Comparison of Patient Perceived Post-Procedure Access Site Pain in Patients Undergoing Transradial versus Transfemoral Coronary Angiography/Angioplasty

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COMPARISON OF PATIENT PERCEIVED POST-PROCEDURE ACCESS SITE PAIN IN PATIENTS UNDERGOING TRANSRADIAL VERSUS TRANSFEMORAL CORONARY ANGIOGRAPHY/ANGIOPLASTY

BY
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ABSTRACT

Coronary heart disease (CHD) is the number one leading cause of death in the United States. According to the most recent statistics, compiled in 2003, an estimated 500,000 cases were attributed to CHD, in the United States alone. Today, there are a number of diagnostic tests available to aid the practitioner in diagnosing a patient who presents with signs and symptoms consistent with CHD. However, when one test remains 100% effective in diagnosing the presence or absence of coronary artery disease, and that is coronary angiography.

Coronary angiography is a percutaneous procedure which provides the operator with direct visualization of the coronary arterial anatomy, as well as measurement of heart function. It also enables the operator (interventional cardiologist) to detect and, when amenable, revascularize blocked coronary arteries. Since its inception, the “gold standard” access site approach for performing this procedure has been through the femoral artery. However, over the past decade a new approach to percutaneous angiography/angioplasty has emerged, this being the transradial approach. Will numerous studies have been conducted to compare the safety and efficacy between these two access site approaches, little has been done to study the difference in patient perceived post procedural access site pain between the two groups.

The purpose of the study was to evaluate and compare patient perceived pain levels following transradial and transfemoral angiography, with or without angioplasty, as it related to the route of vascular access. Fifty patients were enrolled in the study, and of these, 27 patients underwent transradial access site approach and the remaining 23 underwent transfemoral access site approach for the percutaneous coronary procedure.
Following the procedure, each patient was asked to rate the level of pain they were experiencing at the access site.

The hypotheses examined whether or not the use of the transradial approach to percutaneous coronary procedures would result in lower reported levels of perceived access site pain compared to the use of a transfemoral approach. Based on the data collected, there appeared to be no significant difference between the two access site approaches and the patient perceived level of access site pain following the procedure (p = 0.381). Therefore, the researcher’s hypothesis was not supported. A significant negative correlation was found to exist between the patient's BMI score and their level of post-procedural access site pain. He was found that patients with a low or BMI score reported higher levels of post-procedural access site pain.
Coronary heart disease (CHD) is the number one leading cause of death in the United States. According to the most recent statistics, compiled in 2003, an estimated 500,000 deaths were attributed to CHD, in the United States alone (American Heart Association, 2006). Currently, there are more than 13 million individuals who have a history of angina pectoris, myocardial infarction (MI) or both. Statistics show that approximately seven million of those individuals are males and the remaining six million are females (American Heart Association, 2006). In the year 2006, it is estimated that 1.2 million Americans will suffer a new or recurrent heart attack due to CHD, and of that 1.2 million, 300,000 will die in an Emergency Department or without being hospitalized. However, as grim as these statistics appear, the death rate from CHD from 1993 to 2003 actually declined by 30.2 percent. This dramatic decline in coronary related deaths is due in large part to the increased efforts of the medical community, with the help of the media, to educate the population with regards to lifestyle risk factors and the early warning signs of CHD.

Today, there are a variety of diagnostic tests available to aid the practitioner in diagnosing a patient who presents with signs and symptoms consistent with CHD. Among these tests are electrocardiograms (EKG), graded exercise stress tests (GXT), myocardial perfusion studies and 64-slice computed tomography. However, only one test is 100% effective in diagnosing the presence or absence of coronary artery disease (CAD), and that is coronary angiography. Coronary angiography provides direct visualization of the coronary arterial anatomy, as well as measurement of heart function. While coronary angiography enables the operator to diagnose CHD, it also enables the operator (interventional cardiologist) to detect and, when amenable, revascularize blocked coronary arteries (coronary angioplasty). In 2003, a total of 1,244,000 angioplasties were conducted in the United States, with 664,000 of them performed via a percutaneous transluminal approach (American Heart Association, 2006). The “gold
standard” approach to percutaneous transluminal angiography with or without angioplasty over the past several decades has been conducted by means of the transfemoral approach. However, over the past decade a new approach to percutaneous angiography/angioplasty has emerged, the transradial approach. Numerous studies have been conducted to evaluate the safety and efficacy of the transradial approach and have shown that it is just as safe and effective as transfemoral access. However, the question still remains whether there is a difference in discomfort for the patient, as it relates to the access site used.

**Statement of Problem**

Percutaneous transluminal angiographic vascular access is obtained via one of two main routes, the transradial approach and the transfemoral approach. Multiple studies have been conducted to compare these two access site approaches, with the main focus of such studies having been centered on the issues of safety and efficacy. The results of these studies have led professionals in the field of invasive and interventional cardiology to regard the transradial access site approach as equally effective, and potentially safer, than the transfemoral approach when performing coronary angiography, both with and without angioplasty, leading a larger number of physicians to opt for the transradial approach when performing these procedures. While the crucial issues of safety and efficacy have been thoroughly examined, little has been done to evaluate the level of patient perceived pain with regards to these two routes of vascular access.

**Significance of Problem**

Currently, there are a variety of research studies concerning transradial versus transfemoral coronary artery angiography, with or without angioplasty. The vast majority of these studies focus on access site complication rates between these two groups of patients, those undergoing the transradial approach versus those undergoing the transfemoral approach. Likewise, nursing research and subsequent nursing practice in the post-percutaneous transluminal coronary angiography/angioplasty setting, as it relates to vascular access sites, has also focused on patient observation and identification of
vascular access site complications. A thorough, in-depth literature review revealed previously conducted studies that dealt to some degree with patient pain following the percutaneous coronary procedures but failed to identify any studies conducted that focused specifically on the differences in patient perceived post-procedure access site pain between the two vascular approaches. While it is vitally important to recognize signs and symptoms of impending vascular access site complications in order to prevent adverse patient outcomes, it is equally important to ensure that patients undergoing percutaneous transluminal coronary procedures do not experience unnecessary pain and discomfort.

**Statement of Purpose**

The purpose of this study was to evaluate and compare patient perceived pain levels following transradial and transfemoral angiography, with or without angioplasty, as it relates to the route of vascular access. This study will also evaluate the relationship between patient demographics and the levels of post-procedure access site pain. In addition, the relationship between procedural variables and post-procedure access site pain will also be evaluated.

**Research Questions**

The following questions were asked:

1. Is there a difference in perceived post-procedural access site pain levels between the transradial approach and the transfemoral approach, as measured by the visual analog scale (VAS)?
2. Is there a relationship between the patient demographics of age, gender and body mass index (BMI), and reported post-procedural access site pain?
3. Do the procedural aspects of sheath size, length of procedure and total number of catheters used during the patient’s procedure impact the level of perceived post-procedural pain reported by the patient?
Hypothesis

The following hypotheses were generated:

1. \( H_0 \): There will be no difference in post-procedural access site pain levels between the transradial and the transfemoral group.
   \( H_1 \): The transradial access site approach causes less post-procedural access site pain compared to those undergoing the transfemoral approach.

2. \( H_0 \): Patient demographics of age, gender and BMI will not have a significant relationship to the level of access site pain reported by the study patients following their procedure.
   \( H_1 \): There is a significant relationship between patient age, gender and BMI to post-procedure access site pain levels.

3. \( H_0 \): Procedural factors regarding sheath size, length of procedure and the total number of catheters used during the procedure will not have a significant relationship to the amount of post-procedural access site pain reported by the patients.
   \( H_1 \): There is a significant relationship between procedure aspects and post-procedure access site pain levels.

Operational Definitions

Percutaneous transluminal coronary angiography, also known as heart catheterization, involves passing a thin, flexible tube (catheter) through an artery in the groin or arm and threading it up into the heart. Once the catheter is advanced into the coronary arteries, a radiopaque dye is then injected through the catheter into the coronary arteries allowing the doctor to directly visualize the flow of blood through the heart and the location of any blockages. As part of the coronary angiography procedure, most patients will also undergo left ventriculography. This procedure is performed by advancing a small catheter across the aortic valve and into the left ventricle. Once the catheter is in the left ventricle, 30-40ml of radiopaque dye are power-injected into the left ventricle to assess left ventricular wall motion and mitral valve function.
There are two main routes of vascular access for coronary angiography, the radial artery and the femoral artery. When vascular access for the procedure is obtained via the patient’s radial artery, the procedure is termed a transradial coronary angiography, whereas coronary angiography via the femoral artery is termed transfemoral coronary angiography. Patients undergoing coronary angiography who are found to have blockages in their coronary arteries that are amenable to catheter based intervention, have coronary angioplasty. Coronary angioplasty is a medical procedure used to restore blood flow through a narrowed or blocked coronary artery, due to plaque buildup. A thin tube with a balloon is threaded over the angiography catheter to the site of the blockage. Once the balloon is in place it is inflated to push the plaque outward against the wall of the artery, thus widening the internal diameter of the artery and restoring the flow of blood through the previously blocked area. Once the artery has been ballooned open, a stent may be placed in the artery to aid in keeping the area patent.

