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Assessment of limb perfusion by measurement of toe temperatures with a skin probe in patients with intraaortic balloon pumps

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Assessment of Limb

Perfusion by Measurement

of Toe Temperatures

With a Skin Probe in

Patients with Intraaortic

Balloon Pumps.

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Assessment of Limb Perfusion by Measurement of Toe Temperatures With a Skin Probe in Patients with Intraaortic Balloon Pumps.

By

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Abstract

Assessment of peripheral perfusion is one of the most important aspects of care associated with nursing patients receiving intraaortic balloon pump (IABP) therapy. The validity of traditional methods of assessing peripheral perfusion based on colour, warmth, circulatory return, and quality of pedal pulses has been questioned because of their subjective nature. Consequently, there is a need to identify a reliable quantitative method of monitoring peripheral perfusion in patients with IABPs. Measurement of toe temperatures by use of a skin probe has long been established as a reliable quantitative indicator of the state of lower limb perfusion in critically ill patients other than those with IABPs. To date the use of a skin probe to measure toe temperatures in patients with IABPs has not been described in the literature. This prospective study used a descriptive and correlational design to describe characteristic toe temperatures in bilateral limbs of patients receiving IABP support and to examine the relationship between toe temperatures in the presence and absence of the intraaortic balloon catheter (IABC) and in the presence and absence of ischemic changes in the lower limbs. The relationship between toe temperatures and nurses' conventional assessments of peripheral perfusion was also examined. The sample consisted of 30 critically ill adult patients with IABPs in the intensive care unit of a large metropolitan hospital. Skin temperatures were recorded whilst the IABP was in situ and for 24 hours following its removal. Results showed a wide variation in means and ranges of toe temperatures within and between patients. When differences between mean toe temperatures of catheterized limbs and non-catheterized limbs, and catheterized limbs with and without the IABC were compared, results indicated that the

presence of the IABC lowered mean toe temperatures significantly (p < .001), but the temperature differences between means were small (<3°C). Mean toe temperatures of limbs when showing signs of impending ischemia were significantly lower than when such signs were absent (p < .001), with a temperature difference of >3°C. There was consistency between toe temperatures recorded by skin probe and nurses' assessments of peripheral perfusion, in that higher mean toe temperatures corresponded to observations which indicated normal perfusion than poor perfusion (p < .001). However, the skin temperature probe was found to be more sensitive in detecting small changes than were nurses in their estimations of changes in colour and temperature by touch. From this study it is concluded that a difference in mean toe temperatures of ≥3°C corresponds to signs of impending ischemia, and that the presence of the IABC alone did not contribute significantly to any ischemic changes in this sample of patients. Although nurses' qualitative observations were reliable in predicting impending signs of ischemia, the results of this study suggest that toe temperature measurement by use of a skin probe is a simple, convenient and reliable adjunct to the assessment of peripheral perfusion in adult patients receiving IABP support.

Declaration

I certify that this thesis does not incorporate, without acknowledgment, any material previously submitted for a degree or diploma in any institution of higher education and that, to the best of my knowledge and belief, it does not contain any material previously published or written by another person except where due reference is made in the text.

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Chapter One

Introduction

Background and Significance

The intraaortic balloon pump (IABP) is an invasive circulatory device used to aid the failing left ventricle and prevent myocardial ischemia. The cylindrical-shaped balloon, mounted on a catheter which is connected to a pump console, is usually inserted through a femoral artery and advanced into the descending thoracic aorta. The aim is for the balloon to inflate during diastole to increase myocardial oxygenation, and to deflate just before systole to decrease cardiac workload (Funk, Gleason & Foell,1989).

The IABP was introduced into clinical practice in 1967 to treat cardiogenic shock (Kantrowitz et al., 1968). Technical advances such as percutaneous, rather than surgical insertion, and increasing therapeutic use, have led to expanded application in a wide variety of patients. For example, it has now become a commonly accepted tool in the management of unstable angina, in haemodynamically compromised conditions associated with acute myocardial infarction, and in cardiac surgery.

The use of the IABP is not without risks. The most commonly cited complication of IABP therapy is ischemia of the catheterized limb (Chenevey & Sexton-Stone, 1985), with incidence rates of up to 47% having been reported (Funk et al.,1989). This condition is an acute emergency and if undetected and untreated could lead to loss of the affected limb. Intervention in the early stages is essential.

Critical care nurses, as primary care-givers to patients supported by the IABP, have a key role in detecting and minimising vascular

complications by performing accurate nursing observations of limb perfusion. Traditionally, nurses' observations of peripheral perfusion have consisted of visual estimations of colour, assessment of temperature by touch, assessment of circulatory return (CR) and quality of pedal pulses by palpation, and assessment of movement and sensation of the extremities. More recently, a Doppler machine which uses ultrasound waves to transmit audible signals of pulsations to the surface, has become a useful aid in detecting pedal pulses which are faint and difficult to palpate (Durbin, 1983). In the past, nurses' observations of peripheral perfusion have made a valuable contribution to the overall assessment and ongoing management of critically ill patients in the Intensive Care Unit, especially those receiving IABP therapy (Chenevey & Sexton-Stone, 1985). With the advent of increasingly sophisticated equipment and monitoring systems in the ICU, it is especially important that clinical judgements of nurses do not become underestimated. Nursing assessments of peripheral perfusion by observation of colour, warmth, CR, and quality of distal pulses, have however, been faulted because of their qualitative and subjective nature (Fagan,1988).

To avoid the ambiguity of qualitative assessments, the use of quantitative measures to monitor peripheral perfusion, such as skin temperature probes and the ankle/brachial systolic index (ABSI) have been proposed (Funk et al.,1989; Goran, 1989). In clinical practice the use of the ABSI may be an impractical method of monitoring peripheral perfusion in patients receiving IABP support. It is time-consuming and difficult to apply in patients whose leg movements are restrained because of the presence of the Intraaortic baloon catheter (IABC). On the other hand, the application of a skin temperature probe to the great toe is simple, non-invasive, quick and inexpensive (Joly & Weil, 1969).

To date, the use of skin probes to measure temperature of the great toes in the assessment of peripheral perfusion of patients undergoing balloon pump therapy has not been described in the literature, and the effect that the presence of the IABC might have on toe temperatures is not known. Furthermore, the monitoring of toe temperatures by the use of a skin probe is not standard nursing practice in the assessment of peripheral perfusion of adult patients with IABPs. Therefore studies need to be conducted to describe great toe temperatures measured by skin probe, and to determine the relationship between this quantitative method and qualitative nursing observations of peripheral perfusion in patients receiving IABP therapy.

Research Purpose

The purpose of this study is fourfold: to describe characteristic temperatures, measured by skin probe, of the great toes of patients receiving IABP support; to examine the effect of the presence of the IABC on toe temperatures; to determine any differences in toe temperatures when limbs are showing signs of ischemia and when they are not ; and to determine the relationship between measurements of great toe temperatures by use of skin probes, and conventional nursing observations of peripheral perfusion in the lower extremities of patients with an IABP in situ.

Research Questions

The following research questions were designed in order to achieve the study's purpose.
1.   What are the means and ranges of bilateral great toe temperatures, as measured by a skin probe, of patients receiving IABP support?

2. Is there a significant difference between the mean great toe temperatures of catheterized and non-catheterized limbs of patients receiving IABP support?

3. Is there a significant difference between the mean great toe temperatures of the catheterized limbs with the IABC in, and with the IABC out for 24 hours following its removal?

4. Is there a significant difference between the mean great toe temperatures of limbs when they are showing signs of impending ischemia and when they are not?

5. What is the relationship between nurses' conventional assessments of peripheral perfusion and great toe temperatures measured by a skin probe, in the limbs of patients receiving IABP support?

Definition of Terms

The following operational definitions apply throughout the study:

Catheterized limb.

The limb into which the IABC has been inserted, inclusive of the period of time whilst the IABC is in situ and for 24 hours following its removal.

Non-catheterized limb.

The limb without the IABC or contralateral to the IABC insertion.

Percutaneous insertion.

The femoral artery is punctured through the skin surface with a needle and a guide wire is inserted into the needle. The needle is then removed, and the IABC is threaded over the guide wire to its position in

the aorta. Correct positioning is confirmed by use of an Image Intensifier. By using this method, the IABC can be inserted and removed at the bedside.

Surgical insertion.

A surgical incision is made through the skin to expose the femoral artery. The artery is opened, and the IABC is inserted until it reaches the aorta. The IABC is then sutured to the femoral artery. This method requires operating room facilities for both insertion and removal.

Lower limb ischemia.

Lower limb ischemia related to IABP support is defined as the absence of dorsalis pedis (DP) and posterior tibial (PT) pedal pulses as detected by Doppler signals in the catheterized limb when compared with the contralateral limb (Funk et al., 1992). The definition specifies that IABP-related ischemia must be present exclusively in the limb into which the balloon catheter has been inserted and that both pulses must have been detectable prior to the ischemic event.

Signs of impending lower limb ischemia.

These are defined as the appearance of any or all of the following: a cold, blue, mottled, or white distal extremity with a delayed capillary return of greater than four seconds, and or absence of one or more pedal pulses on Doppler (Alvarez, Gates, Rowe & Brady, 1992).

Conventional nursing assessments of peripheral perfusion.

For the purposes of this study these are defined as nurses' observations of the colour, warmth, and CR of the lower extremities; the

quality of pedal pulses by palpation; and the presence or absence of pedal pulses by Doppler signals. Colour was categorised as pink, pale, blue, mottled, white, or "other" to take into account differences that may exist because of ethnicity. Warmth was categorised as warm, cool, or cold to touch. Circulatory return was categorised as normal (≤ 4 seconds), or delayed (> 4 seconds) return of blood flow after the release of finger pressure from the nail bed of the great toe (see Appendix A). Quality of DP and PT pulses was categorised as palpable, present only on Doppler signals, or absent on Doppler signals.

Chapter Two

Literature Review

Introduction

Since studies describing quantitative and qualitative methods of assessing peripheral perfusion in patients receiving IABP support could not be found in the literature, this chapter critiques research related to the assessment of peripheral perfusion in critically ill patients without IABPs.

Numerous studies have demonstrated that lower limb ischemia is a common vascular complication of IABP therapy (Alvarez et al., 1992; Chenevey & Sexton-Stone, 1985; Funk et al., 1989; Hedenmark, Ahn, Henze, Nystrom, Svedjeholm & Tyden, 1988; Iverson et al., 1987). In patients with an IABP, this ischemia is directly related to vascular compromise due to the presence of a relatively large diameter catheter in the femoral artery. The catheter causes partial occlusion of the blood flow and decreases peripheral perfusion in the catheterized limb (Funk et al.,1989).

The importance of accurate assessment of peripheral perfusion for the early detection of lower limb ischemia in patients receiving IABP therapy is well documented (Chenevey & Sexton-Stone, 1985; Conry & Bies,1985; Funk et al., 1992; Funk et al.,1989; Goran, 1989). These authors contend that changes in colour, warmth, CR, and quality of pedal pulses may indicate ischemic changes. Early detection of these changes may enable interventions to be carried out which can prevent a limb from developing permanent ischemic damage.

Simple conventional clinical assessments of peripheral perfusion, such as feeling for the presence and quality of pedal pulses, the warmth of the skin to touch, observing the colour of the skin, and palpating for

capillary return, are, however, largely subjective in nature. Any minute changes in peripheral perfusion may not be detectable by an individual assessor's touch.

Objective methods of assessing peripheral perfusion, such as the ABSI, calf and thigh measurements, or intra-compartmental pressures, have been used in clinical practice. These, however, may be impractical and time consuming in patients receiving IABP support. Measurement of the great toe temperature by skin probe, on the other hand, is a simple, reliable, quick, and non-invasive method of monitoring peripheral perfusion. Clinical application of the measurement of the great toe temperature as a reliable quantitative indicator of peripheral perfusion in patients with shock has been reported since the 1960s (Brock, Skinner & Manders, 1975; Henning, R. J., Wiener, F., Valdes, S., & Weil, M. H. 1979; Ibsen, 1967; Joly & Weil, 1969; Ross, Brock & Aynsley-Green, 1969). These authors advocate the great toe as the most convenient site for skin temperature monitoring because of its negligible local heat production, its distal location in the body, and its remote location from other monitoring devices. Yet despite evidence in the literature of the convenience and reliability of great toe skin temperature monitoring in critically ill patients, no studies could be found which describe the clinical application of the measurement of toe temperature in patients receiving IABP support.

In this literature review, evidence to support the significance of the present study will be grouped into the following areas: simple conventional clinical assessments of peripheral perfusion; alternative methods of monitoring peripheral perfusion; toe temperature studies; and the relationship between toe temperature measurements and nurses' assessments of peripheral perfusion.

<u>Simple Conventional Clinical Assessments of Peripheral Perfusion</u>

Clinical assessments of peripheral perfusion can provide valuable information about the cardiovascular status of the patient in relation to vasoconstriction (Brock et al., 1975), hypovolaemia (Ibsen, 1967), and local blood flow (Jansson, Thomsen & Elfstrom, 1987). With the increasing tendency to rely on technological equipment in the critical care area, clinical assessment of peripheral perfusion, such as observations of colour, warmth, movement, sensation, quality of pedal pulses and CR must remain a dominant feature of patient care. There is no substitute for precise and accurate clinical observations.

There are, however, several problems related to the use of simple conventional clinical methods of monitoring peripheral perfusion, and these are discussed below.

<u>Colour</u>.

The assessment of colour of an extremity is reliant on the individual assessor's perception, and is difficult to judge in people of dark-skinned races, or in dimmed or artificial lighting.

<u>Warmth</u>.

The assessment of the temperature by touch has several disadvantages. Firstly, only gross changes in the skin temperature may be detected (Matthews, Meade & Evans, 1974b). Secondly, assessment may depend upon which part of the hand the assessor uses to feel the extremity (palmar or dorsal surface). In clinical practice this has been found to vary according to the preference of the individual practitioner.

Movement and sensation.

