

COMPARISON OF RADIAL AND FEMORAL APPROACHES FOR CORONARY  
ANGIOGRAPHY WITH OR WITHOUT PERCUTANEOUS CORONARY  
INTERVENTION IN RELATION TO VASCULAR ACCESS SITE  
COMPLICATIONS

by

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# Abstract

## Background

A major population health objective in New Zealand is to reduce the incidence and impact of cardiovascular disease. Cardiovascular disease (CVD) remains New Zealand's leading cause of death (41%). This high demand on health services indicates the need for improved therapies and treatment. Significant advances in percutaneous coronary intervention (PCI) offers many patients who would not typically be eligible for treatment, the chance for a better quality of life living with coronary artery disease (CAD). At present femoral access is primarily used for coronary angiography and or PCI procedures, however more recently there has been a gradual shift to using the radial access approach.

## Study objective

The study's objective was to look at comparing the different access sites used for coronary angiography (CA) and/or percutaneous coronary intervention (PCI) and the significance of the rates of vascular access site complications. The research question considered was; *"Is there a significant difference in the vascular access site complication rates when comparing radial to femoral approaches for coronary angiography?"*

## Methodology and design

A cohort study design used observational prospective data on radial approaches and compared this with historical retrospective data on femoral approaches. The secondary (comparative) data was extracted from historical records, from earlier research I had completed. The collection of the secondary data involved strict criteria so that the observational study participants had similar baseline characteristics to ensure validity of this study. One hundred participants were recruited for each (prospective and retrospective) database and then compared and analysed.

## Findings

The use of a radial approach for CA and PCI has a significant decrease in combined vascular access site complications (haematoma, vasovagal and arterial bleed), (*p value* 0.001), *OR* 0.28 (0.13-0.62). Haematoma is the main vascular complication (*p value* 0.009), *OR* 0.29 (0.11-0.74).

## Conclusion

This study, although small, can be used as a pilot study for a more detailed and bigger national study within New Zealand. From the results it is clear there is a significant decrease in the vascular site complication rates when a radial approach is undertaken for CA and/or PCI. Through education and clinical practice, the radial approach would ensure better patient safety, satisfaction and comfort which would help reduce the patients length of stay and increase patients treated with timely discharges. It could also help decrease the nurses' workload caring for the patient with the radial approach due to the lesser complication rates. More extensive use of radial approaches for CA and or PCI would ensure the above benefits for the patients, staff and the organisation.

## Keywords

Coronary Angiography, Percutaneous Coronary Intervention, Vascular Complications, Coronary artery disease.

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## **Chapter 1 - Background to the study**

This study compares radial to femoral vascular approaches for coronary angiography (CA) and/or percutaneous coronary intervention (PCI) and examining the significance of the rates of vascular access site complications. One of the 13 population health objectives of the Ministry of Health, (2003), is to reduce the incidence and impact of cardiovascular disease in New Zealand. Cardiovascular disease (CVD) remains New Zealand's leading cause of death (41%) which has a large impact on the delivery of health services. This high demand on health services calls for improved therapies and treatment.

Of the cardiovascular diseases, coronary artery disease (CAD) is the major cause of death accounting for 22%, followed by stroke, which is the greatest cause of disability in older people. Cardiovascular disease includes; CAD, heart and circulatory such as acute rheumatic fever, chronic rheumatic heart diseases, hypertensive diseases, pulmonary heart disease and diseases of the pulmonary circulation, other forms include diseases of the arterioles and capillaries and congenital malformations of the circulatory system. In New Zealand 16 people die every day from CAD, or one person every 90 minutes. Death rates are higher in Maori than non-Maori closely followed by Pacific Island people. Maori males over the age of 65 are three to four times more likely to die from heart disease than any other ethnic group (Hay, 2004).

Patients with known or suspected CAD are the target group for this study. These patients are usually admitted with a diagnosis of Acute Coronary Syndrome (ACS). This means they have unstable angina pectoris (USAP) or acute myocardial infarction (AMI) (Jowett & Thompson, 2003). The Ministry of Health defines ACS as patients who suffer angina at rest, or who experience new onset angina with effort, or post angioplasty, coronary artery bypass grafting (CABG) and AMI (Ministry of Health, 2003). In New Zealand the data from 2000/01 shows that 7,338 people were admitted to hospital with AMI and approximately 573 people died during their hospital stay (Ministry of Health, 2003). Ongoing debate around the appropriate treatments for ACS continues. However, recent studies have shown early revascularisation (procedures to restore blood flow the artery) for eligible patients (PCI or CABG) can reduce mortality or subsequent AMI by 22%, and subsequent hospitalisation by 45-50 percent (Andersen, Bregendahl, Kaestel,



Skriver, & Ravkilde, 2005; Elsevier, 2006; Farouque et al., 2005; National Heart Foundation of Australia, 2000).

There have been significant advances in PCI, both technological and pharmacological, over the past 25 years. In 1997 over one million angioplasties were performed worldwide (Hay, 2004). Due to the length of time the procedure has been available, and the numbers of patients undergoing PCI, treatment advances have effectively changed the landscape for patients diagnosed with CAD. Patients now enjoy significantly better health outcomes. This is due in part, because those patients who would have traditionally been revascularised by CABG, a significantly more invasive procedure with associated risks, are now able to be revascularised by PCI. As a result, PCI has become the preferred method of coronary revascularization for patients with coronary artery disease.

### **The procedure or management of coronary angiography and percutaneous coronary intervention**

Coronary angiography (CA) or PCI is an invasive procedure used to make a medical diagnosis for people who may have coronary artery disease. A catheter is introduced into a peripheral vein or artery, which is then advanced under x-ray guidance (fluoroscopy) to the heart and coronary arteries for a detailed contrast image (Hatchett & Thompson, 2002). Percutaneous coronary intervention involves introducing a balloon catheter into the affected coronary artery and inflating the balloon within the stenosis (narrowing of the artery), opening the artery. Generally, a small mesh tubular object (stent) is permanently placed within the stenosis to prevent abrupt artery closure. The most common approach for performing the procedure is the femoral approach. The radial approach can also be used and is becoming a preferred choice by some clinicians (Louvard et al., 2004). Louvard et al, compared transradial and transfemoral approaches for coronary angiography and angioplasty in octogenarians. Results revealed CA or PCI conducted via the radial approach to have a smaller incidence of vascular complications with regards to the aging population >80 years of age.

Since it was first performed in 1962 coronary artery bypass graft surgery (CABG) has advanced technologically. Cardiac surgeons quickly adapted the technique and now CABG surgery is being performed on a beating heart (OFF-PUMP bypass grafting). Coronary artery bypass grafting surgery replaces the blocked or narrowed coronary

arteries by using either the reversed saphenous veins harvested from the legs or the internal mammary arteries (Bakhai, Hill, Dundar, Dickson, & Walley, 2005). The main indication for CABG is symptom relief, but may be used to improve prognosis, even if patients are asymptomatic (Smith, Feldman, Hirshfeld, Jacobs, Kern, King, Morrison, O'Neill, Schaff, Whitlow et al., 2005). Patients undergo CA to determine the extent and location of coronary artery disease. Generally patients who have severe three-vessel or two-vessel disease are referred to the cardiac surgeons if stenting via PCI is not a feasible option. Often, from personal experience patients with left main stem disease (main artery supplying the anterior/pumping part of the heart) are now also being treated (if possible) via percutaneous coronary intervention. However, if the risks associated with PCI are too high, CABG will be the preferred choice of revascularisation.

From experience and through literature ("The Wellbeing Plan", 2007) patients who have a CABG will spend a longer period of time in the hospital post surgery than those having PCI as the heart is exposed through a median sternotomy; a large surgical incision made through the sternum (breast bone). Patients undergoing CABG are ventilated until haemodynamically stable, normally spending 24 hours within an intensive care unit (ICU). These patients are mobilized quickly and usually discharged within seven days. Morbidity and mortality has decreased as surgical expertise has improved. The most important complications following a CABG are neurological caused by hypoxia, hypo-perfusion, hemorrhage or metabolic problems. A very common complication is disturbance of heart rhythm with up to a third of patients in the first five days experiencing this (Jowett & Thompson, 2003). Due to the wide margin in cost for each procedure (coronary angiography \$3,200 to \$15,000 including intervention with stents) and CABG surgery (\$30,000) if PCI can be performed it is clear which is most cost effective (The Wellbeing Plan, 2007).

### **New Zealand context**

Several large tertiary hospitals in New Zealand (NZ) offer cardiac procedures to a wide geographic region, providing services to capture patients from a number of smaller tertiary centers. The hospital where this study took place provided approximately 2,250 coronary angiography procedures in a year, and approximately 55% of these went on to have a percutaneous coronary intervention. Three hundred and eleven CABG surgeries were performed for the year 06/07 at the tertiary hospital I'm employed by. The waiting

list for CABG surgery is still a problem in the hospital where I work. An article written by Ruth Hill of the Dominion Post, February 2008 claimed there had been a report that one person has waited for 14 months for their surgery. The government guideline is a six month maximum waiting list, currently the hospital I'm employed by it is realistically six to 12 months (Hill, 2008) and for CA or PCI six months.

Within the hospital where I am employed, there is a high demand for both PCI procedures and CABG surgery. A weekly meeting is held with cardiac surgeons and cardiologists to discuss cases and what might be best for individual patients. Both CABG and PCI have a place in revascularisation for patients with coronary artery disease. However, studies such as case controlled studies are yet to be performed, identifying what is best for the patient relating to the risks and benefits of CABG compared to percutaneous coronary intervention.

Of the many CA procedures performed, a recent research study I initiated within the CCU at the hospital I'm employed by found there was a 23% adverse event rate at the vascular access site (Woodhead, Harding, Simmonds, Dee, & McBride-Henry, 2007). I initiated this study as through clinical experience there were a lot of vascular access site complications. At the time I undertook this study it was clinical practice to use Diazepam for every patient undergoing CA and or percutaneous coronary intervention. I questioned whether this was a contributing factor in vascular access site complications. This was a randomised controlled trial with data collected on 780 patients looking at vascular access site complications and the use of premedication for coronary angiography +/- percutaneous coronary intervention. The study aimed at finding if there was a significant difference in vascular access site complications when premedication was given. Often vascular access site complications can increase nurse's workload and hinder a patient's recovery. The adverse effects included; haematoma (resulting in diameter >3cm), vasovagal (resulting in extra nursing care for blood pressure or heart rate control/intervention), pseudoaneurysm (resulting in surgical repair), and arterial bleed (requiring further compression following initial haemostasis). This led to my developed interest in nursing research and this area of cardiac nursing. Consequently, a new research question was developed.

### **Aim and objectives of the research**

The research question for this study is;

Is there a significant difference in the vascular access site complication rates when comparing radial to femoral approaches for coronary angiography?

This study was undertaken within a coronary care unit (CCU) at a tertiary hospital in New Zealand. The aim was to conduct an observational study looking at the complications with a radial approach following coronary angiography (CA) or percutaneous coronary intervention (PCI). Once data was collected on 100 participants, a retrospective data review from an established database was used to gain information about the femoral approach for coronary angiography. Results from secondary data were then used to compare the adverse event rates between radial and femoral approaches for coronary angiography and PCI patients.

A data collection sheet (see Appendix 1) was developed to reflect evidence-based practice, and meet the requirements of a panel of clinical experts (Cardiologists). In addition, it took into account current hospital practice and policy to be completed by the nurse/s caring for the patient. The data collection focused on baseline characteristics e.g.; patient's age, sex, heparin or glycoprotein IIb/IIIa antagonist use, any anti-platelet/coagulation medication the patient was on (resulting in an increased risk of bleeding), and data on the three main vascular site complications including; haematoma (resulting in diameter >3cm), vasovagal (resulting in extra nursing care for blood pressure or heart rate control/intervention), pseudoaneurysm (resulting in surgical repair) and arterial bleed (requiring further compression following initial haemostasis). It is a user-friendly tick-box data collection tool to ensure it was easy for staff nurses to use and complete.

All patients admitted for a CA or PCI who have a radial approach within the timeframe of collecting data were eligible for the study. The data was analysed using a *t*-Test method, with a significance level of 0.05.

## **Method**

The use of an observational study is often characterised as qualitative research; it can however include quantitative dimensions. Using a quantitative approach places the emphasis on the objective and systematic nature of the researchers' process. The researcher has no control and there is no attempt to manipulate any independent

variable. However, it is still possible to test the hypothesis (Schneider, Elliott, Lobiondo-Wood, & Haber, 2003).

Together with the observational study design is a retrospective study used as a comparison for the testing of the hypothesis. The retrospective data has been generated from historical records (secondary data), from the researcher's earlier research database. Collecting the secondary data involved strict criteria so that the observational study participants have similar baseline characteristics to ensure validity of this study.

Ethical approval for this study was gained through the Central Regional Ethics Committee of New Zealand (see Appendix 2). The research was undertaken within a large teaching hospital in New Zealand.

### **Post procedure adverse events**

Haematoma development is the most common vascular complication following CA or percutaneous coronary intervention. Several articles looked at haematoma and the definitions are diverse (Andersen et al., 2005; Elsevier, 2006; Farouque et al., 2005). Within these articles haematoma is defined as >5cm in diameter, thus requiring extra nursing intervention and time. Generally, digital pressure is required for anywhere between 5 to 25 minutes to effectively manage the haematoma and decrease the possibility of further problems, i.e., pseudoaneurysm.

Ang, Leung, Lo, French and Juergens (2007), suggest that the vasovagal effect results from a patient's perception of discomfort. They found a trend with less vasovagal effects when patients received intravenous sedation during femoral sheath removal. Another consideration is that because the vagal nerve is alongside the femoral artery it is sometimes stimulated when pressure from the femostop™ device is applied (a femostop™ is a pressure device which sits over the affected artery). This is due to the origin of the nerve. Within our bodies the vagus nerve has extensive branches and radiates considerably around the body. The visceral sensory information is vital for the autonomic control of visceral function. The visceral information is carried long the esophagus, respiratory tract and abdominal viscera (Martini, 1995). When it is stimulated it can cause sensory information that can cause a syncopal (fainting) event. This is because of the autonomic fibers of the vagus nerve also affecting the heart and controlling smooth muscles and glands. This can lead to patients becoming diaphoretic,

cool and clammy (resulting from a drop of their heart rate), feeling nauseated and vomiting.

Therapy for symptomatic bradycardia and hypotension is administered according to the clinical judgment of the nurse caring for the patient. Treatment includes rapid intravenous fluid administration, administration of atropine and anti-emetics. Within CCU there is a “Standard Order” of medications for emergency situations. The drugs used for treatment of the vasovagal complication are charted within 24 hours of giving the drug/therapies.