In addition to left ventriculography, coronary angiography and coronary angioplasty, patients suffering from severe shortness of breath and/or dyspnea may also undergo right heart catheterization. Right heart catheterization involves the insertion of a small catheter into the femoral vein and advancing the catheter up the inferior vena cava and into the right atrium. Once in the right atrium, the catheter can be advanced across the tricuspid valve into the right ventricle and then into the pulmonary artery system, allowing for measurement of pulmonary artery pressures and pulmonary capillary wedge pressure.

This study focused on evaluating the levels of patient perceived post-procedural access site pain. After the patient’s procedure was completed, they were asked to rate the amount of discomfort being experienced at the site of vascular access.

**Theoretical Framework**

The theoretical basis for this study is based on Betty Neuman’s Health Care Systems Model (Neuman, 2002). The relationship between this model and the stated problem will show that patients undergoing transradial coronary angiography will
experience less procedure related pain than those undergoing transfemoral coronary angiography, thus aiding in the maintenance of patient stability.

Neuman’s theory focuses on the concept of holism and “the whole being greater than the sum of its parts”. Each client system is composed of five interrelated variables that, when exposed to stressors, may disrupt the whole client system. These five interrelated variables include physiological, psychological, sociocultural, developmental and spiritual facets. This study will focus on three of these variables, the physiological, psychological and sociocultural.

The physiological variable deals with the patient’s bodily function and structure. In this study, each patient is experiencing some degree of physiological instability prior to undergoing a coronary procedure. Patients are referred to the cardiologist due to symptoms they are experiencing which are indicative of the possible presence of coronary artery disease, such as chest pain and shortness of breath. Additional physiological stressors are added during the procedure itself including femoral artery or radial artery puncture and, when indicated, the revascularization of any blockages present within the coronary arteries.

Psychological instability can also be a contributing factor in many of these patients. This instability will be due, in large part, to such factors as: 1) the negative effects their presenting symptoms are having on their quality of life, 2) the fear of the unknown as it relates to the possibility of their having coronary artery disease and 3) the thought that if coronary artery disease is present, to what extent? Additionally, it is very common for patients to know individuals who have undergone the same procedure, and that individual’s reported experiences, both positive and negative, weigh heavily on the minds of each patient scheduled for the procedure.

In this study, many of the patients were experiencing sociocultural imbalance. In a number of these patients, due to the extent of their symptoms, they had to alter their level of physical functioning in an attempt to minimize their discomfort. This alteration in physical functioning can affect such areas as professional performance, performance of household duties, and sexual activity.
According to Neuman, each client system, or patient, encounters stressors as it continually interacts with the environment, which consists of both internal and external factors. As the patient interacts with the environment, two levels, or concentric rings, of defense are utilized in an attempt to neutralize each encountered stressor and thus maintain patient stability. The first level of defense is termed the “normal lines of resistance”. Factors influencing the patient’s normal lines of resistance include the individual’s developmental state, lifestyle and previous experience. The normal lines of resistance in this study will include adult patients with no previous history as it relates to the procedure they are scheduled to undergo. The second line of defense is known as the “flexible line of defense”, also called the “buffer-zone”. Factors influencing this specific line of defense are based on the patient’s inter-relationships as they relate to the five client variables. More importantly, the flexible line of defense is where nurses have the opportunity to relieve external environmental stressors.

The focus of this study, from a theoretical standpoint, was to evaluate the affect an external environmental stressor, in this case femoral artery and radial artery puncture, has on a patient’s physiological and psychological stability, as evidenced by patient reported access site pain levels, in an attempt to increase nursing knowledge regarding post-procedure access site pain and the need for adequate pain control to aid in maintaining client stability.

Assumptions

During the course of this study, the researcher made several assumptions about the data that was collected:

1. The patient will complete the visual analog scale (VAS) honestly.
2. The patient’s pain will not interfere with their ability to complete the VAS.
3. The VAS will accurately measure the patient’s post-procedure access site pain.
Limitations

The following limitations of this study included:

1. Small sample size.
2. Convenience sample
3. Pain is subjective

Summary

Over one million patients undergo angiography, with or without angioplasty, every year in the United States. While research has proven the transradial approach to percutaneous transluminal angiography/angioplasty to be as safe and effective as the transfemoral approach, the effect these two access site approaches have in relation to patient pain needs to be evaluated. The goal of this study was to compare patient perceived post-procedural access site pain in these two groups. Betty Neuman’s Health Care Systems Model will be used as the conceptual guide for this study. Results of this study will be used to increase nursing and physician knowledge regarding patient access site pain levels following percutaneous coronary procedures.
In the United States, coronary artery disease remains the number one killer of both men and women. Coronary artery disease (CAD) involves the insidious, progressive build-up of plaque along the internal walls of the coronary arteries. The plaque continues to increase until it reaches a dangerous level. As the heart tries to force blood through these narrowed coronary arteries, the individual begins to experience anginal symptoms. The most commonly reported anginal symptoms include chest pain or pressure with radiation of the pain into the shoulders, left arm or jaw, and shortness of breath. These symptoms are typically brought on with exertion early in the course of the disease, but as the arteries continue to narrow, the patient may begin to experience these symptoms while at rest. In individuals experiencing these anginal symptoms, the “gold-standard” for diagnosing the presence or absence of CAD is the coronary artery catheterization.

Coronary artery catheterization, also termed coronary angiography, provides direct visualization of the coronary arteries and coronary anatomy. Currently, coronary angiography is done via one of two routes, the transfemoral and the transradial approach. Initially, the operator uses a needle to puncture the artery, i.e. the femoral artery or the radial artery. Once arterial puncture has been achieved, a sheath is placed in the artery and the needle is removed. At this point, the operator inserts a guide-wire through the sheath and into the artery. The guide-wire, covered by the guide-catheter, is advanced up the arterial system until it reaches the coronary arteries. Dye is then injected through the catheter and into the coronary arteries in order to determine arterial anatomy and the presence or absence of CAD. If CAD is present, and the operator deems the blockage to be amenable to percutaneous coronary intervention (PCI) or angioplasty, it can be done during the same procedure by an interventional cardiologist. The interventional cardiologist removes the guide-wire, while leaving the guide-catheter in place. A balloon catheter, a wire with an inflatable balloon tip, is then inserted into the guide-catheter and advanced to the end of the guide-catheter where the blockage was found. The balloon
catheter is then advanced past the end of the guide-catheter and through the center of the blockage until the balloon bridges the blockage. At this time, the interventionalist inflates the balloon, which pushes the plaque against the walls of the arteries, thus expanding the internal diameter of the coronary artery. The balloon is then deflated and the balloon catheter is removed so that a stent catheter may be inserted. The stent-catheter contains at the tip of the catheter a mesh-like cylindrical cage called a stent and, like the balloon catheter is advanced to the level of the blockage and placed across the area of blockage previously ballooned. Once the stent is deployed, the operator will once again inflate a balloon inside the stent in order to expand the stent and keep the artery open.

Once the procedure is completed and the sheath is removed, the patient is transferred to the Observation Room and monitored. Patient cardiac function is continuously monitored and vascular access sites are routinely checked for signs of vascular access complications. The most common vascular access complications include hematomas, pseudoaneurysms, AV fistulas and retroperitoneal bleeds. If left untreated, especially in patients undergoing transfemoral angiography due to the size of the femoral artery, any of these complications can be life threatening.

This study will be focusing on individuals experiencing symptoms consistent with coronary artery disease. Their symptoms must be deemed stable by the cardiologist in order for their procedure to be scheduled on an outpatient, elective basis.

The first coronary angiographies were performed in the late 1950s, and it was not until September 16, 1977 that the first PCI utilizing balloon angioplasty was conducted on a human subject (King, 1996). In order to obtain vascular access for the procedure, the physician punctured the femoral artery with a large bore needle and placed a sheath over the needle and into the artery. Once the sheath was in place, the needle was removed allowing for insertion of the guide-catheter that could then be advanced up the vascular system into the coronary arteries for direct injection of dye. The injection of the dye into the coronary arteries provided direct diagnosis of the presence or absence of coronary atherosclerosis.

While the advent of percutaneous transluminal angiography marked a major milestone in invasive diagnostic cardiac testing, vascular access complications were, and
remain present with the procedure. Potential vascular complications that may arise during and following coronary angiography, with or without angioplasty, include hematoma, pseudoaneurysms, Arteriovenous fistulas and retroperitoneal bleeds. When taking into account the size of the femoral artery, any one of these vascular access complications can be life threatening. In the mid to late 1980s, vascular access via the radial artery was introduced, providing the operator with, what researchers hoped would be, a safe and effective alternative to femoral access in transluminal percutaneous coronary procedures.