Although changes in sensation or limb movement may indicate the onset of ischemic changes, correct assessment requires cooperation from the patient. This is not always possible in a critically ill patient requiring IABP support who is unconscious, ventilated and sedated.

Palpation of pulses.

Confirmation of the presence and the quality of pedal pulses is again variable between assessors depending on the sensitivity of their finger tips, and level of experience as practitioners. The only true definitive method of confirming the presence of pedal pulses is by Doppler ultrasound signals. Loss of pedal pulses, however, is a late sign of limb ischemia (Chenevey & Sexton-Stone, 1985).

Circulatory return (CR).

The assessment of capillary return is presumed to be an easily obtained non-invasive measure of a patient's peripheral perfusion. In clinical practice, capillary refill time is difficult to assess in patients whose extremities are already blanched, pale, cool and vasoconstricted. A non-experimentally derived upper limit of two seconds for normal capillary refill time has been quoted in the literature (Champion, Sacco & Carnazzo, 1980). Experimental evidence, however, from one study casts doubt upon this assumption (Schriger & Baraff, 1988). These two researchers measured capillary refill times in 100 children, 104 adults, and 100 elderly healthy volunteers. Capillary refill times were measured at the distal phalynx of the middle and index fingers of these volunteers before and after a one minute immersion of the fingers in cold water at 14 degrees Celsius. The results of the study indicated that capillary refill times varied

with age, sex, and temperature. The upper limit of normal, measured as the lowest time that included 95% of the volunteers, was 1.9 seconds for children and adult men, 2.9 seconds for adult women, and 4.5 seconds for the elderly patients. Pre-immersion capillary refill times were found to be significantly shorter than post-immersion times (median = 2.9, p < . 01). As a result of these findings, the researchers suggested that the upper limit of normal for capillary refill times should be changed to these experimentally derived parameters in the respective populations. Because capillary refill varies greatly with temperature, however, the researchers questioned its validity and reliability in clinical practice.

Further studies would be required to determine whether the parameters identified by Schriger and Baraff (1988) could be considered as normal when measured at the great toes of critically ill patients with IABPs. Also required is information to determine whether there are variations in capillary refill at different great toe temperatures.

Thus, simple conventional methods of assessing peripheral perfusion rely on environmental conditions and the individual assessor's experience, perception, and sensation of touch. Variabilities between different observers may make these conventional methods unreliable. These methods of assessing peripheral perfusion must, therefore, be validated and quantified in clinical practice and improvements sought if necessary. There is little written about how this may be achieved.

Alternative Methods of Monitoring Peripheral Perfusion

Alternative methods which attempt to quantify the assessment of peripheral perfusion include: the ankle/brachial systolic index (ABSI); calf diameter measurements; and intra-compartmental pressure measurements.

The ankle/brachial systolic index (ABSI).

The ABSI involves the use of a blood pressure cuff, and a Doppler probe to obtain and compare the systolic blood pressure of the lower extremity with that of the upper extremity so that a pressure ratio can be calculated. This provides a standardised index of the relationship between the pressures which can be compared over time. An ankle/arm index of below 1.0 is considered abnormal (Yao, Hobbs & Irvine, 1969). The amount by which the index is less than 1.0 is a rough estimate of the degree of occlusive disease in the lower limb (Massey, 1986).

The ABSI has been found to be a reliable quantitative measure of the presence of arterial occlusion in patients who have undergone vascular reconstruction surgery, such as aorto-femoral bypass grafts (Yao et al., 1969; Corson et al., 1978). It is also useful in detecting the presence and extent of peripheral vascular disease (PVD) (Massey, 1986); and in the long-term follow-up of limb blood flow in the lower limbs of patients who have required IABP insertions (Felix, Barsamian & Silverman, 1982).

The use of the ABSI for the non-invasive evaluation of arterial occlusive disease prior to IABC insertion has also been proposed (Loebl, Pomajzl, Platt, Mills & Baue, 1981). However, in view of the urgency in which most IABCs are inserted, this may be an impractical proposition. Furthermore, in the author's experience, recording of the ABSI whilst the IABP is in situ is a time consuming process and difficult to perform in patients whose catheterized limb may be splinted to prevent flexion at the groin or knee.

Calf and thigh measurements.

Calf or thigh diameters and an increase in muscle tension may
constitute early signs of impending limb ischemia (Conry & Bies, 1885).
Differences in diameters and changes in muscle tenseness may occur
well before there is loss of pedal pulses (Conry & Bies,1985). Therefore
measurement of calf or thigh diameters should be a valuable indicator of
impaired limb blood flow. However, measurements may vary depending
on the degree of tension which is applied to the tape measure by each
assessor. Palpation of a muscle compartment depends on accurate
comparison with adjacent muscle groups, and is a crude indicator of
increased muscle intra-compartmental pressure (Glenville, Crockett &
Bennet, 1986). Validation of these methods of measurement in the
assessment of peripheral perfusion could not be found in the literature.

Intra-compartmental pressure measurement.

The only true quantified measurement of intra-compartmental
pressure requires the insertion of a needle or catheter into the suspect
muscle compartment and attachment of the needle to a pressure
transducer or manometer (Glenville et al., 1986). Given the invasive
nature of this procedure, it is not considered a feasible option for routine
clinical assessment.

In summary, since the reviewed quantitative methods of assessing
peripheral perfusion may be invasive, cumbersome, time consuming, or
unreliable in patients with IABPs, nurses must continue to monitor
peripheral perfusion by conventional means of touch and observation.
These conventional observations therefore need to be validated as to
their degree of reliability in patients receiving IABP support in which the
assessment of peripheral perfusion is of vital importance.

Toe Temperature Studies

Whilst the reviewed methods of assessing peripheral perfusion are either subjective and unreliable, or cumbersome and invasive, the use of a skin probe for monitoring toe temperatures is a quick, simple, and non-invasive technique. In their study of peripheral and central temperatures of patients following cardiac surgery, Brock et al. (1975) stated that "it should no longer be sufficient to judge what is happening to the skin temperature by touch of the hand" (p. 589), and proposed that advantage should be taken of the exact information that can be provided by sensitive skin probes. The technique of measuring toe temperatures by use of a skin probe in patients who have IABPs, however, is rarely practiced.

Experimental evidence has shown a close correlation between digital temperatures and blood flow (Felder, Russ, Montgomery & Horwitz, 1954; Stoner et al., 1991). These researchers measured finger and toe temperatures by use of surface skin probes, and found that digital skin temperature depends on three factors: (a) the ambient or environmental temperature to which the digit is exposed, (b) the blood temperature, and (c) the blood flow. Under experimental conditions, where factors one and two can be controlled, the digital blood flow per unit of time can be quantified solely from the digital temperature. For clinical purposes, the blood flow to the digit is essentially an indication of the degree of patency (constriction versus vasodilatation) of its vessels and the pressure of the circulation to it (Brock et al.,1975). It would appear that the significance of the relationship between digital temperature and blood flow is that cutaneous vasoconstriction and small changes in skin temperature occur early when tissue perfusion is altered, and therefore may serve as an early predictor of impending limb ischemia (Vincent, Moraine & van der

Linden, 1988). Studies to indicate whether these temperature changes precede or happen simultaneously with changes in other peripheral perfusion variables such as capillary refill, or loss of pulses, could not be found. The toe is preferred to the thumb for monitoring of digital skin temperatures, as it is more convenient for the patient and registers the state of circulation with maximum sensitivity (Ibsen, 1967; Joly & Weil, 1969).

Since peripheral temperature depends on the ambient temperature, the blood temperature and the blood flow, most temperature studies have attempted to derive a quantitative assessment of peripheral perfusion by considering these variables. Thus toe temperature studies have used one of three methods to quantify assessment of peripheral perfusion: (a) the peripheral to core temperature gradient; (b) the temperature gradient between the toe and the ambient temperature; and (c) a direct toe temperature measurement. This review of toe temperature studies will critique the research according to which of the three methods was used.

Studies of peripheral to core temperature gradients.

In 1967, Ibsen reported his results measuring the thumb, great toe, and rectal temperatures of 150 adult patients suffering from all forms of shock (excluding cardiogenic shock). These patients were placed in rooms of an ICU which were specially designed to provide a constant environmental temperature. Any changes in skin temperature could therefore only be the result of a change in the patients' condition. Ibsen found that during vasoconstriction, due to shock or the administration of vasopressors, a 20°C difference between the rectal and big toe skin temperature occurred. When vasodilatation was achieved (in this study by the administration of chlorpromazine or fluids) the haemodynamic

condition was characterised by a difference between the great toe temperature and rectal temperature of only 3 - 4°C. Ibsen concluded that temperatures measured in the rectum and on the skin of the great toe provided a guide to the proper intravenous administration of fluids in patients suffering from shock. Ibsen also pointed out that since the thumb warms before the toe, temperature changes in the toe reflect total body changes more accurately than elsewhere.

Kholoussy, Sufian, Pavlides and Matsumoto (1980) evaluated the use of measuring the peripheral to central temperature gradient in the management of a group of 65 adult patients following multiple trauma (9 patients) and major and complicated abdominal surgery (56 patients). A skin surface temperature probe, taped to the lateral aspect of the great toes, and a rectal probe were used to measure peripheral and central temperatures respectively. The ambient temperature of the ICU/Trauma Unit was relatively stable at 21 - 25°C, and therefore considered to have no significant effect on the peripheral vascular response. A rectal temperature of 36.8 - 37.6°C, and a rectal to toe temperature gradient of 3 - 4°C was considered as normal in this series. Rectal and toe temperatures, together with other simultaneously measured parameters (pulse, blood pressure, central venous pressure, pulmonary artery wedge pressure, and urine output), were gathered for each patient in order to compare and correlate them with the clinical progress. The researchers found that attainment of a normal rectal to toe temperature gradient consistently coincided with haemodynamic stabilisation of the patient, as indicated by other simultaneously measured parameters and by the patient's clinical condition. In contrast to Matthews, Meade and Evans (1974a), who found a consistent toe temperature warm-up pattern in adult patients following cardiac surgery (this study is discussed below),

Kholousy, Sufian, Pavlides, and Matsumoto (1980) found that there was no consistency, either in the time during which the toe temperature remained subnormal, or in the time to reach normal from the start of the increase. Each temperature curve reflected the haemodynamic state of the particular patient. Abnormal changes in rectal to toe temperature gradients (as high as 14.6°C) occurred in cases of hypovolaemia, heart failure, pain, agitation and abnormal ventilation. Correction of the underlying condition resulted in return of the gradient to normal in survivors, whilst in those who died, the rectal to toe temperature gradient gradually and progressively increased. The authors concluded that the central to peripheral temperature gradient accurately reflected the state of peripheral circulation and served as an early warning sign of deterioration in these groups of critically ill patients.

In contrast, several other investigators found poor correlations between peripheral to core temperature gradients and cardiac index, and therefore concluded that the peripheral to core temperature gradient was a poor indicator of haemodynamic status in critically ill patients (Bailey, Levy, Kopel, Tobia & Grabenkort, 1990; Ryan & Soder, 1989; Sommers, Stevenson, Hamlin & Ivey,1995; Woods, Wilkins, Edwards, Martin & Faragher, 1987).

Sommers et al. (1995) found no significant correlation at an alpha level of .05 between peripheral to core temperature gradients and cardiac index in a sample of 21 adult patients studied in the immediate period following cardiac surgery. These researchers maintained that the presence of PVD may decrease the responsiveness of superficial surfaces of the skin and superficial blood vessels to changes in central blood flow, and therefore may influence the correlation with cardiac output.

In a similar study of 40 adult patients during the immediate 24 hour period following cardiac surgery, Bailey et al. (1990) found no discernible correlation between the peripheral to core temperature gradient and cardiac index. These researchers postulated that the reason for the poor correlation is that most patients after cardiac surgery return to the ICU in a hypothermic state. The appropriate physiological response needed to increase core temperature is active thermoregulation via cutaneous vasoconstriction. This has the effect of uncoupling blood flow from overall cardiac output. In the same study, however, a significant correlation was found between the peripheral to core temperature gradient and cardiac index in 20 patients during the first post-operative day ($r = -.60$, $n = 113$, $p < .001$). The investigators maintained that once thermo- equilibrium had been achieved, the effect of overall cardiac output on extremity perfusion is reestablished.

The reviewed studies have provided conflicting evidence of the value of the peripheral to core temperature gradient as a reliable predictor of the haemodynamic status of critically ill patients.

Studies of the gradient between the toe and ambient temperature.
The temperature gradient between the ventral surface of the first toe and the ambient temperature, (referred to as the toe minus ambient temperature gradient) was compared with established haemodynamic measurements, such as blood pressure and cardiac index, in 71 critically ill adult patients without IABPs, by Henning et al. (1979). Of the 71 critically ill patients, 32 had acute myocardial infarctions, 21 had a primary bacteraemia, and 18 had primary hypovolaemia following acute blood loss. Patients who improved after treatment and survived, had increases in the toe minus ambient temperature gradient of more than 4°C, whereas

a gradient of less than 3°C over an interval of 12 hours was typically observed in patients who subsequently died. The results showed that the temperature gradient was a significantly better predictor of survival or fatality than either arterial pressure or cardiac index in each group of patients. The authors concluded that the toe temperature minus ambient temperature gradient provides a valuable, inexpensive and non-invasive monitor of tissue perfusion in adult critically ill patients.

A similar study was carried out by Vincent et al. (1988) who found a significant correlation between the toe minus ambient temperature and conventional haemodynamic parameters (mean arterial blood pressure, cardiac index, and systemic vascular resistance) measured in a group of 15 adult patients being managed for cardiogenic shock (no IABP was inserted).

The above two studies demonstrate the value of the toe minus ambient temperature gradient as a predictor of peripheral perfusion in critically ill adult patients. Toe minus ambient temperature measurements, however, are only necessary where it is difficult to control the environmental temperature. Where the environmental temperature is stable, for example in most modern ICUs, this approach has no advantage over simple skin temperature measurements.

Direct toe temperature measurement studies.

Direct toe temperature measurements are simpler and safer than the above temperature gradient methods, and are equally valuable predictors of peripheral perfusion.

