were recruited in the HIU, prior to and

following their procedure, as well as in the post PCI clinic. Ninety five participants were enrolled in the HIU and four participants were enrolled through the post PCI clinic. In total 99 participants were enrolled in this study. Two participants each had two sites for vascular access, resulting in a total of 101 potential vascular access bruise sites. One participant was lost to follow-up and 54 participants reported no VAS bruising at the time of telephone contact. Six participants either declined to return for follow up bruise measurement or did not present for bruise measurement at their booked follow up appointment. Forty VAS bruise measurements were completed (Figure 1).

Study recruitment ceased prior to completing the target of 42 bruise measurements. This study required the availability of both the PI and RA to complete bruise measurements. Due to scheduling challenges, coordinating availability of both professional raters, combined with slow study recruitment, recruitment for the study closed prior to reaching the study target of 42 bruise measurements.

When the data were audited by the PI it was noted that some of the participant's linear measurement numbers were much smaller than the linear measures of both the research assistant and the principal investigator. A detailed review of each case record form and tracing outlines revealed that six participants recorded linear measurements using inches, not centimeters as instructed. This data collection error was rectified prior to data analysis.

Figure 1. Participant Flow



Participant Demographics and Procedural Details

Prior to analysis all demographic and procedural data were examined for normality of the distributions. The original source data were checked for accuracy and to identify any results that appeared to be outliers (e.g., age > or < mean ± 2 SD).

Participant characteristics and procedural details are summarized in Table 1. The sample included 70 males and 31 females with a mean age of 62.5 years. The mean body mass index of the sample was 29.4, with more than half of the participants having cardiac catheterization (53.5%). Most of the procedures were done using the right femoral

approach (61.4%), with the majority completed using a size 6 French sheath (98%). A small proportion of participants received a femoral closure device (5.9%). At the time of telephone contact 46 (45.5%) participants reported a VAS bruise.

Table 1. Participant Demographics and Procedural Details

Variable		N	%
		101	
Age (mean ± SD)	62.5 ± 10.3		
Body Mass Index (mean ± SD)	29.4 ± 5.2		
Sex			
Male		70	69.3
Female		31	30.7
Level of Education			
< grade 8		9	8.9
Completed grade 8		27	26.7
Completed high school		28	27.7
Completed College/University		36	35.6
Completed Graduate Education		1	1.0
Procedure Completed			
Cardiac Catheterization		54	53.5
Percutaneous Coronary Intervention		45	44.6
Left and Right Heart Catheterization		2	2.0
Vascular Access Location			
Right Femoral		62	61.4
Left Femoral		6	5.9
Right Radial		32	31.7
Left Radial		1	1.0
Sheath Size			
6 French		99	98.0
5 French		2	2.0
Closure Device used			
No		95	94.1
Yes		6	5.9
Bruise Present at telephone contact			
Yes		46	45.6
No		54	53.5
Unknown		1	1.0

Bruise measurements were completed on all participants between 3 to 11 days post-procedure. The mean number of days to bruise measurement was 6.2 days, with a standard deviation of 1.5 days. The majority of bruise measurements were completed on day six post procedure (n = 17; 42.5%). The original intent was to complete bruise measurements between three and ten days. One participant, having agreed to participate in the study, arrived in the post PCI clinic 11 days post procedure with a radial VAS bruise and was included in the study. Self measurement was completed by 29 participants (72.5%); the remainder received assistance with bruise measurement from a family member or individual who accompanied the participant to the follow up appointment.

Demographic and Procedural Comparison Between Groups

This study was not a RCT; however it was felt that a comparison of demographic and procedural details between those participants who developed VAS bruising and those who did not would be useful in order to assess the generalizability of the sample and to identify possible factors associated with the development of a bruise versus no bruise. The Chi Square statistic was used to compare the bruise and no bruise groups on ordinal and nominal level variables including gender, procedure type, sheath size, vascular access location, level of education, and the use of closure devices. The independent T test was used to compare the bruise and no bruise groups for the continuous data variables of age and body mass index. Table 2 provides the details of the comparison between groups.

There was a statistically significant difference between the bruise and no bruise groups in relation to the procedure completed ($p = .000$), and age ($p = .05$). These

findings indicate that a bruise is more likely to develop following PCI as compared to CATH. Younger patients were also more likely to develop a bruise compared to older patients.

Table 2. Demographic and Procedural Variables Related to Presence of VAS Bruising

Variables	Bruise n = 46	No Bruise n = 54	Unknown n = 1	**p value**
Sex				.600
Male	30	39	1	
Female	16	15		
Level of Education				.560
< grade 8	2	7		
Completed grade 8	14	12	1	
Completed high school	12	16		
Completed College/University	17	19		
Completed Graduate Education	1			
Procedure completed				**.000***
Cardiac Catheterization	22	32		
Percutaneous Coronary Intervention	24	21		
Left & Right Heart Catheterization		1	1	
Vascular Access Location				.948
Right Femoral	29	32	1	
Left Femoral	3	3		
Right Radial	14	18		
Left Radial	0	1		
Sheath Size				.295
6 French	44	54	1	
5 French	2	0		
Closure Device used				.949
Yes	3	3		
No	43	51	1	
Age				**.050***
Mean ± SD	60.1 ± 8.8	64.2 ±11.1		
Minimum – Maximum	34.2 - 76.3	35.7 - 86.7		
Body Mass Index				.260
Mean ± SD	28.9 ± 4.7	30.0 ± 5.6		
Minimum – Maximum	21.0 - 41.5	19.5 - 42.5		

***** Statistically significant

Reliability Statistics

The primary objective of this study was to determine the inter-rater reliability of two different tools for measuring VAS bruise size. Analysis of inter-rater reliability was done using the ICC, two-way random effects model, looking for absolute agreement (Karanicolas et al., 2009; McGraw & Wong, 1996; Streiner & Norman, 2008). The hypothesis of the study was that the ICC between professional raters would be high (> .90, standard error 0.05), and the ICC between professional raters and the participants would be lower (> .80, standard error 0.05).

Linear Measurement.

The final calculation of bruise surface area, based on linear measurement, was calculated in SPSS using the formula, bruise surface area = length x width (Appendix A). Descriptive analysis of the linear measurement results is presented in Table 3. The mean bruise size ranged from 155 cm^2 to 188 cm^2 with standard deviations of 253 cm^2 to 331 cm^2. The calculated ICC for linear measurements are presented in Table 4. The ICC between the PI and RA for linear measurement was .955 (95% CI = 0.92, 0.96). The ICC between PI and participant, as well as the RA and participant, was > .80. The ICC between all three raters was also high at .929 (CI = .88, .86).

Table 3. Calculated Bruise Size in Square Centimeters – Linear Measurement

Raters	Mean	SD	Minimum	Maximum
Participant bruise measurement n = 38	155	253	1	1025
PI bruise measurement n = 40	169	261	12	1152
RA bruise measurement n = 40	188	331	18	1400

Note: PI Principle Investigator; RA Research Assistant

Table 4. Intraclass Correlation Coefficients - Linear Measurement

Raters	ICC	95% Confidence Interval
PI - RA	.955	.917 - .976
PI - participant	.946	.899 - .947
RA - participant	.889	.795 - .941
PI - RA - participant	.929	.882 - .957

Note: PI Principle Investigator; RA Research Assistant

Two participants were unable to perform linear measurement and were excluded from the original analysis. Secondary analysis was performed using imputed numbers for the two participants who were unable to complete linear measurement. The mean bruise size for participants, matched for sex, vascular access site (femoral or radial), procedure

completed and age (mean ± SD) was imputed for the missing data. Table 5 shows the calculated ICC after imputation. Using the imputed measures the ICC between the PI and RA remained unchanged at .955 (95% CI = .92, .96). The ICC between PI and participant, as well as the RA and participant, was > .80. The ICC between all three raters was also high at .917 (CI = .87, .96).

Table 5. Intraclass Correlation Coefficients - Linear Measurement (imputed data)

Raters	ICC	95% Confidence Interval
PI - RA	.955	.917 - .976
PI - participant	.925	.863 - .960
RA - participant	.872	.772 - .930
PI - RA - participant	.917	.866 - .957

Note: PI Principle Investigator; RA Research Assistant

Planimetry.

Calculation of the ICC for planimetry measures involved a two step process. Step one involved calculating the ICC between PI and RA for each of the completed tracings. Table 6 shows the high degree of correlation between the PI and RA with the planimetry measures. Due to the high correlation between PI and RA planimetry measures, the PI planimetry measures were used for all further statistical analyses.

Table 6. Intraclass Correlation Coefficient – Comparison of Principle Investigator and Research Assistant Planimetry Measures

Raters	ICC	95% Confidence Interval
Participant Tracings	.913	.839 - .954
PI Tracings	.970	.945 - .989
RA Tracing	.959	.924 - .978

Note: PI Principle Investigator; RA Research Assistant

The final calculation of bruise surface area, based on planimetry, was calculated in SPSS using the formula bruise surface area = FULL squares + (PARTIAL squares x 0.5) (Appendix A). Planimetry measures were done for each tracing by both the PI and the RA. Descriptive analysis of the planimetry results, based on PI planimetry measures, is presented in Table 7. The mean bruise size ranged from 80 cm^2 to 95 cm^2 across raters, with standard deviations from 115 to 151 cm^2.

Table 7. Calculated Bruise Size in Square Centimeters - Principal Investigator Planimetry Measures

Raters	Mean	SD	Minimum	Maximum
Participant bruise measurement n = 37	80	116	0.5	433
PI bruise measurement n = 40	95	151	5	616
RA bruise measurement n = 40	80	115	6.5	477

Note: PI Principle Investigator; RA Research Assistant

Given the very high correlation between PI and RA; step two, the calculation of ICC between measurers was done using the PI planimetry measures. The calculated ICC for planimetry is presented in Table 8. The ICC between the PI and RA for planimetry was .942 (95% CI = .89, .97). The ICC between both the PI and participant, and the RA and participant pair, was > .80. The ICC between all three raters was also high at .914 (CI = .86, .95).

Table 8. Intraclass Correlation Coefficients - Principal Investigator Planimetry Measures

Raters	ICC	95% Confidence Interval
PI - RA	.942	.888 - .970
PI - participant	.877	.771 - .935
RA - participant	.925	.860 - .961
PI - RA- participant	.914	.856 - .951

Note: PI Principle Investigator; RA Research Assistant

Three participants were unable to perform planimetry and were excluded from the original analysis. Secondary analysis was performed using imputed numbers for the three participants who were unable to complete the tracing for planimetry. The mean bruise size for participants who were matched based on sex, vascular access site (femoral or radial), procedure completed and age (mean ± SD) was imputed for the missing data. Table 9 shows the calculated ICC with the imputation measures.