One of the first studies conducted regarding radial access was a study performed by Yokoyama, et al. (1999) that examined the possible anatomic variations of the radial artery of patients undergoing transradial coronary interventions. This study explored not only radial artery anatomy for percutaneous coronary interventions, but also examined the usefulness of ultrasonography in screening patients for radial anatomy conducive to percutaneous coronary intervention. The study consisted of 115 patients, scheduled to undergo elective coronary intervention via the right radial artery. Ultrasound of the radial artery was performed on each patient prior to the coronary procedure. Ultrasonography revealed 11 different anatomical variations in radial anatomy including the following: 1) tortuous configurations (52%); 2) stenosis (17%); and 3) radioulnar loop (0.9%). In three of the patients, ultrasonography revealed a hypoplastic radial artery requiring the interventionalist to perform coronary intervention via the transfemoral approach in this group of patients. Transradial coronary intervention (TRI) was then performed on the remaining 112 patients. Radial artery puncture was successful in all 112 patients, and 119 lesions in 111 patients were treated with TRI. Interventional procedures utilized included, balloon-angioplasty (n=39), stent placement (n=76), cutting balloon angioplasty (n=1), rotablator (n=1), and rotablator followed by stent placement (n=2). Post-procedure ultrasonography was then performed in 95 of the 111 (85.6%) patients in whom TRI had been attempted. Asymptomatic radial artery occlusion was found in six patients (6.3%). No further evidence of vascular injury was identified. Based on this data, the researchers concluded that radial ultrasonography is a useful tool in screening patients for TRI.
Over the next several years, research continued to explore the viability of radial access in transluminal coronary procedures. Gilchrist, Kharabsheh, Nickolaus & Reddy (2002) conducted a study to evaluate the potential for radial heart catheterization using a modified, combined transradial artery and transradial venous approach to right heart catheterization. The researchers conducted a retrospective database query of bilateral heart catheterizations performed over a 6-month period at a single research site. The query revealed 55 of these procedures conducted using the radial artery approach. Twenty-nine (53%) of the patients had right heart access via the forearm, while 14 (25%) were done via the subclavian or internal jugular vein. The remaining 12 (22%) patients required access via the femoral vein due to inability of establishing venous access. This was the first of its kind which showed that bilateral heart catheterization using both the radial artery and nearby radial vein was not only feasible, but offered the same benefits of transfemoral angiography with decreased rates of vascular complications, earlier ambulation times and decreased hospital stays.

Hildick-Smith, et al. (2004) took transradial research a step further by evaluating the safety of transradial coronary angiography in patients with contraindications to a transfemoral approach. The study included a prospective, cross-sectional analysis of 500 patients presenting with the following medical indications requiring transradial access: peripheral vascular disease (305), therapeutic anticoagulation (77), musculoskeletal (59), morbid obesity (32), and failed femoral approach (68). The left radial approach was used in 209 (42%) patients, and the remaining 291 (58%) underwent right radial access. Catheter gauge was 6French (Fr) in 243 (49%), 5Fr in 219 (43%) and 4Fr in 29 (6%). Adverse features such as radial artery spasm, arm pain, vasovagal reactions, ST segment elevation and ventricular fibrillation occurred in 92 cases (18%). These adverse features were more common with the 6Fr catheters (n=57) than the 5/4Fr (n=35, P<0.05). Significant post-procedure complications were noted in 10 of the cases (2%) and included persistent claudication pain on handgrip (n=1), transient ischemic attack (n=2), cardiac arrest 4 hours post-procedure (n=1), small bowel infarction (n=1), ischemic index finger tip in diabetic (n=1), forearm pain for 10 days (n=2), rebleed at puncture site (n=1) and ischemic hand for 4 hours (n=1). Following completion of the study, the researchers
concluded that transradial cardiac catheterization can be successfully performed with a low risk of major complications, even in high risk groups such as the patients in this study. Due to the results of these studies, and others like them, transradial access showed real promise as a viable, safe and effective alternative to transfemoral access.

In 2004, head-to-head studies began to be published comparing transfemoral approach versus transradial approach to PCA, with and without angioplasty. Ziakas, et al. (2004) conducted a retrospective study to compare the safety and efficacy of transradial versus transfemoral PCI of the left main (LM) coronary artery. The LM coronary artery branches into the left anterior descending artery and the left circumflex artery, and is thus responsible for supplying blood and oxygen to the anterior, inferior and lateral portions of the cardiac muscle. Due to the vast area of the heart muscle that is dependent on the LM for oxygenation, patients with coronary blockages in this area are considered to be high risk. The study included eighty patients who underwent LM PCI between February 1994 and January 2002. Forty-four (55.5%) of the patient had unprotected PCI, while 36 (44.5%) had protected LM PCI. Twenty-seven patients (33.8%) had their procedure done via the radial approach. The percentage of unprotected LM PCI in the radial versus femoral group (59.3% versus 63.6% respectively), the location of the LM stenosis, percentage of RCA occlusion, number of significantly diseased coronary arteries, mean arterial reference diameters, mean lesion length and stenosis percent were all similar between the two groups (p<0.05). Sheath size in the femoral group (7 or 8 Fr) was significantly larger (p<0.05) than the radial group (44.4% versus 77.3%), as was the amount of heparin used during the procedure (9,192 + 3,645 versus 11,468 + 5,083 IU, p<0.05). Procedure durations (67.0 ± 27.6 minutes in radial versus 73.4 ± 32.7 minutes for femoral), procedure success rates (96.3% versus 98.1%), total length of stay (4.41 ± 8.23 versus 4.78 ± 7.11 days), and in-hospital major adverse cardiac events (MACE) were all similar in the two groups (p<0.05). Vascular complications occurred only in the femoral group (5.7%). Based on the data collected, the researchers concluded that PCI of LM disease, including the radial artery approach, is a safe alternative to coronary artery bypass.
Louvard, et al. (2004) conducted the randomized OCTOPLUS study comparing transradial versus transfemoral approaches for PCA and PCI in another high risk group, patients over the age of 80. The aim of the study was to compare the incidence of significant vascular complications between the radial approach and the femoral approach thus delaying hospital discharge after PCA and PCI. After data was collected and analyzed on a total of 377 patients (192 radial, 185 femoral), the researchers concluded that the incidence of vascular complications was significantly less in the radial group (1.6% vs 6.5%, p=0.03). No difference was found in PCI efficacy between the two groups, but a slight increase in procedure duration for coronary angiography was seen in the transradial group. Cantor, et al (2005) also found the transradial approach to be equally safe and effective as the transfemoral approach when performing emergent PCI for patients suffering from an acute myocardial infarction.

While numerous studies have been conducted to study the safety and efficacy of the transradial approach to percutaneous angiography and angioplasty versus the transfemoral approach, a thorough literature review found only one study which included, but did not focus on, patient perceived differences between the two approaches. Cooper, et al. (1999) conducted a study focusing on patient perceived effects of transradial catheterization as it relates to quality of life, patient preference and cost. The researchers performed a randomized, single-center trial in which 99 patients underwent transfemoral diagnostic cardiac catheterization, and 101 patients underwent transradial diagnostic cardiac catheterization. The SF-36 and visual analog scales were used to measure patient perceived quality of life and were conducted at baseline, 1 day post-procedure and 1 week post-procedure. All patients were examined 1 day and 1 week post-procedure for vascular complications and costs were measured retrospectively. The results of the study revealed: 1) day 1 measures of bodily pain, back pain, and walking ability favored the transradial group and 2) week 1 changes in role limitation due to physical health, body pain and back pain favored the transradial group. There was also a reduction in bed, pharmacy and total hospital costs in the transradial group. These results led the researchers to conclude that transradial access for diagnostic coronary angiography
improved quality of life after the coronary procedure, as well as reduced overall hospital costs.

