STATE ANXIETY IN THE PTCA AND STENT POPULATION

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Certificate of Authorship/Originality

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Abstract

Percutaneous transluminal coronary angioplasty (PTCA) and stent has become the most commonly performed cardiac procedure in Australia over the last decade. This study investigated the level of anxiety experienced by patients who were undergoing elective PTCA and stent procedures. Anxiety was assessed at three specific times, in-hospital pre-procedure, within 18 hours after the procedure, and one-week post discharge, using two methods to assess anxiety, the State Anxiety Inventory and the Faces Anxiety Scale.

The sample (n = 100) was predominantly elderly (mean 65.63 years), male (80%) and married (83%). Most participants (70%) had previously experienced a cardiac event, of which the most common was PTCA and stent (41%). Almost half of the participants had experienced unstable angina (47%) and the most frequent concurrent condition was hypertension (67%).

The results confirm that most people were not clinically anxious as anxiety SAI scores ranged from 37.72 (mean) pre-procedure and decreased over time to 31.8 (mean) post procedure and again post discharge 28.79 (mean). However, there is a significant group of participants that experienced more than normal levels of anxiety pre procedure (49%), post procedure (32%) and post discharge (19%). . The independent predictors of anxiety were also identified through multiple regression analysis. . Participants at risk of pre-procedure anxiety were those taking medications for the management of the symptoms of anxiety and depression. The predictors of post procedure anxiety included anxiety pre-procedure, having chest pain post procedure, or

undergoing a PTCA and stent procedure for the first-time. Again, post discharge patients were more likely to be anxious if they were anxious pre-procedure and they reported their major concern to be related to the future progression of their coronary artery disease. The Faces Anxiety Scale proved to have low sensitivity and moderate specificity in this sample.

The conclusion is that anxiety is relatively common and needs to be identified and treated, particularly pre-procedure to decrease subsequent anxiety. An instrument to detect anxiety quickly and accurately needs to be developed for clinical use.

Chapter One - Background

1.1 Introduction

This introductory chapter explains the pathophysiology, symptoms and treatment modes for coronary artery disease in order to enable the reader to understand the anxiety provoking nature of coronary artery disease (CAD) and its management. The PTCA and stent procedure is described also, as well as potentially anxiety-provoking issues related to the PTCA experience. The concept of anxiety is introduced, and the rationale for investigating the anxiety experience in the acute phase of the PTCA and stent is explained. The importance of identifying the patients at risk of anxiety is described.

It is important to gain an understanding of the anxiety experience for patients undergoing elective PTCA and stent procedures as anxiety is not only an uncomfortable experience, it also limits the patient's ability to effectively understand information. This is crucial as important information, pertinent to recovery and lifestyle modification is given during admission. High levels of anxiety can also have a pervasive physiological effect and the consequences of untreated anxiety for the cardiovascular population are serious.

It is necessary to investigate anxiety in patients undergoing PTCA and stent as the experience and related issues may in fact provoke anxiety. Such issues include the possibility of coronary artery disease (CAD) being confirmed by the initial angiogram, and pain and discomfort associated with the procedure. The consequences of untreated anxiety include sleeplessness, helplessness and an inability to cope (Bone et al., 1995).

Higher than normal levels of anxiety can prolong hospitalisation, complicating recovery, both in hospital, and after discharge, following the elective PTCA and stent. Because the nature of anxiety in the cardiovascular population can be intense, an understanding of anxiety within this population is warranted.

The literature that has investigated anxiety in this population has generally focused on long-term recovery, consequently the acute recovery in-hospital from the procedure to within the first week after PTCA, remains unknown. In addition, the studies that have explored anxiety have been limited by the use of a diversity of measures and methods, which prevents easy comparison and extrapolation from these studies. It is also apparent that aside from gender the personal characteristics that identify patients at risk of more than normal levels of anxiety and complications during recovery have not been fully investigated. Consequently, there is a need for further research to investigate the anxiety experience and predictors of anxiety in closer timing to the PTCA.

1.2 Coronary Artery Disease

In Australia, coronary artery disease (CAD) is the largest single cause of death and morbidity for men and women, causing 24,576 deaths and affecting 359,500 Australians in 2004 (The Australian Institute of Health and Welfare, 2006). CAD not only causes death, but also causes disability and decreased quality of life for the person and their family (Westin, Carlsson, Willenheimer, Cline, & McNiel, 1997)

The cause of CAD is atherosclerosis, which is characterised by the formation of a lipid capsule (atheroma) in the intimal layers of the medium and large arteries,

resulting in narrowed vessels and reduced blood flow to the myocardium (Cotran, Kumar, & Collins, 1999). Ultimately, the narrowing of the vessels results in reduced blood flow, which does not meet the oxygen demands of the myocardial tissue during activity causing the person to experience angina pain. A patient's initial presentation of CAD may include angina and acute coronary syndrome (ACS).

Although angina is less urgent, it affects many Australians. From 2004 to 2005, angina accounted for 63,989 hospital admissions and an average length of stay of 3.9 days (Australian Institute of Health and Welfare, 2006). Angina can occur during daily activity, extra physical activity, and emotional distress, as coronary blood flow to the myocardium is compromised and does not meet the individual's demands. Symptoms range from temporary chest pain, jaw pain and lethargy, to shortness of breath (DeVon & Zerwic, 2003). Relief from angina is usually achieved by rest and administering sublingual nitrates (Acute Coronary Syndrome Guidelines Working Group, 2006).

In contrast to angina, ACS has a more urgent presentation. A ruptured lipid capsule triggers localized blood coagulation, beginning the formation of a thrombus that may completely occlude the coronary vessel. The blood clot obstructs blood flow, depleting oxygen supply to the myocardial tissue relatively quickly, resulting in myocardial ischaemia and necrosis (Cotran et al., 1999). ACS requires prompt assessment and in-hospital treatment, as the blood clot occluding the coronary vessel needs to be reduced to prevent tissue death (Vlasic, 2004). This is often achieved by intravenous thrombolytic therapy, emergency PTCA and stent, or by coronary artery bypass graft surgery (CABGS). ACS is one of the most common causes of acute

medical admissions to Australian hospitals. Between 2004 and 2005, ACS accounted for 41,882 hospital admissions and an average length of stay of 6.3 days (The Australian Institute of Health and Welfare, 2006).

ACS also includes ST-elevation myocardial infarction (STEMI), which must be promptly treated with an immediate PTCA and stent. Whereas patients diagnosed with a non-ST-elevation myocardial infarction (NSTEMI), have either experienced unstable angina or a non-Q wave MI and are admitted to hospital to undergo a semi urgent-elective PTCA and stent within 24 to 48 hours of admission (Acute Coronary Syndrome Guidelines Working Group, 2006). Whatever the presentation, this may in fact be the first indication of CAD for many patients, causing them significant stress.

PTCA and stents are used to treat both angina and ACS, and it is the preferred treatment as it is a much less invasive procedure in comparison to CABGS and can be performed rapidly. The primary goal of PTCA and stent is to improve quality of life, by reducing the ischaemic symptoms, such as angina, associated with CAD (Vlasic, 2004). Another important goal is to reduce the degree of instability of the plaque, which may cause ACS. Repeat procedures are common, as CAD is progressive. The amount of risk determines the urgency of the procedure, as PTCA and stent are performed as both non-elective and life saving procedures.

Low risk patients with stable symptoms, undergo elective coronary angiography, which will not only diagnose CAD if present, but will also determine treatment options (Lyons, Fanshawe, & Lip, 2002; Vlasic, 2004). If indicated, and the lesions are technically approachable, the coronary angiogram is followed immediately

by a PTCA and stent procedure, performed under similar conditions to angiography in the cardiac catheterisation laboratory (CCL). Depending on the pathophysiology and location, several PTCA and stents may be undertaken.

1.3 The PTCA and Stent Procedure

The PTCA and stent is achieved using a balloon-tipped catheter, which is inserted into the femoral artery and guided into the affected coronary vessels. The balloon tip of the catheter is then positioned within the narrowed coronary vessel and inflated, pushing the plaque against the intimal wall of the vessel, and ultimately dilating the lumen of the artery (Hudak & Gallo, 1997; Shaw, Cohen, Fishman-Rosen, Clark, & Myler, 1986). After the balloon is deflated and removed, another catheter is used to place the stent. The stent is a small metal structure that acts like scaffolding, preventing artery contraction as healing takes place, which may be coated with antibiotic and mitotic inhibitors that ultimately reduce restenosis at the site of the treatment (Vlasic, 2004). The increased vessel lumen allows for return to relatively normal blood flow to the myocardium, therefore reducing anginal symptoms. The stent structure also stabilises vulnerable plaque, reducing the potential for thrombosis in the area.

Over the past two decades, the frequency of PTCA and stent procedure has increased rapidly, in part because of the good outcomes and because it is a less invasive, lower risk procedure than CABGS (Vlasic, 2004). Advances in procedural technique and stent technology have also contributed to the increase in PTCA and stent procedures, with success rates between 90 to 95 percent (Lee et al., 1998; Legrand et al., 2004a; Serruys et al., 2002). Such improvements have allowed elderly patients with multiple comorbidities and patients with complex multi-vessel CAD (multiple lesions,

chronic totally occluded vessels, vein grafts and bifurcation lesions) to be treated successfully by PTCA and stent, when CABGS may have previously been used (Detre et al., 1997; Legrand et al., 2004b). In addition, diabetic patients have also benefited from recent stent technology (Detre et al., 1999) as drug-eluting stents have further decreased the incidence of restenosis in diabetic patients from 20 to 7 percent (Lemos et al., 2004; Serruys et al., 2002). As a result, 32, 855 PTCA and stent procedures were performed in the year 2004 to 2005, making this one of the most commonly performed procedures in Australia (The Australian Institute of Health and Welfare, 2006).

1.4 Patients' Experience of PTCA and Stent

Most patients undergoing PTCA and stent have many experiences that may provoke anxiety. These include the possibility of CAD diagnosis from the initial associated angiogram, rapid preparation by multiple staff, procedural discomfort during the procedure such as pain and pressure and less often, complications from the procedure. These experiences are discussed in the following paragraphs.

As mentioned previously, PTCA and stent procedures are performed as either an elective or non-elective depending on the risk stratification. Patients with low risk undergo elective PTCA and stent, whereas patients presenting with ACS, experience rapid assessment and treatment, which may be very stressful.

Several diagnostic investigations are performed when preparing the patient for the PTCA and stent, often with little time for explanation. This includes a 12-lead ECG, vital signs, coagulation profiles, haemoglobin levels, and renal function tests. These blood tests assess the risk associated with post procedure bleeding and the latter is done

to monitor creatinine levels, as the contrast dye may be nephrotoxic to patients with impaired renal function (Vlasic, 2004). Patients also receive antiplatelet medications, such as Plavix™ and Aspirin™ pre-procedure, to reduce thrombotic complications during and after the PTCA and stent (Bertrand, Rupprecht, Urban, & Gershlick, 2000). It is likely that all of these activities and unfamiliar circumstances increase anxiety, in addition to the experience of hospitalisation itself.

1.5 Procedural Experiences for Patients

Aside from the events preceding the procedure the PTCA and stent is considered relatively safe and routine by health staff, however there are some potentially serious complications associated with the procedure, which may cause the patient concern. The cardiologist discusses these issues and the procedural details, with the patient before the procedure. Such complications include acute myocardial infarction (AMI) (risk of 1%) and death (risk of 0.6%) (Tongni et al., 2004). It is necessary for this discussion to take place, in order for the patient to give informed, written consent before the procedure. However, this awareness may increase pre-procedure anxiety.

Following routine preparation, patients are taken to the CCL, which has the appearance of a surgical theatre, which can be stressful. Sterile instruments and drapes are used to cover the patient and maintain a sterile field. Radiological protection, contaminated waste signs and cardiac monitoring equipment may add to the impression of danger for the patients, heightened by the protective apparel worn by staff. The patient must lie still on a narrow surgical table during the procedure. The patient's chest and groin are exposed, which may make the patient feel awkward and

uncomfortable. Patients may also feel pain as the femoral artery is punctured, even though local anaesthetic is injected at the site to reduce discomfort. Regardless, pressure on the puncture site can be felt, as the introducer sheath is inserted into the artery and catheters are passed into the coronary vessels. Patients often feel a sensation of warmth as the contrast dye is rapidly injected during the coronary angiogram (Vlasic, 2004). Patients undergoing repeat PTCA and stent may experience increased sensations from the dye. Another common experience patients may have during the procedure is anginal discomfort when the balloon catheters are inflated in the coronary vessel (Ronnevig, Bjorsvik, Gullestad, & Forfang, 2003; Vlasic, 2004). This is often unexpected by the patient. Overall, these procedural experiences are anxiety provoking.

At the conclusion of the PTCA and stent, the patient is transferred to the coronary care unit (CCU), where they will have continuous cardiac monitoring for ST-segment changes and frequent observations of the femoral artery site to detect bleeding and haematoma formation (Vlasic, 2004). The sheath will remain in situ until the effect of the intra-procedural heparin wears off, meaning a period of supine bed-rest. Between two-to-four hours post procedure, the femoral sheath introducer is removed and mechanical pressure is applied, which is gradually released over one hour (Chlan, Sabo & Savik, 2005; Jones & McCutcheon, 2002). This pressure can be uncomfortable for the patient, although analgesia is often given.

1.6. Potential Post Procedure Complications and Consequences

Following the procedure, patients may experience chest pain and this is likely to cause them concern. Chest pain may be indicative of a serious complication, such as a distal MI, due to a small thrombus being dislodged by the catheter balloon

manipulation. Another cause of chest pain is acute occlusion, which occurs when a thrombus forms at the treatment site, causing an AMI. Patients may also experience chest pain from an arterial dissection if the catheter balloon is over inflated, tearing the vessel and requiring urgent CABGS (Hudak & Gallo, 1997). Although patients will be aware of the possibility of these complications, when they occur, they may be anxiety provoking and the patient may experience other symptoms including haemodynamic instability, diaphoresis and breathlessness (Hudak & Gallo, 1997). Finally, non-specific chest discomfort without ECG changes, may also occur after the PTCA and stent, which has been suggested to be due to arterial stretching (Ronnevig et al., 2003). Although less serious, this chest pain may still cause concern for the patient.

As PTCA and stent patients do not routinely attend a pre-admission clinic, therefore the admission process is hasty, as the patient is admitted approximately one to two hours before their procedure, directly to the cardiac catheterisation laboratory (CCL). Patients that undergo the PTCA and stent procedure are routinely cared for in the coronary care unit (CCU) for one night. The average length of stay for an uncomplicated PTCA and stent is less than 24 hours. However, patients with co-morbidities that require additional medical treatment will be required to stay for an extra night.

Patients are routinely given an information brochure outlining the PTCA and stent procedure, routine care and bedrest post procedure. In addition to this, all patients receive an education session from the cardiac rehabilitation nurse educator who outlines diet and exercise targets and expectations post discharge. All patients also receive medication education by the pharmacist who outlines medication regimens, interactions

and precautions, and stresses compliance with anti-platelet and anticoagulation therapy. The clinical nurses also provide patients with standard discharge instructions relating to chest pain management strategies, puncture site wound care and observations for complications and contact details of the CCU. Patients are also informed to arrange a consultation with their GP within the first week after discharge and to arrange a consultation with their cardiologist six weeks after discharge.