Following initial haemostasis, a further bleed from the site requiring nursing management by either additional digital pressure or having to reapply the femostop™ is defined as a complication of an arterial bleed. Patients are restricted to bed rest for four to six hours following coronary angiography or PCI, to lessen the risk for bleeding from the femoral groin site. Patients often experience back pain due to the restriction of movement and positioning. If patients have a vascular site complication, this could increase bed rest and restriction times, causing further discomfort.

Vascular complications from CA or PCI are not uncommon and the incidence ranges from 0.7-28%. Within the hospital I’m employed by, the cardiac care unit conducted a research study showing a complication rate of 25% (Woodhead et al., 2007). This result is alarmingly high, and further investigation is recommended to investigate what can be done to reduce this complication. The use of radial approaches for CA/PCI by one clinician has increased. Through clinical experience and general discussions with nurses, it is believed that the use of this approach had fewer vascular complications than that of the femoral approach for the same procedure.

The Carafe study (coronary angiography through the radial or the femoral approach) looked at vascular complications following CA and PCI found the radial approach is becoming more frequently used, as it has a smaller incidence of vascular complications compared to the femoral approach after CA and PCI (Louvard et al., 2004). The vascular site complications pose potential problems for nurses caring for the patient with an increase in patient to nurse time ratio and increased acuity for the patient. Furthermore, it increases morbidity and has serious financial implications to the organisation (Roebuck, Jessop, Turner, & Caplinm, 2000). Vascular assess site complications can be very debilitating for patients following their coronary angiogram

or PCI. Haematoma is the most frequent occurring complication and some patients experience a decreased quality of life for up to two months (Andersen et al., 2005). As PCI is becoming the preferred choice of revascularisation, finding better ways to improve patient healthcare outcomes are expected. Radial approaches for CA and PCI are often more demanding and take more time due to smaller arteries and structure of the anatomy in the arm.

The primary goal of this study was to look at the difference between radial and femoral vascular access sites in relation to coronary angiography (CA) and/or percutaneous coronary intervention (PCI), and the associated common vascular access site complications. From reading extensive literature about this topic, vascular complications for CA and/or PCI vascular access site complications in this study were defined similar to other research. I have defined the vascular complications for my project as; haematoma (resulting in diameter >3cm), vasovagal (resulting in extra nursing care for blood pressure or heart rate control/intervention), pseudoaneurysm (resulting in surgical repair) and arterial bleed (requiring further compression following initial haemostasis).

The clinical workload for nurses has increased significantly in correlation to the occurrence of vascular complications (Elsevier, 2006). The extra care needed for the patient with a vascular complication can range from one nurse spending a one to one ratio care (1 nurse: 1 patient) with a patient for up to three hours or it can take two nurses (2 nurse: 1 patient) spending shared time caring for the patient for a whole eight hour shift. These ratios depend on the type of complication and the patient's reaction to the complication. For example, a patient who has a vasovagal reaction commonly has a reduction in their blood pressure and heart rate requiring intravenous (IV) fluid. They may even require IV medication to increase the heart rate (Jowett & Thompson, 2003). From clinical experience this requires two nurses for the duration of the vasovagal reaction, which can last anywhere between five minutes to 30 minutes. This patient often needs emotional support from a nurse for some time afterward to allow them to feel safe and comforted. A vasovagal reaction can make the patient feel very unwell, and they can experience agitation, tearfulness and nausea. A patient who suffers the ill effect of a haematoma complication however, may need two nurses manually compressing on the site (if the haematoma is hard to touch and is >10cm in diameter) for up to 30-40 minutes to soften the haematoma. This situation also requires intense

monitoring of the site for the remainder of the shift, as it may need further compression if there is further bleeding (e.g. if it reforms and increases in size again) (Jowett & Thompson, 2003). Other measures are often put in place such as bed rest for the patient and ice to the affected area.

Given the vascular complications that can result and the impact on resources, the purpose of the study is to primarily look at the difference between radial and femoral vascular access sites in relation to CA and or PCI, and the associated common vascular access site complications.

As a senior nurse on the CCU my increasing concern is the number of adverse events and sometimes significant flow on effects from haematoma, bleeds and vasovagal complications. The significance of this study, which explores and identifies the difference between radial and femoral approaches for vascular access site complications in CA and/or PCI, is to examine what is the best approach for patient's comfort and satisfaction. The contribution of the results from this study will help aid the correct vascular site approach for each patient therefore minimizing complications and improving healthcare outcomes. It is also significant to the nurses because of the increased workload vascular complications create. The clinical workload for nurses increases significantly in correlation to the occurrence of vascular complications (Elsevier, 2006). The extra care needed for the patient with a vascular complication is a factor when assessing the patient's acuity within the unit for extra staffing or support the nursing team may require for the next shift.

## **Summary**

Cardiovascular disease (CVD) is the leading cause of death in NZ. Within the CVD group, the subgroup that is the major cause of death is coronary artery disease. For patients with CAD the preferred method of revascularization is percutaneous coronary intervention. The usual approach for this procedure is through the femoral artery, a recent shift has seen more radial approaches. Due to the complication rates (up to 28%) with vascular access following CA and or PCI it is vital the best approach and care of vascular complications is taken. This study looks at comparing different access sites for CA and or PCI and the significance of the vascular site complications.



## **Overview of chapters**

In chapter one I presented the background of the study which revealed the impact of CVD in New Zealand. I discussed the treatment options for CAD patients and the intervention required for patients who present with coronary artery disease. Percutaneous coronary intervention is the preferred choice of treatment/management and the technology surrounding CA/PCI is advancing. There are different access sites when performing CA and or PCI, the historical femoral approach and the more recent radial approach. With new technology and techniques arising frequently, research on how to improve the patient's health care outcome when having PCI is vital. Chapter two looks at the literature related to CVD and the treatment options. I review the search strategy used (Population, Intervention, Comparison, Outcome) and critique available literature to identify the common themes about the intervention that surfaced. In particular interest, the literature focused on issues that I identify on a regular basis, which includes back pain, and vascular complication rates when using a femoral approach for CA and percutaneous coronary intervention. Chapter three covers the theoretical underpinnings of my research. Using a cohort study design with retrospective and prospective data for comparison, this study design will be explained in-depth further. The ethics application and the discussion of the methodology are covered. Chapter four uncovers the findings of the research. This includes the results of the demographic data on the study's participants, which is similar to national and international trends. It will also uncover the results of the vascular complications and show how this may help change clinical practice. Chapter five focuses on evidence based health care by drawing on the Joanna Briggs Institute (JBI) model to help uncover what this study means for nursing practice. This chapter looks at how my research can inform nursing knowledge and contribute what is best practice for the patient population in regards to using a femoral or radial approach for CA and or percutaneous coronary intervention.

When raising a research question you must first read literature surrounding your topic. The literature search I performed found many articles and papers that were of relevance and interest to me for this topic, the next chapter outlines the literature in more detail.

## **Chapter 2 - Literature Review**

The integral growth of nursing as a discipline requires ongoing research questions being derived from current knowledge base and known knowledge gaps. Reviewing literature is a complex process which begins with an idea of research interest and undergoes refinement until the reviewer has identified compatible results with the initial research question. The reviewer decides on what information to focus on and what is required to be examined to give the research depth (Schneider et al., 2003).

In this chapter I discuss the literature review conducted for the research topic. I introduce the databases searched and the use of the PICO (Population, Intervention, Comparison, Outcome) framework to ensure my searching was concise and relevant. Throughout the literature, search themes started to emerge and these themes are identified and developed.

### **Developing the PICO**

Using a PICO (Problem/Population studied, Intervention, Comparison, Outcome) framework helps to quickly identify appropriate articles that directly relate to the topic (Dicenso, Guyatt, & Cilksa, 2005). The PICO for this research was;

P – Coronary artery disease/Coronary angioplasty/Coronary angiography/percutaneous coronary intervention

I – Radial approach

C – Femoral approach

O – Decreased risk of vascular complications

### **Search strategy**

The three databases I used for searching included, Cochrane Collaboration, CINAHL, and MEDLINE. These databases are commonly used by all healthcare professionals. A description of the database contents is as follows; the Cochrane Collaboration promotes accessibility of systematic review. The CINAHL database is Cumulative Index to Nursing and Allied Health Literature, and gives reviews of the literature and it contains comprehensive nursing information. Medline is a comprehensive source of life sciences and biomedical bibliographic information. The most relevant articles were chosen from

my search. Google scholar was used to find the relevant references within the articles and to gain a broader understanding of my topic.

I found a vast amount of literature across three main database searches (Refer to Table 1). Using a framework like the PICO can significantly reduce time spent refining the literature searches and having unusable information retrieved (Schneider et al., 2003).

**Table 1 – Database Search History**

<b>CINAHL – Cumulative Index to Nursing &amp; Allied Health Literature (1982 to June Week 1 2007)</b>	
Search	Results
1) Coronary Angiography/ae, mt, mo, ec, nu, pf, st, td [Adverse effects, Methods, Mortality, Economics, Nursing, Psychosocial factors, Standards, Trends]	131
2) Angioplasty, Transluminal, Percutaneous Coronary/ae, mo, nu, pf, st, td, mt [Adverse Effects, Mortality, Nursing, Psychosocial Factors, Standards, Trends, Methods]	356
3) Angioplasty, Transluminal, Percutaneous Coronary/ae, mo, nu, ec, pf, st, td, mt [Adverse Effects, Mortality, Nursing, Economics, Psychosocial Factors, Standards, Trends, Methods]	376
4) Coronary Angiography/ or Heart Catheterization	2340
5) limit 1 to (full text and yr="2000 - 2007")	60
6) 2 and 3 and 4 and 5	8
<b>Ovid MEDLINE (R) (1996 to May Week 5 2007)</b>	
1) Angioplasty, Transluminal, Percutaneous Coronary/ae, mo, nu, st, sn, td, mt [Adverse Effects, Mortality, Nursing, Standards, Statistics & Numerical Data, Trends, Methods]	4549
2) Intraoperative Complications/ or Postoperative Complications	84804
3) 1 and 2 and 3	13
4) limit 4 to (humans and english language and yr="2000 - 2007")	9
<b>EMB Reviews – Cochrane Database of Systematic Reviews (2<sup>nd</sup> Quarter 2007)</b>	
1) coronary angiography.mp. [mp=title, short title, abstract, full text, keywords, caption text]	10
2) percutaneous coronary intervention.mp. [mp=title, short title, abstract, full text, keywords, caption text]	13
3) vascular complications.mp. [mp=title, short title, abstract, full text, keywords, caption text]	23
4) coronary artery disease.mp. [mp=title, short title, abstract, full text, keywords, caption text]	97
5) 1 and 2	4
6) 2 and 3	2
7) 4 and 6	2

The differing search strategies used for each database was used to help gain a comprehensive search. Also, each database looks for journals in a slightly different

way; therefore changing the strategy was required to gain the information I needed for this study.

The literature I found surrounding my topic was focused mainly in Europe and America. There was little evidence or studies completed within New Zealand that answered my research question, therefore conducting my own research and study was required to support international findings to inform my work environment about what is best practice.

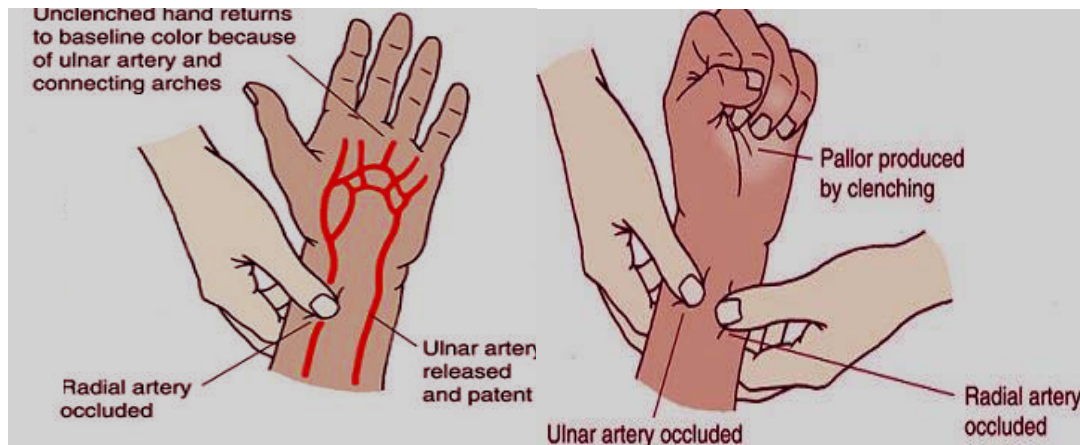
The themes that emerged from the literature search performed included: back pain, bed rest, ambulation times and positioning; pain with removal of the femoral sheath; risk factors associated with vascular complications; patient's experiences and/or 'quality of life' perceptions during and after the procedure; and the cost of complications.

### **Back pain, bed rest, ambulation times and positioning**

The femoral artery has traditionally been the artery of choice for coronary angiography procedures; this approach has its limitations. For example, a patient with peripheral vascular disease (PVD) and in patients with anticoagulation regimes such as Warfarin therapy for mechanical heart valves or atrial fibrillation (AF), all are at higher risk of complications. It also has the added problem of patients requiring post procedure bed rest due to the large artery used for puncture. Lying supine is often poorly tolerated by patients who suffer from left ventricular dysfunction, hip or back pain and lung disease. Despite bed rest, vascular complications at the femoral access site are still reported as 0.7-28% from a number of studies (Archbold, Robinson, & Schilling, 2004; Farouque et al., 2005; Keeling, Taylor, Nondt, Powers, & Fisher, 1996; Lim, Anderson, Walters, Kaye, & Norell, 1997; Roebuck et al., 2000). These combined factors lead to a decrease in patient satisfaction and comfort, morbidity, an increase in hospital length of stay (LOS) and associated costs. Over the past decade this has led to the development of an alternative vascular access site being utilised for CA and/or percutaneous coronary intervention.

The use of the radial artery for CA and PCI is now being performed within my clinical environment. From my experience it has many benefits, such as immediate ambulation, less pain perception from the patients, and a decreased LOS and subsequent cost. The use of the radial artery is performed on patients who have a positive "Allen's Test", as

illustrated in Figure 1. The hand receives dual arterial supply from the radial and ulnar arteries. The radial artery is not an end artery like the femoral or brachial artery and as the ulnar artery is able to supply collateral circulation supply to the hand, it does not compromise the vascular blood supply to the hand. The superficial path of the distal radial artery also provides easy compression of the artery, usually from a device called a TR Band <sup>TM</sup> (Archbold et al., 2004).