Although the study conducted by Cooper, et al. (1999) was, to date, the only study of its kind to include patient perceived pain assessment, as it relates to transradial versus transfemoral PCA, a study conducted by Juergens, et al. (2004) evaluated the level of patient tolerance associated with arterial closure versus an external compression device following transfemoral percutaneous coronary intervention (PCI). The study included 115 patients who underwent PCI via the transfemoral approach with a 7 Fr sheath. Following completion of their procedure, 58 patients were randomized to immediate groin closure using an AngioSeal (sheath-deployed, bioabsorbable, hemostatic closure device) and 57 to delayed sheath removal with the assistance of a Femostop device (external compression device). Patient comfort was assessed based on a short form of the McGill Pain Questionnaire using a Present Pain Instensity scale and a VAS at the end of the procedure, 4 hours post-procedure, 8 hours post-procedure and the morning following the procedure. At baseline, 98% (57) of the AngioSeal and 95% (54) of the Femostop group reported mild or no pain, with 2% and 5%, respectively, reporting worse than mild pain (p = 0.36). At 4 hours, 95% (55) from the AngioSeal and 84% (48) from the Femostop group reported mild to no pain, with 5% and 16%, respectively, reporter greater pain levels (p = 0.06). Pain levels reported at 8 hours were mild to no pain in 56 (97%) AngioSeal patients and 51 (89%) Femostop patients, with worse than mild pain being reported by 3% and 11% respectively, (p = 0.16). The morning following the procedure found 56 patients from each group reporting complete absence to mild levels of pain, with 2 (3%) of the AngioSeal and 1 (3%) of the Femostop group report worse than mild pain levels (p = 1.0). Based on the results of their data, the researchers determined that patients undergoing femoral access closure with an AngioSeal device following PCI experience less pain than patient undergoing femoral artery compression via the Femostop. In addition to the decreased levels of pain seen in the AngioSeal group, the researchers found that patients in this group were also able to ambulate sooner compared to those patients in the Femostop group, potentially reducing the risk of further complications.
Do to the limited number of studies conducted regarding percutaneous coronary access site pain the researcher broadened the scope of the literature review to include studies conducted to assess patient pain as it relates to arterial puncture/line access. Unfortunately, the literature review failed to produce any study findings regarding this topic, the search did however, reveal a number of studies which have been conducted to evaluate patient postoperative pain. Idvall, et al. (2002) conducted a study in order to describe and compare patient and nurse assessments of the quality of care in postoperative pain management in order to evaluate differences between patient subgroups, and to compare patient assessments in different departments. A total of 209 inpatients from five orthopedic, gynecological and general surgical wards were included in the study, along with 64 registered nurses from the same five surgical wards. Each inpatient answered a patient questionnaire on the second postoperative day. The questionnaire was a 14-item Strategic and Clinical Quality Indicators in Postoperative Pain Management and asked patients to rate their answers on 5 and 11 point scales. The nurse’s questionnaire consisted of 12 of the 14 statements found in the patient questionnaire and focused on the nurse’s opinion on how an individual patient’s care was performed. The patients’ mean score on the total scale (14-70) was 58.6, and the nurses’ mean score (12-60) was 48.1. In addition to total scale scores, collected data regarding expected pain was divided into four subscales; communication, action, trust and environment. The communication, trust and environment subscales were associated with more pain than expected ($\beta=-0.24, p<0.01; \beta=0.21, p<0.01$; and $\beta=0.26, p<0.001$, respectively). The action subscale was related to epidural analgesia and showed higher score in those patients’ receiving epidural intervention ($\beta=-0.22, p<0.01$). Based on the data collected, the researchers concluded that measurable differences exist between patient and nurse assessment of quality of care in postoperative pain management, as well as between patient subgroups.

Manias, E., Bucknall, T. & Botti, M. (2004) conducted a study to determine how nurses assessed patients’ pain during painful activities in the postoperative setting. All registered nurses involved in direct patient care in two surgical units of a metropolitan teaching hospital were invited to participate in the study, and of the 76 total nurses, 66
(86.8%) participated. Each of the participating nurses was observed and audiotaped for 2-hour intervals while performing direct patient care. The observation was conducted by a single research assistant with minimal disturbance. After the observation period was concluded, the research assistant asked the nurse any clarifying questions with regards to patient care observed and those responses were also recorded on audiotape. The researchers were able to identify five major themes relating to nursing assessment of patient pain; 1) simple questioning, 2) use of a pain scale, 3) complex assessment, 4) the lack of pain assessment and 5) physical assessment for pain. A total of 74 observations were conducted, and 316 pain activities were detected. It was found that simple questioning was the most common technique used for pain assessment. A smaller number of the nurses conducted pain severity assessments using visual analog scales, and very few of the nurses utilized physical and complex assessment to determine patient pain levels. More than 40% of the nurses failed to conduct any form of pain assessment when pain-related activities were observed. The researchers concluded that there was a need for a system wide approach to pain assessment.

Hsu, et al. (2005) conducted a study entitled, “Predicting Postoperative Pain by Preoperative Pressure Pain Assessment”. The goal of their study was to evaluate whether preoperative pressure pain sensitivity testing was predictive of postoperative surgical pain. The study included 40 women, ages 20-55, scheduled to undergo lower abdominal gynecologic surgery. Prior to surgery, each patient completed a State-Trait Anxiety Inventory (STAI) to measure personal traits and anxiety levels, and underwent testing using an electronic pressure algometer to determine pain thresholds and pain tolerance pressure. Immediately following the patients’ procedure, a handheld slide rule-type VAS (values 0-100) was used to assess immediate postoperative pain. Preoperative pressure pain thresholds and tolerance were 141± 65 kPa and 223±62 kPa, respectively. Immediate and 24 hour postoperative VAS scores were 81±24 and 31±10, respectively. Highly anxious patient had higher immediate postoperative VAS scores (p<0.05), and pressure pain tolerance correlated significantly with 24 hour postoperative VAS scores (p< 0.001, r = -0.52). Data analysis led the researchers to conclude that assessment of
preoperative pressure pain tolerance correlated significantly with the level of postoperative pain levels.

**Summary**

This chapter provided a review of the literature that supported the need for this study. The vast amount of research previously conducted regarding transradial versus transfemoral percutaneous transluminal coronary procedures repeatedly shows that the transradial approach is equally safe and as effective as the transfemoral approach. The research also shows that, while total procedure time in the transradial group may be longer, the overall length of hospital stay was decreased in this group. However, research focusing on patient perceived effects regarding the two access site approaches is desperately lacking, with only one published study indirectly examining the topic.
This chapter will explore the methodology used to collect and analyze data related to the comparison of patient perceived procedural access site pain in patients undergoing transradial coronary angiography versus transfemoral coronary angiography, with or without angioplasty. Discussions on the study design, setting, sampling plan, instrumentation, procedure and data analysis are included. A chapter summary will follow this discussion.

**Design**

A prospective, cross-sectional design was used to compare post-procedural access site pain in patients undergoing coronary angiography, with or without angioplasty, via a transradial versus a transfemoral access site approach.

**Setting**

This study took place at a 770-bed hospital in Northwest Florida. The hospital has over 35,000 in-patient admissions annually and employs over 500 physicians. There are two coronary angiography suites and one electrophysiology suite on site. The hospital ranks in the top 10% nationally in acute myocardial survival rates. The outlying physician referral area for angioplasty procedures covered a 100-mile radius that includes areas of North Florida and South Georgia.

**Population and Sample**

The sample for this study consisted of 50 adult patients referred to a local interventional cardiologist for coronary angiography and possible angioplasty due to anginal symptoms. The out-lying physician referral area covered a 100-mile radius that includes areas of North Florida and South Georgia. Inclusion criteria were patients over the age of 21 who presented with signs and/or symptoms of coronary artery disease.
There was no exclusion criteria. Procedure related data was obtained by means of a retrospective chart analysis. Supplemental demographic information and a cardiac risk profile were also obtained via patient interview.

**Instruments**

During the patient’s initial consultation with the interventional cardiologist, the researcher obtained demographic and cardiac risk factor data (Appendix B).

A 10-point Visual Analog Scale (Appendix A) was given to the patient for completion following the procedure. The Visual Analog Scale (VAS) is a straight, horizontal line usually 100mm. in length with clearly defined boundaries (Graham, 2006). The patient was asked to rate their catheter access site pain on this 0-10 scale, with 0 representing no pain and 10 representing the worst pain imaginable by circling the number that corresponded to the level of pain they were experiencing at their access site. Several studies have been conducted and shown the VAS to be a reliable method of measuring patient perceived pain (Aitkens, 1969; Huskisson, 1983; McCarthy, et al. 2005).

The following data was obtained from the patient’s hospital Procedure Report found in the patient’s medical record (Appendix C):

1. Procedures performed which included coronary angiography, right heart catheterization, left ventriculography, and percutaneous coronary intervention.
2. Procedural outcome which included access route, sheath size, sheath insertion time, catheterization time, hemostasis time, total procedure duration, catheters used per case.

After the patient was discharged from the hospital, the following data regarding access site complications were collected from the patient’s medical record: hematomas, pseudoaneurysms, AV fistulas, retroperitoneal bleeds.
Procedure

Following approval of the Institutional Review Board at Florida State University and the Institutional Review Board at Tallahassee Memorial Hospital, data was collected on perceived procedural access site pain of patients undergoing both transradial and transfemoral angiography, with or without angioplasty. At the conclusion of the patient’s consultation with the interventional cardiologist, when the need for PCA was established, the access site for the patient’s procedure was determined and the PCA was scheduled as an outpatient procedure. In an attempt to control extraneous pain variables related to physician technique, all percutaneous coronary procedures were performed by the same interventional cardiologist. On the day of the patient’s procedure, prior to patient transfer to the catheterization lab, each patient was given an informed consent form (Appendix D) and assigned a patient identification number to be used in lieu of the patient name for patient privacy purposes. After the patient’s procedure had concluded, each patient was given a VAS pain scale to assess the patient’s access site pain on a 0-10 scale. The VAS scale was completed by the patient while in the post-interventional observation suite. Patient post-procedure pain levels, as reported by the patient via the VAS scales, were compared to evaluate the differences in post-procedure access site pain in the transradial versus transfemoral approaches.