Table 9. Intraclass Correlation Coefficients - Planimetry (imputed data)

Raters	ICC	95% Confidence Interval
PI - RA	.942	.888 - .970
PI - participant	.848	.732 - .917
RA - participant	.887	.797 - .939
PI - RA - participant	.893	.829 - .938

Note: PI Principle Investigator, RA Research Assistant

Careful examination of the final planimetry data revealed that some bruise measurements between PI and RA had larger than expected discrepancies. These data are presented in Appendix L. Irrespective of the high inter-rater reliability between PI and RA planimetry measures, examining the raw data it is apparent that the largest measurement discrepancies occur with larger bruises.

Adverse Clinical Events

During the course of the study two participants presented with atypical symptoms related to their VAS. The first participant presented for bruise measurement following CATH via right radial approach. At the time of assessment, six days following the procedure, there were no signs of vascular compromise in the affected extremity. The participant contacted the PI by telephone 5 days later to inform me that although the bruising was receding she was experiencing increasing pain in her right arm which was causing her to wake at night. I spoke directly with the cardiologist who performed the procedure. The patient was assessed by the cardiologist who performed the procedure, including ultrasound of the radial artery, the following day.

The second participant arrived for bruise measurement following CATH via the right femoral approach with a vascular closure device. In the examination room the participant stated that she was not sure if she actually had a bruise. Prior to the participant beginning bruise measurement I examined the VAS. The patient did not have a VAS bruise; however the area was reddened, tender to touch, with a small amount of exudate. The participant also reported having warm spells in the evening. Due to the

potential of VAS infection I escorted the participant to the Emergency room for further assessment and spoke with the cardiologist who performed the procedure the following day. The participant was seen in follow up in the HIU by the cardiologist.

Radial Artery Site Bruising

While it was not the intention of this study to specifically examine radial site bruising, as a newer technique with minimal understanding of the consequences of radial artery puncture for CATH or PCI, it is worthy to comment on the findings from this study related to the radial access site and bruising. Thirty three participants (32.7%) had a radial artery access for either CATH or PCI. Fourteen of the participants having radial artery puncture reported bruising at the VAS, representing 42% of those who had a radial artery puncture. Two participants in the qualitative study had radial VAS, and reported very different experiences, from no discomfort at all, to pain in the wrist which limited the participant's ability to drive and keyboard at work. These are new insights into the concerns of patients and potential impact of radial access site bruising.

Bruise Measurement Questionnaire

This section will review the results of the participant survey conducted following bruise measurement (Appendix H). The goal of the survey was to discern a) if the instructions for each measurement method were clear, b) the ease of completing each measurement method, and c) participant preference for either linear or planimetry measurement of bruise size. Each participant completed the bruise questionnaire, resulting in 39 questionnaires completed. One participant had two VAS however only completed one questionnaire. The questionnaire used a five point Likert scale to

determine; a) the clarity of instructions from one to five, one being very easy and five being very hard, and b) the ease of measurement method from one to five, one being very easy and five being very hard. These questions were asked for both methods of VAS bruise measurement. Results of the Likert scale questions are presented in Table 10.

Table 10. Descriptive Results of Bruise Measurement Questionnaire

Questions	Mean (SD)	Mode (n)	Min	Max
Linear Measurement				
1. Clarity of instructions	1.62 (1.0)	1 (n=26)	1	5
2. Ease of measurement method	2.1 (1.4)	1 (n=18)	1	1
Planimetry				
4. Clarity of instructions	1.55 (1.0)	1 (n=27)	1	5
5. Ease of measurement method	2.42 (1.4)	1 (n=14)	1	5

Note: Questions 1, 2, 4, 5 from Bruise Measurement Questionnaire – Appendix H
Scale: 1 = very easy to 5 = very hard

Linear Measurement

Participants rated the mean ease of instructions for linear measurement at 1.62, with the majority of participants (66.6%) rating instructions as very easy. The mean score for ease of using the measuring tape was 2.1 with the majority of patients (46.2%) rating linear measurement as very easy. The third question asked if the participant had any problems using linear measurement. Twenty three participants replied to this

question as follows a) five participants replied 'No', b) two participants replied 'Yes', c) three participants commented that it would be easier with a mirror, d) four participants commented that it was easier, or would be easier, with the assistance of a second person. The remaining comments summarize the specific reasons participants gave regarding difficult bruise measurement:

ID 155 "because of the massive size of the bruise, trying to carry out a complete measurement was not quite easy";

ID 140 "large stomach hard to see";

ID 105 "unable to do because of bruise location"; and

ID 174 "bruise went around leg and I couldn't see it".

Planimetry

Participants rated the mean ease of instructions for planimetry at 1.55, with the majority of participants (71.1%) rating instructions as very easy. The mean score for ease of using the tracing method (planimetry) was 2.42 with the majority of patients (36.8%) rating planimetry as very easy. The third question asked if the participant had any problems using planimetry. Twenty-nine participants replied to this question with comments. Ten participants replied 'No', one participant commented that it would be easier with a mirror, four participants commented that it was easier, or would be easier, with the assistance of a second person, and three participants commented that it was difficult to handle the tracing sheet due to size and/or location of the bruise. The remaining comments summarize the specific reasons participants gave regarding difficult bruise measurement:

ID 174 "can't see all bruise to measure";

ID 135 "awkward as I had bruising on both sides of the arm"; and

ID 150 "it wasn't clear how to position the acetate – picture confused things".

The final question on the bruise measurement questionnaire was a check box for participants to indicate preference for either linear measurement or planimetry. Seventeen participants completed the final question. Eight participants preferred using the measuring tape, seven participants preferred doing the tracing, one participant indicated both methods, and one participant did not indicate a preference.

Qualitative Description

Study Enrollment

Following REB amendment and approval, participants recruited for the measurement portion of this study were also considered potential participants for the embedded qualitative, descriptive study. Participants were asked to take part in the interview following bruise measurement if; a) the PI felt the individual would provide a rich source of information; b) there was variability in participants in terms of age, sex, VAS, procedure completed and bruise size; and c) there was sufficient time to engage the participant in a meaningful conversation. Ten semi-structured interviews were completed between February 3rd, 2010 and June 23rd, 2010 (Figure 1). No new themes or sub-themes emerged following the eighth interview. A further two interviews were completed in an effort to include more male participants and those with radial access sites. The interviews were concluded following the tenth interview.

Participant Characteristics and Bruise Size

The interview participant characteristics are depicted in Appendix I. There were an equal number of men and women interviewed with ages ranging from 34 to 74 years. Two participants had radial access sites with the remaining participants having femoral access sites. The majority of patients underwent CATH, with three participants having PCI, one having primary PCI. Four participants had previous experience with either CATH or PCI. The bruise size identified in Appendix I was based on the participant linear measurement, and indicates a range of bruise sizes among the interviewed participants.

Major Themes

The major themes and sub-themes will be presented in this section. Each of the major themes will be described, with discussion of the component sub-themes, in turn. Analysis of the participant narrative data uncovered three major themes with several sub-themes. The three major themes identified from the participant interviews included a) concerns, b) impact, and c) mediating factors. Within each major theme several sub-themes were also identified. The major themes and sub-themes are described below with exemplars from participant interviews.

Concerns

The major theme of concerns encompasses participants' comments ranging from no concerns to comments indicating worries, anxieties, apprehension, alarm, distress and unease related to VAS bruising. My inherent biases lead to an initial notion that participant 'concerns' would be such that they might be inclined to seek and use

additional health care resources. However with further interviews, reflection, and discussions with co-supervisor (PS) I came to understand that participant concern was a larger theme that included several sub-themes. The sub-themes were evident in the participant narrative data as they commented not on their 'concerns' but general discussion regarding the development of VAS bruising. Narrative data analysis uncovered participant comments regarding body image, pain and discomfort at the VAS, surprise and shock regarding the size of the bruising and questions related to the VAS bruising. Concern as a major theme incorporates the sub-themes of a) body image, b) pain or discomfort at the VAS, c) surprise or shock, d) questions related to VAS bruising, and e) no concerns. Participant comments related to each of the sub-themes are provided below. Each participant is identified by a code indicating their study ID number, sex, access site (femoral or radial), and bruise size in square centimeters. For example 174 FF 912 indicates a female participant with a femoral access with a bruise size of 912 square centimeters.

Body image.

174 FF 912 I don't want people staring at me or looking at it, it's pretty ugly and it's so big you know it's a public pool. I guess I have some feelings about that

Pain.

138 MF 49.5 there was no pain, absolutely no pain whatsoever

157 FR 12 it was shooting up my arm at one point. I'd say, 10 being the worst I would say about 8 or 9 …it went on till about Tuesday night (5 days)

Surprise or shock.

170 FF 165 This is not just a little bruise you know … you get all … concerned that the bruising is as extensive

146 FF 49.5 Well it's ugly, it's um I was shocked. I am bruising all over the place

Questions related to VAS bruising.

138 MF 49.5 It's three separate bruises, why were the other two?
What causes a bruise? They just putting a needle in, why is it so big?

No concerns.

131 MF 39 She asks me if I was worried and I said no cause there is no real great amount pain it's there and it's noticeable but it's nothing that would send me running

These narratives indicate that although many of the participants stated they had no concerns, there may have been some degree of distress related to VAS bruising that did not reach the level of 'concern' for that individual.

Impact

As the interviews progressed the analysis of the data revealed how VAS bruising was affecting the participants in terms of impacting their daily activities. Data analysis resulted in many coded files related to how participants managed their VAS bruising. Each participant, in their unique and individual way was impacted by the VAS bruising. The impact of VAS bruising was described by many of the participants as minor, however they also described modifying their normal activities, most commonly decreasing physical activity, and using self management methods, such as icing the VAS or using pain medication. One participant went to urgent care and then sought out the family physician due to concerns about the VAS bruising. These sub-themes coalesced to form the major theme of impact. In this study 'impact' was defined as any participant description of how VAS bruising did or did not influence each individual as they carried

out their activities of daily living following CATH or PCI. The major theme of impact included four sub-themes of a) alterations in activities of daily living, b) self-management activities, c) health seeking activities, and d) minimal impact.