It is not at all surprising then that patients feel vulnerable and appraise the PTCA and stent as threatening, especially as patients' experience a short hospital stay full of events, education and procedures. Following discharge, patients taking anticoagulation therapy, such as Warfarin, will be required to have regular INR blood tests to ensure therapeutic dosing and minimise the risk of bleeding. Patients may perceive anticoagulation therapy as threatening, as therapeutic levels require vigilance, compliance and restriction of some physical activities that potentiate the risk of bleeding. Also, alterations to dietary intake and alcohol consumption required when taking these medications, the changes can be overwhelming.

The confirmation of the CAD diagnosis may also be concerning to the patient who is undergoing a coronary angiogram for the first time. It requires time for the patient to adjust to a perceived altered health state and consider the lifestyle changes necessary when diagnosed with CAD. Although there is some presumption of likelihood of CAD given the plan for a cardiac catheterisation in elective circumstances, there is often little time for patients to reflect upon the diagnosis of CAD when it is made immediately preceding the PTCA and stent. Meaning, there is little time for the

patient to cognitively appraise the situation and activate effective coping skills. All of these circumstances contribute to the possibility of the patient being anxious.

1.7 Anxiety

Given the potentially anxiety provoking nature of PTCA and stent, researchers have investigated patient's experiences and outcomes. This literature is reviewed in Chapter Two. One issue identified in the review is that anxiety is often imprecisely defined by the researchers and is occasionally contradictory with researchers using differing constructs of anxiety. However, a common thread to the definitions is that anxiety is an emotional response to a perceived threat and that cognitive appraisal is a prerequisite (Lazarus & Folkman, 1984). For the purpose of this study, anxiety is defined as an unpleasant emotional state or condition that is a response to stimuli (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), in this case the PTCA and stent.

Anxiety is not necessarily problematic and can in fact be helpful, serving as a warning that action needs to be taken to decrease the threat (Bone et al., 1995). Essentially, anxiety is a familiar and common human emotion that is described as a feeling of fear, tension, panic or an expectancy that something unpleasant is going to happen (Spielberger et al., 1983). Anxiety is accompanied by physical symptoms and can be severely distressing (Blair & Ramones, 1996). So in the current study, it is heightened anxiety, which is a more than a natural response and inappropriate or excessive to the reality of the external stimulus, or unrealistic to in proportion to the situation (Bone et al., 1995) that is of interest to the researcher.

The distinction between state and trait anxiety is well recognised. State anxiety exists 'at any given moment in time at a particular level of intensity' (Spielberger et al, 1983, p 4). The subjective and transitory nature of state anxiety precedes psychological and physiological responses (Spielberger et al., 1983). This state is often accompanied by symptoms of worry, tension, agitation, fatigue, difficulty concentrating, nausea, palpitations and chest pain (Bone et al., 1995; Spielberger et al., 1983). Whereas trait anxiety, is a 'relatively enduring individual difference in anxiety proneness' (Spielberger et al, 1983, p5), that is stable and predictable in a person's responses and behaviour. It is important to note that state and trait anxiety are not mutually exclusive, because people with trait anxiety exhibit state anxiety more frequently. That is, they interpret a wider range of situations as dangerous or threatening (Spielberger et al., 1983).

Even patients with good coping skills are likely to experience some anxiety in relation to the PTCA and stent, because of the reasons given previously (Bone et al., 1995; O'Brien et al., 2001). Patients may feel overwhelmed and may be confronted with their own mortality, vulnerability, pain and the loss of control within the critical care environment (Bennett, Conway, Clatworthy, Brooke, & Owen, 2001). In this situation, low to moderate anxiety is a normal, expected response and provides patients with the necessary stimulus to use coping and adaptation strategies (Folkman, Lazarus, Dunkell Shetter, Delongis, & Gruen, 1986; Lazarus, 2000). These authors explain coping as the cognitive and behavioural efforts to manage the demands that are taxing the resources of the person. Less anxiety may be experienced by people using the coping mechanism of denial, which is an important and effective technique for managing a threat, but may cause difficulties in the long run.

It is important to understand this threat because higher than normal levels of anxiety are predictive of in hospital complications, chest pain, rhythm disturbances and poor recovery in cardiac and PTCA and stent populations (Lane, Carroll, Ring, Beevers, & Lip, 2000; Pell et al., 2001; Rozanski, Blumenthal, & Kaplan, 1999; Sirois, Sears, & Bertolet, 2003; Strik, Denolett, Lousberg, & Honig, 2003; Sullivan, LaCroix, Spertus, & Hecht, 2000; Watkins et al., 2002). Given this evidence, it is necessary to undertake the research in this thesis to examine anxiety when it is anticipated to be most intense, that is, within the first week after the procedure, which has not been previously explored.

1.8 Anxiety in CAD Patients

An unwelcome result of untreated anxiety is the potential for an escalating cycle of fear, sleeplessness, helplessness and an inability to cope (Bone et al., 1995). Blair and Ramones (1996) suggest untreated anxiety may prolong hospitalisation and exacerbate physical symptoms. Despite the negative effect of anxiety, the positive effect of anxiety is beneficial as manageable levels of anxiety, for a short duration, can be motivating and provide stimulus for optimal performance (Selye, 1975). Appropriate levels of anxiety may have a positive influence for PTCA and stent patients because it may motivate them to enact lifestyle changes after their procedure.

In contrast to the motivating positive consequences of anxiety, the physiological effects of excessive anxiety may be serious, particularly for patients with CAD. Investigations into the consequences of anxiety in CAD patients have shown that excessive anxiety triggers vulnerable plaque to rupture and the activation of platelet aggregation. This may cause increased myocardial oxygen demand, which in the

presence of decreased blood supply to the myocardium may trigger ventricular arrhythmias and in extreme circumstances, result in death (Astin, Jones, & Thompson, 2005; Crowe, Runions, Ebbesen, Oldridge, & Streiner, 1996; De Jong, Chung et al., 2004; Harkness, Morrow, Smith, Kiczula, & Arthur, 2003; Kim et al., 2000; Kyungeh et al., 2004; Lane et al., 2000; Moser & Dracup, 1996).

Many of these effects occur because of the stimulation of the sympathetic nervous system, as the inability to adapt to a threatening situation activates the fight or flight response (Cotran et al., 1999; Rozanski et al., 1999). Activation of the sympathetic nervous system causes the release of hormones from the adrenal medulla. The release of adrenaline and noradrenaline causes an increase in heart rate, force of contraction and blood pressure resulting in greater oxygen demand. This is problematic in patients with CAD, as oxygen supply is already compromised. In ACS populations, anxiety has been associated with re-infarction and death, prolonging recovery and disability (Crowe et al., 1996). A secondary effect of sympathetic nervous system activation is dilation of blood vessels in skeletal, cardiac, liver and adipose tissue to allow faster blood flow. The respiratory rate also increases, allowing for faster movement of air in and out of the lungs (Cotran et al., 1999). Therefore, the activation of the sympathetic nervous system has serious consequences, as patients with CAD are unable to increase flow to the myocardium for this work, resulting in angina and cardiac arrhythmias (Cotran et al., 1999).

An additional pathway stimulated by anxiety is blood coagulation and inflammation (Moser & Dracup, 1996; Von Kanel, Mills, Fainman, & Dimsdale, 2001). In the presence of haemoconcentration, which is another effect of anxiety for people

with CAD (Rozanski et al., 1999), there is a much higher risk of a thrombus forming on the damaged endothelium inside the stent. The thrombus can therefore potentially negate the effects of the PTCA treatment.

Given the substantial evidence that increased anxiety may cause the patient discomfort and result in adverse outcomes following cardiac events such as PTCA and stent, anxiety is important to assess and treat in this population.

1.9 Anxiety Measurement, Management and Nursing Care

Nurses, for a number of reasons, generally poorly conduct anxiety assessment. Most pertinent of these is that nurses often have difficulty interpreting patients' cues and patients' often find anxiety difficult to articulate (O'Brien et al., 2001). When nurses do engage in anxiety assessment, they often rely on patient behaviours and psychological responses, which are not always observable and do not accurately reflect the level of anxiety experienced (De Jong, Moser, & Chung, 2004; Frazier et al., 2003; O'Brien et al., 2001). Nurses often lack expertise in conducting anxiety assessment and undervalue the importance of psychological well-being, especially when emphasis is placed on physical care particularly in critical care units. The physiological implications of extreme anxiety on the recovery of cardiac patients may not be clearly understood by nurses, as anxiety assessment and management it is not an upmost priority. The result of these affect is that anxiety is neither routinely assessed nor treated in cardiac patients.

When anxiety assessments are performed, they are subjective accounts, which may misrepresent patients' anxiety, as nurses use subjective qualitative descriptors. Additionally, anxiety is also poorly communicated between clinicians, therefore

accounts of anxiety are in some instances, conflicting as clinicians rarely report the level of anxiety experienced (Moser, Chung et al., 2003; O'Brien et al., 2001). Both O'Brien et al.(2001) and Heikilla et al.(1998a) suggest anxiety reports by patients tend to be higher when compared to nurses' assessments. Interestingly, O'Brien et al., (2001) found no association between anxiety assessments by clinicians' and patients' (lambda = 0.03, P >0.05), suggesting that objectively measured self-reports may be the most effective method of assessing anxiety.

Not surprisingly, when strategies were employed to address anxiety, they were often inappropriate or ineffective for PTCA and stent patients. The most commonly used strategies include the use of pre-medications and education (Moser, Chung et al., 2003). One effective pre-medication are benzodiazepine derivatives, but these are not extensively used in day-case and short-stay procedures such as PTCA and stent, because benzodiazapines have a slow onset and long duration and can delay discharge (Walker, Smith, & Pittaway, 2006),

Similarly, patient education has been used in attempt to reduce anxiety (Harkness et al., 2003; Tooth, McKenna, Mass, & McEniery, 1997) but as PTCA and stent patients do not routinely attend a pre-admission clinic, education is undertaken within the hospital setting when anxiety is most intense. This means that this strategy is much less effective as knowledge retention post PTCA was found to be equivalent to pre-procedure knowledge despite education (Murphy, Fishman, & Shaw, 1989). Therefore rendering this strategy as ineffective. Other non-pharmacological interventions such as distraction, meditation, touch and music may be more effective than education, but these interventions are rarely used by clinicians as many clinicians

are unfamiliar with such therapies (Grunberg et al., 2003; Richards, Johnson, Sparks, & Emerson, 2007; Vanderboom, 2007).

1.10 Thesis Structure

This first chapter has described CAD and PTCA and stent as a treatment for CAD. Potentially anxiety-provoking elements of the PTCA and stent have been outlined as well as the construct of anxiety used for the thesis. The clinical features of anxiety and the consequences of untreated anxiety were described. This chapter also discussed the lack of recognition and assessment of anxiety by clinicians and highlights the potential vulnerability of PTCA and stent patients to anxiety.

The second chapter reviews the literature on anxiety in relation to patterns and prevalence in the PTCA and stent and cardiovascular populations. The research aims and questions for the study are provided. Chapter Three describes the method and instrumentation used to assess anxiety in the elective PTCA and stent population. This chapter also outlines the data collected and data analysis techniques. Chapter Four describes the patients who participated and the findings of the study. Finally Chapter Five discusses the meaning of the findings of the study in relation to the existing literature. Chapter Five also summarises the results, outlines the study limitations and provides recommendations for clinical practice and future research.

1.11 Summary

CAD is a major cause of death, disability and hospitalisation. An increasing number of CAD patients are treated with PTCA and stent and are vulnerable to anxiety. This anxiety occurs because patients recognise a threat but may not have a response of a

coping mechanism at hand. While anxiety may have benefits in terms of patient motivation for lifestyle change, at high levels, it is associated with complications in cardiac patients. Unfortunately, anxiety is not routinely well recognised or treated by health professionals in this population. Therefore, it is timely to identify the PTCA and stent patients at risk of high levels of anxiety, so that health care professionals can develop and employ specific, timely management strategies.

Chapter Two - Literature Review

2.1 Introduction

This chapter reviews the research relating to the patterns and prevalence of anxiety in the PTCA and stent population. Where literature specific to this population is limited, evidence from other cardiac populations is included in the review. Key limitations in the existing research in relation to study design, instrument selection, and the timing of anxiety assessments in relation to the procedure are discussed. The instruments developed to measure anxiety that are familiar to clinicians and often used are also detailed. Finally the research question and aims for this study are stated.

2.2 Assessment of Anxiety in PTCA and Stent Patients

As discussed in the previous chapter, there are a variety of reasons nurses do not engage in anxiety assessment and when they do, anxiety is poorly measured. O'Brien et al. (2001) suggested that nurses lack the expertise and confidence in conducting anxiety assessment. Furthermore he suggests that nurses need to consider anxiety management an upmost priority for patient care within the critical care unit as unaddressed anxiety can have serious implications for the cardiac patient..

There are several measures that use self-report available to measure anxiety, including the Hospital Anxiety and Depression Scale (HADS), the Linear Analogue Anxiety Scale (LAAS), the Visual Analogue Scale (VAS), the Brief Symptom Inventory (BSI), the Profile of Mood State (POMS), the Spielberger State Trait Anxiety Inventory (STAI) and the Faces Anxiety Scale (FAS). However, it is not clear which

instruments are most appropriate and efficient in the acute setting for the nurse and patient.

The anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) has been used extensively in the cardiovascular population (Elliott, 1993; Heikkila, Paunonen, Laippala, & Virtanen, 1998; Ladwig et al., 2000; Lenzen, Gamel, & Immink, 2002; Snaith, 2003). The HADS-A is a 7-item, 3-point likert scale with a potential range of scores from 0 to 21. Higher scores reflect higher anxiety and a clinical case of anxiety is indicated by a score of more than 8 points. The HADS-A detects anxiety through alterations in behaviours such as reading. However, the HADS-A may not detect acute changes in anxiety when repeated over a short period of time in a critical care unit.

The HADS-A was compared with two other instruments, the STAI and the Linear Analogue Anxiety Scale (LAAS) in a well-conducted study by Elliott (1993). The LAAS is a 10 cm line with anchors of 'calm' and 'extreme anxiety' and shares some similarities to the VAS. The potential scoring range for the LAAS is low (0 to 33), medium (34 to 66) and high (67 to 99). Elliott found that a similar proportion of patients reported medium-to-high levels of anxiety on all three instruments: STAI (49%), HADS-A (43%) and LAAS (56%), although the LAAS detected the most anxiety. It appears that all the instruments are attempting to measure the same construct of anxiety, even though the HADS-A and STAI have multiple-items and the LAAS has a single-item. The STAI and the LAAS were the most strongly correlated instruments ($r = 0.70$), whereas the HADS-A and the LAAS were only modestly correlated ($r = 0.48$), again suggesting these instruments may have not shared the same underlying

construct of anxiety. However, Elliott's (1993) research lends support for the use of the STAI instead of the HADS-A as well as a VAS type scale to rapidly assess anxiety within the confines of the CCU. An instrument that has established score ranges may be more advantageous than the LAAS, as an arbitrary score range was established for the purpose of this study.