Protection of Human Subjects

Prior to data collection, the researcher met with the Institutional Review Boards at Florida State University and Tallahassee Memorial Hospital to obtain study approval. Once approved, the researcher began to gather patient demographic data, cardiac risk profile data, presenting symptomology data and patient perceived pain data. All of the data collected was kept strictly confidential and keeping with the guideline set forth by both Florida State University and Tallahassee Memorial Hospital. Each patient included in the study was assigned an identification number at the beginning of the study that was used in lieu of their name. The data collected has been kept in the researcher’s locked cabinet and will be shredded at the conclusion of the study. The researcher, statistical consultant and thesis chair viewed the confidential data. In addition, any
patient identifying information will be excluded from any additional reports, presentations or publications that may result from the collected data in this study.

**Data Analysis**

An analysis of the above gathered data was completed and correlated. Descriptive statistics were then implemented to determine the difference in patient perceived procedural access site pain between the two study groups. All categorical data will be presented as frequencies and continuous data as means, plus or minus, standard error. Comparisons between the groups were performed with a 2-tailed unpaired *t* tests and correlation analysis using Pearson’s *r*, when appropriate.

**Summary**

This chapter discussed the research design, setting, population, instrumentation, procedure, protection of human subjects and data analysis of the study. A prospective, randomized, cross-sectional study was used to evaluate and compare patient perceived post-procedural access site pain following transradial versus transfemoral coronary angiography, with or without angioplasty. Data consisted of information obtained from the patient medical record and a visual pain analogue form completed by each patient at the conclusion of their procedure. In addition, procedural data and patient demographic data were examined.
CHAPTER 4
RESULTS

This prospective, cross-sectional study was conducted to compare post-procedural access site pain in two distinct groups of patients undergoing coronary angiography, those undergoing a transradial approach and those undergoing a transfemoral approach. The knowledge gained will aid healthcare professionals in anticipating, preventing and treating post-procedural access site pain following percutaneous coronary procedures. Betty Neuman’s Systems Model guided the investigation. The purpose of this chapter is to provide the results, conclusions and a statistical summary of the findings established through analysis of the data collected during the course of this study as they relate to each research question. The primary objectives of the study were to evaluate and compare patient perceived pain levels following transradial and transfemoral angiography, with or without angioplasty, in an attempt to increase nursing and physician knowledge regarding patient access site pain levels following percutaneous coronary procedures. Tables and figures of the data, ranging from simple frequencies to more in-depth statistical analysis, will be provided, along with all necessary data, interpretation and conclusions.

Description of the Sample

Study approval was received from the Institutional Review Boards of Florida State University and the participating research hospital. Once formal approval was obtained from the aforementioned governing bodies, patients were screened based on the inclusion/exclusion criteria, interviewed and consented for participation in the study.

The sample consisted of 50 adult patients referred to a local interventional cardiologist for coronary angiography and possible angioplasty due to symptoms of underlying coronary artery disease. The physician referral area covered a 100-mile radius including areas of North Florida and South Georgia. The research hospital is a 770-bed facility in Northwest Florida averaging 35,000 in-patient admissions annually.
and employing over 500 physicians. The hospital has two coronary angiography suites, one electrophysiology suite and ranks in the top 10% nationally in acute myocardial survival rates. Study participants were admitted to the hospital on an elective-outpatient basis the day of the procedure. Data were collected from September 22, 2006 to January 25, 2007.

**Descriptive Statistics**

Patient demographic data was obtained via patient interview and compiled using a demographic instrument developed by the investigator (Appendix B). The study sample (n=50) consisted of 29 (58%) males and 21 (42%) females. The transradial access group consisted of a smaller number of females (n = 9, 33.3%) than males (n = 18, 66.7%) males, while the transfemoral group was comprised of a more equal amount of females (n=12, 52.2%) and males (n = 11, 47.8%) males.

The racial makeup of the study participants included 37 (74%) Caucasians and 13 (26%) African Americans, with the transfemoral group being comprised of 16 (69.6%) Caucasians and 7 (30.4%) African Americans, and the transradial group comprised of 21 (77.8%) Caucasians and 6 (22.2%) African Americans. The median age for the total sample was 62 years (mean = 63.5, SD = 11.2); median age of 57 years (mean = 61.27, SD 9.483) in the transradial group and a median age of 62 years (mean = 65.65, SD 12.985) in the transfemoral group.

Patients presented for initial consultation with the following chief complaint(s): 31 (62%) reported chest pain/pressure consisting of 19 (61.3%) from the transradial group representing 70.4% of that sample group, and 12 (38.7%) from the transfemoral group representing 52.2% of the femoral group.

Twenty-six (52%) of the sample suffered from shortness of breath, 10 (38.5%) from the transradial group representing 37.0% of the radial sample, and 16 (61.5%) from the transfemoral group representing 69.6% of that sample. Five (10%) presented with the complaint of shoulder/left arm pain, 2 (40.0%) being transradial patients representing 7.4% of the radial sample, and 3 (60.0%) were femoral patients representing 12% of the femoral group. Fourteen (28%) presented following positive
stress testing suggestive of myocardial ischemia, 11 (78.6%) of which involved patients in the transradial group representing 40.7% of that sample group, and the remaining 3 (21.4%) were transfemoral representing 13% of that sample group.

Variables used to assess the participants risk for cardiac disease included the presence, or absence, of the following conditions: obesity, diabetes, hypertension, nicotine dependence, hyperlipidemia and family history of premature coronary artery disease. Each patient’s BMI was calculated based on their height and weight, and a BMI score of 30 or greater was classified as being obese (Department of Health and Human Services, 2007). Twenty-eight (56%) of the participants were classified as obese, 16 (57.1%) were from the radial group representing 59.3% of the sample, and 12 (42.9%) were from the femoral group representing 52.2% of that total sample group.

Sixteen (32%) of the total sample were diabetic and included 6 (37.5%) from the radial group representing 22.2% of that sample group, and 10 (62.5%) were from the femoral group representing 43.5% of that sample group.

A diagnosis of hypertension was present in 44 (88%) of the sample participants. Of that 44, 23 (52.3%) were from the transradial group comprising 85.2% of the radial sample group, and 21 (47.7%) were from the transfemoral group representing 91.3% of the femoral sample group. Forty two (84%) had hyperlipidemia involving 23 (54.8%) patients from the transradial sample representing 85.2% of the total radial group, and 19 (45.2%) from the transfemoral group representing 82.6% of the that sample group.

Nicotine dependence/smoking was reported in 13 (26%) of the study participants, which included 9 (69.2%) transradial patients equaling 33.3% of the transradial sample and 4 (30.8%) from the transfemoral group equaling 17.4% of the femoral sample. A positive family history of coronary artery disease was reported by 27 (54%) of the study patients, 14 (51.9%) from the radial group representing 51.9% of that sample and 13 (48.1%) from the femoral group representing 56.5% of that group.

In this study group, hypertension was the most prevalent cardiac risk factor, followed closely by the presence of hyperlipidemia. Obesity and a positive family history of coronary artery disease were reported in over half of the sample participants.
and approximately one third of the patients were diabetic. Nicotine dependence was reported in only 26% of the total sample population.

Prior to the patients coronary procedure, intended route of vascular access was determined. Vascular access site determination factors included results of radial Allen test and the need for right heart catheterization. All patients undergoing right heart catheterization were assigned to the transfemoral group per physician preference, as were patients with an abnormal Allen test indicating lack of dual circulation to the palmar arch. Of the 50 study participants, 27 (54%) underwent transradial approach and 23 (46%) underwent transfemoral access site approach.

At the conclusion of the patient’s percutaneous coronary procedure, procedure specific data was obtained from the patient’s operative report. Study participants underwent the following procedures: 49 (98%) (96.3% of the transradial group, 100% of the transfemoral group) underwent coronary angiography; 11 (22%) (0% of the transradial sample group, 47.8% of the transfemoral group) had right heart catheterization; left ventriculography was performed in 48 (96%) of the sample (92.6% of the radial sample and 100% of the femoral sample group) and 12 (24%) (37% of the radial group and 8.7% of the femoral group) underwent percutaneous coronary intervention. While the rates of coronary angiography and left ventriculography were similar between the transradial and transfemoral, more of the transradial group underwent percutaneous coronary intervention compared to subjects from the transfemoral group, and only members of the transradial group underwent right heart catheterization due to operator preference (Figure 1).
Mean sheath size was comparable between the two sample groups (transradial group mean = 5.74, SD = .447 and transfemoral group mean = 5.3, SD = .822). Total procedural time ranged from 5 minutes to 127 minutes (transradial mean = 31.81, SD = 27.616; transfemoral mean = 33.04, SD = 24.206). The number of catheters used during the procedure ranged from 1 to 8 (transradial mean = 3.11, SD = 1.396; transfemoral mean = 4.17, SD = 1.825) (Table 1). There were no access site complications of hematoma, pseudoaneurysm, AV fistula or retroperitoneal bleed reported in the study group.
Research Question 1