**Figure 1 – Allen's Test**

[http://fitsweb.uchc.edu/student/selectives/TimurGraham/Modified\\_Allen's\\_Test.html](http://fitsweb.uchc.edu/student/selectives/TimurGraham/Modified_Allen's_Test.html)

(See appendix 4a for approval to use this illustration)

Archbold, et al, used Medline to search and examine the literature to find conclusions about the use of the radial artery for CA and percutaneous coronary intervention. The conclusions found that the incidence of vascular complications at the radial access site is insignificant when a positive Allen's Test is achieved, even with patients who are treated with anticoagulation therapy. The time to ambulation, LOS, and costs are all reduced and patients seemed to prefer the radial approach to the femoral approach. In conclusion PCI can be achieved with a radial approach in selected patients.

Over the past decade there has been an increasing amount of research providing information to health care professionals of how best to care for patients undergoing CA and/or percutaneous coronary intervention. The TIBSII study (Keeling et al., 1996), focused on reducing time in bed after coronary angiography. They examined the incidence of vascular complications and perception of pain in 86 patients in a randomised experimental study that reduced bed rest from six to four hours post

coronary angiography. They found there was a reduced pain perception from their patients with no increase in vascular complications. Similar studies found the same results (Lim, et al, 1997). Many studies (Andersen et al., 2005; Chair, Taylor-Piliae, Lam, & Chan, 2003; Roebuck et al., 2000), have cited Keeling in their studies when centering their research on back pain post coronary angiography (especially due to the strict bed rest that is imposed in most cardiology intervention units).

Roebuck, et al, found evidence that support patients to mobilize at two hours post coronary angiography. They also examined the incidence of vascular complications following the removal of a six-French femoral sheath following elective coronary angiography. There are different sizes of sheaths used for CA/PCI, depending on the access site and procedure they range from a size five (small) to eight (big). Within Roebuck, et al's study they had 305 patients randomised to a four hour or two hour bed rest group. The end results were consistent with other studies cited within the paper; no differences between the two groups in regards to vascular site complications (major or minor) were noted ( $p$  value of 0.12 for haematoma and  $p$  value of 0.57 for bruising at the site). A positive flow on effect is the reduced nursing workload and the beneficial effect on patient's pain perception.

Chair, Taylor-Piliae et al, examined the use of positioning for patients when on bed rest following coronary angiography. They found there was no difference in the effect of positioning on back pain following CA, and they concluded the longer amount of time spent on bed rest resulted in an increased intensity of back pain. In addition the effect of positioning did not result in an increase of vascular access site complications.

Within my clinical environment, patients currently undergoing a CA with no intervention (femoral approach) need to be flat on their back for one hour post sheath removal, 30° angle for one hour, sitting at 90° for one hour and then mobilise. For patients who have undergone intervention (stenting), heparin is given and depending on the dose and activated partial thromboplastin time (APTT) blood test patients can sit at a 30° until time of sheath removal, then the above procedure is carried out. In total, patients with intervention are on bed rest for up to six to eight hours all things going well. Further time in bed will generally be because of vascular site complications.

The use of the radial artery has gained popularity (particularly for the nurses caring for patients post CA and PCI); the refinements in technique and equipment has allowed

interventional cardiologists to move towards the radial approach for patient satisfaction and decreased length of stay. For patients with a radial approach, mobilisation is allowed when the patient is able, and at the discretion of the nurse caring for the patient. This is for the patient who has had intervention or not. These care plans for mobilisation are consistent with the unit's guidelines.

### **Pain with removal of the femoral sheath**

Pain management for patients generally causes problems for the health care professional. Patients have different pain tolerances, anxieties and perceptions of the pain source. Patients undergoing CA often, from clinical experience, suffer from back pain (due to the bed rest and position in bed) and when the arterial and/or venous sheath is removed. Painful sensations are a result of tissue damage (in the case of removal of sheath), or sensory nerve irritation, often this is perceived at the puncture site due to the signal generation along the sensory pathways (Martini, 1995).

Treatment from analgesics can reduce the inflammation and suppress the release of irritating chemicals, such as the enzymes or prostaglandins in the damaged tissues. Analgesics such as morphine can mimic the action of endorphins; this suppresses the pain by inhibition along the pain pathway (Martini, 1995).

Ang, et al, (2005), found that patients experience the least amount of pain during femoral artery sheath removal when IV sedation is administered prophylactically. Fulton, Peet, McGrath, Hilton, Smith, Sigurdsson and Forrest (2000), found no difference in the pain perception amongst 130 patients receiving a variety of analgesic medications including, fentanyl, morphine and lidocaine. The difference with this finding compared to Ang, et al may have been due to the larger sheath size (all sheaths in this study were of 8F size) and manual compression without a femostop™ which all patients received. The patients also received diazepam which may have altered the patient's perception of pain. In Ang, et al's study, fentanyl and midazolam were administered routinely which may have positively impacted on their results.

Wensley, Kent, Price and Stewart (2006) have written a protocol for a systematic review on pain relief for femoral sheath removal in interventional cardiology patients. They will be collating all the information found in randomised controlled trials (RCT) in relation to pain perception of patients when undergoing the femoral sheath removal.

Pain and discomfort is often and usually experienced by the patient who is not medicated. Even some medicated patients experience pain and discomfort to a lesser degree. According to Wensley, et al, (2006) this may be due to the sheath removal itself or the pressure that is applied for haemostasis post removal of sheath.

Internationally, the current practice in regards to the use of analgesia for the relief of pain prior to removal of sheath varies considerably. A survey within Wensley, et al (2006) literature found in 2004 across New Zealand and Australia there were 17 different analgesia regimens. The common regimens include the use of IV midazolam, valium and fentanyl and subcutaneous lidocaine at the femoral site with or without IV morphine. Within the hospital where I'm employed, there is a protocol currently being written for pain relief for CA and or PCI patients. At present pain relief medication is given as requested by the patient following the procedure.

Ang, et al, looked at vasovagal complications and the effect of the use of anesthesia and IV sedation on pain perception for the patient when the femoral arterial sheath was removed. All patients had a femostop™ successfully deployed by a designated nurse.

When the sheath is removed the device is 'pumped' up and pressure over the artery causes haemostasis. Within the hospital I'm employed by there is a protocol that you inflate (pump up) the femostop™ until it is 20 mmhg above the patient's systolic blood pressure. (Please refer to Figure 2).



**Figure 2 – Femstop™ device**

<http://rnbob.tripod.com/vascularclosuredevices.htm>

(See appendix 4b for permission to use this illustration)

Vasovagal reactions which involve symptomatic bradycardia and hypotension are a common complication following coronary intervention. Ang, et al., (2005) identified common predictors of vasovagal events; a higher pain score from the Visual Analogue Scale (VAS), a lower BMI, receiving a glyceryl trinitrate infusion and the left anterior



descending artery as the treated vessel. When compared with another larger study by (Mager et al., 1994), they had similar findings. Ang, et al., showed the use of prophylactic IV midazolam and fentanyl also reduced the effects of vasovagal events. The use of antiemetics (which act on the central nervous system and in particular acts within the GI tract, for example, metoclopramide and ondansetron) and/or atropine (a anticholinergic parasympatholytic drug, which focuses on blocking vagal stimulation in the heart) prophylactically is also used in some regimens to help prevent vasovagal reactions which may be associated with pain on removal of sheath and haemostasis pressure (Wensley et al., 2006).

Perception of pain and anxiety for patients is associated with increased vagal tone and can generate a vasovagal reaction consisting of symptomatic bradycardia, hypotension, and nausea and vomiting. These reactions can cause serious arrhythmias, closure of the dilated artery, severe hypotension and myocardial ischemia or infarction (Ilia, 1997). The use of vagolytic medication following CA or PCI is supported and used within the unit where I work. Inadequate pain relief during the sheath removal is often associated with an increase in vascular complications. Therefore it is imperative we find the best common pain relief protocol to use. In my unit we have a care plan nurses follow and a protocol which allows nurses to administer atropine, metoclopramide, morphine/codeine phosphate/paracetamol, and or intravenous (IV) fluids when required by the patient. If the drugs are not charted on the drug card, the drugs can be given according to a policy we have called 'permissions understood' drug administration. There are seven drugs we can administer (once appropriate theory and practical certification has been achieved) to a patient for a particular event. For example, a person having a vasovagal event can be given atropine if the heart rate (HR) is below 35bpm and the patient is symptomatic. For any one of the seven drugs they must be charted and signed for by a medical colleague within 24hours of the drug being given.

### **Risk factors for vascular site complications**

Dumont, et al, (2006), looked at predictors of vascular complications in 11,119 patients who underwent CA and/or PCI, using the femoral vascular access route. The study found groin haematoma being the most common complication. This is similar to the research findings within CCU, at the hospital where I'm employed (Woodhead et al., 2007). Furthermore Woodhead, reviewed literature and found similar problems with the

practice guidelines for care of the patient following CA and percutaneous coronary intervention. To date, the care is based primarily on expert opinion and is not evidence based. Dumont, et al's study was a retrospective, descriptive and correlation study, with data collected from the Clinical Automated Office Solutions Database. The results from this study found the predicative factors are patients age >70 years, female, have a history of renal failure, have undergone PCI and have prolonged sheath time in groin, high anticoagulant use, and have the addition of a venous sheath. Cox, et al (2004) found an additional predictive factor in their prospective study on 5,234 patients. An increase of vascular complications was found in patients who were of the smallest BMI (Body Mass Index).

When comparing other studies (Andersen et al., 2005; Cox et al., 2004; Farouque et al., 2005; Hass & Quinian, 1999) looking at similar CA and PCI vascular complications and the associated risk factors, they tend to be in agreement with Dumont, et al. Farouque and colleagues focused their study on one particular vascular access site complication, retroperitoneal haematoma. As already discussed, this complication is the most common of all the vascular complications examined. Farouque and colleagues found similar findings to the Dumont study for significant risk predictors of haematoma. They found being female, having a low body surface area and higher femoral punctures are key predictors of a haematoma.

Another article focusing on haematoma and risk factors associated was by Andersen, et al (2005). They performed an audit on 463 patients undergoing CA and/or PCI via the femoral artery to determine the rate of haematoma development. Subsequently a statistical analysis (performed in the SAS® system, 8.2.) was undertaken to identify the predictors of haematoma development. The factors they found to be associated with haematoma development were similar to other papers and studies looking at vascular complications such as haematoma (Cox et al., 2004; Dumont, Keeling, Bourguignon, Sarembock, & Turner, 2006; Farouque et al., 2005; Hass & Quinian, 1999). The risk factors in this study were female, systolic blood pressure >160 mm Hg, multiple artery punctures, sheath time >16mins, ACT >175, Glcoprotein IIB/IIIa inhibitors, low molecular weight heparin before procedure, personnel change during compression, and anti-coagulation treatment prior to procedure.

## **Quality of life issues and cost benefit analysis**

The aim of any revascularisation procedure is to improve the patient's quality of life. Many asymptomatic patients are being put forward for CA and PCI due to the recommended current guidelines (Smith, Feldman, Hirshfeld, Jacobs, Kern, King, Morrison, O'Neill, Schaff, Whitlow et al., 2005) and not necessarily having the procedure discussed appropriately with the patient and their family/whanau. Spertus and colleagues (2004), found >10% of asymptomatic patients who underwent PCI reported a moderate or large decrease in quality of life following percutaneous coronary intervention. An editorial review by Curtis and Krumholz (2004), of patients undergoing CA and PCI with similar hypotheses titled their paper, "Keeping the Patient in View". The review looked at defining the appropriateness of these interventions. The meta-analysis of randomised controlled trials for PCI versus medical treatment for non-acute coronary heart disease by Bucher, Hengstler, Schindler, et al, (2000) found a common theme in patient's quality of life following percutaneous coronary intervention. Although many patients reported an improved quality of life one year following their PCI, a larger number reported little or no difference. A small percentage even identified a decreased quality of life following percutaneous coronary intervention. The variables for this study looked at demographics, clinical characteristics, procedural variables and baseline health status - the last was found to be the main reason for an increase in quality of life. It is not surprising when coronary arteries are widened through coronary angioplasty or stenting in patients who suffer from frequent angina or a decreased physical activity level have an increase in quality of life following their percutaneous coronary intervention. Those who have less or no symptoms are now free of symptoms or have a significant decrease of symptoms which were previously hindering their day to day living (Curtis & Krumholz, 2004).

The radial approach has a key advantage over the femoral approach. The prompt mobilisation of the patient following the procedure can encourage earlier discharge from hospital. Additional flow on effects include a reduction in bed occupancy which reduces expenditure per patient, and increase in patient turnover which influences waiting times and patient flow.

A quantitative study from Lunden, Bengtson & Lundgren (2006) used content analysis with similar findings to Agostoni, et al (2004). The positive effects around the patients

experience on emotional thoughts, bodily sensations, and nursing interventions of importance and personal strategies. The study highlighted that nurses play a very important role in recognising the negative and sometimes ‘unbearable’ feelings patients have and are able to alleviate them with minor nursing actions to improve a patient’s comfort. What this study also found was patients who have the procedure via the femoral approach have more negative feelings; this is due mostly and in relation to the immobilisation post procedure. Patients experience; more pain and discomfort, feel dependent on someone else which can be difficult (especially for those who have always been ‘well’ or who have never been in hospital before). Specifically, back pain due to immobilisation is often considered difficult, even more so for those who have never experienced back pain problems before. Peripheral symptoms such as feeling too cold or hot and being unable to move freely to provide comfort for oneself are also experienced.

When the procedure is via the radial approach patients experienced a feeling of ‘relief’ that they were able to mobilise promptly and not have to depend on someone else for personal needs (Lunden, Bengtson, & Lundgren, 2006).

An initial study conducted within this tertiary hospital looked at vascular complications and patient satisfaction in regards to the radial approach. They found within their literature review many clinical trials which have described similar procedural outcomes to the femoral approach, with minimal vascular complications, early ambulation and increased patient satisfaction (Arachchi & Matsis, 2003). This study had a total of 99 patients who underwent the radial approach. These patients were admitted for PCI or elective coronary angiography. They were screened for a possible radial approach by using the Allen’s Test (refer to page 12 – Figure 1). If it was negative or there was no palpable radial pulse they were excluded from the trial. Data about procedural time, what the procedure was for e.g. CAD or cardiac valve disease, how many lesions patients had and were they stented and vascular complications was recorded. A questionnaire about patient satisfaction was also used as follow up data. The results showed radial approaches can be used successfully and safely with no major vascular complications, resulting in a high degree of patient satisfaction. Results indicated 93% of the patients who had previously had a femoral approach preferred the radial approach. Arachchi and Matsis (2003) concluded that radial approaches for CA and or PCI can be performed safely with a high degree of success and patient satisfaction. However, the

authors also felt there is an operator learning curve that could hinder the use of the radial approach.