The Spielberger State Trait Anxiety Inventory (STAI) is a comprehensively used self reporting questionnaire that has been extensively used in the cardiovascular population (Astin et al., 2005; Cherrington, Moser, & Lennie, 2002; Elliott, 1993; Frasure-Smith & Lesperance, 2003; Harkness et al., 2003; Heikkila, Paunonen, Laippala et al., 1998; Heikkila, Paunonen, Virtanen, & Laippala, 1998; A. K. Kyungeh et al., 2000; O'Brien et al., 2001; Sirois et al., 2003). The STAI is a 40-item questionnaire that is comprised of two sub-scales, which measure and distinguish between state and trait anxiety. Participants are asked to describe how they feel 'at this moment' on a four point scale ('not at all', 'somewhat', 'moderately so' and 'very much so') in response to the 20-items of the SAI (Appendix A). SAI scores are totalled so that higher scores represented more anxiety. The potential range for the scores is between 20 to 80 points. The 20-item SAI is usually used alone to measure state rather than trait anxiety. Researchers that have measured trait anxiety, found trait anxiety levels did not change in response to the PTCA and stent.

Although the STAI was developed in the United States of America in the 1970's and was tested on college students, prisoners and military personnel, it has proven useful in clinical populations as well. Importantly, the STAI has been successfully administered by non-psychiatrically trained health researchers so that it

may be particularly suitable for nurses. The STAI was designed so participants with a 4th to 5th grade reading level would have no difficulty completing the questionnaire and this may be particularly important in unwell patients. The SAI is particularly useful in clinical populations as it can be completed in as little as 5 minutes or less when repeated (Spielberger et al., 1983). To measure the fluctuating levels of anxiety throughout the PTCA and stent episode of care, trait anxiety was not expected to inform the state anxiety experience (Astin et al., 2005). Therefore the SAI alone will be used in the current study.

An instrument that could be used quickly in the clinical setting was also sought. The VAS used by Heikilla et al.(1998a) is a line 100mm in length, with anchors at each end from 'I don't feel anxious at all' to 'I feel extremely anxious'. They found modest correlations pre-procedure with the HADS-A (r = 0.53) and the SAI (r = 0.52). These correlations were sustained post procedure HADS-A (r = 0.56) and SAI (r = 0.55), suggesting again that the instruments were measuring overlapping, but not exactly similar constructs of anxiety. Therefore this instrument was ruled out.

In a more recent study using multiple anxiety measures, anxiety was measured in 243 MI patients within the first 72-hours post MI (De Jong, Kyungeh, McKinley, Garvin, Hall & Moser, 2005). A VAS style instrument (Anxiety Level Index (ALI)), the SAI, and the 6-item anxiety subscale of the Brief Symptom Inventory (BSI) were used together. Mean anxiety scores were found to be low to medium using all three measures (SAI 36.76, BSI 0.56, and ALI 3.08), which is consistent with all other studies (Kyungeh et al., 2000). Similar to Heikkila et al.(1998a) a moderate positive correlation was reported between the ALI and the SAI (r = 0.52) and the ALI and the BSI (r =

0.45). The investigators also suggest a degree of bias and imprecise measurement was found using the ALI, suggesting construct validity of the ALI is lacking. A limitation of a VAS is that it also has no established clinical cut-off. Despite this, a VAS style instrument is promising because it can be quickly administered without interrupting the pre-procedure preparation for PTCA and post procedure care.

More recently, the Faces Anxiety Scale (FAS) has emerged as a potential instrument that may be suitable for rapid anxiety assessments in-hospital for PTCA patients. The FAS is a relatively new self-assessment anxiety instrument, which uses faces instead of numbers to anchor anxiety ratings. The facial expressions reflecting increasing levels of anxiety and tension should provide a less arbitrary distinction than the LAAS or VAS.

The FAS has five faces placed equidistant on a single card, to create a single item, ordinal and interval scale. The facial expressions that are depicted on the scale range from a neutral face (face one) to a face that depicts extreme fear (face five) (Appendix B) which are derived from universally recognised facial expressions. The eyebrows, forehead and mouth alter as the intensity of anxiety increases (Ekman & Friesen, 1975). The faces were developed by a graphic artist based on photographs of faces showing fear. The faces showing fear were used to represent anxiety for the scale as anxiety and fear have the same physical manifestations (Doctor & Kahn, 1989). The FAS is administered with instructions of verbal anchors, which are 'no anxiety at all' to 'extreme anxiety'. The possible score ranges from one-to-five, with higher scores reflecting higher levels of anxiety. Moderate to severe anxiety is categorised with a score greater than three.

The FAS was designed for use in the intensive care, non-verbal (intubated) population, following development on intensive care and university student / staff population (McKinley, Coote, & Stein-Parbury, 2003). Despite the use in differing populations, the FAS might be useful in the PTCA population as it can be administered quickly with minimal burden to patients and nursing staff during the time pressured admission process. Because of the simple presentation of the scale, it is also presumed to be easier to use in a wide variety of patients.

McKinley, Stein-Parbury, Chehelnabi, & Lovas (2004) tested the validity of the FAS against the nine-item anxiety subscale of the POMS and clinical judgment of physical responses. Clinical judgment was scored on a one-to-ten scale with scores greater or equal to five indicating moderate to severe anxiety. The participants (n= 106) were mostly non-verbal, as they were mechanically ventilated (89%). A positive correlation between clinical judgment and the FAS ($r = 0.64$, $p = 0.001$) was found. More ICU patients responded to the FAS when compared to other self-assessment instruments, possibly because the FAS poses minimal burden in these critically ill patients (McKinley, Stein-Parbury, Chehelnabi, & Lovas, 2004)

The FAS has also been tested in a less ill population of patients transferring from the intensive care unit, who were able to speak. In this study, Gustad, Chaboyer, and Wallis (2005) assessed anxiety, measured on three occasions, firstly in the ICU when the patient was notified of their transfer, secondly, on the ward 4-hours after transfer and finally, the following day after transfer. The FAS scores were compared to the HAD-A. A sample of 44 participants began the study and 80% completed all three-

anxiety assessments. As expected the HADS-A and the FAS were significantly positively correlated ($p < 0.001$) at all three assessments. The correlation strengthened overtime from a modest Pearson's correlation: $r = 0.45$ and increased $r = 0.72$, suggesting that as anxiety decreases the correlation between the HADS-A and the FAS increases. Interestingly, one in five participants had difficulty identifying with the face that represented no anxiety because they reported the face depicted 'looked too tense'.

The clinical utility of the FAS in the PTCA and stent population is unknown but has potential, as it may be able to be administered quickly so anxiety can be assessed as part of routine care. The FAS provides nurses with an objective instrument that is easy to administer and quick to assess. The FAS is considered a superior instrument to a VAS as the FAS is able to discriminate between low, moderate and high levels of anxiety. It is thought the FAS will be a clinically suitable instrument in the elective PTCA and stent population as universal facial expressions are depicted on the scale, which would assist in eliciting an appropriate response. The FAS can be rapidly administered and has resulted in a greater response, than other multiple-item scales (McKinley et al., 2003). Therefore, the FAS will be used alongside the SAI in the current study.

2.3 Anxiety in PTCA and Stent Patients

While researchers report generally low levels of anxiety in PTCA and stent patients, it is clear that a significant proportion, between 24% and 64%, are anxious (Astin et al., 2005; Edell-Gustafsson & Hetta, 2001; Higgins, Dunn, & Theobald, 2000; Lenzen et al., 2002; Sirois et al., 2003). In a recent Australian study, Astin et al. (2005) investigated anxiety in 140 first-time elective PTCA and stent patients. Anxiety

assessments were conducted at a pre-admission clinic two-weeks prior to PTCA, and repeated six-to-eight weeks and six-to-eight months later. Participants were classified as anxious with a SAI score higher than 42. The sample was typical of the PTCA and stent population, with 75% male and an average age of 62 years, although cardiac rehabilitation participation was higher than usual (74%).

Consistent with previous reports, mean state anxiety levels were generally low, with scores of 36.3 pre-admission and decreased significantly to32.6 six-to-eight weeks post procedure. There was little alteration of anxiety scores six-to-eight months after the PTCA and stent (32.0), suggesting anxiety peaked pre-procedure and returned to the individual's usual levels within the first two months of recovery. Interestingly, 24% of women and 16% of men were clinically anxious (SAI score > 42) pre-admission and almost the same proportion, women (21%) and men (11%), at six-to-eight months post procedure. This sustained level of anxiety potentially suggests either prolonged effects of the PTCA and stent or CAD diagnosis, or a distinct overlap in the measurement with trait anxiety.

It is also evident that the period when patients are most likely to be anxious (pre-admission to six-to-eight weeks post procedure) needs further investigation. Another limitation of this study is that Astin et al. (2004) exclusively focused on a cohort of first-time PTCA and stent patients when many patients frequently undergo repeat PTCA and stent procedures. When examined, no participant characteristics such as age, gender, cardiac rehabilitation attendance or previous myocardial infarction were found which predicted patient anxiety.

It is possible that previous PTCA experiences may influence anxiety, and this concept was investigated in a study by Lenzen, Gamel and Immink (2002). Anxiety

was measured before the procedure in first-time (n = 46) and repeat PTCA (n= 40) patients, using multiple instruments. These included the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) (Snaith, 2003), the Heart Patients' Psychological Questionnaire (HPPQ) (Erdman, 1981), which measured well-being and a Visual Analogue Scale (VAS) (Gift, 1989). In addition, five repeat PTCA patients (two with low well-being, and three with high well-being on HPPQ) were interviewed on feelings and experiences in relation to their repeat procedure. The groups were similar for gender (71% male) and age (mean 60 years), but more patients in the repeat group had CABG (30%) than first-timers (13%) (p= 0.05).

Again, anxiety was found to be low in both first-timers (5.0) but also in repeaters (6.5) using the HADS-A and the VAS, first-timers (2.6) and repeaters (4.0). Despite these low scores, many patients were at least borderline anxious using a score of more than 8 on the HADS-A in both first-timers (26%) but more so in repeaters (43%). Both groups had higher proportions of anxious patients than reported by Astin et al. (2005), which the interview data suggests came from the repeaters who stated that the recurrence of symptoms following PTCA was an important source of concern. However, Lenzen et al. (2002) did not provide the specific timing of the assessment, therefore, undertaking anxiety assessment closer to the time before and after the PTCA and stent procedure, and identifying patient concerns is warranted.

A study by Grunberg et al. (2003) is included in the literature review because it focuses on the pre-PTCA period and mood in contrast to anxiety. It is possible that mood may contribute insight into the pre-PTCA anxiety experience. The constructs of mood were measured in 108 patients in hospital immediately prior to PTCA. The moods that were measured included four items shared by the SAI: worry; calm; upset

and satisfied, as well as other moods, which were measured using a VAS (0 to 100). Negative mood levels were generally low (worry and upset) and positive mood levels were generally high (calm and satisfied). That is, similar to the previous reports, patients were found not to be overly concerned about the PTCA and stent procedure.

Another element of mood related to anxiety includes tension, which was investigated by Gulianik and Naito (1994), after first-time PTCA. Assessments were conducted by mail, one-week, six-weeks and twelve-weeks after hospital discharge. Tension and anxiety, which are similar to those measured by the SAI, were measured using a subscale of the Profile of Mood States (POMS). Additionally, other dimensions of recovery including angina recurrence, expected benefits of PTCA and expectation of restenosis were measured on the self-report of recovery questionnaire, which was developed for this study. Tension and anxiety scores were low at one, six and twelve weeks and the majority of participants (80%) were confident that they were able to manage their stress. Significant procedural changes to PTCA have occurred since 1994 that limit the recurrence of atherosclerosis. Consequently, post procedure angina and expectations of restenosis may differ in current populations undergoing PTCA and stent.

Patients that are anxious need to be identified and treated. One identifying characteristic may be female gender, however, there is a lack of consensus regarding the influence of gender on anxiety. In a study conducted by Ladwig, Muhlberger, Walter, Schmacher, Popp, Holle, Zitzmann-Roth and Schomig (2000), anxiety was assessed in 317 PTCA patients 6-months post procedure. Medium-to-high levels of anxiety were reported by more women (43%) than men (30%), however, no gender differences

occurred over the longer term recovery. These results are in contrast to Heikkila, Paunonen, Virtanen and Laippala (1999), who found in their study of 220 participants, that women were significantly more anxious before and after coronary angiography ($p < 0.001$). Although gender may have emerged as a predictor in the analysis, few other potential predictor variables were assessed. Therefore, the influence of gender will be assessed in the current study.

As the literature relating to anxiety in the PTCA population is limited, research that has investigated anxiety in the coronary angiography and myocardial infarction population is now appraised because the population and experiences are similar.

2.3 Anxiety in Coronary Angiography and Myocardial Infarction Populations

There are striking similarities between the cardiac event populations and PTCA and stent groups, in that all report low levels of anxiety and there is a small but significant group of patients that experience clinical anxiety (19%-24%) For instance, a study by Heikkila, Paunonen, Laippala and Virtanen (1998a) investigated anxiety in the coronary angiography population (n = 243) in-hospital immediately pre-procedure, during the procedure and within 4-hours after the procedure. Anxiety was measured by the SAI, HADS-A and a VAS. The average pre-procedure anxiety scores were low-to-moderate on all measures, decreasing significantly after the coronary angiogram. However, some patients were moderate to highly anxious on the VAS (11%), similar to medium levels of anxiety on the HAD-A (13%), but even more so when the SAI was used (30%), suggesting again that at least two instruments should be used to assess anxiety.

Similarly low levels of anxiety in the coronary angiography population pre-procedure were also confirmed in a well conducted study by Harkness et al. (2003). Anxiety was assessed using the SAI on 228 first-time elective coronary angiography patients and found anxiety scores at 42.6 pre-procedure. It appears patients waiting for elective coronary angiography were vulnerable to anxiety to a greater extent, which was possibly due to their longer waiting times (13.4 weeks). A criticism of this study is that the proportion of patients that had moderate to high levels of anxiety was not reported

Relatively low levels of anxiety have also been reported in MI patients (n = 486). This occurred in hospital soon after the event, and then decreased over the following 72 hours (Kyungeh et al., 2004). Despite overall low levels of anxiety throughout the recovery, anxiety was problematic for one in three participants (35%) whose anxiety levels were higher than the general medical and surgical population. Interestingly, anxiety was found to peak within the first 12-hours after the AMI and therefore this time period is worth investigating in the PTCA and stent population. Gender differences in anxiety reports were found as women reported higher levels of anxiety at most times. Apart from gender, no other patient characteristics were investigated to identify which patients were at risk of high levels of anxiety. A criticism of this study is the cross-sectional design is that the patients were not the same at each time point. This means that the differences in the sample may have influenced the results rather than truly reflecting changes in the group.

To summarise, anxiety is low on average in patients having PTCA and stent and coronary angiogram. Despite this, about 20 to 40% of patients will be clinically anxious and these patients need to be identified and treated. There remains a gap in our

knowledge of anxiety in the immediate post procedure period and in the early discharge period. Furthermore, it is unclear who is most likely to be anxious and what are their sources of anxiety.

2.4 Patient Concerns

The patient's concerns that are contributing to their anxiety may include their uncertain future with CAD (Lenzen et al., 2002). This was confirmed in a series of qualitative studies by Higgins, Dunn, and Theobald (2000 and 2001). These studies are important because they examined the broader patient experience during admission and recovery after elective PTCA and stent. Data were collected through semi-structured interviews one-month after discharge on eight men and three women who had undergone elective PTCA. Analysis revealed three major categories: awareness of a problem/situation, coping response and appraisal of the situation (Higgins et al., 2000). Also, three patients reported anxiety during admission, which they felt was provoked by uncertainty and the possibility of life threatening consequences related to the procedure. This occurred for both first-time PTCA patients and patients who had previously undergone cardiac procedures (PTCA or CABGS).