The first research question explored the difference in perceived post-procedural access site pain levels between the two study groups, transradial access approach and transfemoral access approach. Post procedural pain was assessed using a 10-point VAS scale (Appendix A) completed by the patient following their procedure with 0 representing no pain and 10 representing the worst pain ever experienced by the patient. Post procedural access site pain level in the transradial group ranged from 0 to 7 (mean = 1.685, SD = 1.9570), and 0 to 7 (mean = 1.304, SD = 1.9173) in the transfemoral group. The average post-procedural transradial and transfemoral access site pain rating scores differed by a score of 0.381. The calculated standard error of difference, or the amount of difference the researcher can attribute to pure chance, was 0.5502. Therefore, the data indicated that the difference in perceived post-procedural pain scores between the transradial and transfemoral group was not significantly different. Therefore, the difference in perceived pain levels between patients who underwent transradial approach and those who underwent transfemoral access site approach are attributed to pure chance (Table 2).
Table 2 - Comparison of Patient Perceived Post-Procedural Access Site Pain between Transradial and Transfemoral Approach

<table>
<thead>
<tr>
<th>Access Site</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-procedure pain</td>
<td>radial</td>
<td>27</td>
<td>1.685</td>
<td>1.9570</td>
</tr>
<tr>
<td></td>
<td>femoral</td>
<td>23</td>
<td>1.304</td>
<td>1.9173</td>
</tr>
</tbody>
</table>

Levene’s Test for Equality of Variances

<table>
<thead>
<tr>
<th>Post-procedure pain</th>
<th>Equal variances assumed</th>
<th>Equal variances not assumed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F</td>
<td>Sig.</td>
</tr>
<tr>
<td></td>
<td>.046</td>
<td>.830</td>
</tr>
<tr>
<td></td>
<td>.693</td>
<td>47.032</td>
</tr>
</tbody>
</table>

Research Question 2

The second question examined patient perceived post procedural access site pain levels following the patient’s percutaneous transluminal coronary intervention as it related to age, gender and BMI. Post procedural pain was assessed using a 10-point VAS scale (Appendix A) completed by the patient following their procedure, with 0 representing no pain and 10 representing the worst pain ever experienced by the patient. Post procedural access site pain levels ranged from 0 to 7 (mean = 1.510, SD = 1.9285). Two-tailed independent t-tests were performed to compare the variables of gender and race to reported pain levels. Reported post-procedural pain levels in the female group ranged from 0 to 7 (mean = 1.667, SD = 2.4358) and 0 to 5 in the male group (mean = 1.397, SD = 1.4963). The mean difference between genders was 0.2701 resulting in p =
0.656 rendering the difference in pain levels between the two groups non-significant (Table 3).

Table 3 – Association between Gender and Reported Level of Post-procedural Access Site Pain

<table>
<thead>
<tr>
<th>Gender</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-procedure pain</td>
<td>female</td>
<td>21</td>
<td>1.667</td>
<td>2.4358</td>
</tr>
<tr>
<td>Post-procedure pain</td>
<td>male</td>
<td>29</td>
<td>1.397</td>
<td>1.4963</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Levene’s Test for Equality of Variances</th>
<th>t-test for Equality of Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>Sig.</td>
</tr>
<tr>
<td>Post-procedure pain</td>
<td>Equal variances assumed</td>
</tr>
<tr>
<td>Post-procedure pain</td>
<td>Equal variances not assumed</td>
</tr>
</tbody>
</table>

A correlation analysis, using Pearson’s $r$, was used to evaluate the relationship between the reported pain levels and the variables of age and BMI. The relationship between age (mean = 63.50, SD = 11.289) and perceived pain levels proved to be not significant ($r = 0.014$, $p = 0.922$). However, a negative correlation was found between BMI (mean = 31.72, SD= 7.897) and reported pain levels ($p=0.033$), indicating as the BMI went down, the reported pain level increased (Table 4).
Table 4 - Association between Variables of Age and BMI to Reported Access Site Pain Levels

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>BMI</th>
<th>Post-procedure pain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>1</td>
<td>-.212</td>
<td>.014</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.139</td>
<td>.922</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>-.212</td>
<td>1</td>
<td>-.301*</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.139</td>
<td></td>
<td>.033</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td><strong>Post-procedure pain</strong></td>
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<td></td>
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</tr>
<tr>
<td>Pearson Correlation</td>
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<tr>
<td>Sig. (2-tailed)</td>
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<td>.033</td>
<td>.</td>
</tr>
<tr>
<td>N</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

*Correlation is significant at the 0.05 level (2-tailed).

Research Question 3

The third research question examined patient perceived post procedural access site pain levels following the patient’s percutaneous transluminal coronary intervention as it related to sheath size, total procedure time and the number of total catheters used for the procedure. Once again, post procedural pain was assessed using a 10-point VAS scale (Appendix A) completed by the patient following their procedure with 0 representing no pain and 10 representing the worst pain ever experienced by the patient. Correlation analysis, using Pearson’s r, was used to evaluate the relationship between the reported pain levels and the variables of sheath size, total procedure duration and the total number of catheters used during the procedure. The relationship between sheath size (mean = 5.54, SD = 0.676) and reported pain levels proved to be non-significant (r = -0.036, p = 0.807). The relationship between total procedure time (mean=32.38, SD=25.848) and pain levels (r = 0.151, p = 0.294) and total catheters used (mean = 3.60, SD = 1.678, r = -0.301, p = 0.478) also was not significant (Table 5).
Table 5 – Association between Variables of Sheath Size, Procedure Length and Total Catheters to Levels of Reported Pain

<table>
<thead>
<tr>
<th></th>
<th>Sheath size (french) Pearson Correlation Sig. (2-tailed)</th>
<th>Total procedure duration (minutes)</th>
<th>Total catheters used</th>
<th>Post-procedure pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath size (french)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.290*</td>
<td>.032</td>
<td>-.036</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Total procedure duration (minutes) Pearson Correlation Sig. (2-tailed)</td>
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<td>Sig. (2-tailed)</td>
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<td>.011</td>
<td>.294</td>
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<td></td>
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<tr>
<td>Total catheters used</td>
<td>Pearson Correlation Sig. (2-tailed)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sig. (2-tailed)</td>
<td></td>
<td>.355*</td>
<td>1</td>
<td>-.103</td>
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<td>N</td>
<td></td>
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<tr>
<td>Post-procedure pain</td>
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</tbody>
</table>

*. Correlation is significant at the 0.05 level (2-tailed).

Conclusions

The following conclusions were derived from the research analysis:

1. There was no statistically significant difference in reported post-procedural pain levels between the two access site groups. The use of the transradial access site approach did not result in statistically lower levels of perceived post-procedural pain when compared to the transfemoral approach. Therefore, the null hypothesis is accepted.

2. Patient age and gender had no statistically significant relationship on reported post-procedural pain levels, supporting the null hypothesis regarding these two variables and their relation to reported pain levels.

3. A statistically significant difference in reported pain levels related to the patient’s BMI did exist. The data showed that the lower BMI score, the higher the patient’s reported access site pain level following the procedure. This resulted in rejection of the null hypothesis and acceptance of the alternative hypothesis of a significant relationship between patient BMI and post-procedural access site pain levels.
4. Sheath size, length of procedure and total number of catheters used had no significant relationship to the amount of access site pain reported after the procedure. Therefore, the null hypothesis regarding these variables and their relationship to patient perceived post-procedural access site pain was supported and accepted.

Summary

This chapter provided both descriptive and statistical analyses addressing the three research questions posed in this study. Descriptive statistics focused on both the demographics of the participant population, describing such factors as age, gender, race, BMI and comorbidities, as well as, procedural factors including sheath size, total procedure duration and the total number of catheters used during the procedure. Three research questions were presented and examined to determine reported levels of post-procedural access site pain among the study participants.

It was also determined that the route of vascular access did not have a statistically significant impact on the level of patient perceived access site pain following the procedure. Patient age, gender and race did not show any statistically significant difference in reported pain levels, nor did the procedural related data of sheath size, total procedural duration and total catheter use. There was however, one correlation worth noting among the study participants. The data analysis revealed a negative correlation between patient BMI and reported pain levels, revealing that the lower the patient’s BMI, the higher the level of reported pain.
This chapter provides a summary discussion of the research findings, their relation to the conceptual framework and whether findings of this study support, or differ, from previously conducted research. Assumptions and study limitations proposed prior to the study will be discussed. The researcher will also provide conclusions based on the research findings, discuss how these findings can be applied to improve advanced nursing practice and make recommendations for future research.

Discussion of the Study and Study Findings

The purpose of this study was to explore patient perceived access site pain levels following coronary angiography, with and without angioplasty. The study explored three research questions. The first question studied the difference of patient access site pain levels in patients undergoing a transradial access approach compared to those undergoing a transfemoral approach. The second research question explored the relationship between patient demographics and reported pain levels. The third question studied the relationship between procedural factors and the level of perceived access site pain. The researcher proposed three hypotheses: 1.) Use of the transradial access site would result in lower levels of reported access site pain compared to the use of the transfemoral approach; 2.) Patient demographics of age, gender and BMI would have no statistically significant relationship to the levels of reported post-procedural access site pain and 3.) Procedural factors of sheath size, length of procedure and total number of catheters used during the procedure would have no statistically significant relationship to the reported access site pain levels.