Alterations in activities of daily living.

> 157 FR 12 Going back to work Monday at the keyboard typing. I had to take rests cause it was starting to throb … [on] the weekend, I didn't drive because the pain was so, it was painful and I was too scared to aggravate it even more so I kinda waited til Monday
>
> 174 FF 912 I was going to go back swimming next week but I don't think I will

Self management activities.

> 170 FF 165 I did use ice on a couple of occasions and then … on the Tuesday took a Bufferin cause I was out for the evening

Health seeking activities.

> 174 FF 912 I went to a walk in clinic at that point in time and the doctor there said that you know this is normal (accentuated)

Minimal impact.

> 188 MR 108.75 No, I wasn't shocked by the bruising, I was you know, I saw it and I thought holy moly look at the bruise but I had bruises, I've had lots of bruises … so bruising and cuts and bangs don't really bother me as much as they might bother someone else but this is really nothing to me

Mediating Factors

Data analysis revealed a multitude of participant comments relating to factors which appeared to mediate how participants and family members perceived and interpreted VAS bruising. Participants described prior experience of having CATH or PCI, their expectations, both formal and informal education regarding the procedure, as well as the development and healing of the VAS bruise as influencing their concerns.

Some participants had an inaccurate understanding about the procedure and subsequent VAS bruising, and others spoke of their personal interpretations of why the bruising occurred and how it should be managed. Participants also described competing factors; such as sciatica; knee pain; or their pleasure with the outcome of CATH or PCI; the latter overshadowed the impact of VAS bruising. One participant interviewed in this study had a large radial bruise following successful PCI. This patient (ID 188 MR 108.75), identified his bruising as "the red badge of courage". With one participant the influence of an unplanned emergency procedure was found to influence concerns regarding VAS bruising.

Collapsing codes into meaningful sub-themes produced several sub-themes which described individual concerns, response to these concerns, and ultimately the impact of VAS bruising on the individual. These sub-themes were combined in the larger theme of mediating factors. Sub-themes within mediating factors included a) participant expectations, b) information sources (formal and informal), c) participant misinformation, d) participant self explanation e) prior experience, f) competing factors, g) temporal relationship of bruise development, and h) unplanned procedure.

Participant expectations.

> 138MF 49.5 I was expecting it to be much more painful but the whole procedure was not painful at all
>
> 161 FF 108.5 They (nursing staff) told me that I could bruise or could have a bruise. Didn't tell me how big or how much

Information sources.

170FF 165 I went on the internet and punch up hematoma and you know you see somebody's leg with this huge bruise but of course you can't always depend on the internet for maybe a 100% correct information

Participant misinformation.

169 MF 957 I mean it's like blood clots right? … so I was thinking, can that get to my heart? Cause we were away and a friend we were down in Florida … and a friend of ours, a guy that my son played hockey with at school, he was playing hockey and he got a bruise in his shin … and that caused it to go to the heart … and that's all it was a blood clot cause he got a bruise and I'm thinking so that this definitely had to be a lot bigger than what he had on his shin so … so I'm thinking is this going to happen to me or could it happen?

Participant self explanation.

146 FF 49.5 I think it's Placel?? …plavix and ah ah aspirin … I think that's the culprits that's doing it

Prior experience.

131 MF 39 This time around with the groin it's been more sensitive you know there's swelling there wasn't before. There is bruising more bruising more sensitivity and its just taken longer … its lasting longer, the first time around it was maybe two days until I was able to get rid of the bandaids and stuff like that

Competing factors.

186 MF 63.25 I keep walking cause I have a sore knee and I gotta make sure that that gets better

188 MR 108.75 I mean when you think of the whole procedure that I had, I couldn't care if my whole arm was black and blue … I feel so good about you know … so this doesn't bother me at all …I had a stint put in the main artery feeding my heart

Temporal relationship of bruise development.

186 MF 63.25 Initially it wasn't as big but it got bigger you know the first day it wasn't there, but the day after when I think the Friday it was there … I could see, and I didn't have any bruise and the first day after I didn't have anything it was on the second day home … that I went to change ah ah the plaster, and I saw the

> bruise and only part of it was showing above the tape and when I took it off I saw it was bigger and by the time the third day came it was quite, well it was almost as big as where it is now

Unplanned procedure.

> 169 MF 957 (spouse) things were moving along pretty fast for him on the Sunday and he was sedated, um morphine he was having so I'm not sure how much he remembered it and we were kind of just in shock

The results of the qualitative study clearly indicate that VAS bruising has the potential to cause a range of concerns and responses from patients. While some patients may carry on with life, only modestly altering their activity level, others may be concerned enough to seek out health care assistance from urgent care or their family physician. Several individualized mediating factors were identified which may serve to temper the patients concerns and impact of VAS bruising.

Mixed Methods Results

The mixed methods query of this study addressed the question of a relationship between VAS bruise size and consequent concerns and impact of VAS bruising. Ten participants with a variety of bruise sizes were interviewed and each individual had specific concerns and noted impact of VAS bruising. Tables 11 and 12 identify the range of bruise sizes and associated qualitative data findings related to the various themes and sub-themes of concern and impact. While some participants clearly stated they were concerned about their VAS bruise size many indicated they were not concerned. Despite stating they had "no concerns" these same individuals described shock, discomfort, had questions related to VAS bruise size, or concerns related to body image. The impact of VAS bruising ranged from slight alterations in activities of daily living (e.g. decreased

walking distance, more cautious getting into and out of a chair) to taking medications for pain, or seeking out health care professional consultation.

Table 11. Participant Reported Concerns in Relation to Bruise Size

Bruise Size (cm^2)	Concerns	No Concerns	Surprise/ Shock	Pain/ Discomfort	Patient Questions	Body Image
12	√			√		
39		√	√	√		
49.5		√	√	√	√	
49.5		√	√	√	√	
63.25		√	√			
108.5	√		√	√		√
108.75		√	√			
165	√		√	√	√	
912		√		√		√
957	√		√		√	

Table 12. Participant Reported Impact of Vascular Access Site Bruising - Related to Bruise Size

Bruise Size (cm^2)	minimal impact	alterations in activities of daily living	self-management activities	health seeking activities
12		√	√	
39	√	√		
49.5	√			
49.5	√	√		
63.25	√			
108.5	√		√	
108.75	√			
165	√	√	√	√
912	√	√		
957	√	√		

Conclusions

As hypothesized, the ICC for both linear measurement and manual planimetry was > .90 between professional raters, and > .80 between professional raters and participants. Results of the bruise measurement questionnaires did not clearly indicate a participant preference for linear measurement or manual planimetry. Qualitative data analysis uncovered three major themes regarding VAS bruising; participant concerns, impact of VAS bruising and mediating factors. Each major theme is composed of several

sub-themes which represent the diversity of participant concerns, impact of VAS bruising and mediating factors.

Chapter Five – Discussion

This chapter discusses the results of the reliability study as well as the qualitative descriptive study. Strengths and weaknesses of this study are addressed throughout the discussion. A comparison of how the results of the current study relate to previous studies is also undertaken. Finally, implications for future research and nursing practice will be identified.

Reliability of Vascular Access Site Bruise Measurement

This study has enhanced our knowledge regarding VAS bruising in two important and distinct ways. Primarily it has demonstrated high inter-rater reliability of both health care professional and participant VAS bruise measurement. The use of a standard, reliable method for VAS bruise measurement can increase consistency in assessment of VAS bruise size as an outcome measure and aid in the comparison of this outcome across studies. With a clear definition of bruising and a reliable measurement method, VAS bruise size can be used in both research and clinical practice as a quantifiable outcome measure. One of the overall strengths of this reliability study was the variation in bruise size, an important criterion in the establishment of reliability. A further strength of this study is how it meets most of the seven key criteria put forth by Karanicolas et al. (2009) in the design and completion of a reliability study. Specifically, this study utilized raters (patients) who would use these measurement tools in practice, the patients were typical of those who develop VAS bruising, the data was analyzed using ICC, the most suitable statistical analysis of reliability with continuous data, and the sample size was determined based on hypothesized reliability, standard error and number of raters (Streiner &

Norman, 2008). While both linear measurement and planimetry had high inter-rater reliability scores, differences in each method warrant further discussion.

Linear Measurement

As hypothesized, this study demonstrated high inter-rater reliability between professional raters (ICC > .90) as well as high inter-rater reliability between professional raters and participants (ICC > .80) with linear measurement. Secondary analysis, with imputation for missing data, did not alter the findings.

The calculation of bruise size with linear measurement assumes the bruise is rectangular in shape. Using the perpendicular method, maximum bruise length by maximum bruise width at a perpendicular angle, will inevitably result in a calculated bruise size that overestimates the size of the actual bruise. This is apparent when examining the reported mean bruise size using linear measurement (155 cm^2 to 188 cm^2) compared to planimetry (80 cm^2 to 95 cm^2) in this study. Such discrepancies are likely to be more pronounced with significantly large bruises that are irregular in shape.

A data collection error occurred with linear measurement in that participants measured bruise size in inches, not centimeters as instructed. This error may have occurred because the measuring tape provided to participants had inches on one side of the tape, and centimeters on the other side. Had this error not been identified it may have resulted in underestimation of bruise size. The opportunity for this error could be avoided in future studies, especially if measurement is conducted by participants in their home environment, by providing all participants with a measuring tape with only the unit of measure required for the study, in this case centimeters.

Planimetry

Due to the method of calculating bruise surface area with planimetry the calculation of ICC involved a two step process. The inter-rater reliability of planimetry measures between the PI and RA of all tracings was high with ICC > .90. Consequently the calculation of inter-rater reliability between tracings was completed using the PI planimetry measurements. As hypothesized, this study demonstrated high inter-rater reliability between professional raters (ICC > .90) as well as high inter-rater reliability between professional raters and participants (ICC > .80) with planimetry. Secondary analysis, with imputation for missing data, did not alter the findings.