Furthermore, the occurrence of chest pain was anxiety-provoking and found to be an important component of recognizing a problem during recovery and, in this case, serious complications requiring hospitalisation (Higgins, Dunn, & Theobald, 2001). It is not surprising these participants did not achieve the same benefit or view their procedure as positively as those who did not experience chest pain during their recovery. Both studies by Higgins et al. (2000, 2001) were limited by under reporting of the sample characteristics.

Patients' concerns may centre on their uncertainty in relation to the CAD outcome in the long term. Anxiety in relation to the constructs of uncertainty and psychological stress were investigated by White and Frasure-Smith (1995), one month and three-months post discharge from PTCA (n = 22) and CABGS (n = 25). Uncertainty was measured using the Mishel Uncertainty in Illness Scale (MUIS) and psychological distress the General Health Questionnaire (White & Frasure-Smith, 1995). Similar to Higgins et al. (2001), uncertainty was experienced by most of the PTCA patients, and interestingly, more so than CABGS patients. As expected, psychological stress decreased over the three months after discharge for both the PTCA and CABGS patients. Supporting this argument, stress at one and three-months was positively correlated with uncertainty and negatively with social support. However White and Frasure-Smith (1995) did not pursue whether these correlations existed independently through multiple regression analysis, possibly because of the small samples. Without this analysis independent predictors cannot be determined.

The consistently low overall level of anxiety and related constructs of stress in PTCA patients may be explained by Perkins and Jenkins (1998), who investigated mood in PTCA patients (n = 90) in-hospital after the PTCA and again two weeks after discharge at home using the POMS. On average, mood disturbance was low post procedure and significantly improved two-weeks after discharge. Perkins and Jenkins (1998) suggest that perhaps low levels of mood disturbance may be reported because PTCA is not viewed as life-threatening, although unfortunately, the underlying disease process is.

Patient concerns and anxiety after PTCA are an issue because of the influence on subsequent lifestyle and recovery. Gulanick, Bliley, Perino and Keough (1998) investigated patient concerns three-to-eighteen months after PTCA using focus group sessions. In addition the participants (n = 45) were asked to identify nursing interventions that would facilitate recovery. Participants were particularly concerned with the uncertainty of their future due to potential coronary artery disease progression. Participants were unable to identify nursing interventions that would assist in facilitating lifestyle modifications during recovery, but requested access to information in the form of newsletters, hotlines and videos.

Patients may also be concerned with specific physical recovery issues after PTCA. Kimble and King (1998) conducted semi-structured interviews by telephone two-weeks post procedure with PTCA patients (n=62). More than half (52%) experienced issues during the early recovery period, including the most commonly reported issue of groin site discomfort (22.5%) including pain, bruising and swelling, additional concerns related to chest pain (6.5%) and medication reactions (6.5%) were also reported.

In summary, these studies (Gulanick & Naito, 1994; Gulianik, Bliley, Perino, & Keough, 1998; Kimble & King, 1998; Lenzen et al., 2002) support a clearer recognition of patient concerns so that specific interventions may be implemented. It is particularly important to identify patient concerns when the patient has most contact with health care professionals in hospital and in the early recovery period, to enable intervention. Unfortunately few PTCA patients attend cardiac rehabilitation so the opportunity for intervention at that time is less likely.

2.5 Anxiety Assessment

2.6 Summary

In PTCA and stent patients, the literature indicates that anxiety generally is low and decreases over time. However about 20 to 40% experience high levels of anxiety. The studies that have investigated anxiety in this population have generally focused on long-term recovery, consequently the acute recovery period in hospital and the first week after PTCA and stent remains unknown. Also, the studies that have explored anxiety have been limited by a diversity of measures and methods used that prevents easy comparison and extrapolation from the studies used. It is also apparent that the personal characteristics, aside from gender, that identify patients at risk of more than normal levels of anxiety and complications during recovery have not been fully investigated. Consequently, there is a need for further research to investigate the anxiety experience and predictors of anxiety in close timing to the PTCA. Finally, patients' concerns in relation to anxiety are important to identify.

In addition to examining the anxiety experience and identifying the predictors of anxiety, an instrument is required that will rapidly and accurately assess anxiety in the clinical setting. This study will therefore determine whether the FAS might be a useful instrument and will assess the clinical usefulness. The quest for a rapid assessment instrument that poses minimal burden to the patient or health care staff may allow anxiety to be assessed and treated as part of routine nursing care. A clearer understanding of anxiety and patient characteristics that place patients at risk of anxiety will contribute to the limited body of knowledge.

2.7 Research Questions

There is a deficit of knowledge about the patterns of anxiety in the PTCA population. The research questions developed for this study were designed to address this scarcity are listed below, to describe:

1. What are the patterns of anxiety experienced by PTCA and stent patients' pre-procedure, post procedure and one-week post discharge?

2. What are the concerns of PTCA and stent patients' pre-procedure, post procedure and post discharge?

3. What are the characteristics of patients that identify patients with anxiety?

4. What is the clinical utility of the FAS in the PTCA and stent population?

Chapter Three - Method

3.1 Introduction

This chapter describes the methods used to investigate the level of anxiety experienced by coronary angioplasty and stent participants. The study design, including setting and sample, recruitment and tracking of study participants are discussed. Finally data collection and analysis methods used to test the study aims are also described.

3.2 *Design*

The design chosen for this research study was a descriptive design with repeated measures, as it is the best method to examine the patterns and changes in anxiety over time (Burns & Grove, 2001). Anxiety assessments and data collection were undertaken at three time points: pre-procedure, within 18-hours post procedure and one-week post discharge. In addition, a correlational design was used to determine the usefulness of the FAS to measure state anxiety within the coronary angioplasty and stent population. As the FAS has not been previously tested in this population, comparison of state anxiety scores was made between the FAS and the SAI for the pre-procedure and post procedure assessments.

3.3 Setting and Sample

3.3.1 Study Setting

A convenience sample was collected from a 350-bed, private, tertiary-referral hospital in the northern metropolitan region of Sydney. The hospital provides 24-hour percutaneous coronary interventions to privately insured and self-funded participants. The hospital also offers cardiac referral services to regional New South Wales. Six hundred and ten PTCA and stent procedures were performed at the study site in 2006.

At this site, routine care for elective PTCA and stent participants involves admission approximately one-to-two hours prior to the procedure. A medical history, physical assessment, pathology and electrocardiograph (ECG) are performed at this time. All participants receive local anaesthetic prior to the femoral artery being accessed, and then a combination of analgesia and sedation is administered throughout the procedure. Participants routinely stay in the coronary care unit (CCU) overnight for observation and detection of complications such as cardiac arrhythmias, haematoma at the arterial access site and an acute re-occlusion of newly treated vessel. Some elective PTCA and stent participants are already in-patients because they have experienced cardiac symptoms that warrant in-hospital treatment prior to the PTCA and stent. This includes people with ACS. All participants who undergo a PTCA and stent, received a drug-eluting stent as part of standard care. Patient information relating to the procedure, recovery and discharge is provided and the cardiac rehabilitation patient educator also provides the patient with information about diet and exercise targets after discharge. The pharmacist also provides the patient with information about antiplatelet drug therapy.

3.3.2 Sample Inclusion Criteria

Participants were included in the study if they were scheduled for an elective coronary angiogram and/or PTCA and stent procedure with a diagnostic related group code of F15Z and F16Z. All participants were older than 18 years. It was also considered important for participants to be able to read and understand written and spoken English, sufficient to give informed consent and complete the survey. Participants needed to have access to a telephone at the discharge location, so the post

discharge assessment could be performed. Participants were required to complete all three assessments (pre-procedure, post procedure and post discharge) to ensure a similar sample was being compared across time.

3.3.3 Sample Exclusion Criteria

Persons that were excluded from the study were those known to have a psychiatric illness or dementia, as it was anticipated that reports of anxiety may be confounded or misrepresented by the presence of mental illness or cognitive inpairment. Persons that were also known to have visual impairment were also excluded. Visually impaired participants would have difficulty giving informed consent, being able to accurately complete the SAI, and identify the appropriate face on the FAS.

3.3.4 Withdrawal of Participants

Participants were withdrawn from the study if they experienced severe complications that would affect their ability to complete the anxiety assessments. These complications include for example; cardiac tamponade requiring emergency pericardiocentesis, an unscheduled admission to the intensive care unit (ICU) for haemodynamic support (intra-aortic balloon pump therapy, inotropic therapy, intubation and ventilation) or a peri-procedure MI, requiring emergency cardiac surgery. Three attempts were also made via telephone to contact the participant post discharge. If any of the three assessments were missed, the participant was subsequently withdrawn.

3.4 Ethics

Ethics committee approval for the research study was granted by the Sydney Adventist Hospital Human Research Ethics Committee (Appendix C) and by the

University of Technology, Sydney Human Ethics Committee (Appendix D). The most important ethical considerations were informed consent, freedom from coercion, strategies for addressing high levels of anxiety if found, and privacy and confidentiality of participant information.

3.4.1 Informed Consent

Human dignity and the participant's right to freedom from coercion to participate in the research study was respected (Burns & Grove, 2001; Polit & Beck, 2004; Schneider, Elliott, LoBiondo-Wood, & Haber, 2003). Participants were informed that their participation in the study was voluntary and that they were free to withdraw at any time without their care being affected. The name and number of the principal researcher were given to all participants, so information and withdrawal could be communicated at anytime. A patient information sheet (Appendix E) and consent form (Appendix F), were given to each participant. The participants were given time to consider their participation in the study, and were encouraged to ask any questions at this time. All participants who agreed to join the study signed the consent form.

3.4.2 Freedom from Coercion

In some instances, my role as the clinical nurse and the researcher could have potentially influence the participant's decision to participate in the study, particularly if they felt that their clinical care would be affected by refusal. To overcome this concern, other CCU nurses cared for patients that were participants in the research.

3.4.3 Strategies for Addressing High Levels of Anxiety

There was a potential for high levels of anxiety to be detected or serious concerns verbalised. This may indicate increased risk of adverse cardiac events and poor recovery outcomes. Eligible patients who report high levels of anxiety were referred to the cardiac case manager and/or the cardiac patient educator, with the participant's permission. The case manager and patient educator develop a therapeutic relationship with all cardiac patients and co-ordinate psychosocial support within the hospital and discharge setting. Participants undergoing PTCA and stent procedures are routinely seen by these personnel as part of standard care.

3.4.4 Privacy and Confidentiality

Privacy was maintained as the individual details of the participant were kept separately and all data were coded. Anonymous information was then analysed, reported and transferred to a database for research purposes, presentation and future publication. All surveys were stored in a locked filing cabinet in an office at the study site. Electronic data were stored separately on the hard drive of a computer that was password protected. A copy of the electronic data was also stored in a USB mass storage device so coded data could be transferred and shared with the study's research supervisors.

3.5 Data Collection and Instruments

3.5.1 Socio-Demographic Data

Socio-demographic and clinical data were collected using a checklist in order to characterise the sample population (Appendix G). Socio-demographic data included age, gender, marital status, education and employment. The clinical data collected

included co-morbidities, anxiety and depression medications, previous cardiac history and cardiac risk factors. The data collected following the PTCA and stent included procedure characteristics, pre-medication and analgesia, procedural events, complications and chest pain. Data collected post discharge included experiences of chest pain and whether the participant consulted a health care professional or was re-admitted to hospital with cardiac related symptoms.

3.5.2 Anxiety Measures

State Anxiety Inventory (SAI): State anxiety was measured using the State Anxiety Inventory, which has been described in Chapter Two (Appendix A). For the purposes of this study, more than normal levels of anxiety was defined as a SAI score greater or equal to 35. This is justified based upon the results of Astin et al. (2005) and Kyungeh et al. (2004), who examined anxiety in Australian PTCA and MI populations (Astin et al., 2005; Kyungeh et al., 2004), and the Spielberger et al.(1983) age-related ranges for working adults (50-69 years) (male: mean 34.51 ± 10.34, female: mean 32.20 ± 8.96).

The SAI has been administered by various methods including face-to-face and via telephone (Astin et al., 2005; Bartlett et al., 2005; Heikkila, Paunonen, Virtanen et al., 1998; Kyungeh et al., 2004). It was considered appropriate to administer the SAI via telephone for the post discharge assessment, as it would have been difficult to perform face-to-face assessments with some participants in their discharge location in regional New South Wales and Queensland.

A Cronbach's alpha coefficient between .70-.90 is considered to be acceptable when assessing the reliability of an instrument (Streiner & Norman, 1996). The SAI has well established reliability with a Cronbach's alpha coefficient observed by Spielberger et al. (1983) of .92. In the current research study, the SAI proved reliable with a Cronbach's alpha coefficient of .91 pre-procedure, .92 post procedure and .94 post discharge.

Faces Anxiety Scale (FAS): State anxiety was also measured by the FAS and is described in Chapter Two (Appendix B). The FAS was chosen instead of a traditional visual analogue scale (VAS) as the faces pictured are easily identified by the participant (McKinley et al., 2003). The FAS may be a superior instrument to the VAS as the literature indicates, because it is able to discriminate between low, moderate and high levels of anxiety (McKinley et al., 2003).

The FAS was developed for the the purpose of assessment of state anxiety in critically ill participants (McKinley et al., 2003; McKinley et al., 2004). The FAS has been validated as an instrument that is able to measure the level of anxiety in the verbal and non verbal intensive care population (Gustad, Chaboyer, & Wallis, 2005; McKinley et al., 2004). In this population, the FAS moderately correlates with other assessments of anxiety ($r = 0.64$) (McKinley et al., 2004). The FAS was administered pre-procedure and post procedure, but not post discharge as the FAS needs to be administered in person and post discharge interviews were conducted by phone.

Participants' major concern: The participant's major concern was documented verbatim using an open-ended question at each time point. The question 'what would

be causing you the most anxiety / worry at the moment' was posed by the researcher. The intention was to identify concerns that may be connected to the patients' anxiety that are amenable to nursing intervention.

3.6 Procedure

3.6.1 Recruitment

From June 2005 to March 2006, screening visits to the cardiac catheter laboratory (CCL) and the coronary care unit (CCU) identified eligible participants scheduled for coronary angiogram and PTCA and stent procedures. Participants were approached for recruitment and informed written consent was sought.

3.6.2 Sample Participation (Tracking of Participants)

One hundred and fifteen participants were eligible for the research study. Of these, two participants declined to join. Three recruited participants were withdrawn from the study as they were discharged from hospital before the post procedure assessment could be performed. Another ten participants were unable to be contacted post discharge and were considered lost to follow up. The final sample was comprised of 100 participants as illustrated in figure 3.1.