After approval was obtained from the Institutional Review Boards of Florida State University and a north Florida area hospital, study participants were selected based on the inclusion/exclusion criteria. Fifty patients agreed to participate in the proposed study. Following consultation with the interventional cardiologist, patients were scheduled to
undergo elective coronary angiography and possible angioplasty via one of two access routes, transradial or transfemoral.

Patient demographic, procedural and pain rating data were then compiled and evaluated. The results on patient perceived access site pain as it related to the route of vascular access, age, gender, sheath size, length of procedure and total number of catheters used revealed no statistically significant difference within these groups and, as a result, the researcher’s hypotheses regarding access site and it’s relationship to access site pain was not supported. However, the researcher’s hypotheses regarding the relationship between the variables of age, gender, sheath size, length of procedure and total number of catheters to reported pain levels was supported, in that no statistically significant relationship was found. There are several possible reasons why significant findings were not found. The first possible reason is due to limited sample size. Many of the individuals in this study reported complete absence of access site pain following their procedure resulting in a skewed distribution of the reported pain data. Another possible reason is the fact that all procedures were conducted by the same interventional cardiologist. The determination to use only one interventional cardiologist for all procedures was made by the researcher prior to conduction of the study in an attempt to control for the extraneous variable of operator technique, however, after collection and evaluation of the data, this proved to be a limitation of the study. The interventional cardiologist participating in the study has extensive experience performing coronary angiography/angioplasty via both the transfemoral and transradial approach. It is possible that patients undergoing percutaneous coronary procedures done by less experienced interventionalists may report higher levels of post-procedure access site pain secondary to operator technique, however, this relationship could not be explored during this study secondary to a lack of multiple physician operators. In addition, this study focused only on stable cardiac patients undergoing elective coronary procedures and did not take into account patients undergoing emergency percutaneous coronary procedures.

A statistically significant negative correlation was found between patient BMI and reported levels of access site pain, revealing that patients with a lower BMI score reported higher levels of post-procedural access site pain compared to patients with
higher BMI scores. This may indicate higher levels of pain tolerance in obese individuals. Another potential explanation may be that the operator was able to inject greater amounts of local anesthetic (i.e. Lidocaine) at the access site in patients with higher BMI scores compared to the thinner patients. These findings support the researcher’s hypothesis regarding the relationship between BMI and access site pain.

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

The findings of this study confirmed the results of those conducted by Gilchrist, Kharabsheh, Nickolaus & Reddy (2002), Hildick-Smith, et al. (2004), Ziakas, et al. (2004) and Louvard, et al. (2004) showing the transradial access site to be an equally effective and safe approach to coronary angiography/angioplasty as the transfemoral approach. This was evidenced in this study by the operator’s ability to successfully complete each procedure and the lack of access site complications reported in the study. Right heart catheterization performance was not addressed in these previous studies.

The study conducted by Cooper, et al. (1999), which included 200 patients (99 transfemoral and 101 transradial) who underwent diagnostic coronary angiography, assessed the differences in quality of life, patient preference and cost between the two access site approaches. The access site pain levels between the two access site approaches at one day and one week post-procedure reported by Cooper, et al. showed no statistically significant difference in reported pain levels between these two groups, a finding supported by the results of this study. However, the Cooper, et al. study (1999) did reveal higher quality-of-life scores defined by physical functioning (p < 0.05), role limitations (p < 0.01), bodily pain (p < 0.0001), overall discomfort (p < 0.001), back pain (p < 0.0001) and walking ability (p < 0.005) reported in the transradial group versus the transfemoral group, factors not evaluated in this study. In addition, their study showed decreased overall costs in the transradial group versus the transfemoral group. Taking all of these factors into consideration led Cooper, et al. to promote the transradial access site as the favorable approach to vascular access in patients undergoing diagnostic coronary angiography. It is important that all research, whether in support of or opposition to, the researcher’s hypotheses, be made available to the medical community. It is up to
advanced practice nurses and other members of the medical community to research which techniques to implement and which to abandon.

**Relationship of the Results to the Theoretical Framework**

Neuman’s Health Care Systems Model (2002) is based on the patient’s relationship to the environment, and the response of the patient to potential stressors within the environment. The use of Neuman’s model as the framework for this study allowed the researcher to examine a routine, but potentially stressful, coronary procedure. It was important to understand this theory, aiding the researcher in understanding how a person might perceive and react to this stressful situation. The following discussion will attempt to address this study in relation to Neuman’s model.

All four components of Neuman’s model (person, environment, health and nursing) are pertinent factors in relation to patient pain. Pain can be considered a stressful event and experiencing such a stressful event can result in changes within the client system and alterations in the flexible line of defense, normal line of defense and lines of resistance. Therefore, the level of pain experienced by patients undergoing coronary angiography via arterial puncture can vary greatly, depending on the stability of the client system and the degree of alteration in patient perception at the time of the event.

Environmental factors, both internal and external, also play a role in the pain responses obtained. Many individuals have preconceived ideas and biases regarding their experience during the procedure based on previous experiences perceived by individuals known to the client. These preconceived biases may affect the level of access site pain reported by the individual following the procedure. In addition, many individuals view the hospital as a place reserved for the acutely ill and where patients are exposed to uncomfortable procedures. This common viewpoint may also impact the levels of reported pain.

In terms of health, all of the subjects included in this study were referred due to an alteration in their previous location on the wellness/illness continuum as evidenced by the presence of new symptoms. The severity of the symptoms and/or the presence of
comorbidities may lead the patient to perceive the procedure as a further threat to system stability and thus alter the levels of reported access site pain following the procedure.

Nurses are viewed by the majority of the public as trustful, compassionate, competent members of the health care team. As a result, patients will often address concerns and problems with nurses that they would not discuss with other members of the health care team. It is, therefore, imperative that nurses familiarize themselves with factors that may influence a patient’s level of perceived access site pain following percutaneous coronary procedures in order to provide the patient with accurate anticipatory education regarding the procedure. In addition, the nurse must be cognizant of the need to assess for post-procedural access site pain in every individual.

Each client system, or patient as it relates to this study, is comprised of five interrelated variables: physiological, psychological, sociocultural, developmental and spiritual. This study focused on three of these variables: the physiological, psychological and sociocultural. All of the study participants in this study were experiencing some level of instability within these three variables prior to the procedure. According to Neuman’s model, an individual’s degree of reaction to a stressor is dependent upon the time of the occurrence of the stressor, the individual’s present and past condition, the nature and intensity of the stressor and the amount of energy required by the individual to adapt to the stressor. Taking these factors into consideration may explain the difference in reported post-procedural access site pain levels seen among the study participants.

Nurses can assist patients in strengthening their flexible lines of defense through primary prevention aimed at stress prevention and reduction of risk factors in order to increase and maintain the patient’s level of wellness. However, the nurse must be prepared to initiate secondary prevention measures when stressors, in this instance pain, are significant enough to penetrate these defense barriers. Having a thorough knowledge of potential access site complications following percutaneous intervention and ensuring appropriate orders for needed pain medication prior to the procedure are two examples of how nurses can prepare for secondary prevention needs.
Limitations

All of the subjects for this study were selected from patients referred to a single, local interventional cardiologist. While the out-lying physician referral area covered a 100-mile radius including areas of North Florida and South Georgia, selection of the patient from a single consulting cardiologist resulted in a small, convenience sample. As a result, the ability to generalize the study’s findings to the entire cardiac population was reduced.

An additional limitation of this study is the subjective nature of the pain experience. The researcher must record the level of pain as reported by the patient. Depending on how the patient perceives the relationship between himself/herself and the researcher, may affect the level of reported pain in an attempt to provide an answer believed to be accepted to the researcher.

Following evaluation of the data collected in the study, the researcher discovered two additional limitations of the study that were not mentioned prior to data collection. The first of these was failure to assess the amount of subcutaneous lidocaine used to anesthetize the patient’s wrist or groin prior to vascular access attainment. Differences in the amounts of localized anesthesia used between patients could affect the amount of post-procedural access site pain reported by the patient following the procedure. The second limitation revealed during evaluation of the study data was that all study subjects underwent elective coronary angiography, both with and without angioplasty. Therefore, patients undergoing emergent percutaneous coronary procedures were not taken into account, further limiting the ability to generalize study results.

Assumptions

This study made a number of assumptions that the reader must take into consideration when drawing any conclusions on its results. Study patients were expected to rate their level of access site pain following the procedure accurately and honestly. The researcher recorded these reported pain levels believing they represented a true value of the pain being experienced by the participant. It was also assumed that each patient’s level of pain did not interfere with their ability to complete the VAS pain assessment.
form and that the VAS would provide an accurate measure of the patient’s level of post-procedural access site pain.