There is a lot of literature surrounding CA and or PCI and the associated problems such as, vascular complications, pain and mobility, bed rest and ambulation times. Not a lot of literature focuses on the use of radial versus femoral approaches for CA and or PCI that can be implemented in the majority of the NZ population. It is important to consider these issues as it may help nurses reveal patient ratios and improve the care we deliver to patients.

Care of the patient following CA and or PCI is primarily the responsibility of the nurses. Nurses need to take an interest in the research and evidence based practices to develop safe and effective protocols for the care of these patients. The impact of vascular access complications are generally low in incidence, and can be anything between 0.7-28%. However, nurses have an important role in limiting or reducing the effect of these complications. These include morbidity and the financial implications, both in terms of the patient and the health care system. This shows the need to find further ways of decreasing complications to improve patient health care outcomes (Dumont et al., 2006).

The need for the patient to have a skilled nurse caring for them in this area is apparent in all literature read (Agostoni et al., 2004; Lunden et al., 2006; Spertus, Salisbury, Jones, Conaway, & Thompson, 2004; Vlastic, 2004). The patient's perception of pain, discomfort, knowledge of pre/peri and post care in relation to procedure, drawback of complications and quality of life issues are often based on the perceived skill, communication and action of the nurse caring for the patient. From my clinical experience and results found from Lunden, et al, patients become very observant of the staff caring for them and how they react to different situations, what they say and how the atmosphere affects them. A highly skilled and trained nurse in the cardiology setting is an essential part in patient's care following CA and PCI irrespective of whether it is from a radial or femoral approach.

The use of a radial approach is expected to increase as interventionists become more familiar with the equipment and techniques. It's also likely the femoral approach will continue to be used for some patients depending on selection, protocols and criteria. It becomes even more important we continue to research and find the best possible

treatment and care for these patients following their CA or percutaneous coronary intervention.

A vast amount of literature has been read on this topic along with discussion with cardiologists and cardiac nurses to develop my research question: “Is there a significant difference in the vascular access site complication rates when comparing radial to femoral approaches for coronary angiography?”

There is a lot of literature surrounding CA and or PCI and the associated problems such as, vascular complications, pain and mobility, bed rest and ambulation times. Not a lot of literature focuses on the use of radial versus femoral approaches for CA and or PCI that can be implemented in the majority of the NZ population. It is important to consider these issues as it may help nurses reveal patient ratios and improve the care we deliver to patients.

Following the literature review it is fundamental an appropriate research study design is used to help answer the research question. Using the literature to find suitable frameworks the development of how to do the study emerged. The following chapter describes the way this study emerged.

### **Chapter 3 – Methodology, method and design**

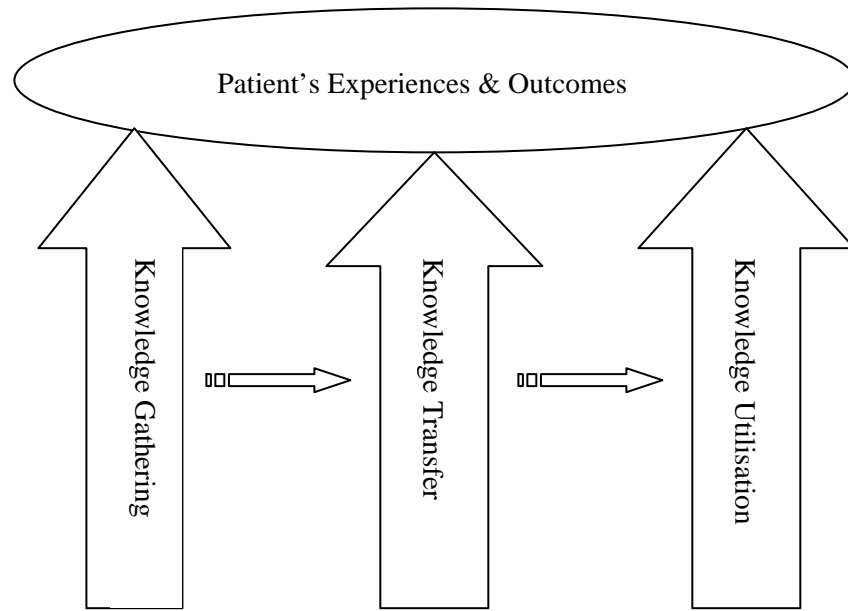
This chapter introduces and discusses the methodology and methods that underpin the research study. Ethical issues considered for this study are explored. The setting of this study, its catchment area within New Zealand, and the participants are introduced. The use of a data collection tool will also be explained. I will then discuss how this research study was managed and implemented, and explore the collection and data analysis process. The rationale for the statistical analysis employed to analyse the findings will also be provided.

#### **Theoretical framework**

Based on the literature review I conducted for this study and investigating different frameworks, the development of my theoretical framework was informed by a number of researchers. In particular, I found Joan Skinner's PhD thesis relevant and insightful. She developed and used a tool to help midwives reflect on their practice and keep them more closely connected to women. It was also used to continue care when risks were identified which required involvement from obstetricians. Her model is a three legged stool and can be used by midwives, educators, managers and researchers (Skinner, 2005). Moss, Crisp and Foureur, (2007) adapted it for a presentation "Homing your research"; it was modified slightly to incorporate the Joanna Briggs Institute (JBI) of evidence based health care.

Using previous frameworks from the above mentioned studies as a guide, I have developed my own framework to help understand and answer my clinical question. Is there a significant difference in the vascular access site complication rates when comparing radial to femoral approaches for coronary angiography?

This can be addressed as knowledge gathering, knowledge transfer followed by knowledge utilisation. I have illustrated this as a basic three legged stool (See Figure 3). The legs of the stool represent each part of knowledge and the stools seat is the patient's experience. This model can be reviewed, and the steps revisited, as new research questions and hypotheses arise.



**Figure 3 – The Basic Three-Legged Stool** (Skinner, 2005 and Moss, Crisp & Foureur, 2007)

When generating clinical questions within our own practice, I applied this model by gathering knowledge on key concepts of patient's experiences, i.e. pain, bed rest, ambulation times, and quality of life issues. The next step is transferring this knowledge to nurses and medical colleagues, which will then help to utilise the appropriate techniques or approaches to give better health care outcomes for our patient population. Utilisation of the knowledge gained will help to provide improved patients perceptions, experiences and outcomes in the changing clinical environment for cardiac conditions.

Very few research studies such as Cox, et al, (2004) and Louvard, et al, (2004) have looked at comparing the incidence of vascular site complications between radial and femoral approaches. Louvard, et al's (2004) study found radial approaches had significant fewer complications; however, this approach was performed only for those >80years. Cox et al's (2004) study compared the risk of vascular complications; however it also compared obese to non-obese patients.

My study compares patients in New Zealand with similar demographics of all ages. The demographics included were mean Body Mass Index (BMI), acute/elective patients, male/female, diabetes, hypertension, current smokers, positive family history of IHD, previous IHD diagnosis, and hypercholesterolemia. Focusing on the CAD population



group within a tertiary centre in New Zealand, I was able to compare two sets of data and look at the difference in complication rates at the vascular access site. The data was taken retrospectively for the femoral approach from a historical database. The data for the radial approach was taken prospectively as an observational study. The study's design was a cohort comparative observational study.

### **Cohort study designs**

A cohort study is a type of epidemiological study and comes under the observational research design umbrella (Schneider et al., 2003). Using an observational framework for a study helps to identify possible effects of a treatment on subjects. For example in this study I expected to reach conclusions about vascular complications associated with each approach. According to Schneider, et al, this type of research often involves a range of methods, for example informal interviews, direct observation, self analyses and life-histories.

Cohort study designs can be used to examine the relationships between outcome variables, both retrospectively and prospectively, as shown in this study. My study aimed to compare the retrospective data to a historical database of patients within similar health status and demographics.

Cohort study designs are used by many nurse researchers (Deary, Watson, & Hogston, 2003; Feyer et al., 2000) to help determine and identify improved ways of caring for their patient population. For example, Billingham, Morgan and Arthur's (2003) study examined patient and nurse-related implications of remote cardiac telemetry. This was a cohort study that focused on a select group of people (telemetry cardiac monitored patients) who were followed over time, using a prospective observational study design to determine the frequency of rhythm disturbance events among the patients on telemetry monitoring. They also explored the impact of managing telemetry on nurses' workload. This was achieved by collecting data for nine days where the nurse's workload was captured (under defined working conditions) and the telemetry nursing response. The data collection was produced from a random selection within an eight-hour time period. Research assistants arrived unannounced to collect the data by observing and recording the actual number of arrhythmia events. The telemetry nurses response to alarms was also monitored. This study indicated there is an impact on nursing workload indicated by the frequent alarm events. This occurs because the critical care nursing responsibility

of remote cardiac telemetry monitoring is more than just arrhythmia detection and associated intervention. The main discussion point from the findings recommended better communication processes to ensure safe and effective remote cardiac telemetry monitoring. This should be in place for the continuation of that particular remote cardiac telemetry monitoring service.

A nursing cohort study by Vavouranakis, et al (2003), used an observational, community based approach that demonstrated they were able to improve the quality of life and reduce hospital readmission rates. This was achieved by implementing intensive home-based intervention with patients who suffer from severe congestive heart failure. This was a cohort study. The patients observed had severe congestive heart failure and were examined through intensive home surveillance including frequent home visits associated with blood tests and telephone contacts to implement standard therapy, treating early symptoms and providing psychological support. With follow up after one year, results showed a reduction of hospital readmission rates and an improved quality of life.

These examples of cohort study designs show, when working with a particular patient population group, the study design focuses the research on a selected group of people over time to answer the research question. Study design is valuable to the nurse in order to question possible risk or probability/prediction of risk within a selected population over time. To do this, observing the incidence of the studied outcomes in relation to Cohort study designs are critical for practice change. This was evidenced the remote cardiac telemetry monitoring research by Billingham, et al, (2003). They followed cardiac telemetry monitored patients over nine days and observed the incidence of the frequency of rhythm disturbance events among the patients on telemetry monitoring, to explore the impact of managing telemetry on nurses' workload. This study helped to identify potential risks to the patients, as nurse's workloads were identified. The large amount of telemetry activity that actually needed arrhythmia assessment was more than anticipated and the nurse who was on telemetry monitoring is not always available for interpretation of arrhythmia assessment. The nurse who was identified as the cardiac monitoring nurse must be experienced, able to identify and treat the arrhythmia quickly and with confidence.

With added responsibility of the remote telemetry monitoring and with the frequent alarm events, nurses were not always available for interpretation therefore putting patients at risk of not being managed appropriately.

Vavouranakis, et al, (2003), looked at how implementing a more comprehensive home-based intervention programme for severe congestive heart failure patients would reduce hospital readmission rates and improve the quality of life for this group of patients. Interventions included frequent home visits, laboratory tests and telephone contacts to implement therapy to treat early symptoms and provide psychological support. This research highlighted the risk of readmission rates to hospital if such interventions were not undertaken. Nurses working in this field had a research question. Using a study design approach to find answers for their patient population group had improved the healthcare outcomes of the patients. In the case of my study a cohort design helped to answer the research question surrounding the CAD patients undergoing CA and/or PCI, observing the incidence of complications at the differing vascular access sites.

In New Zealand cohort study designs have been used to determine various influencing factors that affect our health. These studies also help to understand risk factors and adverse events such as the NZ Asthma and Allergy cohort. This cohort study was established in 1996 which involved expectant mothers being recruited by midwives and their children who also underwent several assessments. These assessments included serial questionnaires, environmental assessment including mould and allergen exposure, skin-prick testing assessment of the presence of disease at six years of age and genetic assessment. The cohort is now fully assembled and is well placed to address many current research questions or hypotheses about the risk factors associated with allergies and asthma (Epton et al., 2007). Cohort studies are often used to determine the usefulness of data observed in randomised trials and evaluate if these findings can be put into the broader population and more realistic settings (Schneider et al., 2003).

A very well known international cohort study is the “Disappearing Teaspoons” study. The researchers wanted to examine their own hypothesis of missing teaspoons within their own working environment and observed an 80% loss of 70 teaspoons within five months. The missing teaspoons were not influenced by the value of the teaspoon. However, the half life of the teaspoon in communal rooms was significantly shorter than those in rooms associated with particular groups. The authors concluded from the

findings of this study they would have to purchase 250 teaspoons a year to accommodate their research institution of 140 employees (Lim, Hellard, & Aitken, 2005). This example shows how a cohort study can help determine the effects and potentially understand the problem to find manageable solutions, or to help implement changes into current practice. This consequently can lead to better outcomes, or understanding of problems for the person involved.

The susceptibility to bias is inherent with the use of subgroups and the length of time to collect data for these studies. The three common causes for bias in a cohort study are; 1) selection of participants, when there are systematic differences in the studies selected participants and those who are not selected, 2) measurement of study factors and outcomes, where the participant and the observer for the collection of data could have the potential to contribute to inaccurate measurements, and 3) when an alteration of measurements is caused by a unrelated factor or exposure that affects the studies outcome and is not considered an intervening variable for the study; causing what is called a confounding bias (Schneider et al., 2003).

Schneider and colleagues, describe prospective studies as a study design through exploration of presumed causes, presumed differences or presumed relationships and more forward in time to the presumed effect. With my research the prospective study does have some presumed differences through clinical experience. Radial approaches for CA/PCI tend to have less vascular access site complications than those of femoral approaches. The presumed causes of complications could be the site of the approach. Femoral approaches result in patients lying on their backs for long periods of time (four to eight hours), causing back ache and irritability and therefore, restlessness in bed. These causes may contribute to affect complications (Chair et al., 2003). From my clinical experience, radial approaches enable patients to mobilise immediately post procedure, reducing the problems of irritability associated with back pain.

Due to the prospective nature of cohort study designs they are stronger than case-control studies when well executed; however, they can be more expensive. Case-controlled studies can be done in a single institute with a small team or individual researcher whereas cohort studies tend to be more structured across many institutes. Cohort studies do not provide empirical evidence due to their observational nature, which is as strong as that provided by properly executed randomized controlled clinical trials. This follows

all literature about the 'hierarchy' of evidence (Schneider et al., 2003). However, other than a randomised controlled trial, Schneider argues that the strength of a well designed cohort study can provide the strongest evidence that a result is likely to occur or not occur. This is why the use of likelihood ratios within quantitative research such as the Pearson chi-square test is used.

Observation using a quantitative approach places emphasis on the objective and systematic nature of the research process. The quantitative researcher is not merely looking at what is happening, but rather watching with a trained eye for certain specific events what were identified following a review of previous research or clinical experience (Schneider et al., 2003). This is demonstrated in this study as Cardiac Specialist Registered Nurses are observing, watching and documenting the effects (vascular complications) in radial approaches for CA/PCI. The allocation of factors is not under control of investigator, and the definition given by Schneider, articulates that an observational study is the combination of self-selection or an experiment of nature. For those questions where it would be unethical to assign factors, investigators are limited to observational studies (Schneider et al., 2003).