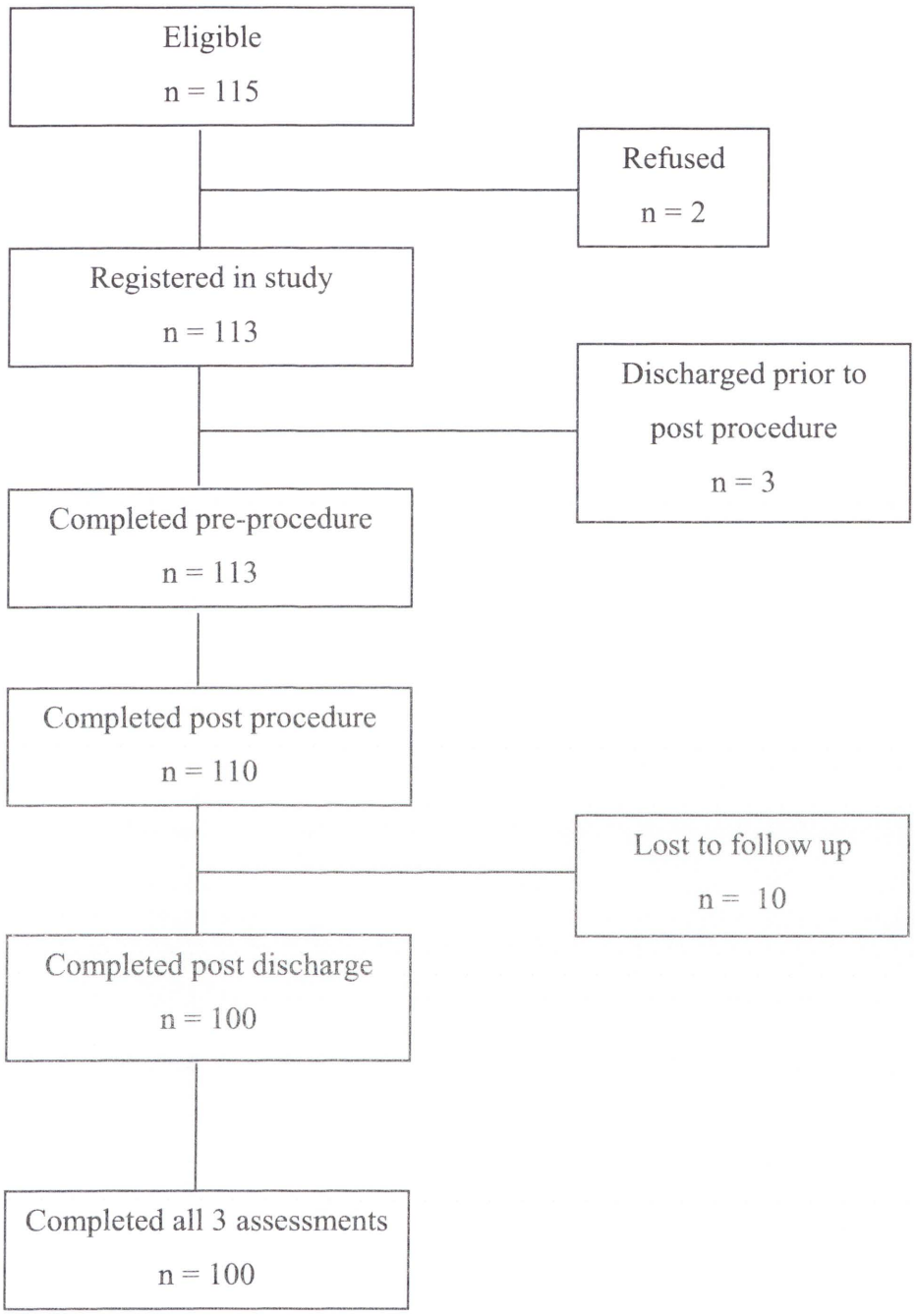

Figure 1 ***Recruitment and tracking of participants***

3.6.3 Timing of Assessments

Pre-procedure: Once written consent was obtained, pre-procedural data were collected, usually within 5-hours of the PTCA and stent procedure. Socio-demographic and clinical data were collected using the checklist (Appendix G). The SAI and the FAS were administered randomly, which was determined by coin toss, and an additional question relating to the participants' major concern was asked.

Post Procedure: Data were collected on average, 15-hours after the PTCA and stent. The case report and medical records were used to collect data, relating to the PTCA and stent procedure, complications and the degree of clinical success. These characteristics were considered important as they could potentially influence post procedure anxiety. The SAI and the FAS were administered in random order and the researcher posed an additional question relating to the participants major concern.

Post Discharge: Data collection was undertaken on average, eight days post discharge from hospital, via telephone interview. Three attempts were made to contact the participant at a date and time identified previously as convenient by the participant. If all attempts to contact the participant failed, the participant was considered lost to follow up. The participants were given a copy of the SAI during admission, which was used as a reference for the post discharge assessment. The FAS was not used at this time, as it is not suitable for administration via the telephone. Participants were asked to identify major concerns, and the actions of nursing staff that influenced their anxiety, within the pre-procedure, post procedure and post discharge context.

3.7 Data Analysis

3.7.1 Data Entry

Data were checked and entered into a database and data analysis was conducted using the Statistical Package for Social Science (SPSS) version 12.0. Data entry was checked by 10 % random double entry. A data entry error rate of only 1% of the spreadsheet was found and this was deemed acceptable for data analysis. Data were described using frequencies, percentages, means and standard deviations. The responses to the additional questions were organised into five major categories of concern at each time by the researcher, and cross-checked with the student's supervisor. These five major concerns were then entered into the multiple regression models for each corresponding time.

3.7.2 Analysis Techniques

Repeated measures analysis of variation (ANOVA) was performed to examine the differences in anxiety between and within the group at the three-time points of assessment. Correlation was also undertaken to determine how well the FAS performed against individual items and the total SAI. Also, the sensitivity and specificity of the FAS for anxiety assessment within the coronary angioplasty and stent population were determined.

3.7.3 Sample Size

A sample of 100 participants was considered satisfactory for the most complex data analysis, which was multiple regression analysis. Multiple regression analysis, using backwards, stepwise methods, were used to identify significant predictors of anxiety pre-procedure, post procedure and post discharge as measured by scores on the

SAI. It is recommended that 10 to 15 participants for each variable be entered into the regression model for this type of analysis (Field, 2005). Accounting for a drop out rate of 10%, 110 participants were initially recruited.

3.7.4 Multiple Regression Analysis

The predictors of anxiety were determined by multiple regression analysis. Regression modelling was conducted as recommended by Field (2005), using backward and stepwise methods. One set of variables was entered in all analyses, and important additional variables were entered, that were specific to each time, as per Table 1.

Table 1

Summary of variables entered into multiple regression models

	Variable	Pre–procedure	Post procedure	Post discharge
Entered into all models	***Socio-demographic***			
	Age	*	*	*
	Gender	*	*	*
	Education	*	*	*
	Marital status	*	*	*
	Previous cardiac diagnosis			
	Previous PTCA ± stent	*	*	*
	Admission pre-PTCA ± stent for ACS[§]	*	*	*
	Anxiety and depression medications	*	*	*
	Major concern			
	Personal: family, finance, home	*	*	*
	Concurrent condition			
	Back pain	*	*	
	Pre-procedure anxiety		*	*
	Major concerns			
	Success of PTCA	*	*	
	Procedure	*	*	
	Future progression of CAD			*
	Recovery		*	*
	PTCA & stent procedure			
	Chest pain		*	*
	Procedural analgesia/ sedation		*	

* Coronary artery bypass graft surgery
§ Acute coronary syndrome

3.7.5 Assumptions of the Analysis

The assumptions of conventional regression modelling techniques were checked. These assumptions being independence, linear relationships between variables and multicollinearity. No linear relationships between variables or multicollinearity were found between the predicting variables of anxiety, as checked by performing Durban–Watson analysis. None of the variables should be highly correlated with any other single variable or combination of variables. Checking variable correlations prevents model bias and errors of statistical significance; therefore the variance inflation factor (VIF) was checked and found not to be violated (Field, 2005).

3.8 Summary of Methods.

The level of anxiety experienced by participants that underwent PTCA and stent procedure was measured pre-procedure, post procedure and post discharge. The researcher performed participant consent and data collection. Socio-demographic data, clinical data and procedural data were collected from the medical record and by interview in which a survey was completed. Anxiety was measured using the SAI and the FAS for pre and post procedure assessment. The SAI was used for the post discharge assessment and was administered via telephone. The predictors of anxiety and cardiac related pain were categorised for analysis. Descriptive, repeated measures and multiple regression analyses were performed to identify predictors of anxiety throughout the PTCA and stent episode of care.

Chapter 4 - Results

4.1 Introduction

This chapter describes the socio-demographic, clinical and procedural characteristics of the sample. The anxiety levels of the participants pre-procedure, post procedure and one-week post discharge are also presented, followed by description of the participants' greatest current concerns. The results of regression analysis, which determined the predictors of anxiety, are also discussed. Finally this chapter appraises the suitability of the FAS for assessing anxiety in the PTCA and stent population.

4.2 *Sample Characteristics.*

Socio-demographic and clinical variables: The sample (n=100) was predominantly elderly (mean 65.63 years) and was largely male (80%), as detailed in Table 2. Most of the participants were married (83%) and lived with another person (80%), had completed high school or more education (66%) and were retired and / or not seeking employment (55%). Most participants (70%) had previously experienced a cardiac event, of which the most common was PTCA and stent (41%). Less than half of the participants had experienced unstable angina (47%) and the most frequent concurrent condition was hypertension (67%).

Table 2

Socio-demographic and clinical characteristics (n = 100)

Characteristic	Number
Age in years, mean (sd)	65.63 (10.17)
Education in years, median (min – max)	13.50 (7 - 32)
Male	80
Living arrangements	
Alone	11
With partner	80
Family / carer	9
Married	83
Employed	44
Previous cardiac diagnosis*	
None	30
PTCA ± stent	41
Myocardial infarction (MI)	10
Coronary artery bypass graft surgery	17
Unstable angina	47
Admission pre-PTCA ± stent for ACS[§]	13
Concurrent condition*	
Hypertension	67
Diabetes	11
Back pain	35
Arthritis	37
Respiratory	13
Renal	8
Smoker	6

* Total equals > 100 as participants could have more than one condition
§ Acute coronary syndrome

Procedural characteristics: approximately two-thirds of the participants in the study received a combination of analgesia and sedation for the procedure. The regime was most commonly midazolam and fentanyl, which was administered intravenously at the beginning and during the PTCA and stent (Table 3). All participants received a drug eluting stent. Most participants had one vessel treated (70%) and about half of the participants (54%) received one stent, although a small number of patients (3%) received as many as five stents in one procedure.

Table 3

PTCA and stent related characteristics (n=100)

Characteristics	**Number**
Number of vessels treated, mode (min-max)	1 (1-3)
Number of stents, mode (min-max)	1(1-5)
Case length time, mean (sd)	1hr 17min (40 min)
	Percent
Procedural analgesia / sedation	68
Fentanyl and midazolam	47
Fentanyl only	3
Midazolam only	12
Midazolam, morphine and fentanyl	6

Procedure related complications: Complications related to the PTCA and stent were experienced by 30 % of participants (Table 4). The most common complication was associated with the arterial access site (14%). A small number (3%) experienced the serious complication of an acute myocardial infarction.

Table 4

Procedure related complications (n=30)

Characteristic	Percent
Arrhythmia	6
Acute myocardial infarction	3
Bleeding / haematoma at arterial access site	14
Hypotension and bradycardia during sheath removal	6
Non-ischaemic chest symptoms	6

Total number > 30 due to combinations of complications experienced

***Post discharge outcomes*:** A total of 31% of participants experienced chest pain post discharge, of which a small number (3%) were concerned and sought medical treatment from an emergency department. One of these patients was discharged from the emergency department as the source of the chest pain was confirmed to be non-ischaemic. One of the patients was diagnosed with ischaemic chest pain and was managed medically, whereas the third patient, who presented to the emergency department with chest pain, experienced a life threatening MI, which required an emergency PTCA, and stent procedure. Additionally, two participants also sought emergency department treatment and were admitted to hospital for procedure related complications. These complications being; femoral bleeding and haematoma (1%) and phlebitis (1%). Refer to Table 5.

Table 5

Post discharge events

Event	Percent
Non-ischaemic chest pain	31
Emergency department visit: chest pain	3
Emergency department visit: procedure	2
Re-admitted: ischaemic chest pain	2
Re-admitted: procedural complications	2

Some overlap in emergency department visit and re-admission

4.3 Anxiety

Anxiety levels measured using the SAI: Anxiety was relatively common and persistent, despite the routine nature of PTCA and stent in Australia today. Anxiety was low to moderate and participants were most anxious pre-procedure (mean 35.72). Almost half (49%) of all participants experienced clinical levels of anxiety (SAI scores ≥ 35). Anxiety reduced overtime (ANOVA: $F = 39.72$, df = 1, 99, p = .000) as did the number of participants with anxiety above normal ($x^2 = 41.657$, df = 2 p = .000). Anxiety levels reduced on average by 3.91 score points from pre-procedure to post procedure times which was a statistically significant difference (p = .002). After the procedure, one-third (32%) remained clinically anxious. Anxiety levels reduced again from post procedure to post discharge by 3.02 SAI score points, which was also a statistically significant difference (p = .014), (Bonferroni, post hoc test). By this time the percentage of people who were clinically anxious had reduced to about one in five (19%) as outlined in Table 6.

Table 6

Anxiety over time, measured by the State Anxiety Inventory (SAI)

Anxiety Measures	Pre-Procedure	Post Procedure	Post Discharge
SAI score: mean (sd)	35.72 (11.15)	31.8 (10.20)	28.79 (9.78)*
Clinically anxious (SAI ≥ 35)	49%	32%	19%‡

SAI score range (20 - 80 most anxious)
* *ANOVA: F =39.72, df =1, p = .000,*
‡ x^2= 41.657, df = 2 p = .000

Participant's major concerns: Participants identified the success of the PTCA and stent, and the possibility of CABGS as their major concern before the procedure. The procedure itself was also acknowledged as a major concern but to a lesser extent (Figure 2). Additionally, 15% of participants thought personal issues, involving family and finances to be their major concern. After the procedure, concerns about recovery involving physical limitations, femoral site pain and chest pain were the most common. Interestingly, participants became concerned again about the possibility of CABGS and questioned the success of the PTCA after they had gone home. Personal concerns remained the most important for some participants throughout.