Despite the fact that there was high inter-rater reliability between the PI and RA in planimetry measures, examination of PI and RA planimetry measures, based on counting of squares, revealed larger than expected discrepancies with large bruise sizes (Appendix L). The method of counting FULL and PARTIAL square centimeters, using a grid, is time and labor intensive, significantly so with large bruises, which may lead to fatigue during with manual counting. This can potentially lead to systematic error in the final calculation of bruise surface area. This issue became apparent in the current study when comparing planimetry measures between PI and RA of the same tracing

The calculation of bruise size using planimetry will result in a bruise surface area that is closer to the exact size of the VAS bruise; however the potential for error inherent in manually counting squares needs to be acknowledged. Alternative methods to calculate bruise surface area from tracings could be explored in future research as options to minimize this potential for error. The potential for a larger size digitizer for the

automatic calculation of bruise surface area could be explored with industry. Given the exponential growth in digital technology, it may be possible in the future to utilize this technology for a patient friendly, cost effective and reliable method of VAS bruise measurement.

Participant Preferences Between Two Methods

In terms of participant preference for linear measurement or planimetry, neither method was identified as superior by study participants. Participants found the instructions for measurement clear, with the ease of completing planimetry only slightly more difficult than linear measurement. Some participants indicated they found linear measurement easier to accomplish than tracing due to manual dexterity issues with holding a tracing film and drawing at the same time. Participant comments reflected that bruise size and location were issues which hampered bruise measurement with both methods. Several participants commented that bruise measurement would be easier if given a mirror, or with assistance from a second person. These comments support the notion that VAS bruise measurement could be carried out at home by patients and family members following CATH or PCI. Potential challenges with either method include ensuring participants understand the instructions and providing participants with appropriate measurement tools.

In summary, potential challenges related to linear measurement of VAS bruise size include, overestimation of bruise size and potential data collection error if appropriate equipment is not provided to participants. Challenges with manual planimetry measurement of VAS bruise size include increased personnel resources for

manual calculation of bruise size, as well as fatigue and potential systematic errors related to manual calculation of bruise size. With both linear measurement and planimetry some participants found it difficult to complete VAS bruise measurement due to the location of the VAS bruising or challenges related to manual dexterity. Although not apparent in this study, a potential challenge for both linear measurement and planimetry might be related to participant difficulty in visualizing the VAS bruising related to impaired vision.

Choosing a Bruise Measurement Method

Both linear measurement and planimetry offer inexpensive and reliable methods for collection of data related to VAS bruise size, and both are viable options for VAS bruise measurement. Strengths and weaknesses are inherent in each particular method. Practical advantages of linear measurement over planimetry include relatively quick calculation of bruise surface area once linear measurement completed. Planimetry may yield bruise size measurements closer to the actual bruise size, but at the cost of potential systematic errors and increased time and resources in the calculation of bruise surface area. It is essential to consider the purpose of VAS bruise measurement and the available resources prior to deciding to use either linear measurement or planimetry. For example, if conducting a RCT comparing compression techniques with sheath removal, a more exact determination of bruise size might be preferred. In contrast, if the goal was to determine the incidence and extent of VAS bruising of the current state of practice in a given clinical setting, a large scale preliminary audit using linear measurement may be preferred.

Participant Perspective of Vascular Access Site Bruising

My clinical background and experience with patients who developed VAS bruising following CATH or PCI was one component which drove the initial stimulus for this embedded qualitative study. The goal of the embedded qualitative study was to enhance our understanding and awareness of VAS bruising through exploration of participant narratives and identification of themes within patients' narratives. This is the first study of this kind to specifically explore the patient perspective of VAS bruising.

Participant narratives demonstrate that many patients did have concerns related to VAS bruising. These data, revealing the breadth of participant concerns were somewhat unexpected. I found the commonly reported surprise and shock at the extent of bruising, even from participants who had prior experience with CATH or PCI, surprising. Previous studies have indicated that participants continued to have pain or discomfort at the femoral VAS; however comments from participants with radial VAS regarding pain, which impacted their ability to work, were unanticipated.

The qualitative data identified how VAS bruising has the potential to affect patients' activities of daily living. While some participants stated VAS bruising had no impact, many went on to describe their how they had altered their normal activities. I found it intriguing that participants indicated they had no concerns, but went on to indicate they had limited their daily activity level. Although previously conducted research found that 4% of patients seek out health care professional advice regarding VAS concerns, I was surprised to find that one of the participants went to urgent care, called the family physicians office, had VAS bruise measurement with myself, and had

plans to see the family physician two days later. This participant personified how individual patients use health care resources to manage concerns related to VAS bruising. Novel and unforeseen findings were the numerous and individualized mediating factors identified by participants of this study. These factors appeared to influence the participants' concern and impact of VAS bruising. While participant expectations, prior experience, and information or knowledge of participants were expected mediating factors, there were some unpredicted findings. Of particular note was participant misinformation and self explanations regarding not only VAS bruising but their understanding of the procedure they had undergone less than a week before the interview.

The results of this qualitative study have enhanced awareness and understanding of the range of concerns, impact, and numerous mediating factors which individual patients may experience with VAS bruising.

Interviewer Bias

As the interviews progressed I made a conscious effort to remain open to the participants and explore their comments related to their VAS bruising. As a clinician involved with the overall care of this patient population I was surprised by the lack of understanding patients demonstrated regarding the procedure and the possibility of subsequent bruising. I felt the pull of clarifying misinformation during the interviews, which may have distracted me from fully probing the meaning of VAS bruising with some of the participants. A potential sub-theme that I could have explored further was the participants' perception of the success or failure of the procedure as a mediating factor influencing participant concerns and impact of VAS bruising.

This qualitative descriptive study reflects the narrative data from ten men and women who developed VAS bruising following CATH or PCI. The participants were a diverse group in terms of sex, age, type of procedure and VAS utilized. While this study and the findings are unique, they represent the data from this specific group of participants. As an exploratory study, where little is known about the phenomenon, the aim of this qualitative study was to provide a deeper understanding of patient perceptions of VAS bruising (Sandelowski, 2010). The goal in most qualitative research is not to generalize the findings, but to create a deeper understanding of a phenomenon (Polit & Beck, 2010). The findings of the qualitative descriptive study provides an opening for future dialogue between health care professionals and patients regarding the concerns of patients and the impact of bruising that may occur following CATH or PCI.

Mixed Method Question

One of the goals of this study was to see if there was a relationship between VAS bruise size and the concerns and impact of VAS bruising on the participant. The results of this study do not support the notion of a relationship between bruise size and participant concerns, or bruise size and impact on participant. Some participants with quite large bruises were very nonchalant about the bruise size and even touted the bruise as their badge of honor, whereas other participants with smaller bruises were disturbed by the VAS bruising to the point of seeking out professional health care advice.

This finding highlights the importance of thorough nursing assessment and education of patients and family regarding their expectations related to VAS bruising following CATH or PCI. While advances in techniques and changes to nursing practice

may eventually minimize the incidence and extent of VAS bruising, individual patients may continue to have concerns related to VAS bruising that will impact their activities of daily living.

Relationship to Prior Research

Prior to the initiation of this study an extensive literature search was conducted looking for methods of measuring VAS bruise size following CATH or PCI. The vast majority of the research has focused on major VAS complications examining; a) factors which may lead to increased risk of major complications, and therefore the ability to predict who will develop significant complications; and b) clinical practice of sheath removal, with the goal of minimization of VAS complications, and defining optimal nursing practice related to sheath removal. No research literature was identified which focused specifically on VAS bruising, and very few studies acknowledged VAS bruising as a complication occurring after CATH or PCI. There has been very little high quality research on VAS bruising, the most commonly occurring complication following CATH or PCI.

As this is the first known study to specifically examine the reliability of VAS bruise measurement techniques there are limited studies for comparison. The study by Botti et al., (1998) briefly addressed inter-rater reliability of VAS bruise measurement. In their study examining the impact of pressure dressings following CATH, Botti et al., (1998) reported completing a pilot study to examine the inter-rater reliability of VAS bruise measurement. Using linear measurement on bruise tracings they reported a high correlation coefficient (.92) with bruises < 50 cm^2. However the information in the paper

did not describe the pilot study with enough detail to evaluate the method of bruise measurement, the statistical analysis of reliability, the participants completing the pilot study or the number of participants. This study did not clearly define the terms bruising or hematoma and used them interchangeably throughout the paper. Changes in clinical practice related to sheath removal limit the applicability of these findings in the current era. Technology related to CATH and PCI is an evolving field and, as such, knowledge related to the development of VAS complications, including bruising, needs to continually advance. Although no other studies were found that specifically examined reliability of VAS bruise measurement, there have been some studies that have examined the incidence and size of VAS bruising.

Incidence and Size of Vascular Access Site Bruising

The reported incidence of VAS bruising in the current study, based on participant self report, was 45.6% (n = 46). In a recent study of same day discharge following PCI, 60% of the participants reported VAS hematoma (Lauck et al., 2009) at the time of telephone contact, two to five days after discharge. Unfortunately the authors did not define how the patients identified VAS hematoma versus VAS bruising and the hematoma was not objectively assessed, as bruising was in this study.

A RCT of 1,075 patients examined the effect of pressure dressings following CATH and found at 41.9% of participants reported new or persistent VAS bruising at the time of telephone follow up (Botti et al., 1998). In this study Botti et al., (1998) had participants identify the extent of VAS bruising as local, moderate or extensive. Participants indicated the size of bruising based on 3 line drawings with increasing

degrees of bruising. This study found that 33.2% of the participants who had no evidence of VAS bruising 12 hours after CATH reported VAS bruising at the time of telephone follow-up, and that 21% of those patients reported moderate to extensive bruising. The findings regarding the timing of bruise development are similar to the findings reported by Cosman et al. (2011).

An observational study of VAS bruising found that 68.6% of participants reported VAS bruising five to seven days following CATH or PCI (Cosman et al., 2011). Similar to the study by Botti et al., (1998) only 6.3% of participants had any indication of VAS complication at the time of discharge.

In a study examining the use of pressure dressings Robb and McLean (2000) had patients trace both their VAS bruise and hematoma 72 hours after CATH. The incidence of bruising in this study was 61% with pressure dressing and 59% without pressure dressing. The median bruise size was reported as 19 cm^2 in the group receiving a pressure dressing and 30 cm^2 in the group with no pressure dressing. This is an older study and there have been significant clinical practice changes in CATH since this study was reported.

A study comparing manual compression with a closure device reported VAS bruise sizes from 28.5 cm^2 to 82.5 cm^2 one week following CATH (Behan et al., 2007). The method of bruise measurement was poorly described in this study and the statistical analysis and results were unclear (Behan et al., 2007).