To overcome the self-selection side of this observational study, I had all patients entered into my study with minimal exclusion criteria. The only patients who did not participate were those who were in another study or who were too unwell to partake. Of the patients I entered into the study I had no patients needing to be excluded.

Observational studies typically fall under the qualitative research methodology which is usually exploratory. Quantitative research is generally more conclusive. With quantitative data being measurable (vascular complications are measured, e.g. how many?) qualitative data can not be put into a context that can be graphed or displayed as a mathematical term (Schneider et al., 2003). Both definitions are agreeable, yet I believe the two can be entwined habitually. Research often generates more questions outside of the specific research question being answered. When doing this research the question of whether nurse's workload is decreased when caring for a patient who has had angiography via the radial access site arose. So then the research could become quantitative (how many complications per each approach?) and qualitative (what difference is each approach site making to the nurses workload?). It is difficult to define qualitative research since it doesn't involve the same terminology as ordinary science.

The simplest definition for qualitative research when reading at great length about the two methodologies is to say it involves methods of data collection and analysis.

Within my research the qualitative aspects of the study includes the nursing workload and acuity of patients. The workload will decrease if it is found that there are fewer vascular complications in one particular vascular access site group. The quantitative part to my study is looking directly at the vascular complications and the number of complications. These complications are being systematically documented and recorded in a database.

Historically, qualitative research did not emerge as a way of uncovering knowledge in healthcare until the 1970s. During this decade and into the 1980s the use of qualitative research began to gain dominance within differing research fields such as, women's health, educational studies, information studies, disability and human service studies (Mann, 2003). New methods during these two decades helped overcome the criticisms from the quantitative researchers. These new methods were designed to help ensure reliability and accurate modes of data analysis (Mann, 2003).

To analyse the data, I drew a sample of subjects/participants who did, and who did not, have the exposure of interest, which for the purposes of this study was the vascular site complications. The occurrence of the outcome of interest in both groups can then be analysed (Schneider et al., 2003). In relation to this research I was testing the hypothesis by comparing the two differing study groups (radial and femoral approaches), and investigating the occurrences of vascular complications within each. Then analysing the data collected to answer my initial research question: "Does having a radial approach for CA/PCI reduce vascular access site complications?" The outcome of my study will aim to enhance patient comfort and reduce nurse workload. However, to ensure the safety of the patient's followed throughout the study the researcher first required input from the Central Region's Ethics Committee.

### **Ethical considerations**

Researchers need to take every step to ensure the minimisation or absence of harm, trauma, anxiety and/or discomfort of the research participant. The ethical and legal issues are considered by a variety of ethics committees and there has been a code of ethics for research developed by the American Medical Association (Schneider et al.,

2003). This was established following World War II and flowed from the outcomes of the trials for war criminals committee by the Nazi physicians on concentration camp prisoners.

#### ***Observational /current data collection***

The objective of my study was to compare observational prospective data with retrospective data, looking at vascular access site complications. Following a conversation with one of the representatives of the Central Region Ethics Committee of New Zealand, an application form for an observational study was completed and sent for approval in April 2007. Approval was obtained prior to commencement of the observational cohort study within the cardiac care unit.

#### ***Retrospective audit of data***

A discussion with the committee about the use of the retrospective database for comparison also occurred at the time of approval for the observational study. Written permission and approval was obtained to include this data in the current study. The rationale for the comparison of prospective and retrospective data was that I already had a database of 780 patients who had undergone a femoral approach for CA and/or PCI; this was from the study I completed in 2006 in CCU. This database had all the necessary information (demographics and vascular complications) collected to use as a comparison for the prospective observational study I was to undertake in the cardiac care unit.

#### **Cultural safety**

Cultural safety is a concept that focuses on power in health-care relationships. The treaty is acknowledged in legislation through principle obligations of partnership, protection, participation and equity, all patients from all cultures were included within this study. Working within a framework such as the Treaty of Waitangi ensures not only Maori, but people from other cultural/ethnic backgrounds are identified and their personal and professional cultural beliefs and values are considered by all nursing staff.

To ensure this research study was carried out within the framework of the Treaty of Waitangi and cultural safety was sustained, a discussion with the Kaumatua was held. Their input is important as they have an in-depth knowledge, understanding and experience in the language, protocols and practices of Maori. This person is based

within the Whanau Healthcare Service in the tertiary hospital where the research was undertaken. With all patients eligible to enroll in this study, considerable care was taken to ensure the research method and data collection was kept confidential and the Treaty principles upheld.

### **Method/Data collection/Recruitment of participants**

The recruitment of patients by the nurses to the study was done within the CCU at a large tertiary hospital. The patients had been admitted to the unit for investigation of coronary artery disease. Patients enrolled in this study had experienced the effects of CAD. The demographic data that was collected indicated 48-55% of the patients already suffered from ischemic heart disease (IHD) (described in this study as previous CABG or MI in past). While CAD is declining in New Zealand, it still results in the highest number of deaths of CVD related deaths (91 per 100,000) (Ministry of Health, 2003). In New Zealand, Cancer is the leading cause of death. Coronary artery disease is the second leading cause of death resulting in 23% of all deaths. Myocardial infarction (MI) accounts for 52% of the deaths in this group. The most preferred choice of treatment worldwide is PCI for coronary artery disease (Ministry of Health, 2003)

My study's work environment is an acute CCU consisting of 18 inpatient beds and four elective procedure beds. There is a daily (Monday-Friday) change of patients (40%) within the unit due to the acute coronary angiography list. The CCU receives acute patients daily (n=4-6) from seven regional hospitals within our catchment area.

My study involved all patients admitted to the CCU where I am employed within the timeframe of collecting the data which was from May to September 2007, or until the number of participants needed was achieved who had a CA and/or PCI via the radial access approach. There were no exclusion criteria.

### **Development and use of data collection tool**

All observational data was recorded on a data collection tool by the nurses who were working within CCU and the cardiac catheter laboratory. I held four separate meetings with the nursing staff to go over the data collection tool. This was to ensure they were prepared and informed how the data was being collected and or what purpose. When developing the tool for the prospective observational study I was able to adapt the data collection tool I used for my earlier research (Woodhead et al., 2007). The retrospective



data collection tool had an extensive amount of data including status of the patient (acute or elective), co-morbidities, any previous IHD, the vascular access, what was done (angiogram, angioplasty, PCI, valvuloplasty), how much heparin was administered, sheath size, what haemostasis method was used (digital pressure, femostop), what the recent blood results were, the vascular complications (same definition as the prospective observational study), and any extra medications that may contribute to vascular access complications (reopro, clopidogrel).

The prospective observational data collection tool needed to be easy to use as I wanted staff to want and be able to refer to it and understand it. This led me to consider what level of detail I needed to record. With multiple conversations with the hospitals Cardiologists and in addition a meeting with the CCU's Research Nurse and Nurse Educator, I developed the data collection tool to reflect evidenced-based practice. Data collection can often be made more efficient by enlisting the help of people who are working in the field (Ministry for the Environment, 2007). Once the data sheets were completed they were then placed into a folder to then be entered into a database.

The data collection tool enabled me to measure patient demographics and background variables including: height and weight, fasting time, co-morbidities, and previous is IHD, which consisted of any previous history of ST elevation myocardial infarction (STEMI), non ST elevation myocardial infarction (NSTEMI) or coronary artery bypass grafting (CABG). In addition, it documented what procedure they had (angiogram, PCI, plasty, heart studies), sheath size, the antiplatelet therapy given to patient, blood results and whether the procedure was elective or acute.

When the data sheets were collected for entering into the database, I would check each one to make sure all the necessary data was recorded. I entered the data into the database and for every 20 I entered I would check the data against the patient's notes to ensure it was correct and therefore checking the accuracy of the data collection tool.

### **Data management**

Data was collected over a six month period from April to September 2007. I manually entered the data on a daily basis into an Excel data spreadsheet. The data was entered daily so that if any information was missing from the form, I could easily go to the patients notes and collect the missing information. This ensured correct and complete

data was entered. The decision to use Excel was that I am familiar with the programme. The transcribed data was kept in a folder inside a locked filing cabinet within my clinical area.

The historical (retrospective) database was also Excel, which make it easier to extract and collate all data required for the study. The transcribed data was also kept in a folder locked in a filing cabinet within my clinical area.

Following the end of the prospective data collection and once all data was entered into the database, I was able to analyse the data using the Pearson's chi-square test.

### **Data analysis**

Data was extracted from the retrospective database and compared with the prospective data, then analysed using the Pearson's chi-square test. The Pearson's chi-square test was chosen as it is used to assess two types of comparison, which is the focus of this study; comparing the difference between radial and femoral coronary angiography sites, and the complications that may occur.

When exploring the correlation or association of two or more variables, statistics are used to help identify the connection between two variables. When exploring the variables within research (for example, weight, age, sex), the researcher attempts to understand how and why there are differences in one variable and how they are related to differences in another variable. When testing a hypothesis you want to be able to find a correlation or association with and ensure it exists in the target population. This is called inferential statistics. With these statistics, the study is designed to collect appropriate data, and then analyse the data using measures of association. Inferential statistics commonly reports on hypothesis testing. Statistical hypothesis testing allows the researcher to ask questions and find answers, having already objectively made decisions about the study's outcomes. As with this study, I hypothesized that radial approaches were less likely to result in vascular access site complications.

It is interesting to note that statistics first emerged as its own discipline due to the work of Pearson and his colleagues. Karl Pearson (1857-1936) was an English statistician in 1900, who invented the chi-square statistic. It is still used today in its original form making it the oldest inference procedure used within statistical fields (Moore & McCabe, 1993).

Once the Pearson's chi-square tests are calculated, the distribution for this test is examined to determine whether the p-value obtained was likely to have occurred by chance. The chi-square is one of the more popular statistical tests, as it is easier to calculate and the resultant interpretation is uncomplicated (Key, 1997). The two-way analysis, which is what is used to calculate this study's results, is used to determine whether the observed frequencies are different from the frequencies that we would expect by chance (Rosner, 2006). The study's results have been calculated using an interactive statistical calculation web page by (StatPac, 1997-2007). I then emailed the hospitals statistician to check over the numbers and calculations to ensure they were correct to comment on.

It is also important to recognise the difference between statistical significance and clinical significance. When the researcher tests a hypothesis and finds it is statistically significant, it means that the finding is unlikely to have happened by chance. Significance for a sample has been set at 0.05, that is the conclusion would be incorrect only 5 times in 100, that is the result would be obtained by chance only 5 times in 100. The researcher aims to discover the probability that the findings of their experiment occurred randomly by chance.

When looking at statistical results and the values of distribution a null hypothesis is either rejected or accepted by the researcher. A null hypothesis simply means that there is no difference in the hypothesised values; the researcher then reports both the statistical result and its probability (Schneider et al., 2003).

### **Confidence intervals**

A confidence interval (CI) gives a range of values, which is likely to include an unknown population parameter, with the estimated range being calculated from a given set of sample data. When independent samples are taken repeatedly from the same population, and the CI is calculated for each sample, then a certain percentage (confidence interval) of the intervals will include the unknown population parameter. Confidence intervals are usually calculated at 95% (Schneider et al., 2003). This study has used a CI of 95%.

The width of the CI gives us some idea about how certain we are about the unknown parameter. A small CI is more reliable than a large confidence interval. A wide interval

may indicate that more data should be collected before anything definite can be said about that parameter (StatPac, 1997-2007).

Validity of a study is based on what the researcher wanted to measure, in terms of this research the measurement of complications at the radial and femoral access sites, and the accuracy of data. For the study to have practice and theory development, and form a basis for further research, the findings must be believable and dependable. To examine and determine the validity of a study the two results both internal and external validity are addressed.

### **Internal validity**

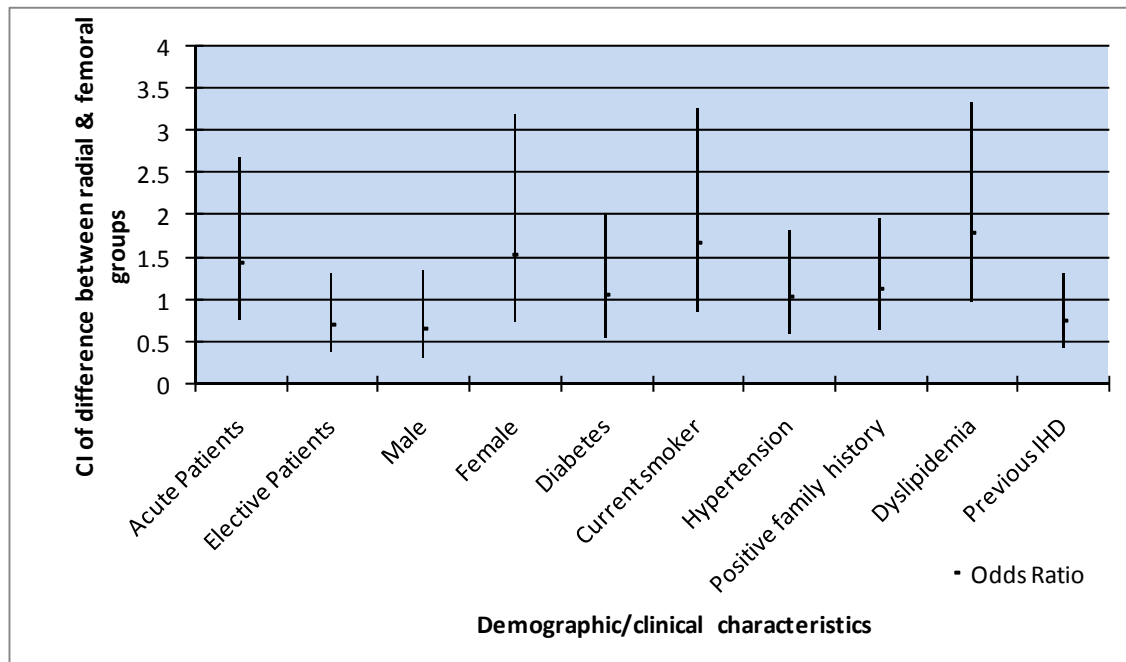
Internal validity is the approximate truth about inferences regarding cause and effect or causal relationships. It means you have evidence to show that what you did in your study caused what you observed (outcome) to happen in your study. When looking at the threats to internal validity it indicates the researcher is looking at the extent to which the observed difference in outcomes between the two groups has happened due to the intervention and not explained by other factors (Schneider et al., 2003).