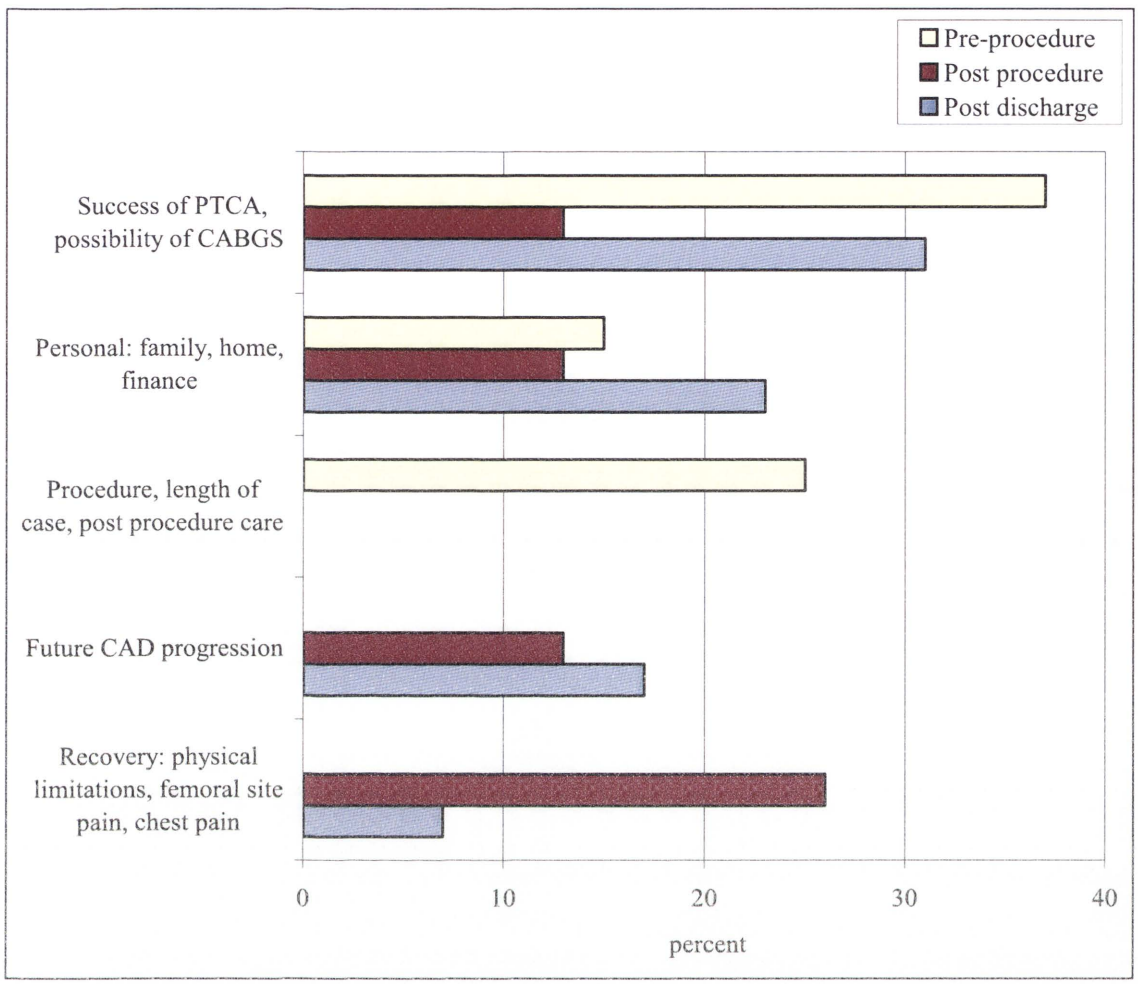

Figure 2 ***Concerns identified by participants at each time***

4.4 Nursing Interventions Suggested by Participants to Manage Anxiety

Participants identified nursing interventions that influenced anxiety in three key categories of information, support and the CCU environment. Aspects of information thought to be important in managing anxiety included recovery, cardiac rehabilitation and post procedure complications, such as cardiac related symptoms, bladder discomfort, haematoma and vasovagal episodes. Information was found to be useful to participants, if it facilitated the recovery process and complimented their lifestyle. Most participants generally found information to be helpful in reducing

anxiety. However, some of the participants found 'too much' information was in fact anxiety provoking.

Another aspect of nursing care that was thought to be important by participants was support, particularly when chest pain was experienced following the procedure. Participant's suggestions for nursing care and support included comfort measures and reassurance. Participants who reported positive support, suggested support strategies that worked, equally participants noticed when support strategies were lacking or ineffective. To a lesser extent, the CCU and CCL environment was also acknowledged to influence anxiety. The cardiac monitor alarms and the close proximity of the intensive care unit increased anxiety. Participants suggested distraction strategies that could reduce anxiety and these included crosswords and music.

4.5 Predictors of Anxiety

Pre-procedure: The pre-procedure model was significant, although only six percent of the variation in anxiety was explained (Table 7). Participants that were most anxious were those taking medications for anxiety and depression. It was somewhat expected that this group of participants would report differing levels of anxiety, however, it was not anticipated how much more anxious (seven SAI score points) these participants were.

Table 7

Predictors of anxiety; pre-procedure, post procedure and post discharge

Variables	β	95% CI*	P value
Pre-procedure			
Anxiety and depression medication	7.12	1.43 - 12.95	.014
r = .24, r^2=.06 F= 6.29, p =0.014, Durbin- Watson = 2.065, VIF = 1			
Post procedure			
Pre-procedure anxiety	.49	0.34 - 0.64	.000
Chest pain	7.63	3.43 - 11.85	.001
Previous PTCA ± stent	-4.44	-7.82 - 0.11	.011
r = .604, r^2 = .365, F = 18.366, p = .000, Durban-Watson =1.817, VIF =1			
Post discharge			
Pre-procedure anxiety	.37	0.23 - 0.53	.000
Major concern: future progression of CAD	7.51	3.12 -11.96	.001
r = 0.539, r^2 = .29, F = 19.821, p = 0.000, Durban – Watson = 1.790, VIF = 1			

* CI = Confidence Interval, β = Beta

Post procedure: The post procedure model was significant and explained 36% of the variation in anxiety (Table 7). The participants who were more anxious after the procedure had been most anxious pre-procedure, experienced chest pain following the PTCA and stent or were undergoing a PTCA and stent for the first-time.

Post discharge: The post discharge model was significant and explained 29% of the variation in anxiety (Table 7). Again, the participants who were more anxious following discharge had more anxiety pre-procedure and were worried about the future progression of CAD.

4.6 Evaluation of the FAS in the PTCA and Stent Population

Anxiety levels (FAS) When the FAS was used to measure anxiety, participants were most anxious pre-procedure (median 1.8), however only 4% were categorised as clinically anxious, compared to 49% with the SAI. Similar to the SAI, anxiety levels reduced post procedure (median 1.5) (Wilcoxin test $z = -3.135$, $p = 0.002$) so that only 3% were found to be anxious by the FAS. In comparison, the SAI found 32% of participants were clinically anxious post procedure (refer to Table 8).

Table 8

Anxiety measured by the State Anxiety Inventory compared to the Faces Anxiety Scale

	Pre-procedure		**Post procedure**	
Instruments	**SAI†**	**FAS***	**SAI**	**FAS**
Score, mean (sd)	35.72 (±11.15)	1.8 (1-4)§	31.8 (±10.20)	1.5 (1-4)§
% clinically anxious	49%	4%	32%	3%

† SAI range (20 – 80 most anxious) clinical anxiety point ≥ 35
*FAS range (1-5 most anxious) § FAS range clinical anxiety point ≥ 3

Sensitivity and Specificity of the FAS: In this study the FAS was used in a previously untested sample, therefore the sensitivity and specificity of the FAS was tested. That is, the ability of the instrument to detect true cases of anxiety when it actually exists and exclude false cases of state anxiety when the anxiety is not present (DiCenso, Guyatt, & Cliska, 2005). The ability of the FAS to detect true cases of state anxiety pre-procedure was low (sensitivity = 38%), however, the ability of the FAS to confidently rule out cases when no anxiety was present was high (specificity = 92%). The sensitivity of the FAS decreased to 31% and the specificity of the FAS increased to 95% post procedure as per Table 9. This means the sensitivity was unacceptably low at both times, but the specificity was satisfactory (DiCenso et al., 2005).

Table 9

Sensitivity and specificity of the Faces Anxiety Scale pre and post procedure

	Pre-procedure	Post procedure
Sensitivity	38%	31%
Specificity	92%	95%

The ability of the SAI versus the FAS in detecting clinical anxiety, pre-procedure and post procedure is outlined in Figure 3. The FAS did not prove to be a suitable instrument in measuring anxiety in the elective PTCA and stent population, as the FAS clearly did not detect a similar level of anxiety compared with the SAI. Therefore, many anxious patients would not be detected.

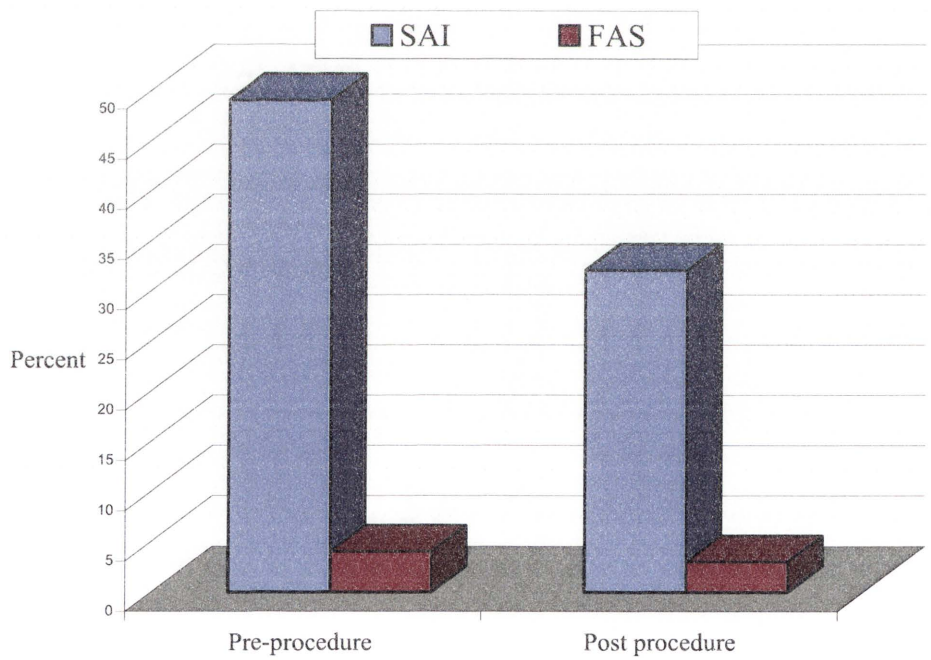

Figure 3 ***Comparison of the number of participants found to be clinically anxious using the FAS and SAI***

Association Between the FAS and SAI: Although both the FAS and SAI are intended to measure the same construct of state anxiety, the measures were only modestly correlated as per Table 10. This is possibly due to the FAS being a single-item versus the multiple-item SAI.

Table 10

Correlations of the FAS vs. SAI

	Pre-procedure	**Post procedure**
FAS vs. SAI	r = .445, p = .001	r = .590, p = .000

4.7 Summary of Predictors

A summary of the predictors of anxiety in the PTCA and stent population pre-procedure, post procedure and post discharge are provided in Table 11. The only predictor of pre-procedure anxiety is whether the patient was taking medications for anxiety and depression. Predictors of increased anxiety post procedure include chest pain, if the patient was undergoing a PTCA and stent for the first-time. Concern regarding progression of CAD in the future was also an important characteristic of anxiety post discharge. Participants that were anxious before the PTCA and stent were more likely to be anxious after the procedure.

Table 11 ***Summary of predictors of anxiety pre-procedure, post procedure and post discharge***

Characteristic	Pre-procedure	Post Procedure	Post Discharge
Anxiety and depression medications	*		
Pre-procedure anxiety		*	*
Chest pain		*	
Previous PTCA ± stent		*	
Major concern: Future progression of CAD			*

* Significant predictor for this variable p = ≤.05

4.8 Summary of Results

Anxiety was low to moderate and persisted throughout the PTCA and stent experience. The sample comprised of mostly elderly, male PTCA and stent patients. Whilst there was a decrease in mean anxiety scores (seven SAI points), over the study time, anxiety was common. Almost half (49%) of all participants were anxious pre-procedure, decreasing to one in three participants post procedure and then to one in five participants post discharge.

Complications were frequent post procedure (30%), including bleeding and haematoma formation at the femoral arterial access site (14%). More critically, a post procedure MI was experienced by three percent. A significant proportion of the sample unexpectedly experienced chest pain following discharge (31%), although this proved to be ischaemic for only two percent of participants.

The categories of the participants' major concern pre-procedure included the success of the PTCA and stent and the possibility of CABGS, followed by the procedure itself. Subsequent to the procedure, concerns were focused upon aspects of

recovery, and again the success of the PTCA and stent, and the possibility of CABGS emerged as the dominant concern following discharge.

The nursing interventions that patients identified to influence anxiety were providing information, support and altering the critical care environment. Information was found to be useful in facilitating the recovery process if it complimented the participant's lives. Support was also identified to be an important aspect of nursing care and participants noticed when support was lacking or ineffective. To a lesser extent, the CCU and CCL environment was also noted to influence anxiety.

The FAS did not prove to be a sensitive instrument to detect anxiety in this study sample. The correlation of the FAS and the SAI was only modest pre-procedure ($r = .445$ $p = .001$) but improved somewhat post procedure ($r = .590$ $p = .000$). Furthermore the FAS was unable to detect many cases of anxiety (sensitivity 38% pre-procedure and 31% post procedure), although the ability of the FAS to exclude non-cases of anxiety was relatively high (specificity = 92% pre-procedure and 95% post procedure).

The predictor of pre-procedure anxiety was whether the participant was taking anxiety and depression medication. Predictive characteristics post procedure included chest pain, pre-procedure anxiety and previous PTCA and stent. After discharge, participants who experienced pre-procedure anxiety were found to be at risk of anxiety. Patient's major concerns were related to the future progression of CAD and this was also found to be an independent predictor of anxiety. Nevertheless a great deal of

variation in anxiety was not explained by the variables included in the analysis, particularly pre-procedure.

Chapter Five - Discussion

5.1 Introduction

This study investigated the occurrence of anxiety amongst elective PTCA and stent patients and examined the possible association between anxiety and patient characteristics. It was thought that anxiety would naturally decrease over time, as patients would recover and resume normal activity, and patients would be most anxious prior to the procedure. Results from this study confirm that the PTCA and stent population generally experience low levels of anxiety, which decreases over time. However, 19% to 49% of patients experienced more than normal levels of anxiety over the whole PTCA and stent experience. Several characteristics identified the patients at increased risk of anxiety at each time. However, the only predictor of anxiety in patients' pre-procedure was whether the patient was taking medications for anxiety and depression. Pre-procedure anxiety also predicted subsequent anxiety in patients. Patients who had previously undergone a PTCA and stent experienced less anxiety, whereas the presence of chest pain after the procedure increased anxiety post procedure. Post discharge anxiety was influenced by patients' major concerns regarding future CAD progression.

5.2 Occurrence of Anxiety

Most patients undergoing PTCA and stent have low levels of anxiety pre-admission and post discharge, which the current study confirmed, but our study also identified that anxiety was also low in the immediate post procedure, in-hospital time (Astin et al., 2005; Harkness et al., 2003; Heikkila, Paunonen, Laippala et al., 1998; Heikkila, Paunonen, Virtanen et al., 1998; Heikkila, Paunonen, Virtanen, & Laippala,

1999; Higgins et al., 2000; Higgins et al., 2001; Sirois et al., 2003). It is interesting to note that anxiety was low, given that many aspects of the procedure and diagnosis would be expected to be anxiety provoking, and this may reflect a decreased perception of threat, because PTCA is a common procedure with low levels of risk (Perkins & Jenkins, 1998).

It is possible also that the anxiety reported may underestimate the real level of patient anxiety. Firstly, this is because the predominantly male sample (80%) may be reluctant to report anxiety in comparison to women. This gender discrepancy has been reported previously by Heikilla et al. (1999) and Ladwig et al. (2000). Secondly, the low anxiety scores may reflect the use of denial as a means of coping as reported by Lazarus (2000) and Teasdale (1995). Interestingly, evidence for the use of denial was found in the patients' comments and by the fact that many patients were not concerned, as it would have been appropriate to have concerns. Patients using denial find this mechanism is difficult to maintain in the face of information from health staff, so some patients reported being given 'too much information' made them feel more anxious. In fact, some patients may have preferred less information, a finding which was consistent with results of other studies (Phatouros & Blake, 1995; Teasdale, 1995).