Implications for Advanced Nursing Practice

The results of this study support the fact that medical practice cannot be based on the results of a single study. The results of this study support those reported by Cooper, et al. (1999) in relation to patient perceived access site pain following transradial versus transfemoral percutaneous coronary procedure. However, there are additional quality of life factors, such as those explored by Cooper, et al. (1999), which warrant further research as they relate to the two vascular access approaches.

Advanced practice nurses are leaders in the field of nursing and, as such, must take responsibility for advancing the profession through research and education. The improvement of nursing practice and patient care are dependent on the information obtained through the conduction of research studies such as this. Therefore, it is crucial that more advanced practice nurses replicate this type of study, and that of Cooper, et al. (1999) to promote high quality nursing practice, by using larger, randomized sample sizes and multiple physician operators.

Recommendations for Future Research

One recommendation for future research would be to increase the number of physician operators. By doing so, this would not only increase the study population but would also take into account the difference of operator technique and its potential affect on the levels of access site pain perceived by the patient following their procedure.

Once again, this study only included stable cardiac patients undergoing elective coronary procedures. A future study may want to also include unstable patients undergoing emergent coronary angiography/angioplasty procedures. The inclusion of both stable and unstable cardiac patients might reveal a difference in the levels of access site pain experienced by these two groups of patients.

A further recommendation would be to assess the levels of reported access site pain at different time intervals following the procedure in an attempt to evaluate pain
fluctuations following the procedure. In addition, including a quality of life survey would aid in evaluating perceived limitations placed on the individual following the procedure as it related to the route of vascular access. It is the hope of the researcher that readers of this study will relate to its goal and objectives and by doing so, elect to take an active role in pursuing future research in order to both advance the profession of nursing and improve the quality of patient care.

**Summary**

This chapter provided further discussion regarding the study findings as they related to the three proposed research questions. Following data analysis, it was determined that the route of vascular access did not have a statistically significant impact on the level of patient perceived access site pain following the procedure. Patient age, gender and race did not show any statistically significant difference in reported pain levels, nor did the procedural related data of sheath size, total procedural duration and total catheter use. There was however, one correlation worth noting among the study participants. The data analysis revealed a negative correlation between patient BMI and reported pain levels, revealing that the lower the patient’s BMI, the higher the level of reported pain.
APPENDIX A
Post-Procedure Pain Assessment

Date:

Time:

Patient Identification Number:

Please indicate the amount of wrist access site pain you are currently experiencing using the scale below.

![Pain Scale]

No pain Worst ever
Post-Procedure Pain Assessment

Date:
Time:
Patient Identification Number:

Please indicate the amount of groin access site pain you are currently experiencing using the scale below:

0 1 2 3 4 5 6 7 8 9 10

No pain Worst ever
APPENDIX B
Patient Demographics

Date: 
Patient Identification Number: 
D.O.B.: 
Gender: 
Weight: 
Height: 
BMI: 
Race: W B H Other

Presenting Symptoms:
    Chest pain/pressure _____
    Shortness of breath _____
    Shoulder/Left arm pain _____
    Positive stress test _____

Cardiac Risk Factors:
    DM _____
    HTN _____
    Smoking _____
    Hyperlipidemia _____
    Obesity _____
    Family history _____
APPENDIX C

Procedural Data

Date:
Patient ID Number:

Procedure Performed:
- Coronary angiography _____
- Right heart catheterization _____
- Left ventriculography _____
- Percutaneous coronary intervention _____

Procedure:
- Access site:
- Sheath size:
  - Sheath insertion time:
  - Catheterization time:
  - Hemostasis time:
- Total procedure duration:
- Fluoroscopy time:
- Contrast volumes:
- Total catheters used:

Access Site Complications:
- Hematoma _____
- Pseudoaneurysm _____
- AV Fistula _____
- Retroperitoneal bleed _____
APPENDIX D
Human Subjects Committee
Informed Consent for Adults

A Comparison of Patient Perceived Post-Procedure Pain in Patients Undergoing Primary, Elective Transradial versus Transfemoral Coronary Angiography/Angioplasty

I HAVE BEEN INFORMED THAT:

Nancy Anne Wagner, who is a Registered Nurse and graduate student at Florida State University, has requested my participation in a research study at this institution. The purpose of the research is to evaluate and compare patient perceived pain levels following transradial and transfemoral angiography, with or without angioplasty, as it relates to the route of vascular access. The main focus is to determine whether one access approach is superior to the other in terms of minimizing patient discomfort following a percutaneous coronary procedure. Research has proven that both the transradial and transfemoral access approach are equally safe and effective, but research regarding the patient discomfort as it relates to the two approaches is lacking.

The subjects included in this research study are adults experiencing symptoms of coronary artery disease undergoing their first coronary angiography. Approximately 60 subjects are needed for the study. The data will be collected from the Northwest region of Florida.

My participation will involve completing two visual analog scales (VAS) to report the amount of pain I may be experiencing at the access site being used for my procedure. One VAS is to be completed prior to the coronary angiography and the second VAS is to be completed following the coronary angiography prior to discharge from the hospital. This is a non-experimental research study and only the pain assessment scores, demographic information and procedural data will be collected. Nonparticipation or withdrawal from the study will not affect treatment or care. There are no foreseeable risks or discomforts to me if I agree to participate in the study.
Although there may be no direct benefits to me, the possible benefit of my participation in this research study is to learn which access approach results in less post-procedural discomfort to the patient with regards to access site pain.

The results of this research study may be published but my name and identity will not be revealed. In order to maintain confidentiality of my records, the researcher, Nancy Anne Wagner, will use patient identification numbers to identify and pair up the VAS forms from pre-procedure and post-procedure periods. The identifiable information will be destroyed after assigning the subject codes. The only persons who will have access to the data are Nancy Anne Wagner – researcher, Dr. Wayne Batchelor – Interventional Cardiologist and Dr. Laurie Grubbs – Research Chairperson. The surveys will be kept in a locked box at the researcher’s home office.

I will not be paid for my participation. Any questions I have regarding the research study or my participation in the study, before or after my consent is signed, will be answered by Nancy Anne Wagner at 1652 N Alshire Court, Tallahassee, Florida 32317, 850-201-4836 or 850-510-1809.

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

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

Signature_______________________________________Date__________________
APPENDIX E

Tallahassee Memorial Healthcare
Institution Review Board Approval Letter
July 25, 2006

Nancy Anne Wagner, RN
1652 North Ashville Court
Tallahassee, FL 32317

Dear Ms. Wagner:

Your study IRB # 2006-25 Title: Comparison of Patient Perceived Post-procedural Pain in Patients Undergoing Transradial Versus Transfemoral Coronary Angiography/Angioplasty met the criteria for an Expedited Review. Larry C. Deeb, M.D., Tallahassee Memorial HealthCare (TMH) Institutional Review Board (IRB) Chairperson reviewed and approved the study on July 12, 2006 for one year. The expiration date of this approval is July 11, 2007.

IRB # 2006-25

Principal Investigator:
Nancy Anne Wagner, RN

Informed Consent:
Version July 2006

Reporting Requirements:
1) You will need to report to the IRB any: 1) You will need to request approval before making any amendments to the informed consent and prior to implementing them; 2) Report to the IRB any planned change in the study or study protocol and do not implement any change without receiving prior approval, except to eliminate immediate hazard; 3) Report to the IRB any unanticipated problems involving risks to subjects; 4) Report to the IRB any new information on the project that adversely influences the risk/benefit ratio; 5) Report to the IRB any adverse events (AE).

None

Expiration Date:
July 11, 2007
APPENDIX F

Florida State University
Institutional Review Board Approval Letter
Office of the Vice President For Research
Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-8673  FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 8/17/2006

To: Nancy Anne Wagner
1652 N.Alshire Ct.
Tallahassee, FL 32317

Dept.: NURSING

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research
Comparison of Patient Perceived Post-Procedure Pain in Patients Undergoing Transradial versus Transfemoral Coronary Angiography/Angioplasty

The forms that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and two members of the Human Subjects Committee. Your project is determined to be Expedited per 45 CFR § 46.110(b) 7 and has been approved by an accelerated review process.

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

If the project has not been completed by 8/16/2007 you must request renewed approval for continuation of the project.

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

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

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

Cc: Dr. Laurie Grubbs
HSC No. 2006.0553
REFERENCES


Nancy Anne Wagner was born on October 11, 1973 in Woodbridge, VA, to Robert and Nancy Wagner. Her family moved to Durango, Colorado when she was two weeks old to run a campground, where she lived until moving to Tallahassee, Florida at the age of fifteen. She lives with her partner, Sonya Bush and stepson, Tyler, and works as a Registered Nurse for Dr. Wayne Batchelor at Southern Medical Group.

Miss Wagner has previously worked in the areas of primary care and home health. She went to work for Dr. Batchelor in April 2002. It was her nursing experience with Dr. Batchelor in the field of interventional cardiology that provided the desire to pursue her advanced nursing education. The current study provided an opportunity to explore nursing and patient care as it relates to cardiac patients undergoing percutaneous procedures with the hope of improving such care.

Miss Wagner returned to Florida State University in the Spring, 2005, after being formally accepted into the School of Nursing Graduate Program.