Internal validity is enhanced with studies such as randomised controlled trials (RCT), because the random allocation of subjects, acts to minimise selection bias. With cohort studies, such as this study, it can become a vulnerability of validity as factors that determined whether the person received the intervention could result in the groups differing in factors related to the outcome. A comprehensive approach includes selection of appropriate comparison groups that minimise differences between the populations being compared in the groupings. I achieved this with my study. Looking at the results for the demographic data (Table 3 – *Findings Chapter*); the two comparable groups match with their demographic and clinical characteristics. The statistical findings show there is no significance between the two groups (see Table 3 for the comparative groups - *Findings Chapter*). Ideally the comparison groups will be identical to the intervention group, but they have either no or different treatment/intervention (in this study, the radial approach) (Rochon et al., 2005).

### **External validity**

External validity ensures that the conditions such as in this study relating to CAD, for example hypertension, diabetes, and the types of participants in the study will have the

same results expected to occur within other populations or environments (Schneider et al., 2003). Due to the small confidence intervals within the results and within the literature review about this patient population, it is evident that the external validity is adequate (see Figure 4). The literature shows this patient population has similar baseline characteristics in most studies showing the implications of the risk factors and ages of this group. Figure 4 has shown this study is dependable and has sufficient validity for either further research or for practice and theory development.



**Figure 4 – Odds ratio and confidence intervals**

When looking at the confidence intervals within figure 4, it is clear that the data collected was sufficient. The intervals are small and therefore reliable to comment on.

## Summary

The theoretical underpinnings of this research was to look at the difference between radial and femoral vascular access sites in relation to CA and or PCI and the associated vascular access site complications. Following a literature review I performed the theoretical framework has been illustrated as a adapted three legged stool model (Skinner, 2005) integrated with a evidence based health care model from JBI (Pearson, Wiechula, Court, & Lockwood, 2005).

Using a cohort comparative observational study design I have compared retrospective data from a historical database which looked at femoral approaches for CA/PCI of those

in the current study with prospective data from observation looking at radial approaches for CA/PCI and the comparisons of vascular access site complications.

Ethical and cultural considerations have been considered for this study and implemented. The selection of patients for this study had all been admitted to the tertiary hospital's CCU for the investigation for CAD. All patients undergoing a radial approach for CA/PCI were eligible and data was collected over six months. There were no exclusion criteria. There were no patients that crossed over from a radial to a femoral approach in this study. All observational data was collected using a data collection tool I created from clinical expertise. The data was collected by nurses in CCU and the CCL. The comparative data was extracted from my database and the two sets of data were analysed using the Pearson's chi-square test.

The findings from this study show consistency with similar studies (Andersen et al., 2005; Chair et al., 2003; Roebuck et al., 2000) in relation to the demographic data. The results from this study were also predicted, as I hypothesised, radial approaches have a reduced rate of vascular complications and therefore better healthcare outcomes for the patient. The following chapter will discuss the findings in detail and what this means for nursing practice.

## **Chapter Four - Findings**

### **Background**

Following discussion with a cardiologist at the hospital I'm employed by, the short time frame for collection of data for this study determined the sample size. Even though the sample size is relatively small, the findings have revealed significant results with small confidence intervals. The findings from this study could become a pilot study within a bigger study in New Zealand (NZ), and interest in this is high.

All patients admitted to CCU in the tertiary hospital where I'm employed and undergoing a radial approach for CA and/or PCI within the timeframe of the research being carried out were eligible for this study. The CCU where I'm employed will typically have six to eight patients who will have a radial approach; this is performed primarily by one cardiologist who has one day within the cardiac catheter laboratory (CCL). Their day in the CCL is Monday; therefore it was imperative I was available on that day to ensure the collection of data was completed.

Data on 100 participants was collected and all were included in the study. No radial approach patients crossed over to the femoral approach. The retrospective data for comparison (femoral approach) was specifically chosen from a historical database to ensure validity by selecting demographic and clinical data that was similar. This established two comparable groups that matched. The statistical findings show there is no statistical significant difference between the two groups.

This chapter explores the findings on the clinical and demographic data in relation to how this fits with national data trends. The results from the outcome of this study looked at vascular complications in relation to answering the research question, 'Is there a significant difference in the vascular access site complication rates when comparing radial and femoral approaches?'

The New Zealand population is aging, which increases the volume of hospital admissions. The three top main causes for hospitalisation are angina, congestive heart failure and respiratory infections ("Health of Older People," n.d.) This is consistent with the findings of my study. Within this chapter I report on two of the common admissions to CCU that can affect the outcome of complications following CA and percutaneous coronary intervention. Within the eight months, data was collected using a data

collection tool previously discussed. Nurses were asked to observe and document the findings of each patient eligible for the trial. Within an eight month period, data was gathered on the 100 participants needed for this study.

### **An aging population**

When reading literature and other studies of similar nature (Archbold et al., 2004; Farouque et al., 2005; Keeling et al., 1996; Lim et al., 1997; Roebuck et al., 2000), the demographic and clinical characteristics very similar. One of the most important factors when working within the health care sector is the knowledge that our population is aging (Statistics New Zealand, 2006). With this in mind we must strive to ensure treatment and management plans are sufficient to deal with what lies ahead in our health care setting.

Treatment and management plans are being continually restructured to accommodate for this trend. Medical technical advances are also changing to accommodate for this known factor. The recent census in 2006 showed a true reflection of the aging population within New Zealand. The median age was 35.9 years, up from the 1996 census which was 33 years. However the change of the proportion of population aged 65 and over had little change showing 12.3% up only by 2% from 2001 (Statistics New Zealand, 2006). Over the next 25 years the number of people aged 65 and over is projected to rise significantly to reach 924,400 by 2026. By that time they will make up around 20 percent of the total population (Statistics New Zealand, 2006). Within this research, the percentage of people who were 65 years and over was 43%.

Eighty five percent of coronary heart disease deaths happen in those over 65 years of age (Ministry of Health, 2004). This is why appropriate revascularisation, together with the best possible approach is so important. The best common practice is to endeavor to give these patients the best possible outcome, not only from the intervention or decided surgery, but also the revascularisation technique for patient comfort.

### **PCI vs CABG**

The dramatic improvements of PCI in the past 30 years have shown a definite decline in CABG surgery. There has also been a steady decline in CABG surgery. Since 1990 it has reduced from 8% to 1% in 2005 (Resnic, 2007). Even though the complexity of clinical and anatomical conditions are increasing, the continual progression and



advancement of PCI techniques and procedural experience has ensured vascular complications have decreased (Resnic, 2007). However, there are still known vascular complications with the femoral access site being the main culprit. Further research and trials are required to show the radial approach is the superior option for the majority of patients undergoing CA and/or PCI.

### **Quality of life**

The key of any revascularisation procedure is to improve the patient's quality of life (Dawkins et al., 2005). Since 1977 when the beginning of PCI emerged, there have been remarkable advances. Due to the medical device industry the change for the treatment of CAD has progressed and Dawkins argues that it continues to evolve at a rapid rate. Due to this advancement in coronary intervention it is important to ensure interventional centers are doing everything they can to ensure the patient's comfort and quality of life following these procedures. The treatment involving PCI for CAD has transformed many patients' lives. Once limited by their symptoms, they are now returning to full activity with low risk to procedure related cardiac events (Archbold et al., 2004). New medical devices are constantly changing and evolving to provide better patient care, and so to should the techniques of cardiologists when performing the intervention.

Findings from my study showed in CCU at the hospital where I work, PCI's were performed on 58% of the patients admitted for the CA procedure. The use of PCI is rapidly developing with further development in recent years with the use of drug eluting stents (DES). This allows further lesions to be stented in a wider population who would not otherwise be eligible for coronary artery stenting. For example, patients with Type 2 Diabetes Mellitus (T2DM) or peripheral vascular disease (PVD) (Dawkins et al., 2005). These patients tend to have smaller coronary vessels and have tighter lesions which make the stenting more technically difficult. My study showed that 23.5% of patients undergoing CA and/or PCI were diabetic. The introduction of DES has enabled these patients to receive the intervention and therefore have a better healthcare outcome (Bakhai et al., 2005).

### **Complications of heart failure**

The symptoms of heart failure are; shortness of breath (especially when lying flat) and odema (especially in the feet, legs and abdomen). Odema is caused by the build up of fluid in the lungs due to insufficient heart pumping function, irregular heart beat due to

the inefficient heart pumping function, and dry hacking cough which is a result of the medication that heart failure patients are prescribed (Gandelman, 2006). From the symptoms you can see how having a CA and or PCI could affect the recovery of the patient. When using a femoral approach on these patients, from clinical experience more complications are often going to happen as they a) cannot lie flat for a lengthy period of time as it causes a shortness of breath, b) cannot lie still due to the coughing and c) have trouble passing urine when in a horizontal position due to the diuretics they are prescribed for their heart failure.

One of the leading causes of hospital admissions for people 65 years and over is heart failure. Statistics from the New Zealand heart failure registry show heart failure admissions increased by 50% between 1988 and 1997. This means approximately 1% of the NZ health budget is directly consumed by heart failure patients (Devlin, 2006).

My research shows 43% of the participants of the trial were 65 years and over, many of these patients will suffer from some degree of heart failure or left ventricular dysfunction. What's more 73% of the patients were acutely admitted to CCU and 51% of those patients having had a previous IHD event (MI or CABG).

For these patients a radial approach is far more logical and optimal for patient comfort and satisfaction. Patients can mobilise immediately, which is helpful as they can go to the toilet independently, they do not have to lie flat therefore decreasing the effects of shortness of breath and if they cough they are less likely to suffer ill consequences at the procedure vascular site. A similar clinical characteristic which is equally problematic when performing CA and or a PCI is patients who have a high body mass index (BMI).

### **Complications of high BMI**

In New Zealand more than 50% of the adult population has a BMI greater than 25. The normal range is 18.5-24.9 (New Zealand Guidelines, 2003). The risks of co-morbidities such as T2DM, CAD, CHF, hyperlipidaemia and hypertension start to rise when your BMI is above 20. Within this study the mean average BMI for patients was 25.3; this puts our patient population in the 'pre-obese' range and gives all patients an increased risk for the co-morbidities listed above.

When looking at implications of an increased BMI, this does have an effect on the femoral approach for CA and or PCI. When patients present with a high BMI it is

harder (through clinical experience) to apply the femostop™ device properly for good haemostasis of the femoral artery, due to large abdomens. Patients with a high BMI generally have more complaints of back and hip pain, due to the increased pressure from their weight and they also have more problems with shortness of breath when lying flat due to the increased pressure on their lungs from their abdomen pushing up. Also a lot of high BMI people suffer from obstructive sleep apnoea (Bassetti, 1999), which is even worse when lying flat.

In a retrospective review by Cox and Colleagues (2004), a large number of patients (n=5234) who underwent either CA or PCI (n=5234) found morbidly obese patients had a higher incidence of vascular complications. They concluded the use of radial approaches and arterial access closure devices were associated with a reduced vascular complication rate in the population of the obese patient. A reduced vascular complication rate ensures an improved quality of life for the patient.

As discussed earlier, the increasing number of people suffering from LV dysfunction due to an aging population with increasing heart failure of all types and degrees and the flow on effect from the increasing problem with obesity nationally are causing hip and back pain. The New Zealand Guidelines (2003) state more than 50% of New Zealanders have a BMI greater than 25, this is also shown in the results of this study with the mean BMI being 25.3. These are two major factors of concern when related to femoral approaches for CA and PCI – these people have a decreased tolerance of the strict bed rest care following the procedure.

### **Vascular access site complications**

Most literature I have read indicated the rates of vascular complication vary from 0.7-28% in differing studies (Archbold et al., 2004; Farouque et al., 2005; Keeling et al., 1996; Lim et al., 1997; Roebuck et al., 2000). Despite very clear care plans to manage these patients on bed rest, vascular complications at the femoral access site are still highly reported. These factors are known and lead to a decrease in patient satisfaction and comfort, an increase in morbidity, hospital length of stay (LOS) and consequently costs to the organisation. This has over the past decade led to the development of an alternative vascular access sites being utilised for CA and/or percutaneous coronary intervention.

The findings in this study show a high combined complication rate. I suspect there is actually a lesser combined complication rate in both vascular approaches due to the definition of the haematoma complication. Most literature (Archbold et al., 2004; Farouque et al., 2005; Keeling et al., 1996; Lim et al., 1997; Roebuck et al., 2000) defines a haematoma as being 5cm in diameter or bigger. Within this study it was defined as 3cm in diameter or bigger. The reason for requesting documentation on hematomas of this size was to capture the workload of the nurses caring for that particular patient. From clinical experience a haematoma of 3cm is still going to require extra nursing care. A nurse would typically need to apply further pressure, spend increased time observing the access site and the patient may require further time on bed rest. The factors contributing to the haematoma complication can also be heart failure and or a high BMI (Cox et al., 2004; Gandelman, 2006).

The findings from my study are not surprising. As hypothesised, radial approaches for CA and PCI has a significant decrease in vascular access site complications (haematoma, vasovagal, arterial bleed and pseudoaneurysm). As demonstrated in Table 3, the baseline characteristics of both groups (femoral and radial access) are of similar nature, thus not affecting the primary endpoint.

**Table 3 – Demographic and clinical characteristics**

Clinical Features	Radial Group (n=100)	Femoral Group (n=100)	P Value	Odds Ratio	Relative Risk
Age (yrs)	36-78 years (ave 60 yrs)	37-79 yrs (ave 63yrs)	N/A	N/A	N/A
Acute patients	77	70	0.262	1.43 (0.76-2.68)	1.11 (0.93-1.29)
Elective patients	23	30	0.262	0.69(0.37-1.30)	0.76 (0.48-1.21)
Male	80	86	0.259	0.65 (0.31-1.36)	0.93 (0.83-1.05)
Female	20	14	0.259	1.53 (0.73-3.21)	1.42 (0.77-2.66)
Body Mass Index (kg/m2)	25.5	25.1	N/A	N/A	N/A
Diabetes	24	23	0.86	1.05 (0.55-2.02)	1.04 (0.63-1.71)
Current smoker	27	18	0.12	1.68 (0.86-3.28)	1.50 (0.89-2.54)
Hypertension	61	60	0.88	1.04 (0.59-1.83)	1.01 (0.81-1.27)
Positive family hx.	51	48	0.67	1.12 (0.64-1.96)	1.06 (0.80-1.40)
Dyslipidemia	77	65	0.06	1.80 (0.97-3.34)	1.18 (0.99-1.40)
Previous IHD (CABG, MI)	48	55	0.32	0.75 (0.43-1.31)	0.87 (0.66-1.14)
Diagnostic angio	41	43	0.77	0.92 (0.52-1.61)	0.95 (0.68-1.32)
PCI	59	57	0.77	1.08 (0.62-1.90)	1.03 (0.81-1.30)
Fasting time (hrs)	45 mins – 21 hrs (ave 8.7 hrs)	3.2 hrs – 22 hrs (ave 10 hrs)	N/A	N/A	N/A
Heparin	5000-12500u	5000-11000u	N/A	N/A	N/A

When looking at the results of the vascular site complications (Table 4), haematoma still remains as the main risk. Six haematoma were recorded in the radial group and a significantly higher presentation of 18 was recorded in the femoral group. This gives a significant statistical result with the p value calculated to 0.009.