These studies support the notion that VAS bruising occurs in the range of 41.9% to 68.6% of patients following either CATH or PCI (Botti et al., 1998, Cosman et al.,

2011, Lauck et al., 2009). Studies also indicate that significant VAS bruise formation most frequently occur following hospital discharge, even in those patients who have no evidence of VAS bruising at the time of discharge (Behan, et al., 2007; Botti et al., 1998; Cosman et al., 2011; Robb & McLean, 2000).

There are several potential explanations for the wide range in the incidence of VAS bruising reported in the literature. One potential explanation is the patient population being examined for VAS bruising. The study by Lauck et al. (2009) included participants having PCI, the study by Botti et al. (1998) included participants undergoing CATH and the study by Cosman et al. (2011) included both procedures, as well as radial access sites. It is well documented in the literature that the incidence of VAS complications is higher with higher doses of anticoagulation and extended indwelling sheath times associated with PCI (Konstance et al., 2004).

The procedures of CATH and PCI have undergone technological advances which have reduced major vascular complications. Smaller sheath size and changes in anticoagulation practices, as well as the use of the radial artery for vascular access may impact the incidence and size of VAS bruising.

Because there is no globally accepted best practice for sheath removal, institutions have developed site-specific practices related to sheath removal which vary widely across institutions both locally and internationally. An Australian study demonstrated a range of practice patterns related to method of sheath removal, time to ambulation, patient positioning and pain relief (Rolley, Salamonson, Dennison, & Davidson, 2010). In the multi-site study by Botti et al., (1998) patients were on bed rest for either 6 or 12 hours

following CATH, varying with the clinical practice of the specific site. In the study by Lauck et al. (2009), the mean length of stay following PCI was 9 hours and 50 minutes, whereas during the completion of this study practice at Hamilton Health Sciences was to have post PCI patients observed in the hospital overnight.

While the incidence of bruising in this study is somewhat lower than other studies it should be acknowledged that the goal of the current study was not to ascertain the incidence of VAS bruising following CATH or PCI. Participants in this study had either CATH or PCI through both the femoral approach and the newer radial approach. In this study six participants reported bruising but did not complete the bruise measurement. Two of the participants declined return visit to the hospital for bruise measurement, and four participants failed to appear at their scheduled time for bruise measurement. As all participants did not return to visually verify the presence or absence of VAS bruising, it is possible that some participants stated they did not have bruising in order to avoid a return visit to the hospital.

Impact of Vascular Access Site Bruising

A search of the literature did not find any qualitative studies which focused specifically on the patient experience of VAS bruising. Some quantitative studies were found that did report findings related to patient concerns about VAS bruising. Lauck et al. (2009) found that 37.6% of participants reported groin pain with a mean pain score of 2.5 (SD = 1.7), where 0 represented no pain and 10 represented the worst pain. At the time of telephone contact 52% of the participants reported limitations in their physical activity at home and 4% had been to the emergency department for management of VAS

concerns within 24 hours of discharge. Cosman et al. (2011) also found 25.7% of participants reported ongoing VAS pain or discomfort at the time of telephone contact five to seven days post procedure. However, only 13.3% of participants reported taking any medication for pain.

In a recent phenomenological study examining patients' experience following day surgery, the authors reported that some participants were not prepared for the skin discoloration associated with bruising (Gilmartin, 2007). The bruising was described as shocking and the authors suggest that this might be perceived as a "threat to body image and appearance" (Gilmartin, 2007, p. 117). Participants in this study also described the VAS bruising as shocking and stated that the bruising was extensive enough to prohibit them from taking part in particular activities, like swimming, due to concerns about the appearance of the bruising.

Implications for Research and Clinical Practice

The results of this study have several implications for both research and nursing practice. The development of a reliable measurement tool to assess VAS bruising is a step forward for research examining methods to minimize VAS bruising. A tool that can be used by patients to measure VAS bruise size opens the door to collecting data on an outcome that occurs in a large number of patients outside of the traditional 'time of discharge' VAS assessment. The qualitative study findings acknowledge VAS bruising as an important outcome for patients, and therefore as an essential outcome measure in future research related to VAS bruising. The qualitative descriptive study was a first exploratory step towards a greater understanding of the concerns of patients related to

their VAS. Future qualitative research might focus on the significance of pain, or the impact of education related to the procedure and potential for bruising post procedure in relation to patient concerns. An example of how VAS bruise size could be used in future research follows.

Historically research comparing two different compression techniques with sheath removal would have examined the VAS at the time of discharge for major vascular complications, such as retroperitoneal bleeding, bleeding requiring transfusion or development of a pseudoaneurysm. If this study found no difference between techniques in terms of major vascular complications the recommendation of the study might be to use the technique which was less time consuming or less expensive. If the study included VAS bruise size and use of health care resources to manage patient concerns related to VAS bruising as outcome measures, the recommendations of the study might be altered. For example, in the study by Botti et al., (1998) although participants without pressure dressings had a statistically higher incidence of bleeding, the authors also examined other less common complications associated with femoral sheath removal. Participants who had pressure dressings following CATH were found to have a higher incidence of back, groin and leg pain, nausea and urinary difficulties. The final recommendation of the authors was not to use pressure dressings after sheath removal following CATH.

The findings of this study draw attention to the role of the nurse caring for patients undergoing CATH or PCI. In practice, VAS bruising may be an outcome that is directly impacted by clinical practice changes. As such nurses involved in the care of these patients need to be aware that VAS bruising is common following CATH and PCI

despite the fact that the patients may have no indication of VAS bleeding or bruising at the time of discharge. Nurses also need to be cognizant of the fact that some patients do have concerns related to VAS bruising, and that this may impact their daily lives. The importance of educating both the patients and the families cannot be overlooked when explaining not only the procedure but also what the patient can expect after discharge. Rolley et al., (2010) found that psychosocial care following CATH was rated as a lower priority than other tasks by cardiovascular nurses in Australia and New Zealand.

Many of the mediating factors identified in the qualitative study point to the importance of ensuring patients are educated regarding the procedure, as well as what to expect following the procedure. The importance of informing both the patient and family members regarding the potential development of VAS bruising should not be underestimated. Patients should be made aware of the potential size of the bruising to expect, not just "you might get a bruise". Specific information regarding symptoms, other than bruising, that warrant early follow-up should be discussed. The nurse should ensure that the patient and family members have an understanding of what may happen at the VAS following discharge. For example, explaining to patients that as they stand up and walk around at home the bruise may be displaced and migrate down their leg may alleviate some of the concern related to 'growing' bruise size. Lastly, these patients may be given medications for pain or anxiety and are often under considerable stress as they undergo these procedures. Any teaching provided to the patient and family should be supplemented with written materials which provide specific information regarding the

potential for VAS bruising, and details regarding symptoms that warrant health care personnel follow up.

Conclusions

This reliability study demonstrated high inter-rater reliability of VAS bruise measurement, using either linear measurement or planimetry. These findings support patient self measurement of VAS bruise size, the most common complication following CATH or PCI. Research examining nursing actions to minimize VAS complications, specifically bruising, can utilize patient VAS bruise size as an outcome measure. This study confirmed two important aspects related to VAS bruising a) it typically occurs beyond the conventional timeframe used in most studies, and b) though this complication is often considered minor by most health care professionals, it is of concern to the patients experiencing VAS bruising. Participants' responses did not indicate a preference for either linear measurement or planimetry as the method of choice for VAS bruise measurement. The researcher or practitioner should consider the goal of VAS bruise measurement and the resources available when choosing either linear measurement or planimetry as an outcome measure in research or clinical practice.

Participants with a range of bruise sizes and concerns were interviewed in the embedded qualitative descriptive study. Participant interviews revealed that many patients do have concerns related to VAS bruising, and that VAS bruising impacts their activities of daily living. Some participants sought out health care consultation related to VAS bruising. Acknowledging the significance of VAS bruising from the patient perspective is a significant advancement in thinking from the idea that VAS bruising is

not a clinically significant issue. This study did not identify a relationship between the size of the bruise and the concerns of impact of VAS bruising. Mediating factors, unique to each individual, were identified as influencing the concerns and impact of VAS bruising on the participants.

This study has demonstrated the reliability of new and innovative methods for measuring a common, often overlooked, complication following CATH or PCI. It has highlighted the significance of VAS bruising from the perspective of the patient, and it has reminded us that the unique characteristics of each individual will influence how a person will respond to a surprising consequence of CATH or PCI, such as VAS bruising. There is no doubt that patient VAS bruise measurement can be a reliable and useful method for measuring VAS bruise size in both clinical practice and research.