In a study by Joly and Weil (1969) the peripheral skin temperatures of 100 adult patients who presented with clinical signs of circulatory shock were analysed. Skin temperatures were measured, using thermistor

probes, at four different sites: the digital pad of the third finger, the great toe, the deltoid region of the arm, and the lateral portion of the thigh. The recorded temperatures were compared with the patients' cardiac output. Of the four sites, great toe temperatures were found to have the most significant correlation with cardiac output and therefore provided the best indication of changes in blood flow. Joly and Weil (1969) also found that if the direct toe temperature remained at less than 27°C for three hours or longer this was highly prognostic of death.

Matthews et al. (1974a) measured toe temperatures of 148 adult patients who had undergone cardio-pulmonary bypass (CPB). Surface temperature probes were applied to the plantar surface of the patients' great toes. Control of the ambient temperature was achieved by keeping the limbs covered with blankets. The principal finding to emerge from this study was that peripheral warm-up after open-heart surgery is not a random event. Eighty-one of the 148 patients (55%) warmed in a remarkably similar manner despite all the variables that might have theoretically affected the pattern such as length of time on bypass, age, and blood lactate levels. The normal restoration of the peripheral circulation, (defined in this series as a great toe temperature of 34°C or more) was reached within 6.5 hours if the patients were breathing spontaneously, and within eight hours if they were on a ventilator. The researchers found that the temperature curves of the remaining sixty patients in the series who did not show a typical warm-up pattern, had been modified by drugs such as isoprenaline, lignocaine (48 cases), or by an episode of peripheral cooling (causes were not specified) after the warm-up had begun but before it was complete (12 cases).

The precise limits of warm-up defined by Matthews et al. (1974a) may only apply to adults operated on and cared for in that particular ICU.

Its validity in other Units where different techniques may be employed during or after operation remains to be investigated. Matthews et al. (1974a), however, maintained that in any cardiac surgical unit where there is an established routine, there will be an equally constant warm-up pattern in patients with a normal circulation following cardiac surgery.

In a further study by the same researchers (Matthews et al.,1974b), abnormally prolonged peripheral cooling was detected in 15 (11.5%) of 131 adult patients during the period following CPB. Eight of the 15 patients died, representing an increased mortality from 6% (in patients who had demonstrated a normal warm-up pattern) to 53%. A detectable pathological cause was discovered in all of the 15 cases, and in seven of the 15, the abnormal temperature pattern was the first or only evidence of a circulatory disorder. The researchers concluded that since toe temperature measurements give early warning of potentially serious pathological processes and provide a sensitive index of the effectiveness or otherwise of therapeutic interventions in adults who have undergone cardiac surgery, they should be an indispensable part of routine post-operative care. This statement was later verified by Crew, Stoodley, Naghdy and Unsworth (1984) who found that skin temperature (measured at the dorsum of the foot), mean arterial pressure, and urine output reliably reflected the cardiovascular status of groups of adult patients following cardiac surgery.

Toe temperature warm-up patterns have been found to be accurate predictors of survival in paediatric patients following cardiac surgery. Kirklin et al. (1981) found that pedal skin temperature, and the strength of pedal pulses, most accurately predicted in-hospital deaths in infants under 3 months who had undergone intra-cardiac surgery. Later Alexi-Meskhishvili, Popov and Nikoljuk (1984) found skin temperature to be a

reliable criterion in evaluating the adequacy of the central and peripheral circulations in the post-operative haemodynamics of infants with congenital heart disease. These researchers concluded that toe temperature measurement is a useful, inexpensive, and non-invasive addition to established monitoring following open-heart surgery in paediatric populations.

Findings in the literature therefore support the significance of direct toe temperature measurement as a reliable clinical parameter of circulatory failure in groups of critically ill adults without IABPs, and in paediatric patients. Most of the previous studies, however, relate the peripheral skin temperature with the body's compensatory vasoconstrictive responses to circulatory failure, and not to any localized lower limb ischemic events. Very little research could be found which evaluates the use of peripheral skin temperatures in the assessment of local blood flow to the lower limbs, and there are no studies specifically on patients receiving IABP therapy.

In 1987, however, Jansson et al., and later Thomsen and Elfstrom (1988) evaluated the efficacy of post-operative bilateral ankle skin temperature as a predictor of graft patency in patients who had femoro-popliteal bypass surgery. The difference between ipsilateral and contralateral ankle temperatures was found to be significantly greater in the patients with patent grafts than in those with occluded grafts, indicating that the limb with the successful graft had significantly improved perfusion. In the latter study, ankle temperature was found to be reliable in predicting graft patency, with an overall accuracy prediction of 89%.

Despite the fact that the IABP has been used in clinical practice since 1968 as a mechanical device designed to aid the failing hea cardiogenic shock (Kantrowitz et al., 1968), the value of measuring

bilateral toe temperatures in patients with IABPs has not been studied. Therefore the research question of how the presence of the catheter may affect toe temperatures in the catheterized limb has not been addressed. The assumption is that small changes in the toe temperature of the catheterized limb in comparison to the contralateral limb may indicate developing limb ischemia due to the presence of the catheter. To date, there have been no published reports which describe typical toe temperature patterns or the clinical application of the measurement of toe temperatures by skin probe in patients receiving IABP support.

The Relationship between Great Toe Temperatures and Nurses' Assessments of Peripheral Perfusion

Only one study could be found which attempted to quantify nurses' observations of peripheral perfusion. This is a study by Fagan (1988), who examined the relationship between toe temperatures measured by skin probe, and two peripheral perfusion assessment scales. The two scales were used separately: one by the regular bedside nurses, and the other by a group of trained observers. The nurses used a nominal scale consisting of a choice of three subjective statements for the assessment of each of the following: quality of peripheral pulses, lower extremity warmth, and capillary refill. The trained observers used a semi-quantitative, ordinal data five-point scale for the assessment of the same categories. Fagan found both scales to be accurate when compared to toe temperatures measured by the skin probe.

There are, however, several limitations to this study. It was a small study using only 17 paediatric patients who had undergone cardiac surgery (IABPs not inserted), and therefore the results cannot be generalized to adult populations. Since the scales were used separately

by the two observer groups, and a cross-over design was not conducted, the reliability of the more specific five-point scale when used by regular staff was not evaluated. Furthermore, since the study does not define any normal values for great toe temperatures against which to assess the accuracy of the nurses' observations, true relationships between the two scales and toe temperatures as measured by skin probe, may not have been discovered.

In summary, attempts to quantify nurses' subjective assessments of peripheral perfusion, and to establish a relationship between these and the measurement of great toe temperatures by skin probe, have so far been inconclusive, and furthermore, have not been researched in patients receiving IABP therapy. Alternative quantitative methods of assessing peripheral perfusion, such as the ABSI, calf/thigh measurements, and intra-compartmental pressure measurements, are cumbersome, time-consuming, and invasive in patients with IABPs. Studies investigating the value of peripheral to temperature gradients have produced conflicting evidence of their value in predicting haemodynamic status. Previous studies have, however, shown that the measurement of lower limb skin temperature can be a reliable and useful quantitative indicator of circulatory failure in groups of critically ill patients, in adult and paediatric patients following cardiac surgery, and in determining graft patency after femoro-popliteal bypass surgery. None of the critiqued studies, however, refer to patients with IABPs.

Research Focus

In conclusion, there is a lack of studies which investigate the monitoring of the great toe temperature by use of a skin probe in adult patients receiving IABP support. In order to fill this gap in nursing

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Ignored

research, this study sought to determine the characteristic toe temperatures in bilateral limbs of patients with IABPs, the effect of the presence of the IABC on toe temperatures, and temperature changes occurring in the toes of patients who develop limb ischemia. The relationship between measurements of great toe temperatures by use of skin probes and conventional nursing observations of peripheral perfusion in the lower extremities of patients with IABPs was also examined.

Chapter Three
Conceptual Framework

The conceptual framework for this research is based on Betty Neuman's Systems Model (Neuman, 1989). This model views people as open systems in constant interaction with the environment and focuses on the reactions of an individual to environmental stressors.

The client system (or person) is conceptualised as having a central core of survival factors protected by a flexible line of defence, a normal line of defence, and lines of resistance (see Figure 1 below). Illness is seen to occur when stressors, such as insertion of an IABC, penetrate the lines of defence. If the client system's lines of resistance (homeostatic mechanisms) are unable to maintain stability, or overcome any mechanical trauma caused by the IABC, then complications such as limb ischemia may occur.

Whilst attaining and maintaining client system stability, the critical care nurse is primarily concerned with watching for, and detecting the onset of ischemic changes in the limbs. According to Neuman, this would involve three steps. Firstly, the nurse must acquire an appropriate data base that identifies various client risk factors and helps to predict how the client system will interact with environmental stressors. Secondly, the nurse is responsible for assessment of the client system's ability to maintain equilibrium, which in reference to the care of a patient receiving IABP therapy, involves making careful observations of lower limb perfusion. Thirdly, if complications occur, the nurse intervenes to prevent invasion of the client system's central core. For example, the nurse collaborates with medical staff to remove the IABC sheath, remove the IABC entirely or prepare for an operative intervention.

The Flow Chart (Figure 1) illustrates how the concepts underlying the Neuman Systems Model are related to components of this study. As can be noted on the Flow Chart, the operational components form the foundation from which the research questions have been formulated and each relates to a physiological and theoretical concept within the conceptual framework.

Several assumptions arise from the conceptual framework. Firstly, measurement of means and ranges of toe temperatures by use of a skin probe may establish normal baseline parameters for patients with IABPs and help nurses to recognise normal and abnormal patterns. Secondly, comparison of toe temperatures in the presence and absence of the IABC and in the presence and absence of ischemic changes will determine the effect of the IABC on toe temperatures and altered limb perfusion. Thirdly, the use of the skin temperature probe may help nurses to detect signs of limb ischemia early in the chain of events leading to penetration of the core system. Early detection and intervention may then prevent complications from occurring.

Theoretical Concepts	Physiological Concepts	Operational Components	Analysis Methods	Assumptions
Stressor	IABC insertion	Means and ranges of toe temperatures of bilateral limbs	Descriptive	Baseline parameters from which to recognize normal patterns
Lines of defence broken	Altered limb perfusion	Toe temperatures in presence and absence of IABC	Descriptive and Correlational	Presence of IABC may lower toe temperatures and alter perfusion
Lines of resistance breached	Clinical signs of impending limb ischemia: - abnormal temperature, colour delayed CR, diminished pulses	Toe temperatures in presence and absence of impending ischemia. Nurses' qualitative observations of peripheral perfusion	Descriptive and Correlational	Use of skin probe thermometer for measuring toe temperatures and knowledge of changes in temperatures will alert nurses to signs of impending limb ischemia.
Core System penetrated	Limb ischemia with threat to loss of limb	Collaborative nursing and medical interventions: - removal of IABC - removal of sheath - vascular surgery	Descriptive	Early detection and intervention to prevent complications
Illness, disability or death		Prevention of complications		

IABC = Intraaortic Balloon Catheter
CR = Circulatory Return

Figure 1. Flow Chart Illustrating the Conceptual Framework, based on The Neuman Systems Model by B. Neuman, (2nd.ed.), 1989.

Chapter Four

Methodology

This chapter identifies the research design used in the study and describes the sample and setting, access to the sample, and ethical considerations. The instruments used for data collection are described and discussed in terms of their validity and reliability. Data collection procedures are outlined including patient recruitment, the role of the Researcher or Shift Coordinator of the ICU and the role of the ICU bedside nurses.

The Design

This was a prospective study consisting of two design components - descriptive and correlational.

The descriptive component was considered appropriate because no previous data could be found which describes normal means and ranges of great toe temperatures in patients receiving IABP support. In this component of the study bilateral great toe temperatures were measured by skin probes attached to the ventral surfaces of bilateral great toes in a sample of patients receiving IABP support. Great toe temperatures were recorded during the course of the IABP therapy and for twenty four hours following removal of the IABP.

A correlational component was included in order to determine any differences between toe temperatures of the catheterized and the non-catheterized limbs, of catheterized limbs with the IABC in and the IABC out, and of limbs when signs of ischemia were absent or present. The correlational component of the study was also used to examine the

relationship between toe temperatures recorded by the skin probes and nurses' conventional methods of assessing peripheral perfusion such as palpation of pedal pulses, assessment of colour, warmth and CR in the lower limbs of patients receiving IABP support.

<u>Setting and Sample</u>

The study was carried out over a six month period in a 12-bed adult cardio-thoracic ICU of a large metropolitan teaching hospital in Western Australia. Between April 1994 and October 1994, a total of 37 patients admitted to the ICU required IABP support. During this 6 month period, all patients requiring IABP support were considered eligible for inclusion in the study if they were over 18 years of age, and if the IABP had been inserted either percutaneously or surgically via the right or left femoral artery.

The sample consisted of 30 patients who met these criteria. The remaining seven patients were excluded for the following reasons: one patient refused to give consent, three patients died before data collection was completed and consent was obtained, two patients had a ventricular assist device <u>in situ</u> which precluded the availability of a temperature recording slot on the bedside monitor, and one patient had the IABP inserted via a transthoracic approach. The patients' ages ranged between 54 and 83, with a mean age of 70 years. Thirteen (43%) were female, and 17 (57%) were male. Twenty - nine patients were Caucasian, and one was Asian.

All patients in the sample had percutaneous insertions of a Datascope 9.5 Fr. Percor Stat, Dual Lumen, 40 cc, Intra-Aortic Balloon Catheter (Datascope B. V. Hoevelaken, Holland).Twenty - two (73%) of the patients had the "sheathed", and eight (27%) had the "unsheathed"

types of IABC inserted. Seven (23%) of the patients had the IABC inserted into the same limb from which the saphenous vein had been harvested during cardiac surgery; twenty (67%) had the IABC inserted into the opposite limb; and three (10%) had not required removal of their saphenous veins. The presence or absence of palpable pedal pulses prior to IABP insertion was documented in the medical or nursing records of 23(77%) of the 30 patients in the study.