Pre-procedure anxiety: Anxiety was highest pre-procedure and quite common, with almost half (49%) of the patients experiencing higher than normal levels of anxiety. It is particularly worthwhile to assess and treat anxiety at this time because of its pervasive effect on subsequent anxiety during recovery. Therefore, conducting assessment pre-procedure is well-justified as patients at risk may be readily identified and subsequent anxiety managed. Once anxiety is identified, one intervention may

include information about the likelihood of outcomes such as CABGS, as patients suggested that their most important concern at this time was the success of the procedure and the possibility of CABGS. This result is in keeping with earlier findings of Heikkila et al. (1998b), who found the possibility of CABGS was the greatest concern for male (77%) and female (88%) coronary angiography patients. This concern is not easily addressed except for providing patients with specific statistics and it is likely that more generalised treatment of anxiety, including music and distraction may be effective.

Curiously, no other demographic or clinical variables, other than whether the patient was taking medications for anxiety and depression, predicted pre-procedure anxiety. Therefore, patients prescribed these medications should have their anxiety levels assessed and additional treatment provided if it is needed. It is possible that these patients are under treated and may have benefited from additional pre-medication. Furthermore, it was thought that patients who had previously undergone a PTCA and stent procedure would report lower levels of anxiety than first-time PTCA and stent patients because of their past experience. However, consistent with Lenzen et al. (2002), anxiety levels were equal for both first-time and repeat PTCA and stent patients and both shared the concern about the outcome of the PTCA and stent at each time. This suggests that similar strategies are necessary for both groups.

We do not have a precise understanding of pre-procedure anxiety based upon the results obtained by this study. The pre-procedure regression model was weak and lacked predictive power. Therefore, there are additional factors that were not measured in this study that may have been influential. These may include aspects of quality of

life and co-morbidities. Sirois et al. (2003) and Kimble and King (1998) measured quality of life and found the frequency of pre-procedure angina to be associated with anxiety during recovery in hospital, and up to six-months after discharge. Therefore, further research into the impact of anginal symptoms and quality of life on anxiety may be warranted.

Post procedure anxiety: Overall patient anxiety decreased over time, consistent with the findings of other researchers who have investigated the longer-term recovery patterns after PTCA and stent (Astin et al., 2005; Higgins et al., 2000; Sirois et al., 2003). However, 32% of patients experienced more than normal levels of anxiety post procedure. It is possible that these patients may in fact be also high in trait anxiety and therefore more likely to have increased state anxiety throughout the recovery (Astin et al., 2005; Spielberger et al., 1983). Interventions for these patients are important and may include medication or general stress-reduction strategies.

Interestingly, while previous PTCA and stent experience had no effect pre-procedure, patients that had previously undergone a PTCA and stent were less anxious after the procedure. It is likely that this group were somewhat familiar with the experience and had realistic expectations of recovery. The major concerns shared by almost one third of patients, at this time, focused upon chest and femoral site pain and the physical limitations during the first few hours after the PTCA. Patients expressed concerns about lying flat in bed after the procedure, which is consistent with the findings of Beatie and Geden (1990) and Heikilla et al.(1998b).

The effect of chest pain on increasing patients' anxiety was substantial and expected (Sirois et al., 2003). It is likely that patients thought that chest pain signalled a complication or failure of the procedure. However, many patients appeared to be experiencing non-specific chest pain associated with vascular stretching from the PTCA and stent (Ronnevig et al., 2003). Patients may benefit from nursing interventions that provide reassurance and knowledge about the likelihood and treatment of non-ischaemic chest pain.

Post discharge anxiety: In addition to pre-procedure anxiety, the only post discharge predictor of anxiety was whether the patient was concerned about the future progression of their CAD on their life. It is possible that the first week after discharge provides time for the patient to reflect upon the diagnosis and the impact of CAD, especially as many patients were experiencing their first diagnosis of CAD at the time of the PTCA and stent. Patients need time to adjust to their diagnosis, the PTCA and stent and the lifestyle changes required to prevent disease progression. During the post discharge phase, patients are regularly reminded that they have CAD and the PTCA and stent because post discharge care includes arterial puncture site care and observation and a strict medication regime for anticoagulants reinforces the disease process.

On the other hand, it was surprising that the majority of patients (83%) did not identify future concerns about CAD progression as a major concern. It is quite possible that personal concerns were considered to be more important at the time. Despite being informed of restenosis statistics, many patients naïvely believe PTCA is a cure for CAD. Therefore, important lifestyle changes of diet and exercise are not considered a priority. Such denial of the severity of the illness results in poor participation in

cardiac rehabilitation, and unfortunately 'a majority of eligible Australians are failing to achieve the potential gains from our network of outpatient cardiac rehabilitation programs' (Bunker & Goble, 2003). Gulanik and Natio (1994) confirm that patients generally think restenosis is highly unlikely, even though as many as one in five patients in their study experienced chest pain after discharge. Therefore, it is important to persuade PTCA and stent recipients to attend cardiac rehabilitation. Cardiac rehabilitation may provide an appropriate platform for realistic expectations of recovery and motivation for lifestyle change, particularly when knowledge is lacking.

Overall, many of the concerns raised by patients post discharge could be addressed by cardiac rehabilitation. Lavie and Milani's (2004) research confirms cardiac rehabilitation would be beneficial to PTCA and stent patients, as cardiac rehabilitation facilitates improvement in cardiac risk factors, decreases anxiety and improves quality of life in patients who experience moderate to high levels of anxiety. In Australia, very few PTCA and stent patients (30%) routinely attend cardiac rehabilitation (Sundararajan, Bunker, Begg, Marshall, & McBurney, 2004). At the study site only nine percent of PTCA and stent patients utilize cardiac rehabilitation services. PTCA and stent patients are even less likely to attend because cardiac rehabilitation commences as late as six weeks after the PTCA and stent, when patients' anxiety and perhaps motivation has declined. Patients may not have an accurate perception of the purpose of cardiac rehabilitation and not understand that cardiac rehabilitation offers support for lifestyle change. This is important because PTCA and stent patients mostly rely on standard information available from brochures. It is likely that seeking involvement by the family in the decision to attend cardiac rehabilitation would be helpful as most PTCA patients depend on social support offered by family

(Moser & Dracup, 2004). Therefore, it is also worthwhile involving carers in cardiac rehabilitation programmes given that carers provide post discharge support to the PTCA and stent patient.

5.3 Measuring Anxiety in Cardiac In-patients

This study identified a priority need for nurses to assess anxiety in this population. The measure of choice would be the, SAI, however although the SAI is brief, completed in less than 5 minutes, it is still too long to be incorporated into routine assessment. A number of scales were identified that could potentially have been used to measure anxiety in this study, including the anxiety subscale of the Brief Symptom Inventory (BSI) (De Jong & Hall, 2006) or a single-item VAS (De Jong et al., 2005; Heikkila, Paunonen, Laippala et al., 1998). The difficulty associated with measuring anxiety in the elective PTCA and stent population is that undertaking assessments in the pre-procedure setting needs to be rapid because many patients are admitted to hospital as little as one hour before their procedure. During this time many admission processes, including procedural preparation need to occur. Therefore, the administration and scoring of anxiety instruments should be as seamless as possible and pose minimal burden to the patient and nurse.

The FAS was evaluated for this purpose because it was a single-item instrument that could be administered and completed in five seconds (McKinley et al., 2003). It is not surprising that the FAS performed differently as it was used in a different, more able population, but the low-moderate correlations between the between the FAS and the SAI were not anticipated. The FAS proved to have limited sensitivity, and unable to detect many cases of anxiety. One of the issues with the FAS appears to

be that, similar to Gustad et al.(2005), patients experienced difficulty identifying with some of the faces of the FAS. Patients generally did not identify with face one, representing no anxiety, and often commented that they thought a face that represented no anxiety needed to be placed below (left) of face one as face one looked 'too tense'. That is no face on the scale was representative of no anxiety. The patients' perception of what is 'no anxiety' is challenging, as 'no anxiety' may in fact from the patients' perspective, be represented by a happy facial expression. Also, many researchers have conducted studies that have correlated a single-item VAS style, anxiety instrument with multiple-item likert scale instruments such as the HADS, SAI and BSI (De Jong et al., 2005; Elliott, 1993; Gustad et al., 2005; Heikkila, Paunonen, Laippala et al., 1998). It is possible that the multiple-item scales measure a broader construct of anxiety, whereas the VAS uses a specific, narrow approach that may not necessarily match. The VAS has limited utility to measure anxiety as a value for clinical cut-off points have not been established.

In the face of this outcome, a potentially suitable instrument that may provide rapid assessment of anxiety in the elective PTCA and stent population is the BSI. The BSI was designed to assess anxiety not only in psychiatric and medical patients but other populations as well. The 6-item anxiety subscale has been extensively used in cardiovascular research in the AMI population (De Jong, Chung et al., 2004; De Jong et al., 2005; Kim et al., 2000; Moser, Dracup, & McKinley, 2003). Patients respond to the scale based upon how they were affected during the past seven days (Derogatis & Melisaratos, 1983). Therefore, changes in anxiety within a short period of time from pre-procedure to post procedure may not be detected. There is convincing evidence supporting the validity of BSI. Convergent validity between the anxiety subscale and

the Minnisota Multiphasic Personality Inventory was found. A strong correlation of 0.95 supporting the validity of the BSI was established between the BSI and the Symptom Checklist –90R. The reliability of the anxiety subscale of the BSI has been demonstrated by a Cronbach's alpha range of .85 to .90 in cardiovascular populations (Kim et al., 2000; Moser & Dracup, 1996; Moser, Dracup et al., 2003).

5.4 Strengths and Limitations

The key strengths of this study include the use of repeated measures and the timing of anxiety assessments. No published research has investigated anxiety shortly before and after the PTCA and stent or within the acute recovery one-week after discharge. The study was strengthened by ensuring a consistent sample across the study, as patients were only included if they completed all three assessments. Another strength is that this was the first study to date that has attempted to identify predictors that characterise patients at risk of anxiety. Furthermore, the choice of the SAI to measure anxiety was sound, as the SAI is a well established instrument with normative values. It was therefore suitable to compare and assess the clinical usefulness of the FAS. It was also advantageous to limit response bias by random order of the administration of instruments.

This study also had several limitations that must be considered. Firstly, the use of one private hospital setting as the study site means the results may not be generalisable to the wider PTCA and stent population. Although the sample was similar in relation to many socio-demographic and clinical variables to reported samples (Astin et al., 2005), it is possible a sample from one site may be subtly different from the general PTCA population. Secondly, one of the regression models that identified

individual predictors of anxiety was weak, suggesting other characteristics that affected anxiety were not measured in this study or perhaps a bigger sample may have been useful. Thirdly, the clinical cut-off for the SAI for this study was a score of 35, which was based upon the results of Astin et al. (2005) and Spielberger et al. (1983) working adult range. However it was difficult to compare results with the work of other cardiovascular researchers, as the clinical cut-off for anxiety for the PTCA and cardiovascular population was difficult to determine. Previous cardiovascular researchers have compared results with the normative score ranges defined by Spielberger et al.(1983) for neuro-psychiatric and medical-surgical populations. Therefore, it is somewhat difficult to precisely compare the proportion of patients that were clinically anxious with other studies, because the clinical the proportion is represented differently with indicators / thresholds of more than normal levels of anxiety ranging from 35 to 42 SAI score points. In relation to this study which used a cut off of greater than 35 score points, between 5% and 22% of participants reported an average score, comparable to the results of Astin et al. (2005). In addition, 13% to 27% of participants reported anxiety levels similar to Spielberger et al. (1983) general medical surgical samples (mean 42.38 ± 15.66), so the cut-off seems reasonable.

Finally, it is possible that the influence of trait anxiety on state anxiety was under-estimated, given the influence of pre-procedure anxiety on subsequent anxiety. Trait anxiety was not measured in this study, as Astin et al. (2005) found it to be an enduring construct that was not predictive of state anxiety. Also it is likely that trait anxiety is not amenable to intervention.

5.5 Implications for Nursing Practice

This study demonstrates that a small but important proportion of patients in the PTCA and stent population are anxious. The presence of this group justifies pre-procedure, post procedure and post discharge assessment of anxiety, yet anxiety assessment rarely occurs as a part of routine care. Currently this is an issue because under-detection and under-treatment of anxiety is relatively common, given the potentially serious consequences of untreated anxiety (O'Brien et al., 2001). Critical care nurses rely on behavioural and physiological indicators in their clinical evaluations of anxiety which can lead to the underestimation of anxiety especially when patients are most vulnerable (Frazier et al., 2002). Furthermore, there is a need for an anxiety assessment tool, which can be incorporated into routine care rather than the variety of presentations of anxiety that clinicians may rely on, such as physiological and behavioural indicators. Nurses have been particularly reluctant to incorporate anxiety assessment into routine care as it impacts workload and nursing practice for a variety of reasons (O'Brien et al., 2001). Even though many nurses think the management of anxiety is important and beneficial (Frazier et al. 2003), it is perceived as an extra task added to their workload especially in the pre-procedure context when patients are hastily prepared for their procedure. If nurses assessed and found higher than normal levels of anxiety, the nursing staff would have a responsibility to treat the anxiety.

A variety of anxiety management strategies are needed for coronary care nurses. Moser et al. (2003) identified 62 % of the large sample of nurses (n= 593) used anti-anxiety medication and sedation and analgesia, and these were by far the most common strategies used. Despite the frequent use of analgesia in that study, very few nurses recognised pain as a manifestation of anxiety (8.6%). Some of the commonly used

strategies that are non-pharmacological, such as music and touch are time consuming and may encroach upon the rapid admission and procedural preparation process. In order to positively influence nursing practice, the serious consequence of untreated anxiety needs to be understood by nurses (Frazier et al., 2003; O'Brien et al., 2001). Importantly an anxiety instrument that is easy to administer and score is needed because a positive assessment initiates the process of treatment.

It is feasible for nurses to identify and assess anxiety as nurses are present throughout the entire PTCA and stent episode and, of all health care professionals, PTCA and stent patients have the most direct contact with nursing staff. Nursing is pivotal to providing psychosocial support, especially within the discharge setting. Nurses are able to communicate with the people who are closest to the patient, and include spouses and family in strategies to reduce anxiety. As PTCA and stent patients rely upon psychosocial support offered by their family, by including family in post discharge, care may positively influence post discharge anxiety, cardiac rehabilitation attendance and health related behaviours that eliminate cardiovascular risk factors.

Cardiac rehabilitation should be included in post discharge care and be accessible to patients within the first week, especially when they are most vulnerable to anxiety after discharge. Patient's anxiety may be managed through education and strategies offered by cardiac rehabilitation, particularly when patients are concerned about CAD progression. This could be an important motivator to ensure cardiac risk factors are modified before patients resume previous lifestyle (Bunker & Goble, 2003; Gaw-Ens, 1994).

It would be worthwhile exploring other pre-procedural characteristics that place patients at risk of anxiety. Pre-procedure measures should include quality of life and a closer examination of angina frequency and duration because it may be predictive of anxiety. This is particularly important as the pre-procedure multiple regression model was weak. The inclusion of quality of life measures particularly angina frequency, may be particularly useful (Sirois et al., 2003; Strauss, Fortin, Hartigfan, Folland, & Parisi, 1995; Westin et al., 1997).