**Table 4 - Vascular site complications**

<b>Adverse Response</b>	<b>Radial Group (n=100)</b>	<b>Femoral Group (n=100)</b>	<b>P Value</b>	<b>Odds Ratio</b>	<b>Relative Risk</b>
Haematoma	6	18	0.009	0.29 (0.11-0.74)	0.33 (0.14-0.77)
Arterial Bleed	2	3	0.65	0.66 (0.12-3.38)	0.66 (0.13-3.29)
Vasovagal	2	4	0.40	0.49 (0.10-2.35)	0.50 (0.10-2.29)
Combined	10	28	0.001	0.28 (0.13-0.62)	0.35 (0.18-0.67)

Haematoma is the common complication found in multiple various studies (Andersen et al., 2005; Cox et al., 2004; Dumont et al., 2006; Farouque et al., 2005). Most studies look at the different predictive risk factor for a haematoma and how these could possibly be managed to decrease the risk of haematoma. However, even with all these studies and known predictors, haematoma still remains the highest and most common complication. A change in practice and potential easy answer to the problem of vascular complications (in particular the debilitating haematoma complication) is the sensible use of a radial approach. The findings in my study show a dramatic decrease in a haematoma complication (from 18% down to 6%), by performing the procedure using the radial approach.

### **The problems with vascular access site complications**

The prevention of vascular access site complications is an important issue to solve. Cardiology nurses need to be aware of the correct way to care for arterial access sites due to the significant impact to patient's morbidity, mortality and the hospital costs that vascular access site complications can incur (Elsevier, 2006). The results showed within this tertiary centre, the combined complication rate is high in the femoral approach (28%) with a much lesser combined complication rate total of (10%) in the radial group. One further complication is a pseudoaneurysm (small tear in the artery causing bleeding), this has not been discussed as there were no pseudoaneurysm in either group within this study. According to Elsevier the role of the cardiology nurse is expanding

within routine practice and these nurses are expected to actively manage the access site from sheath removal to prevention, detection and diagnosis of complications.

In the literature review chapter discussed earlier, I found many research studies (Archbold et al., 2004; Farouque et al., 2005; Keeling et al., 1996; Lim et al., 1997; Roebuck et al., 2000) have concentrated on the femoral vascular access site complications and ways in which to prevent, treat and manage them. Although internationally research has been conducted, there is still a substantial rate of complications (0.7-28%). Complications result in the patient having decreased satisfaction and comfort and a poorer quality of life following discharge from hospital. A haematoma for patients can be quite debilitating (due to pain/discomfort of the groin) causing a short term decrease in their quality of life. These complications can also lead to an increase in the length of hospital stay, leading to increased costs for the organisation.

As a tertiary center the health provider is always looking to reduce costs. The use of radial approach could be one of the interventions to do this. The radial approach reduces costs through reducing nursing time spent caring for the patient with a vascular access site complications. There is also a reduced cost from a patients' decreased length of stay (LOS). The radial approach has also been found to decrease post PCI complications. Restenosis (this is when a plaque buildup forms on the inside of the stent, causing a life threatening myocardial infarction (MI) if not treated immediately) (Goyal et al., 2006), is one complication reduced through a radial approach reducing costs with patients treatment and LOS. The radial approach has criticisms from the operators due to the technical difficulties some have performing the procedure and also the access to the LIMA (left internal mammary artery) graft post CABG patients. However, the evidence has shown the radial approach decreases vascular access site complications and post PCI complications, therefore is better for the patients outcome and organisational costs.

The American Heart Association in 2005 had the presenters for the Early Discharge After Transradial Stenting of CoronarY Arteries (EASY study) commenting on their results. They found using radial approaches improved the likelihood of same day discharge of patients with non-complicated PCI (Goyal et al., 2006). This would also be a cost saving strategy for the organisation as admission/discharge rate of patients would be higher.

The literature review conducted by Archbold, et al (2004) concluded that when a positive Allen's Test is used there is an insignificant rate of complications. This includes patients on anticoagulation therapy and patients who suffer from PVD. These findings in conjunction with the results of my study, and others of similar nature, such as Arachchi and Matsis (2003), should provide sufficient evidence for interventional cardiologists to be encouraged to perform radial approaches for CA and PCI. The most significant disadvantage mentioned by cardiologists when using the radial approach is the time it takes to perform a radial approach as opposed to the more traditional femoral approach. It is also a much easier route with larger vessels. This was also noted within Arachchi and Matsis study, they identified there is an operator learning curve and therefore maybe some resistance.

When presenting the findings at a cardiology forum in the hospital where I'm employed, changing from a femoral to radial approach was described by a cardiologist as having to teach "old dog's new tricks". The main consensus from the medical staff following the presentation of findings was the radial approach was better for the patients' satisfaction and comfort. It was acknowledged that with practice they will become more confident and familiar with performing the procedure. Nursing staff within the cardiac catheter laboratory (CCL) also had reservations about performing radial approach CA and or PCI as it takes longer to set up.

The common concerns from the nursing staff within the CCL (where CA and PCI are performed) was the longer procedure times (Elsevier, 2006). However, becoming familiar with a radial approach research and in my clinical experience has shown a decrease in the nursing workload both in the cardiology wards and the CCL (Elsevier, 2006). The use of radial approaches allows for easy compression of the small artery access site resulting in minimal bleeding and earlier mobilisation of the patient. The patients discharged earlier and overall cost to the organisation are decreased.

From the findings of this study and the hospital's cardiology medical expert opinion, radial approaches for CA and PCI of 70-80% are recommended for all patients who have a positive Allen's test (Goyal et al., 2006).

Now with a detailed understanding of the results of this study the implications and the significance of how this may influence nursing practice are discussed in the following chapter.

## **Chapter Five - Discussion**

Based on the Joanna Briggs Institute (JBI) Model of Evidence Based Health Care (2005) (Appendix 3), I now to discuss how this study and its design can be used to inform nursing practice. This study can also influence further research within the area of interventional cardiology (Pearson et al., 2005).

### **Health care interventions/activities**

Current future developments are being made by the New Zealand health strategy group to put together a national cardiovascular action plan. As one of the 13 population health objectives for New Zealand, as healthcare professionals we need to ensure we are striving to reduce the impact, incidence and prevalence of this cardiovascular disease (CVD). This disease has a considerable effect on the health care services, remaining one of the leading killers of New Zealanders today (Ministry of Health, 2003). Of the cardiovascular diseases, Coronary artery disease (CAD) is the leading cause of death, therefore primary, secondary and cardiac rehabilitation are of utmost importance when working in this area.

Currently, studies (Bakhai et al., 2005; Dawkins et al., 2005) are showing the significant benefit from early revascularisation for eligible patients with PCI or CABG. This can reduce mortality or subsequent acute myocardial infarction (AMI) by 22% and subsequent hospitalisation by 45-50% (National Heart Foundation of Australia, 2000).

Data used within the hospital from the cardiac catheter lab (CCL) and from our own data collected (not for use other than for interest) shows a gradual increasing trend in PCI numbers. Just three years ago 51% of patients admitted required PCI, now it is at 58%, this is following a national and international trend (Avezum et al., 2005; Huang, Bruce, & Shaw, 2006; Tognia et al., 2004). Literature shows the key of any revascularisation procedure is to improve the patient's quality of life (Dawkins et al., 2005). The definite growing trend of more PCI procedures has also been observed in the hospital where I'm employed from the data collected over the past five years. The use of drug eluting stents (DES) (a stent covered in a anti-thrombin drug to reduce the chance of plaque growing within the stent subsequently blocking it) seems to also be an increasing growing trend (Tognia et al., 2004). As discussed previously, this allows for a wider population i.e. patients with T2DM or PVD to have more choice about their treatment and management options (Dawkins et al., 2005). These patients tend to have smaller coronary vessels and have tighter lesions which make the stenting more



technically difficult. The introduction of DES in 2004 has enabled these patients to receive the intervention and therefore have a better healthcare outcome (Bakhai et al., 2005).

The contribution to nursing through doing a study like this is identified through using a framework like the JBI Evidence Based Nursing (EBN) model. Nurses firstly need to identify the problem or issue. With my study I identified within our tertiary CCU, we have a high turnover (rate of admissions and discharges) of patients undergoing CA and/or PCI (n=8/day). Could there be a better way to alleviate patient's dissatisfaction of vascular complications following the procedure, therefore increasing their healthcare outcome and quality of life? Could there also be a better way to decrease the workload of the nursing time spent with these patients? This could be from managing and treating vascular access site complications to the initial management of different vascular access sites.

When analysing the health care evidence generation section of the JBI evidence based healthcare model, it incorporates the experience of a nursing professional. When working within CCU, patient experience and experiencing the trends in treatment for CAD, nurse involvement in the new advancements around PCI and wanting the best outcomes for patients, it's possible to question what new advancements may work and what does not. This introduces questions which turn into research searching to seek answers and then literature.

In recent times within our tertiary hospital, few cardiologists have been using radial approaches for CA and PCI patients. Many nurses noticed the increase in patient satisfaction of being able to mobilise immediately and therefore, not having to endure the backache most patients get with femoral approaches. Subsequently, less pain relief was given to patients. The most important factor was less complications at the site when a radial approach was used. There seemed to also be a noticeable decrease in patient acuity.

A literature search on the difference between the radial and femoral approaches was performed to support my research. There were vast and various studies (Archbold et al., 2004; Farouque et al., 2005; Keeling et al., 1996; Lim et al., 1997; Roebuck et al., 2000) on how to manage and care for patients following the CA/PCI. Many studies (Arachchi & Matsis, 2003; Archbold et al., 2004; Louvard et al., 2004) have been conducted on the radial versus femoral approaches, along with literature reviewing closure devices for femoral approaches. However, there was no research that specifically answered my research question.

The significance of my study question for this research was to look at the difference between radial and femoral approaches for vascular access site complications in CA and/or percutaneous coronary intervention. I wanted to examine what the best approach for patients comfort and satisfaction was. It was of significance to the nurses because of the increased workload vascular complications will create.

By using a cohort study design this study compared retrospective data from a historical database looking at femoral approaches for CA/PCI and prospective data through observation looking at radial approaches for CA and or percutaneous coronary intervention. Comparisons were made of vascular access site complications from each set of data. Each group had consistent baseline demographic data therefore ensuring the results were validated.

With greater intervention via the radial approach operators will become more confident with the technical aspect of the radial procedure. This will reduce costs of these procedures as we will be able to perform more as staff become more proficient. With more patients being treated the hospital will consequently be conducting more operations for less cost. The cost savings could then be used for further education on the use of DES, which are more effective new stents being used worldwide (Goyal et al., 2006).

Patients who do suffer from PVD of the abdomen, pelvis or lower limbs are treated with either bypass surgery or percutaneous transluminal angioplasty and stent placement via the femoral approach (De Santis, 2001). This is generally for the patient who is unable to be treated though conservative management. The use of radial approaches are now becoming more utilised within this vascular surgical domain. Also, (Yamashita et al., 2007) found similar results within their literature review to those of CAD patients. They discovered it is useful for interventions and has an advantage of low risk and reduced distress on the patients.

The contribution of the results from this study will help aid the correct vascular site approach for each patient therefore, minimising complications and improving healthcare outcomes. By setting up a protocol and using an algorithm to guide the medical professional who is pre-assessing the patient prior to the procedure, this will ensure all patients who are eligible for a radial approach, will get one. The use of an algorithm and the knowledge for the CL staff that most patients will be having a radial approach will take some time to get use to. I believe with education about the benefits for the patients receiving a radial approach for CA and or PCI

there will be improvement to the Cardiology service as a whole, leading to better outcomes for patients and the hospital.

### **Evidence synthesis**

From the literature search, gathering the theory behind what research has been performed on vascular site complications and the use of radial approaches becoming more utilised, clear themes emerged about what has been researched around this topic. The femoral approach causes common issues, including back pain, bed rest, ambulation times and positioning. The risk factors associated that may enhance vascular site complications and lastly the quality of life issues and cost to the organisation in regards to vascular assess site complications.

In reviewing the methodology of how to do this study (as previously discussed), a cohort study design was adopted. It uses observational prospective data on radial approaches and compares this with historical retrospective data on femoral approaches. A data collection tool was used to gather the information and entered into an excel database. This was then used to analyse the results using Pearson chi-squared tests. Using a cohort study design is a very common way for nurses to understand and answer their clinical research questions about a particular patient group. Nurses who are undertaking research are generally expert nurses in their field or have identified the area they want to specialise in, for example cardiology, oncology or neurology. Patients benefit from these studies as they are specific to their disease or illness.

The results from my study are consistent with other studies (Agostoni et al., 2004; Arachchi & Matsis, 2003; Goyal et al., 2006). I have clearly shown the improved effects and significant benefits for the patient where a radial approach is performed for CA and/or PCI. As Goyal and colleagues (2006) study showed, with the use of an Allen's Test for prior knowledge of the patients eligibility for a radial approach, indicates there are less vascular assess site complications with an increase in patients satisfaction and comfort. As this is the desired effect for any patient undergoing any procedure, the organisation should be encouraged about the use of radial approaches. It also has the added benefit of a decreased cost to the organisation as complications can cause an increased length of stay in hospital. Patients who have radial approaches can mobilise immediately, which could in time encourage a higher turnover of patients with appropriate education and discharge resources.

## **Evidence (knowledge) transfer**

The use of radial procedures for CA and PCI especially for the elective patients may indicate in the hospital where I work, there could be more patients undergoing the procedure. Unfortunately due to the limited resources in the current location for elective CA and PCI there is no room to increase the numbers. However, if a hospital was able to identify another area, for example the day procedures unit (DPU) or short stay unit (SSU), elective patients could be assessed for the procedure and if they fit the criteria for a radial approach they could be cared for by nurses in these areas. The nurses could undergo a training regime to ensure safe care for the radial access procedure site. Most of the elective patients for CA (which generally include the patients having a CA for a work up for their CABG or valve surgery) are of low risk for intra CA complications. The use of the radial approach lessens the risk of vascular complications and the patients are able to mobilise immediately following the procedure. This means they are not delaying discharge from the short stay areas. As a result, from Arachchi and Matsis (2003), even patients who had coronary intervention did not have any post procedure vascular complications and patients who had previously had a CA beforehand preferred the radial approach to the femoral approach.