Thirteen (43%) of the patients had the IABP inserted prior to cardio-thoracic surgery. These included: critical left anterior descending coronary artery stenosis (four patients); severe mitral regurgitation (one patient); severely depressed left ventricular function (three patients); unstable angina pectoris (two patients); pulmonary hypertension (one patient);and a dissected left main coronary artery during angioplasty (one patient). Fifteen (50%) of the patients had the IABP inserted during cardiac surgery for the following reasons: failure to wean off cardio-pulmonary bypass (13 patients); pulmonary hypertension (one patient); pulmonary oedema with left ventricular failure (one patient). Two patients had the IABP inserted post cardiac surgery after return to the ICU: one for severe coronary artery spasm as evidenced by gross ST segment elevation on the ECG; and the other for post-operative myocardial infarction with ischemic changes on the ECG.

In this sample, the length of time that the IABC remained in situ varied from five hours to 99 hours. There were three complications related directly to IABP therapy. One patient developed limb ischemia as defined in this study as "the absence on Doppler of previously palpable DP and PT pedal pulses in the limb with the IABC". This patient required premature removal of the IABC after only five hours in situ. The IABC

ruptured in two patients, which also necessitated urgent removal of the IABCs.

All patients had the IABC removed in the ICU by direct traction and then application of a pressure clamp in order to control the bleeding. The length of time that the clamp was applied varied from a minimum of thirty to a maximum of ninety minutes.

Instruments

The research instruments consisted of skin temperature probes and data collection sheets. All temperatures were measured in degrees Celsius (°C).

Skin temperature probes.

A thermistor skin probe (Y.S.I. 1200, Yellow Springs Instrument Company, Yellow Springs, Ohio 45387, USA) was attached to both great toes of patients receiving IABP support and then connected to the bedside monitor (Siemens Sirecust 1281, Siemens Medical Electronics Inc., Denvers, MA 01923, USA). A continuous digital recording of the bilateral great toe temperatures was displayed on the monitor for the duration that the skin probes were attached. The information could be stored in the memory of the monitor for 24 hours. A print-out of toe temperatures was obtained by accessing the trend mode at any convenient time within this 24 hour period.

Data collection sheets.

Since no previous studies disclosed any suitable data collection sheets, these were specifically developed by the researcher for the purposes of this study, and were consistent with observation charts already used in the ICU for the monitoring of peripheral perfusion.

There were two data collection sheets used in the study: a Nurses' Assessment Sheet (colour coded green), and a Toe Temperature Recording Sheet (colour coded pink). These are described below:

The Nurses' Assessment Sheet (Appendix B) was used by the bedside nurses caring for the patients with IABP and consisted of four sections.

Section One was used to record patients' baseline data such as: (a) demographic details - age ,sex, ethnicity; (b) the date and time of IABP insertion; (c) the reason for insertion; (d) the method of insertion (percutaneous or surgical); (e) the site of insertion (right or left femoral artery); (f) the catheter size and type (sheathed or unsheathed); (g) the presence of palpable pedal pulses pre- IABP insertion; and (h) whether any saphenous vein graphs had been removed from the catheterized limb during cardiac surgery. The catheter size was documented because catheter dimensions may affect perfusion in some patients (Iverson et al.,1987). The purpose of the sheath is to aid introduction of the IABC into the femoral artery. The presence of the sheath, however, widens the lumen of the IABC, and may compromise blood flow (Phillips et al., 1992). A sheathless IABC may therefore be preferred for patients with pre-existing PVD. The presence of palpable pedal pulses prior to IABP insertion was recorded so that any subsequent absence of a pedal pulse would not be falsely attributed to the presence of the IABC, and to help in the diagnosis of any pre-existing PVD. Finally the limb from which saphenous veins were removed was documented because removal of saphenous veins may also affect lower limb blood flow (Chenevey & Sexton-Stone, 1985).

Section Two was used to record the core temperature, the room temperature, and nurses' conventional assessments of peripheral

perfusion such as the quality of the pedal pulses, the colour, warmth, and CR of the lower limbs of patients with IABP in situ. These observations were recorded hourly whilst the IABP was in situ and for 24 hours following its removal (as per this ICU's protocol for IABP patients). Observations of core temperature and room temperature were recorded in order to detect wide fluctuations which may affect the toe temperature recordings.

Section Three was used to record the occurrence of limb ischemia and the interventions. This information was considered necessary in order to describe any changes in toe temperatures which may have occurred if complications had arisen, and as interventions to treat them were administered. In the context of this study, limb ischemia is defined as "the absence on Doppler of previously detected DP and PT pedal pulses in the limb with the IABC". Clinical signs of impending limb ischemia include coldness, pallor, blueness or mottling, with decreased capillary return and/or absent palpable pedal pulses in the affected extremity.

Section Four was used to record details about the removal of the IABP, namely: method of removal, type of pressure (manual or clamp) and the duration of pressure. These details were documented since they are factors which may provoke ischemic events and subsequent temperature changes in the big toes of the catheterized limb.

The Toe Temperature Recording Sheet (Appendix C) was used by the researcher or, in her absence, by the Shift Coordinators of the ICU to collect hourly recordings of the bilateral toe temperatures from the Siemens monitor.

Validity and Reliability

Reliability of the temperature probes.

Accuracy of the temperature probes was achieved by placing each thermistor probe separately into cold water at 15°C and then into hot water at 40°C , and calibrating it against a glass general purpose thermometer to an accuracy of 0.1°C. Calibration is certified by the Medical Electronics Department of the hospital twice yearly according to hospital policy.

Core temperature was measured from the thermistor port of the pulmonary artery catheter lying in the pulmonary artery of the patient. In the ICU in which the study was undertaken, pulmonary artery catheters are routinely inserted in all patients who may require an IABP. The core temperature was recorded continuously on a bedside monitor which is also calibrated by Medical Electronics Department at six monthly intervals according to hospital policy.

In this ICU, the environmental temperature is controlled thermostatically within a range of 22 to 24°C. In order to confirm that gross fluctuations in the ambient (environmental) temperature did not occur, the room temperature was recorded from a glass mercury wall thermometer placed close to the patient's bed whilst the skin probes were in place.

Content validity of the data collection sheets.

Content validity was established by a panel of ICU experts (two ICU Clinical Nurse Specialists, two ICU Medical Consultants, and two experienced ICU Clinical Nurses). These experts were asked to read the data collection sheets and accompanying protocols and to evaluate their content. As a result of the panel's advice, the normal CR time was

extended from an original ≤ two seconds, to ≤ four seconds. A CR time of two seconds was considered to be an unrealistic expectation in this population of patients, many of whom are peripherally cool and vaso-constricted after cardiac surgery, and may suffer from pre-existing PVD. All of these factors may affect CR time (Schriger & Baraff,1988).

An amendment was also made in the categories for assessing peripheral pulses where the researcher had originally included four categories: "palpable", "not palpable", "present only on Doppler", and "absent on Doppler". The panel considered that "not palpable" and "present only on Doppler" were identical alternatives. The category "not palpable" was therefore eliminated, reducing the categories in this section from four to three.

Prior to commencement of the main study, a pilot study of five patients was undertaken in order to determine the clarity of each data collection sheet, whether the format was appropriate, and if any categories needed to be added or modified.

After using the instruments during the pilot study no further adjustments were made and the patients were therefore included in the main study.

Concurrent validity.

Concurrent validity of the data collection sheets was not established since no existing instruments could be found which would have been relevant for use in this study.

Inter-Observer Reliability.

In order to investigate inter-observer reliability of the bedside nurses' qualitative assessments of peripheral perfusion (colour, warmth,

presence of pulses, and CR), the researcher's own observations were compared with 20 different bedside nurses' observations (four nurses during the pilot study involving two patients, and 16 nurses during the main study involving 16 patients).

Phi coefficients with an alpha level of .05 were chosen to correlate the data. The 20 coefficients ranged between 0.40825 and 1.0000. Sixteen of these were significant ($p < .05$), and 13 were perfect at 1.0000. These results indicate that there was good inter-observer reliability between nurses in this study and the researcher.

The Procedure

Education and quality control.

Training of ICU staff was undertaken by the researcher over a period of four weeks prior to the commencement of the Pilot Study. During this period 10 training sessions of 30 minutes duration were held for groups of between 6 - 12 nurses according to a pre-arranged timetable drawn up in conjunction with the ICU Staff Development Nurses. The timetable was displayed on the Staff Education Notice Board. During day time shifts the sessions were conducted during the afternoon overlap period in order to ensure that a maximum number of nurses were able to leave the bedside to attend. Two training sessions were held for permanent night staff prior to commencement of their shifts. In addition, the researcher conducted training on an individual basis for nurses who were unable to attend the formal group sessions. Copies of the research data collection sheets and protocols were displayed on the Staff Information Notice Board for the duration of the study.

Quality control of data collection was ensured by the researcher, or by the two ICU Clinical Nurse Specialists supervising data collection and

checking that the research protocols were adhered to by bedside nurses and ICU Shift Coordinators.

The ward communication book was regularly used by the researcher to document how the study was progressing and to express gratitude to the ICU nurses and Shift Coordinators for their ongoing support and assistance. In addition, regular progress reports were given by the researcher to the ICU staff at monthly General Staff Meetings.

Patient recruitment.

The collection of data for this study was spread over a six month period. Within this period, information was collected on the status of lower limb perfusion of all patients meeting the inclusion criteria, and observations were commenced within one hour after insertion of the IABP, or after returning to the ICU from the operating theatre with an IABP in situ.

The researcher or the ICU Shift Coordinators and the ICU nurses caring for the patient undergoing IABP therapy were responsible for recording the data.

Role of the researcher or shift coordinator.

The researcher or Shift Coordinator was responsible for attaching the skin temperature probes to both great toes according to the research protocol (Appendix D).

The protocol for the application of the skin temperature probes was based on that described by Joly and Weil (1969), and later as used by Henning, et al. (1979). The flat surface of the thermistor probe was placed onto the plantar (under surface) of the great toe and covered with a 2 cm by 2 cm piece of waterproof adhesive tape.

This protective covering was used in order to prevent heat loss and to maintain an evenly saturated environment, since fluctuations in humidity may affect temperature (Henning et al., 1979; Joly & Weil, 1969). The temperature probes were then secured to the bottom of the feet with a strip of adhesive tape. The probes were connected to the Siemens monitor on which a continuous digital recording of the toe temperatures was displayed. The display slot was covered with masking tape so that the bedside nurses remained unaware of the toe temperatures whilst collecting data about the status of peripheral perfusion of patients with an IABP. The rationale for this was to avoid any bias that knowledge of skin probe temperatures may unwittingly incur. Since information is saved on the Siemens monitor for up to a period of 24 hours, the Shift Coordinators or researcher were able to collect and document the hourly toe temperatures at a convenient time towards the end of their shift.

In the researcher's absence, the Shift Coordinators also issued the data collection sheets, guide-lines, and protocols to the bedside nurses, and collected data for Sections One, Three, and Four of the Nurses' Assessment Sheet. These data were obtained from the medical and nursing records or directly from medical and nursing personnel involved with initiation and on-going management of IABP therapy.

Role of the bedside nurses.

The bedside nurses were asked to record the core temperature, the peripheral pulses, the colour, warmth and CR of the lower extremities, and the room temperature hourly on Section two of the data sheet, both whilst the IABP was in situ, and for 24 hours following its removal, or until discharge of the patient to the ward (whichever occurred first, according to standard ICU protocol).

The patient's core temperature was obtained by attaching the thermistor port of a pulmonary artery catheter (a routine insertion in any patient receiving IABP) to the Siemens monitor. This was then documented hourly from the continuous digital display.

The nurses performed hourly palpations of the bilateral DP and PT pulses, and recorded these by choosing one of the following codes: 1 = palpable, 2 = present only on Doppler, 3 = absent on Doppler.

The nurses assessed the colour of both feet each hour by choosing one of the following: 1 = pink, 2 = pale, 3 = blue, 4 = mottled, 5 = white, 6 = other (that is, ethnic variation).

Whilst remaining unaware of the actual toe temperatures measured by skin probes, the nurses felt the patients' feet hourly and assessed the temperature according to the following codes: 1 = warm, 2 = cool, 3 = cold, 4 = other.

Nurses assessed the CR hourly by choosing either a delayed return (1 = greater than four seconds), or a normal return (2 = less than, or equal to four seconds).

A written protocol (see Appendix A) for assessing CR, based on that described by Schriger and Baraff (1988), was attached to each Data Collection Sheet.

Environmental temperature was recorded by the bedside nurses hourly from a mercury glass room thermometer hanging in a convenient position close to the foot of the bed. The room temperature was recorded in order to monitor any gross variations. The patients' toes were protected from minor changes in ambient temperature by covering them lightly and evenly with a cellular blanket (as recommended by Fagan, 1988).

All completed data collection sheets were placed in a posting box marked "IABP Research", housed in a prominent position in ICU, to await

collection by the researcher. Additional Data Collection Sheets were available adjacent to the posting box for easy access to data collectors.

Access to the Sample and Ethical Considerations

Written approval to conduct the study was obtained from the Committee for the Conduct of Ethical Research, Edith Cowan University; the Hospital's Nursing Research Review Committee and Ethics Committee; and the Medical Director of the ICU. Verbal permission and assistance were also sought from the two Clinical Nurse Specialists of the Intensive Care Unit.

Since insertion of an IABP is rarely an elective procedure, the Ethics Committees of the two Institutions gave approval for retrospective consent (that is, consent gained after commencement or completion of the data collection) to be obtained from the patients, or their representatives. The decision to obtain retrospective consent, as an appropriate alternative when prior consent could not be obtained, was based on the following premises. An IABP is generally inserted urgently at a time when the patient may be critically ill and/or unconscious. Furthermore, since it may not always be possible to anticipate which patients will require an IABP during cardiac surgery, it was considered that to gain consent from all patients prior to surgery may provoke unnecessary anxiety in the majority. Also, since the study did not involve any risks or discomfort to patients or their families, and did not involve any invasive procedures, it was considered appropriate to attach the skin probes and commence observations of peripheral perfusion prior to consent being obtained.