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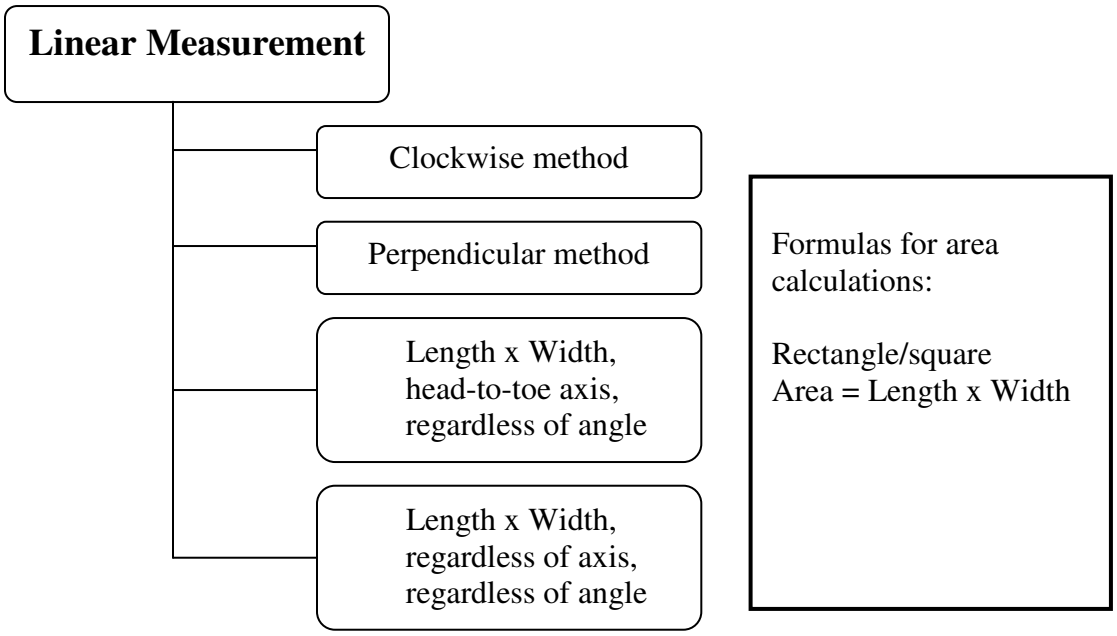
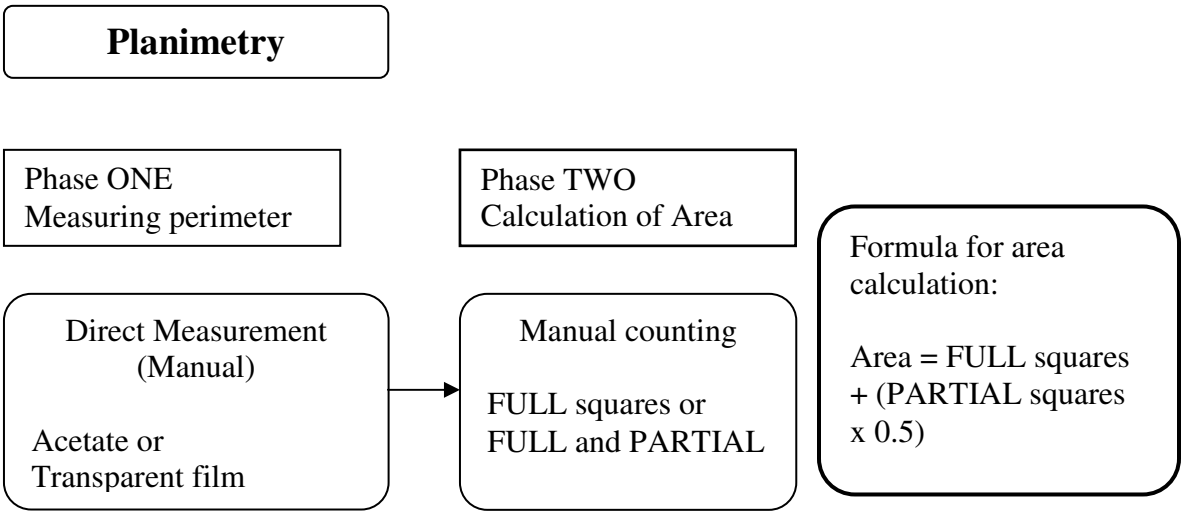
Appendix A

Measurement Techniques


Linear Measurement
Clockwise method
Perpendicular method
Length x Width, head-to-toe axis, regardless of angle
Length x Width, regardless of axis, regardless of angle
Formulas for area calculations:
Rectangle/square
Area = Length x Width


Planimetry
Phase ONE
Measuring perimeter
Phase TWO
Calculation of Area
Direct Measurement (Manual)
Acetate or Transparent film
Manual counting
FULL squares or FULL and PARTIAL
Formula for area calculation:
Area = FULL squares + (PARTIAL squares x 0.5)

Appendix B

Research Ethics Board Approval Letters

September 17th, 2009
December 3rd, 2009
April 13th, 2010

Hamilton Health Sciences

RESEARCH ETHICS BOARD

McMaster University

REB Office, 1057 Main St. W., Hamilton, ON L8S 1B7
Telephone: 905-521-2100, Ext. 42013
Fax: 905-577-8378

September 17, 2009

PROJECT NUMBER: **09-436**

PROJECT TITLE: Comparison of Two Methods of Patient Vascular Access Site Bruise Measurement: A Reliability Study

PRINCIPAL INVESTIGATOR: **Tammy Cosman**
LOCAL PI: **Dr. Heather Arthur**

As you are aware your study was presented at the September 15, 2009 Research Ethics Board meeting where it received ***final approval*** from the full Research Ethics Board. The submission, protocol version 1 dated August 15, 2009, including the Participant Information Sheet, version dated August 19, 2009 along with the Bruise Measurement Instructions, the Case Record Form and the Tools Questionnaire was found to be acceptable on both ethical and scientific grounds. ***Please note*** attached you will find the Information Sheet with the REB approval affixed; all consent forms used in this study must be copies of the attached materials.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the REB meeting on September 15, 2009. Continuation beyond that date will require further review and renewal of REB approval. Any changes or amendments to the protocol or information sheet must be approved by the Research Ethics Board.

The Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations.

PLEASE QUOTE THE ABOVE-REFERENCE PROJECT NUMBER ON ALL FUTURE CORRESTPONDENCE

Sincerely,

S. Salama, PhD.
Vice Chair, Research Ethics Board

McMaster University Health Sciences

RESEARCH ETHICS BOARD

Hamilton Health Sciences
EXEMPLARY CARE • ACADEMIC EXCELLENCE

AMENDMENT REQUEST

REB Project #: 09-436

Locally Responsible Investigator: Dr. Heather Arthur

Title of Study: Comparison of Two Methods of Patient Vascular Access Site Bruise Measurement: A Reliability Study

Document(s) Amended with version # and date:

- Consent Form (Main) - Participant Consent Form Ver: 2 November 26, 2009
- Protocol - Reliability of Patient Bruise Measurement Ver: 2 November 26, 2009
- Other - Bruise Measurement Instructions (Femoral) Ver: 2 November 26, 2009
- Case Report Form - A Mixed Methods Reliability Study Ver: 2 November 26, 2009

Research Ethics Board Review
(this box to be completed by REB Chair only)

[X] **Amendment approved as submitted**

[ ] **Amendment approved conditional on changes noted in "Conditions" section below**

[ ] **New enrolment suspended**

[ ] **Study suspended pending further review**

Level of Review:

[ ] Full Research Ethics Board

[X] Research Ethics Board Executive

Conditions:

The Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board operates in compliance with the ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Division 5 Health Canada Food and Drug Regulations.

Dr. Jack Holland, MD, FRCP, FRCP(C), Chair
Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board

03-Dec-09
Date

All Correspondence should be addressed to the REB Chair and forwarded to:
REB Coordinator, Hamilton Health Sciences
293 Wellington St. N., Suite 102, Hamilton ON L8L 8E7
Telephone: 905-521-2100, ext. 42013
Fax: 905-577-8378

McMaster University Health Sciences

RESEARCH ETHICS BOARD

Hamilton Health Sciences
EXEMPLARY CARE • ACADEMIC EXCELLENCE

AMENDMENT REQUEST

REB Project #: 09-436

Locally Responsible Investigator: Dr. Heather Arthur

Title of Study: Comparison of Two Methods of Patient Vascular Access Site Bruise Measurement: A Reliability Study

Document(s) Amended with version # and date:

- Protocol Amendment – Version 3 dated March 20, 2010
- Consent Form (Main) – Participant Information Sheet and Consent Form Version 3 dated March 20, 2010
- Recruitment – Bruise Management Study Version 1 dated March 20, 2010
- Questionnaire – Bruise Management Questionnaire Version 2 dated March 20, 2010
- Interview Guide – Semi-Structured Qualitative Interview Questions Version 2 dated March 20, 2010

Research Ethics Board Review

(this box to be completed by REB Chair only)

[X] **Amendment approved as submitted**

[ ] **Amendment approved conditional on changes noted in "Conditions" section below**

Level of Review:

[ ] Full Research Ethics Board
[X] Research Ethics Board Executive

Conditions:

The Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board operates in compliance with the ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Division 5 Health Canada Food and Drug Regulations.

S. Salama

for Dr. Jack Holland, MD, FRCP, FRCP(C), Chair
Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board

April 13, 2010
Date

All Correspondence should be addressed to the REB Chair and forwarded to:
REB Coordinator, Hamilton Health Sciences
293 Wellington St. N., Suite 102, Hamilton ON L8L 8E7
Telephone: 905-521-2100, ext. 42013
Fax: 905-577-8378

Appendix C

Consent Form

PARTICIPANT INFORMATION SHEET

Title of Study:
Comparison of Two Methods of Patient Vascular Access Site Bruise Measurement: A Mixed Methods Reliability Study

Study Sponsor:
HSFO/Michael G. DeGroote Endowed Chair in Cardiovascular Nursing

Principal Investigator:
Tammy Cosman RN(EC), MN, Advanced Practice Nurse
Surgical Oncology & Orthopedics Program, Hamilton Health Sciences, Henderson Site

You are being invited to participate in a research study conducted by Tammy Cosman RN(EC), MN, PhD student. This is a student research project conducted under the supervision of Dr. H. Arthur RN, PhD. The study will help the student learn more about the topic area and develop a measurement tool which may be used in future studies requiring bruise measurement.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family.

WHY IS THIS RESEARCH BEING DONE?
Having a cardiac catheterization (CATH) or percutaneous coronary intervention (PCI) requires the doctor to place a small tube in an artery that leads to the heart. Occasionally patients develop complications where the tube was placed. The most common problem seen by patients is a bruise in that area. Many patients get bruising after they are sent home from the hospital.

There is no standard tool used for measuring bruises that happen when the patient gets home.
Research to decrease bruising is difficult without a standard way to measure bruises.
This study will compare how patients and nurses measure bruises in two different ways.

Patients will tell us how easy it is to measure bruises with each method. The impact of bruising following CATH or PCI on patients is not clear. This study will explore how bruising impacts your ability to perform daily activities and how you perceive the bruise.

WHAT IS THE PURPOSE OF THIS STUDY?
This study will give us information about two different ways to measure bruises at the wrist or groin site. This study will also help us determine if patients have the ability to measure and report bruise size. This research may support the use of a standard tool for patient bruise measurement. Understanding the impact on patients of bruising that develops after hospital discharge will expand our understanding of how patients cope with bruising once at home.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?
If you volunteer to participate in this study, you will be asked to do the following things:
The study investigator/research assistant will approach you to talk about your participation in this study. The study will be explained to you in detail, and you will have an opportunity to ask any questions. If you are eligible for the study and you wish to participate, you will be asked to sign a consent form. If you chose not to participate in the study you may be provided with a study information/contact sheet should you decide to participate at a later time. Your care will not change in any way if you chose to participate in this study.

You will be contacted by telephone after your procedure. If you have no bruising, nothing further will be requested of you. If you have any bruising at all you will be asked to return to the hospital for a follow up visit. If you are returning to the hospital for bruise measurement you will be given directions to an outpatient area where you will be met by the study investigator or research assistant.