The use of a pre-assessment nurse would be highly appropriate. These nursing roles would have to be skilled and experienced cardiology registered nurse's (RN's), who have excellent assessment skills. The pre-assessment nurse could assess the patient for a potential radial approach, knowing the history and background of the patient. They should also perform an Allen's test. All patients who were having elective CA or PCI with a positive Allen's test would be referred for the procedure in the SSU or DPU. This would address the current problems faced in the CCU with limited resources available. The other challenges are the limited resources in the CCL. However, I believe if patients were able to be pre-assessed with the pre-assessment nurse, the higher turnover of patients during the day could be better managed as the staff in the CCL would know what to get ready and when as they would have advance notice of which patients are able to have a radial approach. This will assist the elective list getting beyond the recommended waiting list timeframes.

The technicalities of performing a radial approach for the operators would lessen as they do more radial interventions. Through education and practice of this technique it would soon become as straightforward as the femoral approach. Assistance and encouragement from the nursing staff in the CL once they were satisfied with the new pre-assessing processes,

provides more time to get ready for the radial approach for each patient eligible will help to assist the operator doing the radial approach for the procedure.

Evidence based nursing helps nurses make clinical decisions based on the best available research evidence, clinical expertise and patient preferences (Stevens & Cassidy, 1999).

The contribution of this research to the nurses within a cardiology setting is to understand that when we initiate and undertake research we are not just trying to find ways to improve the experience for the patient. This knowledge can help decrease the acuity of some of these patients so more time can be spent in other areas, such as, discharge planning, cardiac rehabilitation and education. Time spent on these areas for patients is much more achievable if nurses are not spending time on vascular complications or managing the femoral approach, which generally from my clinical experience takes more time and monitoring than a radial approach.

### **Evidence utilisation**

When utilising the evidence found in this study and the impact it could have within the systems of the hospital, new protocols are required for assessing patients undergoing CA and/or PCI. The pre-assessment for these patients would have incorporated within their physical examination an Allen's test to show if the patient is able to have radial approach. I consider we would not have to limit the radial approach for the elective patients, although this could be a place to start from. I believe all patients undergoing this procedure, with a positive Allen's test, could be eligible for the radial approach. For those patients who are eligible, the CL staff should be made aware for the set-up of the catheter lab for the impending procedure and therefore lessening the problems they encounter when setting up for the wrong approach. Better communication through the pre-assessment tool and with the trend of more radial approaches should help alleviate the reluctance of this approach from the CL staff.

Changing practice is always a challenge, especially when it crosses areas (CCU and the CL). From this study and its clear results we would be looking to change practice across the cardiology service. From the initial appointment with the cardiologist or registrar within clinics, if patients are going to be put on the waiting list for an elective CA/PCI, they could be talking about the possibility of the radial approach. Performing an Allen's test and documenting the result would be an important first step. From the moment a patient comes in for pre-assessment the nurse or junior doctor would know the result of the Allen's test and

ensure all necessary people are notified the patient is eligible for the radial approach. Acute patients would be assessed for the radial approach as soon as they arrive within the CCU. Changing practice for the operators in the CL performing the procedure will be through education and ensuring the results from this and other trials are explained on a regular basis.

The change for the organisation will be on the basis that the operators change their practice and become more comfortable with the radial approach. As discussed previously, the benefit of decreased costs to the organisation will occur. Complications from the femoral approach can cause an increased length of stay in hospital and patients who have radial approaches can mobilise immediately, which would encourage a greater turnover of patients through appropriate education and discharge resources.

### **Global health - summary**

In summary, the findings this research suggest that when using a radial approach on all patients (elective and acute) who are eligible and suitable for the radial approach e.g. a positive Allen's test, there are better healthcare outcomes for the patient. First, the patient has an increased satisfaction and comfort when the radial approach is used for CA and or PCI (Arachchi & Matsis, 2003). The patient is able to mobilise immediately following the procedure, therefore reducing the frequent problems associated with femoral approaches (i.e. back pain). Second, there are less vascular access site complications when performing a radial approach. Studies like this one have already shown a dramatic decrease in vascular complications when using the radial approach (Arachchi & Matsis, 2003; De Santis, 2001; Goyal et al., 2006). Third, due to the decreased vascular access site complications there will be less resources required and less nursing time needed. This results in cost savings for the organisation. There is also potential for a higher patient turnover by shortened procedure times.

### **Nursing Implications**

The result from this study implies that nursing workload would decrease due to the reduced vascular complications when a radial vascular approach for CA/PCI is used. However, when the radial approach becomes the primary vascular approach this may impact on the nurse's workload as there will likely be a higher turnover of patients. Therefore, the workload will once again increase due to preparation, education and post procedure care required for all patients regardless of the vascular approach.

## **Recommendations**

Given what I know now from undertaking this study, I would recommend radial approaches become the primary choice of vascular access for CA and or PCI. From the results of this study it is clear there is a significant decrease in the vascular site complication rates when a radial access is used. The benefits of the radial vascular approach being used outweigh the disadvantages. Through education and ongoing clinical practice from the cardiologists and the team in the Catheter laboratory, I believe the radial approach would ensure better patient safety and reduced risk and increase their satisfaction and comfort. It would also help decrease the nurse's workload (e.g. one nurse to care for patient without vascular complication) on the unit and reduce hospital costs, length of stay (LOS) and thus becoming an economical benefit. Although my study is small, it could be used as a pilot study for a more detailed and bigger national study within New Zealand. The limitation of this study is that it is small, therefore it cannot be generalised to the greater population in New Zealand. However, it is a good pilot study within a CCU in NZ and could lead to a randomised experimental study design on a larger scale.

# Appendices

## Appendix 1 – Data collection tool

### Data Collection Sheet – Radial Approach Only

*Please circle*

Acute

Elective

*Patient Sticky*

Height \_\_\_\_\_ cm

Weight \_\_\_\_\_ kg

Fasting since \_\_\_\_\_ hours

Co-Morbidities	Yes	No	Angiography / Percutaneous Coronary Intervention	Yes	No
Smoker			Diagnostic		
Hypertension			PCI ( <i>balloon only</i> )		
Diabetes <i>Please state which type</i> _____			PCI (stenting)  <i>Where</i> _____		
+Family Hx. Of IHD			Angiomax		
Hypercholesterolemia			Angioseal		
High BMI >30  <i>Wgt (kg)/ Hgt (m)<sup>2</sup></i> <i>(Hgt x Hgt =m<sup>2</sup>)</i>			Heparin  <i>How much</i> _____		
Previous IHD  <i>Please state which type</i> _____			TR Band  <i>How long left on : _____ min</i>		

Sheath	Insertion	Time	Sheath Size	Sheath	Removal	Time	APTT (secs)	
_____	_____	hrs	_____	_____	_____	hrs	_____	
<b>Adverse Event</b>			<b>Yes</b>	<b>No</b>	<b>Has the Patient ever had these?</b>		<b>Yes</b>	<b>No</b>
Haematoma  Please record the size _____ cm					Glycoprotein IIb/IIIa inhibitors ( <i>reopro/aggrastat</i> )			
Arterial Bleed ( <i>following initial haemostasis</i> )					Aspirin			
Vasovagal ( <i>requiring HR/BP control</i> )					Clopidogrel			
Surgery ( <i>repair of pseudoaneurysm</i> )					Clexane			
					Warfarin			



## Appendix 2 – Ethics approval



16 May 2007

### Central Regional Ethics Committee

Ministry of Health  
Level 2, 1-3 The Terrace  
PO Box 5013  
Wellington  
Phone (04) 486 2455  
Fax (04) 486 2191

Jonele Woodhead (Clinical Nurse Coordinator)  
Cardiac Care Unit  
Capital and Coast District Health Board  
Private Bag 7902  
Wellington South

Dear Jonele

#### **CEN/07/13/EXP – Comparison of radial and femoral approaches for coronary angiography and percutaneous intervention**

The above study has been given ethical approval by the Chairperson of the Central Regional Ethics Committee.

#### **Progress Reports**

The study is approved until **January 2008**. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in **January 2008**. The report form is available on <http://www.newhealth.govt.nz/ethicscommittees>. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

#### **Amendments**

It is also a condition of approval that the Committee is advised if the study does not commence, or is altered in any way, including all documentation eg advertisements, letters to prospective participants.

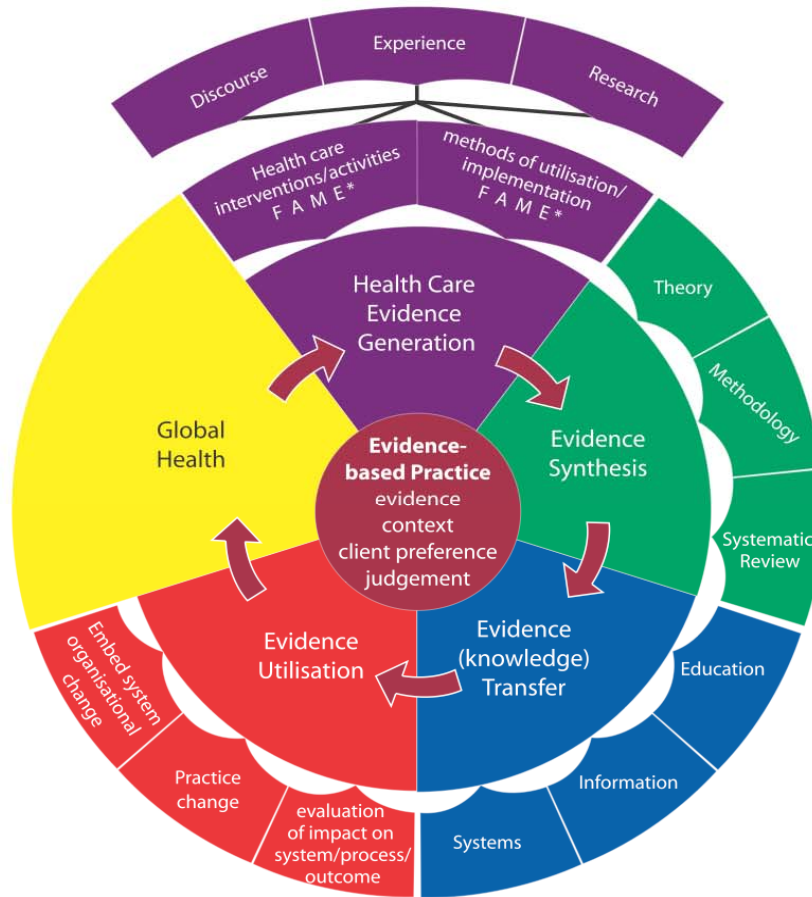
**Please quote the above ethics committee reference number in all correspondence.**

**It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. The organisation may specify their own processes regarding notification or approval.**

A handwritten signature in cursive script, appearing to read 'Claire Yendall'.

Claire Yendall  
Administrator Central Regional Ethics Committee

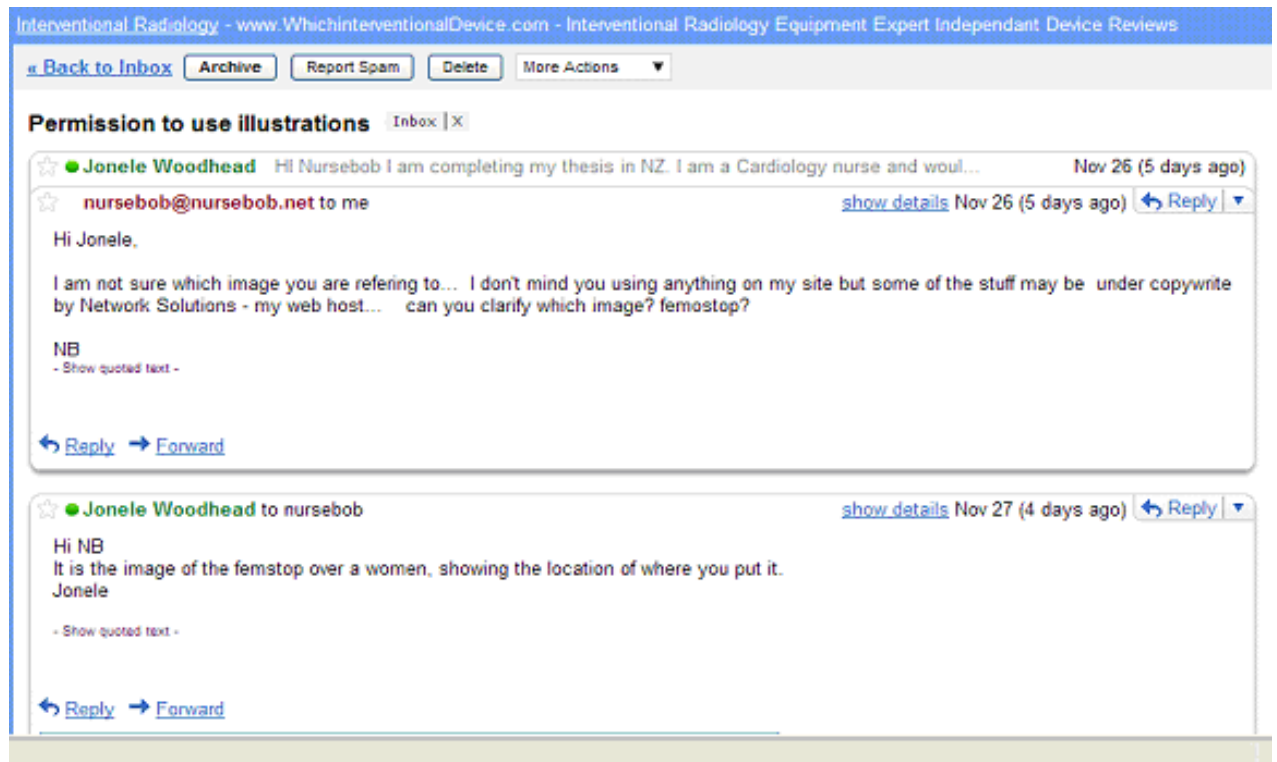
### Appendix 3 – Joanna Briggs Institute of Model of Evidence Based Health Care



Pearson, A., Wiechula, R., Court, A., & Lockwood, C. (2005).

The screenshot shows a Gmail inbox in a Windows Internet Explorer browser. The email is from Timur Graham to Jonele Woodhead. The subject is 'Images'. The email body says: 'Hi, to whom this may concern, You have my permission to use the images, thank you. Sincerely, Timur Graham, MD 3rd Year Resident Internal Medicine Residency Program'. The right sidebar shows various advertisements like 'Free Numerology', 'Photo on Canvas', 'Sales Letter Design', and 'Sample Business Le'.

## Appendix 4b - Approval for use of illustration: Femostop™



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