Retrospective consent (Appendix E) was sought when the patients were sufficiently alert and able to read and understand the information sheet (Appendix F). This procedure complies with the National Health and

Medical Research Council's Statement on Human Experimentation (Supplementary Notes for Unconscious and Critically Ill Patients, 1992, p.10).

Prior consent was able to be obtained from two patients recruited to the study, and retrospective consent was obtained from the remainder. The time at which consent was obtained varied from patient to patient. Most consents were obtained after the IABP had been removed, but whilst the patient was still in the ICU (27 patients). A minority of consents were obtained after the patients had been discharged to the cardio-thoracic ward (three patients).

For those patients subsequently refusing to proceed with the study, the data were destroyed, and only the code numbers, age, sex, and reason for IABP insertion was retained by the researcher. Confidentiality of data was maintained throughout the study with information being secured in a locked drawer, accessible only to the researcher. During data analysis, anonymity of participants was achieved by utilising a coding system for computer analysis. A list containing the participants' names and corresponding code numbers was kept in a locked drawer separate from the data collection sheets.

Chapter Five
<u>Results</u>

This chapter outlines the results of the study under the headings of the research questions.

The first section describes the means and ranges of great toe temperatures recorded by skin probes attached to patients receiving IABP support. The second section discusses the results of t - tests used to compute the differences between the means of toe temperatures in the catheterized and non-catheterized limbs. The third section discusses the results of t - tests used to compute the differences between the mean toe temperatures of the catheterized limbs when the IABC is in and when the IABC is out. The fourth section discusses mean toe temperatures of patients when signs of impending ischemia in limbs are present or absent. The last section discusses the relationship between mean toe temperatures measured by a skin probe and each category of nurses' conventional assessments of peripheral perfusion, that is: colour (pink, pale, mottled, blue and white), temperature (warm, cool, and cold), quality of pedal pulses (palpable, present on Doppler, and absent on Doppler), and CR (≤ four seconds and > four seconds).

The computer statistics programme SPSS for Windows, Release 6.0, Student Version, (SPSS Inc., 444 North Michigan Avenue, Chicago, Il 6061) was used to analyse the data. An alpha level of .05 was used for all statistical tests.

The bilateral great toe temperatures of all patients were described by calculation of the means. Where the means stood alone as descriptive data, the range was selected as the measure of variance in order to serve

as a clinical reference for nurses. However, when the differences between means were calculated for statistical significance, the measure of variance chosen was the standard deviation. Paired samples t - tests were used to compare the mean toe temperatures of catheterized and non-catheterized limbs. Independent samples t - tests were used to compare mean toe temperatures of catheterized limbs with IABC in and with IABC out, and to compare mean toe temperatures when limbs were showing evidence of ischemia and when they were not. Independent samples t - tests were also used to determine the significance between mean toe temperatures corresponding to each category of nurses' assessments of peripheral perfusion. Where the numbers of observations in each category were very different and Levene's Test for Equality of Variances showed significant differences in variances, t - values for unequal means were chosen to determine statistical significance. Where the numbers of observations in each category were very small (less than 10), a non-parametric t - test (the Wilcoxon Mann - Whitney U Test) was used to determine statistical significance.

The Means and Ranges of Bilateral Great Toe Temperatures

The first research question sought to determine the means and ranges of bilateral great toe temperatures, measured by a skin probe, in patients receiving IABP support. Since the means and ranges of great toe temperatures in adult patients receiving IABP therapy are not known, this research question was designed in order to establish "normal" parameters which may then serve as baselines for further studies and help nurses to recognise abnormal measurements.

The toe temperatures were recorded by the bedside nurses every hour whilst the IABC was in situ and for a period of 24 hours following its

removal, or until the patient was discharged to the ward. This period of time was different for each patient. Thus the number of observations ranged from 27 for Patient 17, to 120 for Patient 2. There was a total of 1806 paired toe temperature observations across all patients. Summary statistics of the means and ranges of toe temperatures in the catheterized and non-catheterized limbs, the differences between the means, and the number of paired toe temperature observations for each of the 30 patients are shown in Appendix G. There is a wide variation in the mean toe temperatures in both limbs across the sample, and within patients. The mean toe temperatures of the catheterized limb varied from 24.33°C in Patient 27, to 33.93°C in Patient 1. The mean toe temperatures of the non-catheterized limb varied from 24.86°C in Patient 27, to 33.84°C in Patient 1.

These data are illustrated graphically in Figure 2 which shows the mean toe temperatures of the catheterized and non-catheterized limbs for the 30 patients in the sample. The mean toe temperatures of the non-catheterized limbs are arranged in ascending order across the 30 patients. This Figure shows that the general trend is for the mean toe temperatures in the catheterized limbs to be lower than those of the non-catheterized limbs.

There was also a wide variation in mean core temperatures both between patients and across the sample (36.59°C in Patient 19 to 38.83°C in Patient 2).

In summary, mean toe temperatures showed wide variation within and between patients, irrespective of the presence of the IABC.
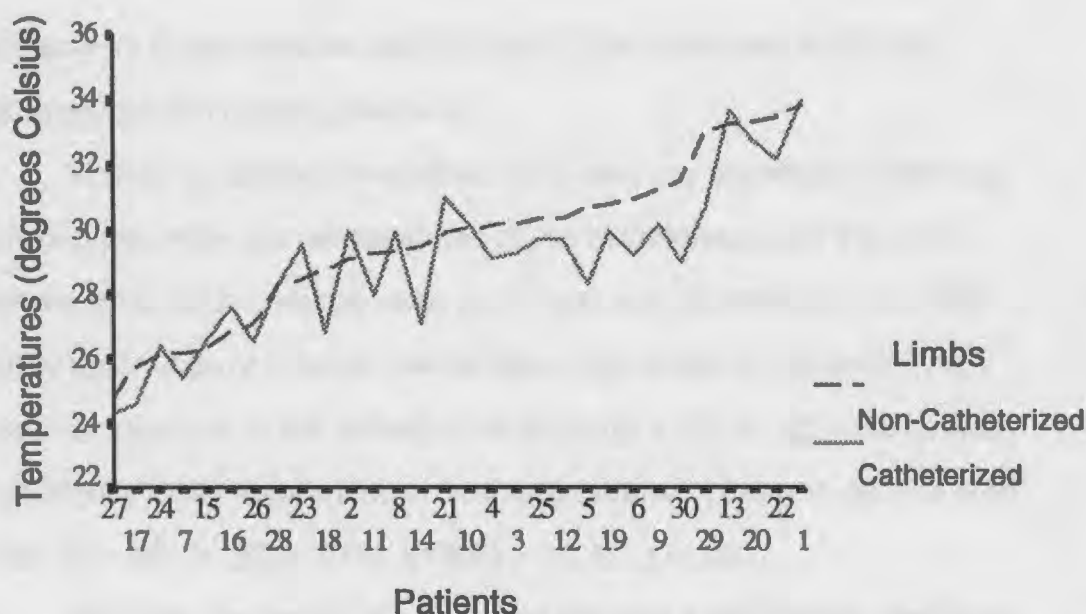
Figure 2. Mean toe temperatures of catheterized and non-catheterized limbs of all 30 patients (temperatures of non-catheterized limbs shown in ascending order).

Differences Between Mean Toe Temperatures of Catheterized and Non-Catheterized Limbs

The second research question asked whether there was any significant difference between the mean toe temperatures of the catheterized and non-catheterized limbs. This research question links with the following one, and was designed in order to determine the effect of the presence of the IABC on toe temperature measurements. In this case, where mean toe temperatures of catheterized and non-catheterized limbs were compared, the non-catheterized limb acted as the control.

Twenty (67%) of the patients had a mean toe temperature in the catheterized limb lower than that of the non-catheterized limb. Ten (33%) of the patients showed the opposite trend, that is, the mean toe

temperature in the catheterized limb was higher than that of the non-catheterized limb (see Appendix G).

In order to determine whether there was any significant difference between the mean toe temperatures of the catheterized and the non-catheterized limbs, a paired samples t - test was performed on the 1806 hourly recordings of bilateral toe temperatures for all 30 patients. The mean temperature of the catheterized limbs (M = 29.24, SD = 3.91), was significantly lower than the mean toe temperature of the non-catheterized limbs (M = 29.79, SD = 3.76), t(1805) = 11.46, p < .001.

Although the results of this t - test showed a statistically significant difference between the two means, the actual difference in mean temperatures was small (0.66°C). Greater temperature differences, however, did exist between the mean toe temperatures of catheterized and non-catheterized limbs in individual patients. In four of the patients, the mean toe temperature of the catheterized limb was more than 2°C lower than the mean toe temperature of the non-catheterized limb (Patients 5, 14, 29, and 30). In those patients having a mean toe temperature in the catheterized limb higher than that in the non-catheterized limb, the difference between the means in all cases was less than 2°C (see Appendix G). Figure 3 illustrates the differences between the mean toe temperatures of the catheterized and non-catheterized limbs in the form of line graphs for Patient 30.

In summary, mean toe temperatures of catheterized limbs were significantly lower than the means of the non-catheterized limbs. Except in four patients, the actual temperature difference between the means, however, was minimal.
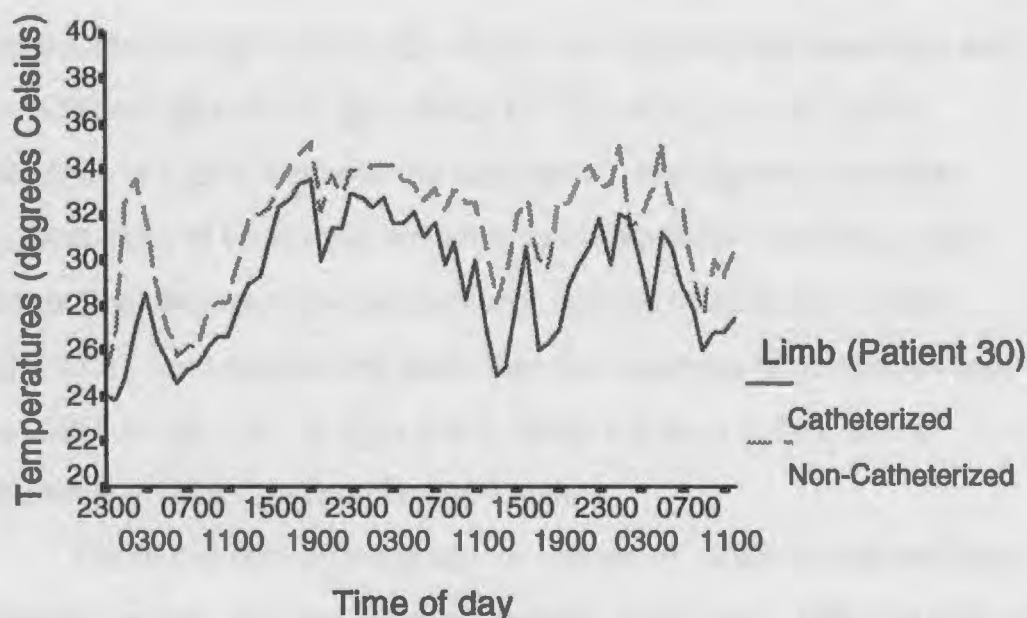
Figure 3. Toe temperatures of catheterized and non-catheterized limbs of Patient 30.

Differences Between Mean Toe Temperatures With IABC In and IABC Out

The third research question asked whether there was a significant difference between the mean great toe temperatures of the catheterized limbs with the IABC in, and for a period of 24 hours following its removal. This research question links with the former one, the purpose of both questions being to determine the effect of the IABC on toe temperature measurements. By comparing the mean toe temperatures with IABC in and IABC out, this research question was designed so that the catheterized limb itself acted as the control.

Differences between the mean toe temperatures of the catheterized limbs with the IABC in and with the IABC out were compared in a group of patients classified as showing impending signs of ischemia, and in a group of patients not showing evidence of ischemia. In the latter group, independent samples t - tests showed that the mean toe temperatures

with the IABC in ($\underline{M}$ = 29.50, $\underline{SD}$ = 3.82) were significantly lower than with the IABC out ($\underline{M}$ = 30.74, $\underline{SD}$ = 3.62), $\underline{t}$(715) = 5.00, $\underline{p}$ < .001, with a difference of 1.24°C between the two means. In the group of patients showing signs of impending ischemia, the independent samples $\underline{t}$ - test showed that the mean toe temperatures with the IABC in ($\underline{M}$ = 27.99, $\underline{SD}$ = 3.68), were significantly lower than the mean toe temperatures with the IABC out ($\underline{M}$ = 29.13, $\underline{SD}$ = 4.13), $\underline{t}$(545) = 3.91, $\underline{p}$ < .001, with a difference of 2.86°C between the two means.

Figure 4 illustrates the graph for Patient 15, which shows the rise in temperature that occurred following removal of the IABC. This was typical for the remainder of the sample.
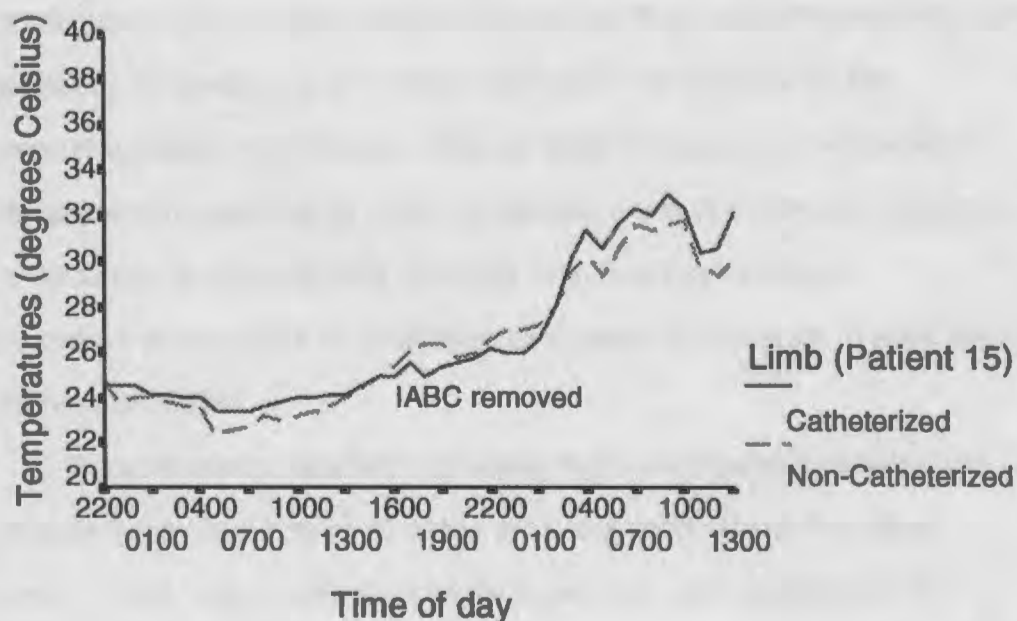
Figure 4. Toe temperatures of catheterized and non-catheterized limbs of Patient 15 showing removal of intra-aortic balloon catheter (IABC).