If are returning to the hospital for a pre-booked follow up appointment by staff in the Heart Investigation Unit you may be given a study information sheet by a nurse. If you agree, you will be contacted by the study investigator/research assistant regarding your participation in this study. If you choose to participate, the investigator/research assistant will explain the study in detail and have you sign the consent form at the time of your scheduled appointment. The study will be completed at the end of your pre-booked clinic visit and will take no longer than 30 minutes.

You will be given written instructions (with diagrams) showing you how to measure any bruising at your access site (either wrist or groin). You will be asked to measure the bruise using two different methods. One method will use a measuring tape; the second method involves tracing the outline of the bruise onto a clear plastic film. This will occur in a private exam room. Following your measurement both a research assistant and the study investigator, an Advanced Practice Nurse, will repeat the bruise measurements using both methods. Before you leave you will asked to complete a 5-minute

questionnaire regarding the two measurement tools. This entire visit should take no longer than 30 minutes.

If you experience bruising you may be asked to provide some further information about how this bruising has, or has not, affected you and the quality of your home and work life. An interview with the study investigator will be conducted following the bruise measurement. The interview will be tape recorded for research purposes. The tape recordings will only be heard by the study investigator, research assistant and transcriptionist. The interview should take no longer than 30 minutes. You may choose to not answer any of the questions and remain in the study.
Your name will not be used in any documents related to this study. You will have an assigned number so that all the information you give us remains anonymous and confidential.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
There are no known risks associated with this research. All other aspects of your care remain unchanged. If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research.

HOW MANY PEOPLE WILL BE IN THIS STUDY?
There will be approximately 50 people enrolled in this study.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?
We cannot promise any personal benefits to you from your participation in this study. However, your participation may help other people in the future who are having cardiac procedures.

Having a standard method for bruise measurement, done by patients, will help with future research to decrease the amount of bruising after cardiac procedures.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?
It is important for you to know that you can choose not to take part in the study. **Choosing not to participate in this study will in no way affect your care or treatment.**

WHAT INFORMATION WILL BE KEPT PRIVATE?
Your data will not be shared with anyone except with your consent or as required by law. All personal information such as your name, address, phone number will be removed from the data and will be replaced with a study number. A list linking the number with your name will be kept in a secure place, separate from your file. The data, with identifying information removed, will be securely stored in a locked office. The data for this research study will be retained for a maximum of 10 years.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Health Sciences/FHS McMaster University Research Ethics Board may consult your research data and medical records. However, no records, which identify you by name or initials, will be allowed to leave the hospital. By signing this consent form you authorize such access.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. However, it is important to note that this original signed consent form and the data, which follows, may be included in your health record.

CAN PARTICIPATION IN THE STUDY END EARLY?

If you volunteer to be in this study, you may withdraw at any time and this will in no way affect the quality of care you receive at this institution. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

If you agree to take part in this study you will be provided with a parking voucher for the hospital parking ramp to cover the parking costs associated with your return visit to the hospital. You will also receive $50 to cover the transportation costs associated with your return to the hospital.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

It is highly doubtful that you will experience a research-related injury in this particular study. However, if you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research now or later, or if you think you have a research-related injury, please contact Dr. Heather M. Arthur, McMaster University, 905-525-9140, Ext. 22270.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Health Sciences / Faculty of Health Sciences Research Ethics Board at 905-521-2100, ext. 42013.

CONSENT STATEMENT

SIGNATURE OF RESEARCH PARTICIPANT/LEGALLY-AUTHORIZED REPRESENTATIVE

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

_____
Name of Participant

_____ _____
Signature of Participant or Legally Authorized Representative Date

Consent form administered and explained in person by:

_____
Name and title

_____ _____
Signature Date

Appendix D

Study Information Sheet

BRUISE MEASUREMENT STUDY

What is the Bruise Measurement Study?

Patients having an angiogram or angioplasty may develop bruising in their wrist or groin area after they are discharged from the hospital. There is no standard way for patients to report the size of the bruising once they are at home. This study will test two bruise measurement tools for patients to use at home.

What is involved?

- **You will be asked to return to the hospital one time for bruise measurement 3-10 days after your procedure**
- **You will be given instructions on how to measure your bruise in a private exam room**
- **An Advanced Practice Nurse and research assistant will also measure your bruise**
- **You may be asked to participate in a interview after you measure your bruise**
- **You will receive a parking pass and $50 for your participation in this study**

How can I help?

If you experience a bruise following your angiogram or angioplasty, and are able to return to the hospital for bruise measurement on:

_____

Please contact:

Tammy Cosman RN (EC), MN Principal Investigator
Phone: 905 527-4322 extension - 43894
You will receive a call from the principal investigator or research assistant to explain the study in more detail.

Appendix E

Case Record Form

Comparison of Two Methods of Patient Vascular Access Site Bruise Measurement: A Mixed Methods Reliability Study

CASE RECORD FORM Study ID: _____

Procedure Date (dd/mm/yyyy)**:** _____

Telephone Follow up Date (dd/mm/yyyy): _____

DEMOGRAPHICS:

DOB (dd/mm/yyyy): _____

Sex:

01 Male
02 Female

Highest Level of Education Achieved:

01 less than grade 8
02 completed grade 8
03 completed high school
04 completed College/University Undergraduate
05 completed Graduate education

Anthropometrics:

Height (cm): _____
Weight (kg): _____

PROCEDURE INFORMATION:

Procedure Completed

01 Cardiac Catheterization
02 Percutaneous Coronary Intervention

Vascular Access Location (Arterial)

01 Right Femoral Artery
02 Left Femoral Artery
03 Right Radial Artery
04 Left Radial Artery

Sheath Size:

01 6 French
02 7 French
04 Other

Vascular Closure Device used (Femoral only)

01 Yes
02 No

Study ID: ____

Follow up Visit – VAS Bruise Measurement:

Follow up Visit Date (dd/mm/yyyy)**: _____**

Patient Measurements:

01 Self Measurement
02 Assisted Measurement

Linear Method:
Length (cm) _____
Width (cm) _____

Tracing Method:

Number of FULL squares in tracing perimeter:
_____

Number of PARTIAL squares in tracing perimeter:
_____

Appendix F

Participant Instruction sheet – Femoral

Bruise Measurement - Instructions Study ID _____

Please measure any bruise that is visible at your groin site. Include the purple/blue colored area only; do not include yellow/green area.

Please remove any bandages before measuring bruising.

In order to maintain your privacy please place a towel as shown in FIGURE ONE. The edge of the towel should be in line with your inner thigh. Bruising that is under the towel will not be measured.

You may have a second person assist with measurement if required. Please check who measured your bruise area.
_____ Self _____ Other

When both measurements are completed, place the clear film and this instruction page in the envelope provided.

Bruise Measurement - Instructions

Study ID _____

Part ONE - Linear measurement
(Using Measuring Tape)

1. All measurements should be in centimeters.
2. Look at your bruise to find where it is **longest.** See **L** on FIGURE TWO.
3. Using the measuring tape provided, measure the greatest length of the bruise. Record the measurement in the space below.

Length _____(cm)

4. Imagine a line the length of your bruise.
5. Look at your bruise to find where it is widest, at a right angle (90 degree angle) to the length of the bruise. See **W** on FIGURE TWO.
6. Measure the **greatest width** of the bruise. Record the measurement in the space below.

Width _____ (cm)

FIGURE ONE

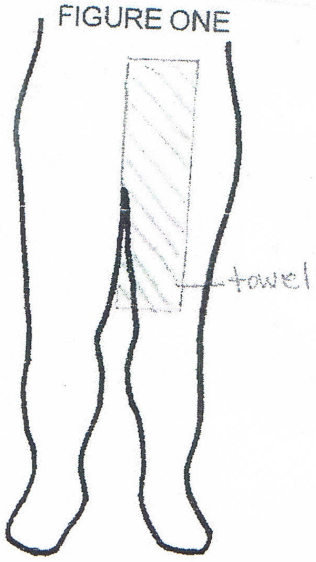
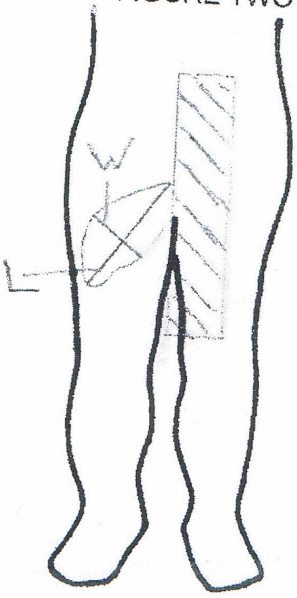


FIGURE TWO

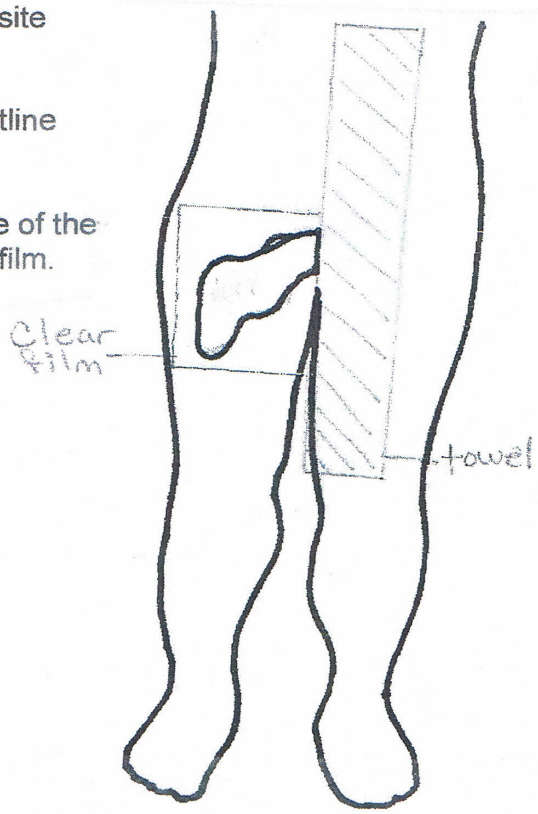


Bruise Measurement - Instructions Study ID _____

Part TWO - Tracing Method

1. Place towel as shown in FIGURE ONE.
2. Place clear film over bruise at groin site as shown in FIGURE THREE.
3. Use marker provided to trace the outline of the bruise.
4. Remember to mark the straight edge of the bruise (the towel edge) on the clear film.

FIGURE THREE



When both measurements are completed, place the clear film and this instruction page in the envelope provided.

Thank you for participating in this study.