5.6 Conclusion

To summarise, this thesis has reported on the occurrence of anxiety amongst elective PTCA and stent patients and examined the possible association between anxiety and patient characteristics. As anticipated, anxiety levels were low and naturally decreased over time, most likely because patients recover and resume normal activity and patients are most anxious prior to the procedure.

Chapter One explained the pathophysiology, symptoms and treatment modes for CAD and its management. The PTCA and stent procedure was described and the potentially anxiety-provoking issues related to the PTCA experience were discussed. The construct and clinical manifestations of anxiety were defined and the rationale for investigating anxiety in the acute phase of the PTCA and stent was explained. This chapter also discussed the lack of recognition and assessment of anxiety by clinicians and highlights the potential vulnerability of PTCA and stent patients to anxiety.

The second chapter reviewed the literature on anxiety in relation to patterns and prevalence in the PTCA and stent and cardiovascular populations. The key

limitations in the existing research relating to study design, instruments, and the timing of anxiety assessments were discussed. The research aims and questions for the study were provided. Chapter Three describes the method and instrumentation used to assess anxiety in the elective PTCA and stent population. This chapter also outlined the data collected and data analysis techniques.

Chapter Four described the socio-demographic, clinical and procedural characteristics of the sample. The anxiety levels of the participants pre-procedure, post procedure and one-week post discharge were also presented, followed by description of the participants' greatest current concerns. The results of regression analysis, which determined the predictors of anxiety, were also discussed. A critique of the FAS for assessing anxiety in the PTCA and stent population was also provided. Chapter Five discussed the meaning of the findings of the study in relation to the existing literature. Chapter Five also summarised the results, outlined the study limitations and provided recommendations for clinical practice and future research.

The results from this study confirm that most PTCA and stent patients are not clinically anxious. On average low levels of anxiety were experienced and anxiety decreased over time. However, there was a significant proportion of patients (19% to 49%) who experienced more than clinical levels of anxiety at all times assessed of the PTCA and stent experience. There were several characteristics that identified patients at increased risk of anxiety at each time, however the only predictor of anxiety in patients' pre-procedure was whether the patient was taking medications for anxiety and depression. Pre-procedure anxiety also predicted subsequent anxiety in patients at both times. Patients who had previously undergone a PTCA and stent experienced less

anxiety, whereas the presence of chest pain after the procedure increased anxiety post procedure. Post discharge anxiety was influenced by patients' major concerns regarding future CAD progression. Importantly the results reinforce the need for nurses to assess anxiety routinely and provide treatment as part of routine care.

In conclusion, the material presented in this thesis contributes to the emerging knowledge of the patterns of anxiety in patients undergoing PTCA and stent procedures. In summary, most patients were not anxious but there is a significant group that are at high risk of moderate to high levels of anxiety and need to be identified and treated. It is vital that a clinically useful, rapidly administered anxiety instrument is identified to ensure that appropriate treatments are implemented.

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Appendix A: Spielberger State Anxiety Inventory

SELF-EVALUATION QUESTIONNAIRE **STAI form Y-2**

Please provide the following information:
Code: _____ Date: _____ S_____
Age: _____ Gender (circle) **M** **F**

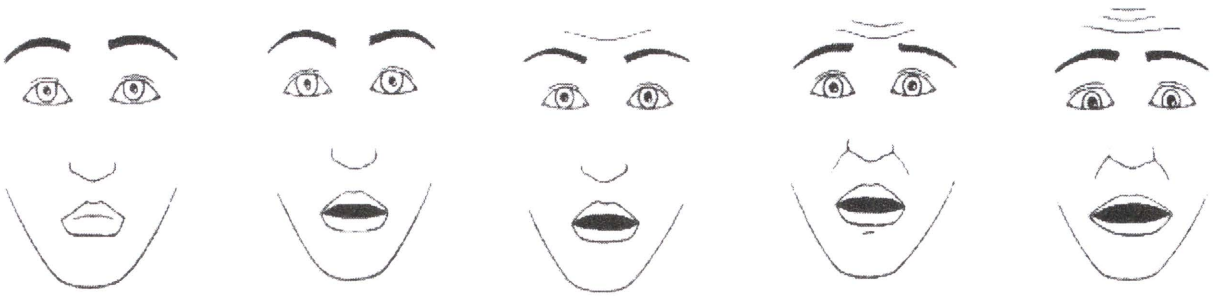
Directions:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate value to the right of the statement to indicate how you feel right now, that is, at this moment. There is no right or wrong answers. Do not spend too much time on any one statement but give your answer which seems to describe your present feelings best

	Not at all	Somewhat	Moderately so	Very much so
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I feel jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Spielberger et al. (1983) *State Trait Anxiety Inventory* Form Y

Appendix B: Faces Anxiety Scale



The presentation of the FAS is in the form of an 11cm x 47cm laminated card which is verbally anchored by none (left) to severe anxiety (right)

The verbal instructions given to participants are:

1. 'This face shows no anxiety, a little bit more right up to extreme anxiety' (researcher sweeps finger from left to right along the scale)
2. 'Now look at these faces and choose the one that show how much anxiety you are feeling at the moment'

Reference: McKinley et al.(2003)

Appendix C: Ethics Approval from Study Site

21 April 2005

Mrs Renee Trotter
Cardiac Care Unit
Sydney Adventist Hospital

Dear Renee,

02 / 05 (Resubmission) – Anxiety in Patients undergoing Percutaneous Coronary Intervention

At the Ethics Committee meeting of 6 April the following minute was recorded:

Mrs Renee Trotter presented an amended proposal for the study entitled *Anxiety in percutaneous coronary intervention (PCI) patients: pre-procedure, within 18 hours post PCI and one week post PCI* with particular reference to the issues raised by the Ethics Committee when considering the original proposal on 2 February 2005. Apart from some editorial suggestions for the patient consent form, the Committee was satisfied with the amended documentation.

Action: voted to confirm ethical approval of the above study on condition that a report is submitted on the progress of and at the conclusion of the study, and that the Committee is informed of any significant changes to the protocol, or any significant complaints or problems encountered.

I trust the study goes well.

Sincerely

Dr Thomas Ludowici
Secretary, Hospital Ethics Committee
toml@sah.org.au
9487 9410

Appendix D: Ethics Approval From The University of Technology, Sydney

Research & Commercialisation Office

PO Box 123
Broadway NSW 2007
Australia

Tel +61 2 9514 9681
Fax +61 2 9514 1244

UTS CRICOS Provider Code 00099F

University of Technology, Sydney

13 May 2005

Dr Robyn Gallagher
KG05.02.20
Faculty of Nursing, Midwifery and Health
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Robyn,

UTS HREC REF NO 2005-0045 – GALLAGHER, Dr Robyn, DONOGHUE Professor Judith, (for TROTTER, Ms Renee – Masters of Nursing student) - "Anxiety and PCI over time" *[External Ratification Sydney Adventist Hospital Ethics Committee].*

At its meeting held on 10/05/2005, the UTS Human Research Ethics Committee considered the above application, noting that it had already been approved by an accredited HREC, and I am pleased to inform you that your external ethics clearance has been ratified.

Your UTS clearance number is UTS HREC REF NO. 2005-045A

Please note that the ethical conduct of research is an on-going process. The *National Statement on Ethical Conduct in Research Involving Humans* requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Commercialisation Office, on 02 9514 9615.

Yours sincerely,

Production Note:
Signature removed prior to publication.

Professor Jane Stein-Parbury
Chairperson,
UTS Human Research Ethics Committee

Appendix E: Patient Information Sheet

Stress in Coronary Angioplasty and Stent Patients

PATIENT INFORMATION SHEET

Renee Trotter, Clinical Nurse Specialist of the Sydney Adventist Hospital and Master of Nursing (Honours) student of The University of Technology Sydney.

I am seeking your assistance in a study that investigates stress associated with having a coronary angioplasty and stent. I am undertaking this study because coronary angioplasty and stent is the most common cardiac procedure performed in Australia yet we do not have a clear understanding of what support is required for patients. This study aims to identify stress associated with this procedure so we can provide appropriate care to meet the individual patient needs.

In this study, men and women will be invited to join the study if they are:
Scheduled for coronary angioplasty and stent
Free from any other chronic illness
Able to understand, speak and read English
Older than 18 years of age

If you agree to participate in the study you will be asked to complete a short questionnaire related to how you are feeling on three occasions: before the procedure, within 18 hours following the procedure and one week after the procedure when you are at home (by telephone). The questionnaire will take 5-10 minutes to complete.

It is up to you to decide whether or not to take part in the study. If you do decide to take part, you will be given this information sheet to keep. You are free to withdraw from the study at any time without having to give a reason. A decision to withdraw or a decision not to take part will not affect the standard of care you receive.

Renee Trotter will inspect your current medical record and collect clinical information including age, medical history and information about your specific coronary angioplasty and stent. Confidentially will be maintained and your information will be coded. Names will not be disclosed outside the hospital. If you are identified to be at risk of stress that may hinder your recovery, Renee will ask your permission to contact the cardiac case manager who will coordinate appropriate services for your needs.

There may or may not be any direct benefit to you from taking part in this study. However the information gained from this study will help nurses provide future patient care.

If you have any concerns or wish to complain about any aspect of the way you have been approached or treated during the course of the study you can contact representative of the UTS or SAH ethics committee as detailed below. . The normal health service complaint mechanisms are also available to you. During this study Renee is supervised by Dr Robyn Gallagher, Faculty of Nursing Midwifery and Health, University of Technology, Sydney

You may contact these people if you have any concerns about the way the study is conducted:

Principal Researcher:	Mrs Renee Trotter	Tel:
Research Supervisor:	Dr Robyn Gallagher	Tel: 9514 5746
SAH Ethics Committee Secretary:	Dr Tom Ludowici	Tel: 9487 9111
Research Ethics Officer UTS:	Ms Louise Abrams	Tel: 9514 9615

Appendix F: Patient Consent Form

Stress in Coronary Angioplasty and Stent Patients

PATIENT CONSENT TO PARTICIPATE IN RESEARCH STUDY

1. **Participation in a Research Study:** By signing this form you are consenting to participate in the research study.

2. **The Purpose of the Study:** Is to investigate the stress in coronary angioplasty and stent patients.

3. **Duration of the Study:** The study duration is one week from before the coronary angioplasty and stent to one week after you are discharged from hospital.

4. **Study Procedures:** Renee Trotter (principal researcher) will visit you before your procedure, within 18 hours after your PCI procedure and will telephone you one week after you are discharged from hospital. This visit will take approximately 10 minutes.

5. **Access to Medical Records:** Your medical records will be accessed for socio-demographic and procedural data. The information obtained will be de-identified and strict confidentially will be maintained.

6. **Risk Associated with Study Participation:** Possible adverse effects or risks related to the study are unlikely. If you are identified to be at risk of stress, Renee will ask your permission to contact the cardiac case manager who will contact you and coordinate appropriate support services.

7. **Benefits Associated with Study Participation:** The results of this study may or may not be of direct benefit to by medical management.

8. **Voluntary Participation and Withdrawal:** Your participation is voluntary and you are free to withdrawal at any time without your medical care or legal rights being affected.

9. **Confidentiality:** Anonymous information about you will be collected, analysed, reported, and transferred to others for research purposes. All information arising from the questionnaires and questions will be treated confidentially.

10. **Cost of Participation:** Participation in this project will not result in any extra medical or hospital costs.

11. **Ethics Approval:** Approval has been given by the Sydney Adventist Hospital Ethics Committee and the University of Technology Sydney Human Research Ethics Committee.

12. **Questions or Concerns:** If you have any questions or concerns about this research study, you can contact the Principal Researcher or the Research Supervisor. If you have any concerns in relation to your rights as a participant in the research study you may contact the Ethics Committee Secretary or the University of Technology Sydney (UTS) Research Ethics Officer.

Principal Researcher
Renee Trotter
Telephone:
Email: renee.trotter@uts.edu.au

Research Supervisor
Dr Robyn Gallagher
Telephone: (02)9514 5746
Email: robyn.gallagher@uts.edu.au

Ethics Committee Secretary
Dr Tom Ludowici
Telephone: (02)9487 9111
Email: Toml@sah.org.au

Research Ethics Officer UTS
Ms Louise Abrams
Telephone: (02) 9514 9615
Email: louise.abrams@uts.edu

Appendix G: Data Collection Sheet

ANXIETY AND PCI DATA COLLECTION SHEET

Pre-Procedure Assessment

Code No: **Date:**_____

Age:_____years **Gender**: Male ☐ Female ☐

DEMOGRAPHIC DETAILS: (Patient Questions)

Employment Status:

Employed ☐ Unemployed but seeking work ☐ Unemployed and not seeking work ☐

Living Arrangement: Lives alone ☐ With partner ☐ With Family or Carer ☐

Marital Status: Married ☐ Widowed ☐ Co-habitate ☐

Divorced ☐ Single ☐ Separated ☐

Education Level: _____ years

Cardiac History: New diagnosis ☐ CABGS ☐ UAP ☐ Other ☐

Previous PCI ☐ Previous Stent ☐ most recent:

Co-morbidities: DM ☐ Backpain ☐ Arthritis ☐ Resp ☐

OSA ☐ Renal ☐

Risk Factors: Hypertension ☐ Smoker ☐ ACS (+CE /Trop) ☐

Drug therapy: Are you taking medications for anxiety and depression? (List)

Audit chart for medications for anxiety and depression (List)

(Check on medical record)

STAI ☐ **FAS** ☐ (order administered) FAS Score: 1 2 3 4 5

Comments about the FAS (use patients words)

Thank-you for helping me with the questions. . I would like you to take a moment and think about what would be causing you the most anxiety / worry at the moment? (use patients words)

Have you been experiencing and pain, discomfort or different sensations in your upper body? (List)

POST PROCEDURALDATA: (4-18 hrs post) **Code No:**

STAI (two copies)

Consultant Visit: ☐ (ask patient)

STAI ☐ FAS ☐ (order administered) FAS Score: 1 2 3 4 5

Thank-you for helping me with the questions. . I would like you to take a moment and think about what would be causing you the most anxiety / worry at the moment? (use patients words)

Have you been experiencing any pain, discomfort or different sensations in your upper body during or since your angioplasty or stent? (List)

Check details for one week from today (fill in tracking sheet)

Telephone No:

Appropriate time and date to contact:

PROCEDURAL DATA: (Obtained from MR)

Time of Assessment post PCI (hours):

Interview delayed: Post Procedure Complications ☐ Staffing ☐ T2>2000 ☐

Time Case	Time Waiting	Premed Valium	No. . of Vessels Stented	No. . of Stents	> TIMI2 flow	Ca2+ blockers
	Start	Yes / No			Yes / No	Yes / No

Analgesia	Arrhythmia	Complications
Yes / No List:_____ _____	VT SVT AF Bradycardia	Yes / No AMI Post PCI ☐ Arterial site ☐ Vasovagal ☐ Other _____ ☐

DISCHARGE DATA:

(one week post Discharge after PCI **Code No:**

Planned

Actual date contacted:_____ (range 5-10 days)

Re-hospitalisation □ GP Visit □ Visit ED □

STAI □

Thank you for helping me with the questions. I would like you to take a moment and think about what would be causing you the most anxiety / worry at the moment?

(use patients' words)

Have you been experiencing any pain, discomfort or different sensations in you upper body recently (List)

What do you think nursing staff could to help patients like yourself manage anxiety at any time during your angioplasty and stent and your recovery? (Suggestions)

Drug therapy: Are you taking medications for anxiety and depression? (List)