In summary, results showed that irrespective of whether patients showed signs of impending ischemia or not, the mean toe temperatures with the IABC in were significantly lower ($p < .001$) than the mean toe temperatures following its removal. The actual temperature differences, however, were minimal and the clinical significance of this will be discussed in the next chapter.

Differences Between Mean Toe Temperatures of Limbs in the Presence and Absence of Signs of Impending Ischemia

The fourth research question asked whether there was any significant difference between the mean great toe temperatures of catheterized and non-catheterized limbs when they were showing signs of impending ischemia and when they were not. The purpose of this research question was twofold: firstly to determine any toe temperature changes which occurred as limbs developed signs of impending ischemia, and secondly to establish any clinically significant temperature parameters which might be indicative of impending ischemia in samples of patients with IABPs.

Patients were classified as having signs of impending lower limb ischemia if they had any or all of the following recorded on the data sheets: a cold, blue, mottled, or white lower limb, with a delayed CR greater than four seconds, and or absence of one or more pedal pulses on Doppler.

Fourteen (47%) of the patients showed signs of impending ischemia in the catheterized limbs as defined above. One patient (Patient 17) developed definite ischemia in the catheterized limb, defined in this study as "the absence on Doppler of both previously palpable DP and PT pedal pulses in the same foot". This patient had a mean toe temperature

in the catheterized limb of 23.71°C. This was the lowest mean toe temperature in the catheterized limb for this group of patients who were showing signs of impending ischemia. Eleven of the above 14 patients (37% of the sample) also developed signs of impending ischemia in their non-catheterized limbs. Possible reasons for this are discussed in the next chapter.

In order to determine any significant differences between the mean toe temperatures when limbs were showing signs of ischemia and when they were not, an independent samples t - test was carried out on all the hourly observations of the group of patients classified as developing signs of impending ischemia in their limbs. Results comparing differences in catheterized limbs showed that mean toe temperatures when the limbs were showing signs of impending ischemia (M = 26.39, SD = 3.27) were significantly lower than when they were not (M = 29.65, SD = 3.71), $t(718)$ = 13.09, $p < .001$. Results comparing differences in the non-catheterized limbs showed that mean toe temperatures when limbs were showing signs of impending ischemia (M = 26.68, SD = 3.58) were significantly lower than when they were not (M = 30.06, SD = 3.74), $t(641)$ = 11.25, $p < .001$).The temperature difference between the two means was 3.26°C in the catheterized limbs and 3.38°C in non-catheterized limbs. The clinical significance of this will be discussed in the next chapter.

The Relationship Between Toe Temperatures Measured by Skin Probe, and Nurses' Assessments of Peripheral Perfusion

The fifth research question asked what was the relationship between nurses' conventional assessments of peripheral perfusion and great toe temperatures in the limbs of patients receiving IABP support.

This research question was designed for the following reasons: to determine the relationship between nurses' qualitative assessments of peripheral perfusion and a quantitative method of measuring toe temperature by use of a skin probe; to assist in the validation of nurses' existing methods of assessing peripheral perfusion; and to evaluate the measurement of toe temperatures by use of a skin probe as a useful means of monitoring peripheral perfusion in adult patients with an IABP.

In order to answer this research question, mean toe temperatures and the categories of nursing observations were compared only when the categories were recorded on the data collection sheets as having been present together in the same patient. This was done in order to eliminate differences which may have arisen as a result of individual patient characteristics.

In this section the results are presented according to the four conventional nursing observations of colour, warmth, quality of pedal pulses, and CR.

Toe temperatures and nurses' observations of colour.

Table1 shows the statistical results of t - tests comparing mean toe temperatures of bilateral limbs with colour categories that were recorded as having been present together in the same patients. Table 1 also indicates the differences between the mean toe temperatures that corresponded to one colour category and another, the number of patients and the number of observations. As can be noted on Table 1, the colours "pale" and "pink" occurred together in the catheterized limbs of 16 patients, and in the non-catheterized limbs of 15 patients. The other paired colour categories, however, occurred together in very small numbers of patients.

Table 1

Comparison of Mean Toe Temperatures (°C) and Nurses' Observations of Colour

Category	n (Patients)	n (Observations)	M (SD)	M difference	t (df)	Z
		Catheterized Limbs				
Pink	16	474	32.43 (3.23)	3.85	17.43 (1025)***	
Pale		553	28.58 (3.84)			
Pink	1	10	32.68 (0.38)	5.98		-2.1559*
Mottled		2	26.70 (0.42)			
Pale	2	82	28.78 (3.10)	3.20		-2.5367*
Blue		5	25.58 (1.10)			
Pale	3	90	27.37 (3.34)	2.44	4.93 (129)***	
Mottled		51	24.93 (2.49)			
Pale	1	63	28.99 (1.72)	2.20	3.97 (36)**	
White		27	26.79 (2.65)			
		Non-Catheterized Limbs				
Pink	15	502	32.22 (2.89)	3.20	14.66 (867)***	
Pale		468	29.02 (3.82)			
Pale	1	43	26.99 (2.02)	2.12		-2.4059*
Blue		3	24.87 (0.31)			
Pale	2	52	26.18 (2.79)	1.53	2.90 (99)**	
Mottled		49	24.65 (2.49)			
Pale	1	63	29.12 (1.93)	2.49	5.25 (88)***	
White		27	26.63 (2.36)			

*   p < .05   m = Mean Toe Temperature
**   p < .005
***   p < .001

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The number of observations recorded also varied across the different colour categories. Where the numbers of observations were very small, that is, between the colour categories "pink" and "mottled", and "pale" and "blue" in catheterized limbs, and between "pale" and "blue" in non-catheterized limbs, the Wilcoxon - Mann Whitney U Test was used to compute the statistical significance. For the remaining paired colour categories, the number of observations was considered large enough to use parametric independent samples t - tests. As indicated on Table1 results of both parametric and nonparametric t - tests showed that the differences between means of all colour categories were statistically significant at an alpha level of .05.

As expected, nurses' observations that indicated good perfusion, that is "pink", and "pale", corresponded to higher mean toe temperatures than those colour categories that indicated a gradual deterioration in perfusion of the limb, that is "pale", "mottled", "blue" and "white". In the bilateral limbs of one patient (Patient 28), however, the colour category "white" unexpectedly corresponded to a higher mean toe temperature than did "blue" or "mottled" in bilateral limbs of other patients. The relationship between toe temperatures and the colour categories "white" and "pale" recorded for Patient 28 is illustrated in Figure 5. This patient was being warmed by an electric blanket when toe temperatures were being recorded, which may account for the toe temperatures corresponding to the colour "white" being unusually high.

Figure 5. Comparison between toe temperatures and colour categories in the catheterized limb of Patient 28.

The greatest temperature difference (5.98°C) was found between the colour categories "pink" (a sign of good perfusion) and "mottled" (a sign of poor perfusion) in catheterized limbs. However, these two colour categories occurred together in only one patient in whom the category "mottled" was recorded only twice. Unexpectedly large temperature differences of 3.85°C in catheterized limbs, and 3.20°C in non-catheterized limbs were also found between the colour categories "pink" and "pale". Both these colour categories were considered as signs of normal perfusion. Figure 6 illustrates this trend in the catheterized limb of Patient 6, whereby the nurses' recordings of "pink" (M = 30.97°C, $Range$ = 28.60 - 33.20) corresponded to higher mean toe temperatures than did the recordings of "pale" (M = 27.51oC, $Range$ = 24.00 - 32.00).
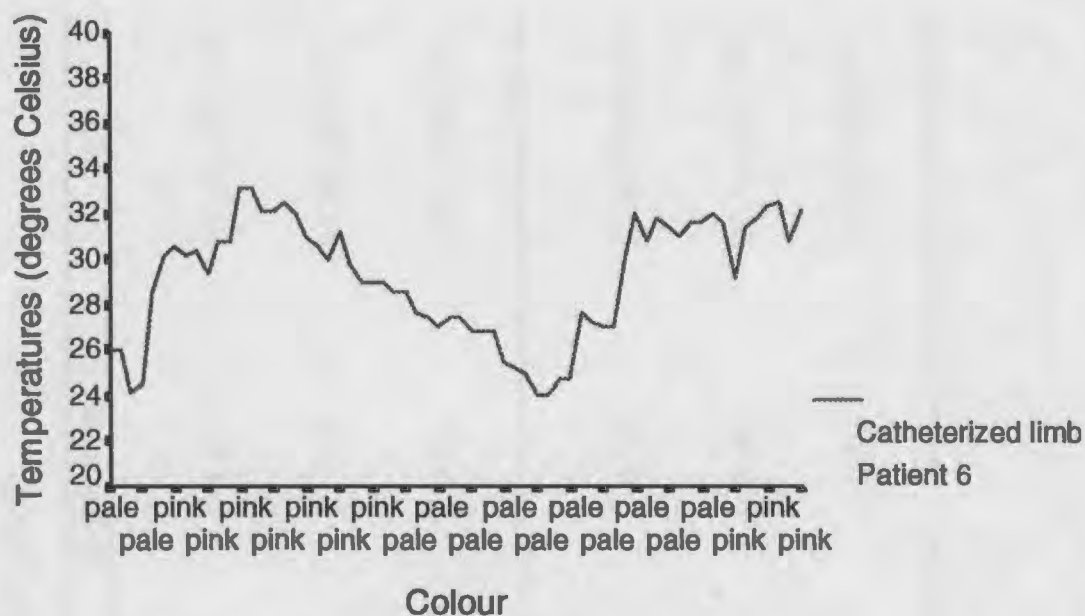
Figure 6. Comparison between toe temperatures and colour categories in the catheterized limb of Patient 6.

In summary results showed that nurses' observations of colour were consistent with expected mean toe temperatures in all colour categories, except for "white". Results of nonparametric and parametric t - tests showed that the differences between the means were all significant at an alpha level of .05. As expected, the greatest toe temperature difference was found between "pink" (indicating normal perfusion), and "mottled" (indicating poor perfusion). However, an unexpectedly large temperature difference was found between two adjacent colour categories "pink" and "pale".

Toe temperatures and nurses' observations by touch.

The statistical results of the differences between mean toe temperatures and nurses' tactile interpretations of the temperature of lower limbs are displayed in Table 2.

Table 2

Comparison of Mean Toe Temperatures (°C) and Nurses' Observations of Temperature by Touch

Category	n (Patients)	n (Observations)	M (SD)	M difference	t (df)
Catheterized Limbs					
Warm Cool	28	958 658	31.53 (3.23) 27.12 (2.92)	4.41	28.59 (1501)***
Warm Cold	13	383 125	31.21 (3.15) 24.62 (1.51)	6.59	31.35 (439)***
Cool Cold	14	384 133	27.18 (2.95) 24.56 (1.49)	2.62	13.21 (450)***
Non-Catheterized Limbs					
Warm Cool	29	1010 633	31.54 (3.03) 27.35 (2.85)	4.19	27.87 (1641)***
Warm Cold	8	223 84	30.63 (2.52) 24.20 (1.41)	6.43	28.14 (261)***
Cool Cold	8	242 84	27.60 (2.90) 24.20 (1.41)	3.40	14.06 (290)***

*** $p < .001$
m = Mean Toe Temperature

The number of observations of each compared touch category was considered large enough to use parametric independent samples t - tests to determine any statistical significance between the means. As indicated on Table 2 results of the independent t - tests showed that the mean toe temperature differences between all compared touch categories were statistically significant at an alpha level of .001. These results indicate that nurses' assessments of temperature by touch in both the catheterized and non-catheterized limbs of patients in this sample, were consistent with the mean toe temperatures, in that nurses' observations of the category "warm" corresponded to higher toe temperatures than did the categories "cool" or "cold".

This trend is illustrated in the catheterized limb of Patient 7 (Figure 7) whereby "warm" corresponded to a mean toe temperature of 30.98°C (Range = 26.80 - 33.40), "cool" corresponded to a mean toe temperature of 24.06°C (Range = 22.40 - 27.20) and "cold" corresponded to a mean toe temperature of 23.29°C (Range = 22.20 - 24.20).