Appendix G

Participant Instruction Sheet – Radial

Bruise Measurement - Instructions Study ID _____

Please measure any bruising you can see at your wrist. Include the purple/blue colored area only; do not include yellow/green area.

Please remove any bandages before measuring bruising.

Bruising that goes around the wrist should be included in the measurement.

When both measurements are completed, place the clear film and this instruction page in the envelope provided.

You may have a second person assist with measurement if required. Please check who measured your bruise area and indicate if you are left or right handed.

_____ Self _____ Left handed
_____ Other _____ Right handed

Part ONE - Linear measurement (using the measuring tape)

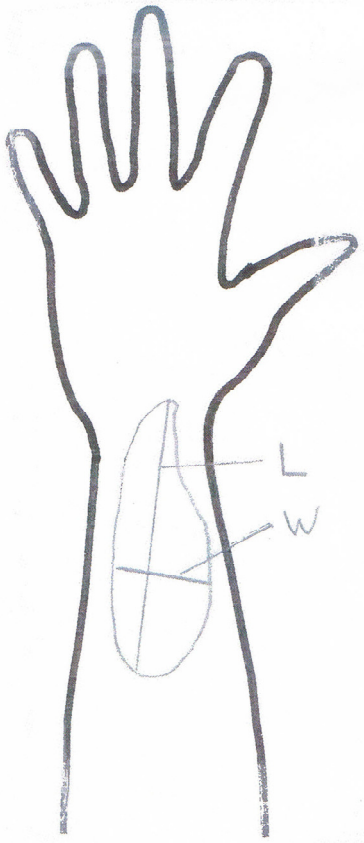
1. All measurements should be in centimeters.
2. Look at your bruise to find where it is **longest.** See **L** on FIGURE ONE.
3. Using the measuring tape provided, measure the **longest area** of the bruise. Record the measurement in the space below.

Length _____(cm)

4. Imagine a line the length of your bruise.
5. Look at your bruise to find where it is **widest.** Measure the **widest area** of your bruise at a right angle (90 degree angle) to the length of the bruise. See **W** on FIGURE ONE.
6. Measure the **greatest width** of the bruise. Record the measurement in the space below.

Width _____ (cm)

FIGURE ONE



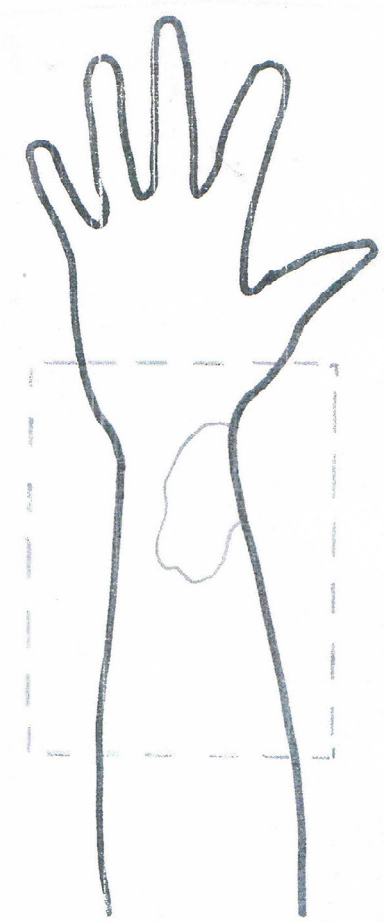
Bruise Measurement - Instructions

Study ID _____

Part TWO - Tracing Method

1. Place clear film over bruise at wrist as shown in FIGURE TWO.
2. Use the marker provided to trace the outline of the bruise.
3. Remember to include bruising that wraps around the wrist.

FIGURE TWO



When both measurements are completed, place the clear film and this instruction page in the envelope provided.

Thank you for participating in this study.

Appendix H

Bruise Measurement Questionnaire

Thank you for your involvement in this study. Your help is appreciated with this important research. Please take the time to complete both pages of this questionnaire about the two ways to measure bruising.

Linear measurement (using a measuring tape)

On a scale of 1-5 please rate each question.
1 = very easy **5 = very hard**

1. How easy was it to figure out the instructions about how to use the tape measure?
   1 = very easy 5 = very hard
   1 2 3 4 5

2. How easy was it to measure the bruise using the tape measure?
   1 = very easy 5 = very hard
   1 2 3 4 5

3. Did you have any problems measuring your bruise using the tape measure? Please describe below.

_____

_____

_____

_____

_____

Bruise outline measurement (tracing method)

On a scale of 1-5 please rate each question.
1 = very easy **5 = very hard**

4. How easy was it to figure out the instructions about how to trace the bruise?

1 = very easy 5 = very hard
1 2 3 4 5

5. How easy was it to measure the bruise using the tracing method?

1 = very easy 5 = very hard
1 2 3 4 5

6. Did you have any problems measuring your bruise by tracing the outline? Please describe below.

_____
_____
_____
_____
_____
_____

Did you prefer to use: ☐ the measuring tape or

☐ tracing the outline of the bruise?

_____
_____
_____

Thank you for your participation in this study!

Appendix I

Interview Participant Characteristics and Bruise Size

Interview Participant Characteristics and Bruise Size

Study ID	Sex	Site	Age	Bruise Size (cm^2)	Procedure Completed	Prior Procedure
131	**M**	**F**	**56**	**39**	**Cath**	**Yes**
138	**M**	**F**	**74**	**49.5**	**Cath**	**Yes**
146	**F**	**F**	**72**	**49.5**	**PCI**	**Yes**
157	**F**	**R**	**34**	**12**	**Cath**	**No**
161	**F**	**F**	**65**	**108.5**	**Cath**	**Yes**
169	**M**	**F**	**55**	**957**	**Primary PCI**	**No**
170	**F**	**F**	**69**	**165**	**Cath**	**No**
174	**F**	**F**	**59**	**912**	**Cath**	**No**
186	**M**	**F**	**62**	**63.25**	**Cath**	**No**
188	**M**	**R**	**69**	**108.75**	**PCI**	**No**

Note: Sex M = male, F = female; Site F = femoral, R = radial, Procedure Completed Cath = cardiac catheterization, PCI = percutaneous coronary intervention, Primary PCI = primary percutaneous coronary intervention

Appendix J

Interview Guide

1. Can you tell me about the bruise at your (name specific) site?

   Probe: How did you notice that you had a bruise?
   When did you notice and what made you notice the bruise?
   Does the bruise bother you in any way?
   What are your thoughts about the bruising?
   Have you ever had this type of procedure and developed a bruise in the past? How has this influenced what you think about this bruise?

   Added after seventh interview:
   What does a bruise mean to you – what do you think causes it?

2. What action(s) did you take, if any, once you noticed the bruise forming?

   Probe: At what point would the bruise have been bad enough to do something?
   How bad would the bruise have to be before you would seek advice from a health care professional (GP, Emergency dept, other)?

3. Please describe any symptoms or concerns you have related to your bruise.

   Probe: Have you had any pain or discomfort at your bruise site?
   Have you noticed any other symptoms?

4. Can you describe what you have done/will do to deal with this (name symptom)?

   Probe: Did this work?
   What other things did you try?
   What are you thinking of trying?

5. How has this bruise affected your ability to perform your normal activities?

   Probe: How has the bruise limited any of your work, home or recreational activities?

6. What did your family members or friends think about the bruise?

   Probe: Did you ask any family or friends what they thought you should do?
   Did any of your family or friends suggest things you should do?
   Did any family or friends encourage you to seek medical attention?

Added after first interview following discussion with committee member:

Do you remember being told what to expect at your (wrist/groin) site after discharge?

What were you told to expect regarding bruising? Anything else regarding the access site?

7. If you were helping someone prepare for this procedure, what would you tell them about bruising?

8. Do you have anything to add?

Appendix K

Contact Summary Sheet

Questions to pose to self following interview:

Main issues or themes that struck you?

Summarize information obtained for each question

New or remaining questions

Anything that struck you as important

Am I asking the right questions to get the information I want?

Appendix L

Planimetry Measurement Results - PI and RA Measures

Planimetry Measurement Results – PI and RA Measures

Study ID number	PI measures patient Planimetry	RA measures patient Planimetry	PI measures RA Planimetry	RA measures RA Planimetry	PI measures PI Planimetry	RA measures PI Planimetry
174	433	462	469.5	696	616.5	747
165	419.5	472.5	215	213.5	294	387
168	385	380.5	477	457.5	502.5	383
155	293.5	612	355	397	532.5	540
140	185	183	240.5	241	375	248.5
170	156.5	77.5	85	81	88.5	88
169	133.5	143	134.5	130.5	171	171
134	86.5	74.5	85.5	96	91	85.5
150	79.5	72	68	72.5	73.5	70
188	73	68	40	35	78	77.5
135	67.5	61.5	93	87.5	74	68
161	63	59	56	56.5	56	60.5
116	55	45	142	137.5	137.5	129.5
207	50	46.5	61.5	56.5	54	48
107	48	47	51	45.5	52	54
128	39	36.5	54	50	41.5	37
138	37.5	36	23	24	29.5	25.5
186	34.5	32	32.5	31	37	36
146	34	34	18	17	28.5	26
159	28.5	27.5	23.5	22.5	34	31.5

Note: PI Principle Investigator, RA Research Assistant

Planimetry Measurement Results – PI and RA Measures (continued)

Study ID number	PI measures patient Planimetry	RA measures patient Planimetry	PI measures RA Planimetry	RA measures RA Planimetry	PI measures PI Planimetry	RA measures PI Planimetry
148	28	25.5	19	18.5	31.5	28.5
108	27	26	27	25	7.5	6
190	26.5	26.5	38	35	30	29.5
126	22	19	26	23	16.5	15.5
177	21	20.5	35.5	36.5	28	29
185	19	19	22	23	24	21
127	18.5	17	41.5	37	23	17
162	18.5	18.5	15	15.5	11.5	11.5
100	18	18	20	20	13	13
121	16	13.5	21	20.5	12	13
119	12.5	6	26.5	26	29.5	28
145	11.5	10	12	10	7	4.5
178	10.5	8	40	40	47.5	41
144	10	10.5	8.5	7.5	40.5	37
131	8.5	6.5	14.5	13.5	12	10.5
106	7.5	7.5	13.5	11	10.5	11
157	0.5	0.5	6.5	5.5	5	3.5
105			30	29.5	31	27
182			31	30.5	31	30.5
1211			22.5	23.5	17.5	16.5

Note: PI Principle Investigator, RA Research Assistant