As expected, the greatest temperature differences occurred between the categories "warm" and "cold" (6.59°C in catheterized limbs, and 6.43°C in non-catheterized limbs). As occurred in the colour categories, an unexpectedly large temperature difference (> 4°C) was found in both limbs, between the means of two touch categories ("warm" and "cool") that were classified as signs of normal perfusion in this study.
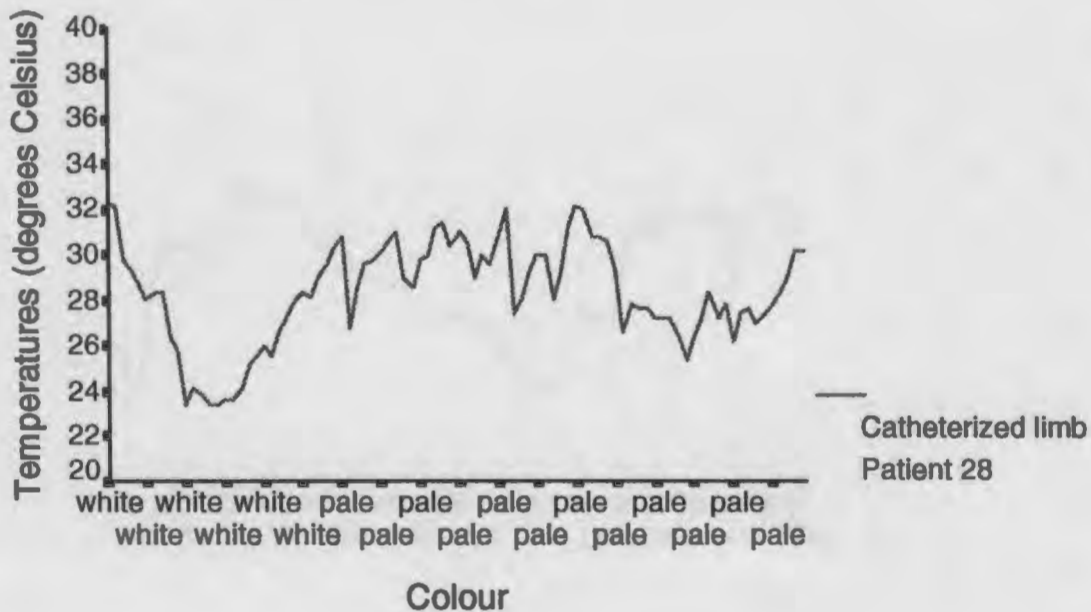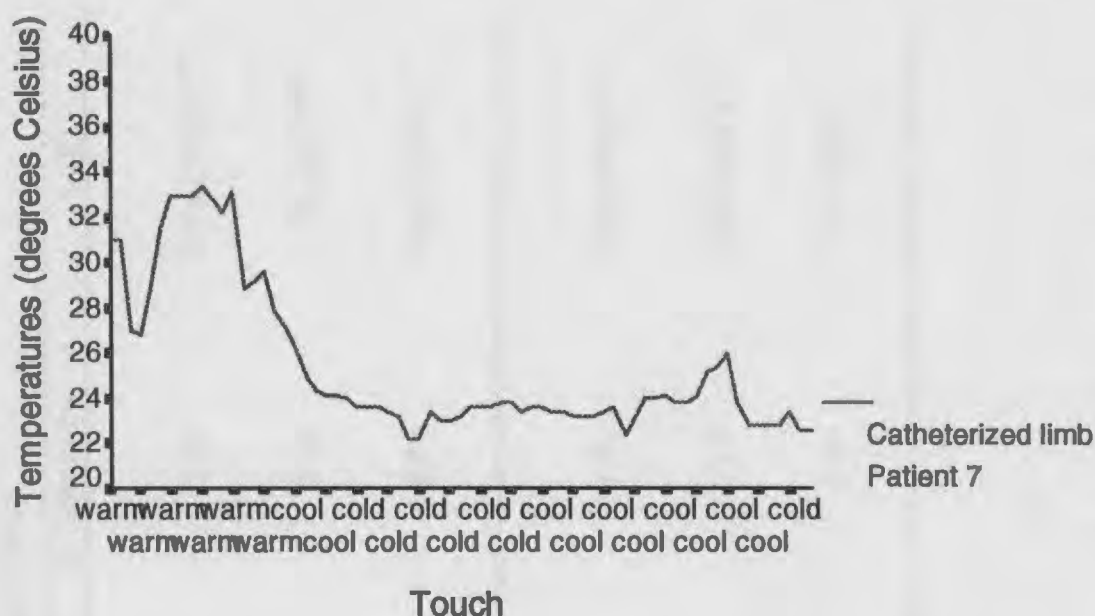
Figure 7. Comparison between toe temperatures and touch categories in the catheterized limb of Patient 7.

Toe temperatures and nurses' observations of pedal pulses.

Tables 3 and 4 show the statistical results of the differences between mean toe temperatures, as measured by skin probe, and nurses' observations of the quality of pedal pulses in the bilateral limbs of patients receiving IABP support.

As with the temperature by touch categories, the numbers of observations for both DP and PT pulses, were considered large enough to use parametric independent samples t - tests in order to determine the statistical significance between the compared means. As indicated on Tables 3 and 4, results of the independent samples t - tests showed that the differences between mean toe temperatures in most paired categories of quality of pedal pulses were significant at an alpha level of .05

Table 3

Comparison of Mean Toe Temperatures (°C) and Nurses' Observations of Dorsalis Pedis Pulses

Category	n (Patients)	n (Observations)	M (SD)	M difference	t (df)
Catheterized Limbs					
Palpable Present on Doppler	19	675 435	29.76 (3.68) 28.89 (3.86)	0.87	3.74 (1108)***
Palpable Absent on Doppler	7	161 88	29.24 (4.01) 26.06 (2.83)	3.18	7.26 (231)***
Present on Doppler Absent on Doppler	10	282 155	28.17 (3.64) 26.10 (3.17)	2.07	5.94 (435)***
Non-Catheterized Limbs					
Palpable Present on Doppler	17	674 353	30.56 (3.30) 28.93 (3.80)	1.63	6.83 (633)***
Palpable Absent on Doppler	7	181 68	30.29 (3.08) 26.52 (2.28)	3.77	8.46 (247)***
Present on Doppler Absent on Doppler	9	247 96	27.17 (3.83) 26.60 (3.52)	0.57	1.27 (341)

*** $p < .001$
m = Mean Toe Temperature

Table 4

Comparison of Mean Toe Temperatures (°C) and Nurses' Observations of Posterior Tibial Pulses

Category	n (Patients)	n (Observations)	M (SD)	M difference	t (df)
Catheterized Limbs					
Palpable Present on Doppler	23	736 629	29.97 (3.76) 28.81 (3.91)	1.16	5.56 (1363)***
Palpable Absent on Doppler	4	106 20	30.31 (4.23) 26.25 (2.86)	4.06	5.35 (37)***
Present on Doppler Absent on Doppler	7	251 53	27.86 (3.79) 26.30 (3.12)	1.56	2.79 (302)*
Non-Catheterized Limbs					
Palpable Present on Doppler	21	706 556	30.57 (3.45) 29.25 (3.85)	1.32	6.34 (1126)***
Palpable Absent on Doppler	3	40 21	31.48 (2.61) 27.52 (3.30)	3.96	5.12 (59)***
Present on Doppler Absent on Doppler	5	190 44	28.14 (4.25) 28.59 (3.54)	0.45	.73 (75)

* $p < .05$

*** $p < .001$

m = Mean Toe Temperature

The exception was the differences between mean toe temperatures in the categories "present on Doppler" and "absent on Doppler" for DP and PT pedal pulses in non-catheterized limbs. In these categories, although the mean toe temperatures were higher for "present on Doppler" than "absent on Doppler", the difference was not significant.

These results indicate that nurses' assessments of the quality of pedal pulses were consistent with mean toe temperatures, in that higher mean toe temperatures corresponded to the categories "palpable", and lower mean toe temperatures corresponded to the categories "present on Doppler" and "absent on Doppler" respectively, in both limbs.

This trend is illustrated in the catheterized limb of Patient 15 (Figure 8) whereby the pulse categories "palpable", "present on Doppler" and "absent on Doppler" corresponded to mean toe temperatures of 31.77 °C (Range = 30.40 - 33.00), 27.72°C (Range = 25.00 - 32.40) and 24.18° C (Range = 23.40 - 25.60) respectively.
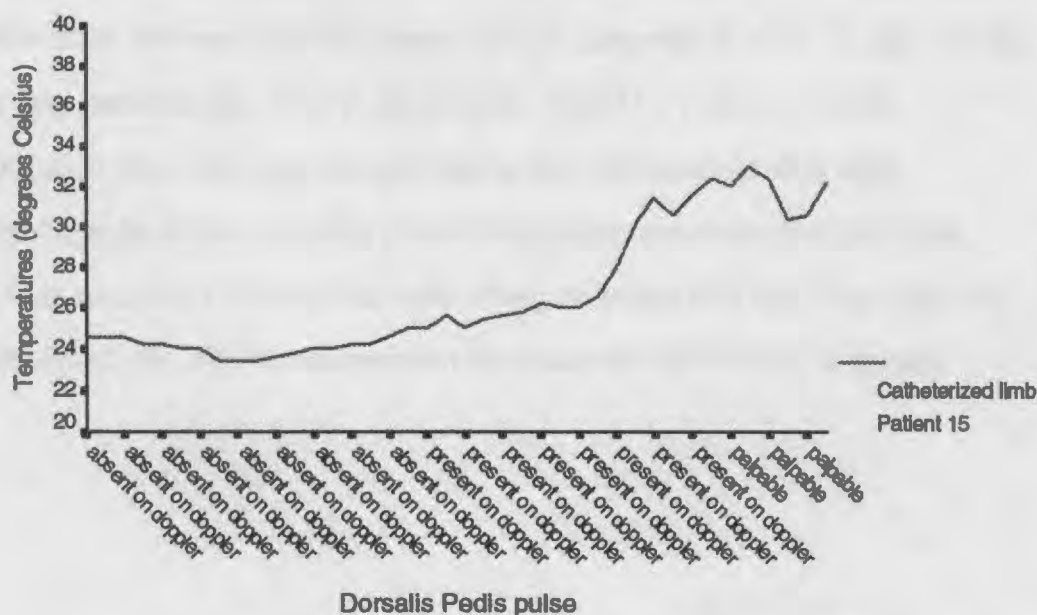
Figure 8. Comparison between toe temperatures and the dorsalis pedis pulse in the catheterized limb of Patient 15.

The greatest mean toe temperature differences occurred between the categories "palpable" and "absent on Doppler" in bilateral limbs. The differences between these categories were 3.18°C (catheterized limbs), and 3.77°C (non-catheterized limbs) for DP pulses, and 4.06°C (catheterized limbs) and 3.96°C (non-catheterized limbs) for the PT pulses.

Toe temperatures and nurses' observations of circulatory return.

Table 5 shows the statistical results comparing mean toe temperatures recorded by the skin probe, and nurses' observations of CR, (either normal, ≤ four seconds, or delayed, >four seconds). Results of independent samples t - tests for catheterized limbs showed that the mean toe temperature corresponding to ≤ four seconds CR (M = 29.46, SD = 3.93) was significantly higher than the mean corresponding to > four seconds (M = 27.59, SD = 3.94), $t(1188)$ = 6.43, p < .001. For non-catheterized limbs, however, there was no significant difference between the two means (≤ four seconds M = 29.17, SD = 3.59), (> four seconds M = 28.71, SD = 4.03), ($t(267)$ = 1.44, p = .150). Although the mean toe temperature in the catheterized limb was significantly higher (p <.001) when the nurses recorded the CR to be ≤ four seconds (normal) than when they recorded it to be > four seconds (delayed), the difference between the means (1.87°C) was minimal.

Table 5

Comparison of Mean Toe Temperatures (°C) and Nurses' Observations of Circulatory Return

Category	n (Patients)	n (Observations)	M (SD)	M difference	t (df)
		Catheterized Limbs			
≤ 4 seconds	19	967	29.46 (3.93)	1.87	- 6.43 (1188)***
> 4 seconds		223	27.59 (3.94)		
		Non-Catheterized Limbs			
≤ 4 seconds	15	730	29.17 (3.59)	0.46	-1.44 (267)
> 4 seconds		187	28.71 (4.02)		

***   p <.001
m = Mean Toe Temperature

In conclusion, nurses' observations of peripheral perfusion, that is, colour, warmth, quality of pedal pulses, and CR, were consistent with mean toe temperatures, measured by skin probe, in the sample of patients in this study who were receiving IABP support. Differences in the mean toe temperatures between all paired assessment categories of peripheral perfusion were similar in catheterized and non-catheterized limbs. The greatest toe temperature differences occurred between means that corresponded to nursing observations that indicated well perfused limbs ("pink" "warm" or "palpable pulses"), when compared with those that indicated clinical signs of ischemia ("mottled", "cold" or "absence of pulses on Doppler").

Summary of Results

Means and ranges of bilateral toe temperatures varied widely both across the whole sample of patients and within patients.

Although the mean toe temperature of catheterized limbs was significantly lower than that of non-catheterized limbs ($p < .001$), the actual temperature difference between the means was negligible (0.66°C). In only four patients was the difference between the means found to be greater than 2°C. Furthermore, contrary to expectations, 10 patients had mean toe temperatures in the catheterized limbs higher than those in the non-catheterized limbs .

The mean toe temperatures of catheterized limbs were significantly lower with the IABC in, than with the IABC out ($p < .001$). This finding applied to all patients irrespective of the presence or absence of impending ischemia. The temperature differences between the means, however, were less than 3°C. The mean toe temperatures of catheterized and non-catheterized limbs which were showing signs of

impending ischemia were significantly lower than when not showing signs of impending ischemia ($p < .001$), and the actual temperature difference was > 3°C. The clinical significance of the differences which were found between toe temperature means in the above results will be discussed in the next chapter.

The relationship between all categories of nurses' observations and toe temperatures measured by a skin probe were consistent. Nurses' observations that indicated signs of poor perfusion corresponded to lower toe temperatures than those observations which indicated good perfusion.

Chapter Six

Discussion

The main aims of the study were to establish normal parameters of toe temperatures in patients receiving IABP support, and to examine the relationship between toe temperatures and the presence of the catheter and toe temperatures and ischemic changes. Another aim of the study was to examine the relationship between toe temperatures and nurses' conventional observations of peripheral perfusion. Since studies describing toe temperatures measured by a skin probe and relating these to nurses' conventional observations of peripheral perfusion in adult patients receiving IABP therapy have not been sighted in the literature, this study may be the first of its kind to examine these issues.

Previous research has established that lower limb ischemia is a common complication of IABP therapy (Adams & Bregman, 1987; Alvarez et al., 1992; Funk et al.,1989). In the context of the conceptual framework of this current study (Neuman, 1989), limb ischemia is viewed as a pathophysiological phenomenon that may occur when the body's lines of defence and resistance are broken, and the core system is penetrated by a precipitating stressor, in this case, the presence of the IABC. This study has linked the operational concepts of the conceptual framework (nurses' qualitative observations of peripheral perfusion) with quantitative measurements (recordings of toe temperatures by a skin probe), and has related these to the physiological concepts of altered blood flow and toe temperature changes. The information arising from the linking of these concepts may help nurses to prevent complications, such as ischemia , loss of limb, disability, or death that may occur as a result of penetration of the body's core system. The importance of this current study, therefore

is its potential to provide quantitative information which may help nurses to detect impending limb ischemia in the population of critically ill patients receiving IABP support.

The following major issues which have arisen from the research questions will be discussed in this section: baseline toe temperatures; the effect of the IABC on toe temperature and blood flow in catheterized limbs; temperature changes which may be considered clinically significant in the prediction of impending ischemia; and the relationship between toe temperatures measured by a skin probe and nurses' conventional observations of peripheral perfusion. This chapter will discuss these major findings under the headings of the research questions. Where appropriate, the findings will be related to the concepts of the theoretical framework. Limitations of the research, implications for nursing practice, and recommendations for further research will also be discussed.

The Means and Ranges of Bilateral Great Toe Temperatures

Since mean toe temperatures in patients receiving IABP therapy have not been described in previous studies, it was considered important to establish baseline parameters of these observations in order to determine changes which may occur due to the presence of the IABC. Toe temperatures have been found to be valuable parameters in the overall assessment of the haemodynamic status of patients in shock, but without IABPs (Brock et al.,1975; Joly & Weil, 1969; Kholoussy et al., 1980). These quantitative observations may have similar value in the assessment of peripheral perfusion in critically ill patients with IABPs.

In the current study, the mean toe temperatures of bilateral limbs were found to vary widely across the sample. These variations may be accounted for by a number of extraneous variables. Since the purpose of

this research was to provide an overall description of toe temperatures across the sample, it was considered beyond the scope of this study to examine the specific effect of each of these variables on individual temperature recordings. Extraneous variables which may have contributed to variations in temperature recordings include: pre-existing factors in a patient's medical history, intra-operative factors, and post-operative factors. According to the theoretical framework for this study, many of these factors may serve as additional "stressors" which, by their very presence, may have already penetrated the body's lines of defence and resistance, making the patient more susceptible to potential complications of IABP therapy.

Pre-existing factors in a patient's medical history include the presence of PVD (Kvilekval et al., 1991; Lewis, Sumida, Hwang & Loeb, 1992); diabetes mellitus (Kantrowitz et al., 1986), or recent smoking habit (Mackenzie et al.,1992). These conditions may alter blood flow to the peripheries and therefore lower the distal skin temperature.

An intra-operative factor which may affect peripheral skin temperature is the length of time the patient remains on cardio-pulmonary bypass (CPB) during cardiac surgery. In this hospital, during CPB the patient's body temperature is therapeutically cooled to <35°C. On return to the ICU it is policy to monitor the patient's core temperature continuously and to cover any patient who has a core of temperature of ≤ 35.5°C with an electric warming blanket until the core temperature reaches 36°C. Five patients in this study required the application of a warming blanket, which may have affected the accuracy of the toe temperatures until after the blanket was removed. One patient (Patient 27) had the lowest mean bilateral toe temperatures in the sample of patients, despite the presence of the warming blanket.

Another group of variables which may affect distal skin temperature are post-operative factors. These include the patient's haemodynamic status, the administration of vasoactive drugs, the patient's body core temperature, and the environmental temperature.

It has already been established that haemodynamic instability may affect peripheral perfusion, and thereby lower peripheral skin temperature (Brock et al., 1975; Crew et al., 1984; Funk et al., 1992; Joly & Weil, 1969; Vincent et al.,1988). All the patients in this study required IABC insertion for cardiovascular instability or for potential instability, and therefore may have had lower toe temperatures than stable patients without IABPs. Indeed, mean toe temperatures were found to be lower (24.33 - 33.93°C) than those suggested by Matthews et al. (1974a). These authors found a toe temperature of 34°C to be normal for post cardiac surgical patients whose haemodynamic status was not compromised and who did not have IABPs in situ.

Vasoactive drugs are another post-operative variable which may have affected toe temperatures of patients in this sample. Vasoactive drugs used in this post cardiac surgical period include inotropic agents, such as Adrenaline, Noradrenaline and Dopamine, as well as nitrates such as Sodium Nitroprusside and Glyceril Trinitrate (Whipple et al., 1992). Inotropic agents may lower peripheral skin temperature because of their vasoconstrictive effects (Miller, Dodson, Salam & Smith,1992), whilst the administration of nitrates, because of their vasodilatory mode of action, may have an opposite effect and raise the peripheral skin temperature (Ibsen, 1967). Additional significant drugs frequently used in the post-operative surgical patient include anti-arrhythmic agents, angiotensin converting enzyme inhibitors, beta-blocking agents and diuretic agents. All of these drugs may affect peripheral perfusion.

Although all of the patients were receiving one or more of these agents, use of the above categories of drugs was not controlled for or recorded in this study. This limitation provides an avenue for further research into the effect of these particular drug categories in patients receiving IABP therapy.

Another factor which may affect toe temperatures is the body core temperature. A wide variation in mean body core temperatures was found in the sample of patients in the present study (36.59°C - 38.83°C). Following cardiac surgery, the core temperature may fluctuate for a variety of reasons, such as, an inflammatory reaction to surgery, sepsis, presence of a warming blanket, and degree of exposure to the environment. For these reasons measurement of the toe to core temperature gradient may not always be a reliable indicator of peripheral perfusion. Previous studies have found conflicting evidence that the toe to core temperature gradient is a valuable indicator of the overall haemodynamic status of critically ill patients. Some investigators found poor correlation between toe to core temperature gradients and cardiac index during the immediate period following cardiac surgery when patients are usually hypothermic and peripherally vasoconstricted (Bailey et al.,1990; Sommers et al., 1995). Matthews et al. (1974a & 1974b), however, found toe to core temperature gradients valuable indicators of the warming patterns in adult patients following cardiac surgery, in that core and toe temperatures were shown to rise concurrently. In view of the conflicting evidence, and because of the wide variation in mean core temperatures found in the sample of patients in the current study, the author chose not to investigate toe to core temperature gradients. However, toe temperatures which do not rise in accordance with the core temperature may be indicative of an ischemic event occurring in the lower

limbs. Further research could test this hypothesis for patients receiving IABP therapy.

Another post-operative variable which might have affected toe temperature recordings in this sample of patients is the environmental temperature. Throughout the study the environmental temperature in the vicinity of the patient was monitored and found to vary no more than 2-3°C. The patients' feet were covered with a cellular blanket to prevent room temperature fluctuations affecting temperature recordings. However, it was not possible to control the amount of time that the feet were exposed by nursing or medical staff during their frequent assessments of peripheral perfusion. The time of exposure to the environmental temperature may have caused spurious recordings in the toe temperatures of some patients.

In conclusion, the variations which existed in the mean toe temperatures of bilateral limbs of patients receiving IABP could have been influenced by variables which were not controlled in this study. Since toe temperatures of patients receiving IABP support have not been studied before, it is not possible to compare the mean toe temperatures found in this sample with others. However, mean toe temperatures of bilateral limbs in this study fall outside the parameters of normal suggested by Matthews et al. (1974a) for adults without IABP support.

The Effect of the Presence of the IABC on Toe Temperatures

The effects of the "stressor" (or IABC) on mean toe temperatures was determined in two ways. Firstly, when mean toe temperatures in catheterized limbs were compared with those in non-catheterized limbs, the non-catheterized limbs acted as controls. Secondly, each catheterized limb itself served as a control when mean toe temperatures with the IABC

in were compared with mean toe temperatures following IABC removal. Each of the two methods of control, however, have their limitations. A limitation to the first method of control is that pre-existing differences in toe temperature due to factors which influence perfusion, such as the presence of PVD, may have existed between the two limbs. The monitoring and comparing of toe temperatures prior to IABC insertion would have helped to overcome this limitation. However, given the small number of patients who require IABP therapy (three to five per month in this ICU) in relation to the large number of patients who undergo cardiac surgery (approximately 80 per month), and considering the unplanned nature of the procedure, this was not considered a feasible option.

A limitation to the second control method is that the presence of the IABC may continue to exert its effect on perfusion and temperature recordings for a period following its removal. In this ICU it is policy to monitor the peripheral perfusion for 24 hours after removal of the IABC, or until the patient is discharged to the ward. However, in a long-term follow-up study of 151 patients who had received IABP therapy, Funk et al. (1992) found that signs of lower limb ischemia such as ipsilateral discomfort and diminished pulses, were evident up to 20 months later in 18% of the patients. It was considered beyond the scope of this study to examine the residual effects of the IABC after its removal.

The effect of the IABC on toe temperatures involves discussion of the findings of two research questions: the difference between the mean toe temperatures of catheterized and non-catheterized limbs; and the difference between mean toe temperatures of catheterized limbs with the IABC in and with the IABC out. In terms of the conceptual framework of the study, these research questions are designed to examine the links

between theoretical concepts (stressors) and physiological concepts (altered blood flow and temperature changes).

Differences between mean toe temperatures of catheterized and non-catheterized limbs.

Since the presence of the IABC in the femoral artery affects blood flow to the extremity (Adams & Bregman, 1987), it can be expected that a larger proportion of patients would have a toe temperature in the catheterized limb lower than the non-catheterized limb. This was the case in 67% of patients in the present study. A relatively high proportion (33%) of patients, however, had a mean toe temperature in the catheterized limb higher than that of the non-catheterized limb. A possible explanation for this could be that if the patient has pre-existing PVD, the limb with the better peripheral perfusion, is chosen for insertion of the IABC. This limb may then continue to have better perfusion than the non-catheterized limb despite the presence of the IABC. However, since the presence of pre-existing PVD was not documented in this study, this assumption is difficult to support and further research is required to examine this relationship.

Another explanation for the mean toe temperature of the catheterized limb being higher than the non-catheterized limb, may be that perfusion of the lower limb can be affected by the removal of the saphenous vein harvested during cardiac surgery (Chenevey & Sexton-Stone, 1985). In the current study, only seven (23%) patients had the saphenous vein harvested from the catheterized limb, whilst 20 (67%) patients had the vein removed from the non-catheterized limb (three patients did not have saphenous vein grafts). Seven out of the 10 patients whose mean toe temperature in the catheterized limb was higher than that in the non-catheterized limb had the saphenous vein removed

from the non-catheterized limb, suggesting that the lower temperatures in the non-catheterized limb may have been related to the harvesting of the saphenous vein. It is interesting to note that of the group of 14 patients in this study who developed signs of limb ischemia in the catheterized limb, only two had the saphenous veins harvested from the catheterized limb (Patients 30 and 17). Patient 17 is the patient who had premature removal of the IABC after only six hours because of the development of acute lower limb ischemia. The combination of the presence of the IABC and the removal of the saphenous veins from this limb may have contributed to the ischemia in this patient.

Although the mean toe temperatures of the catheterized limbs were found to be lower than the mean toe temperatures of the non-catheterized limbs ($p < .001$), the paired samples t - test which compared these means was based on a large number of observations across the 30 patients (1086 observations). This may account for the statistically significant result. The actual temperature difference between the two means (0.66°C) was considered to be clinically insignificant and was >2°C in only four of the patients. Therefore, it cannot be concluded from the results of this study, that the presence of the IABC caused a clinically significant reduction in the great toe temperatures of catheterized limbs compared with those of non-catheterized limbs. Observations of a larger sample size are required to determine any definitive conclusions.

Differences between mean toe temperatures with the IABC in and the IABC out.

When patients were categorized into groups based on the presence or absence of signs of impending ischemia, the mean toe temperatures of the catheterized limbs with the IABC in were found to be

significantly lower than with the IABC out in both groups (p < .001). As expected, the actual temperature difference between the mean toe temperatures with the IABC in, and with the IABC out was greater in the group showing impending signs of ischemia (2.86°C) than in the group not showing impending signs of ischemia (1.24°C). Results elsewhere in the study found mean temperature differences of >3°C when nurses' observations which indicated a state of good perfusion were compared with those that indicated signs of limb ischemia (see discussion below). Therefore a difference of 2.86°C can be considered of marginal clinical importance. This difference, however, must be considered in relation to other events associated with IABC removal. For instance, upon removal of the IABC, a pressure clamp is applied to the groin in order to produce haemostasis. Application of the clamp can reduce blood flow and temperature to the feet considerably, especially since the whole leg is exposed to the environment during the time that the clamp is required. Furthermore, since it was not possible to establish baseline toe temperatures of this sample of patients before IABC insertion, the rise in toe temperatures which followed the removal of the IABC in most patients (illustrated in Figure 4, Patient 15), may have been substantially related to patients' improving haemodynamic status and general warming patterns, rather than to the removal of the IABC. Therefore, contrary to previous studies (Chenevey & Sexton-Stone, 1985; Funk et al.,1989) which found the presence of the IABC to be the major factor contributing to lower limb ischemia, events superimposed onto the presence of the IABC, which were not identified in the current study, may have contributed significantly to the ischemic changes in this sample of patients.

One factor affecting blood flow in the catheterized limb is the size of the IABC and whether it is sheathed or unsheathed. Iverson et al.

(1987) found that the use of a smaller sized IABC (10.5 French Gauge) contributed to a lower incidence of vascular complications. All patients in the current study had size 9.5 French Gauge IABCs inserted, one size smaller than in Iverson's study. Phillips et al. (1992) found that sheathless IABCs contributed to less lower limb ischemia than did the sheathed varieties because of the relatively reduced diameter size in the lumen of the femoral artery. In the current study, twenty two patients (73%) had the sheathed and only 8 (27%) had unsheathed IABCs. Although a larger proportion of patients had the sheathed varieties, the smaller French Gauge may have helped to reduce the incidence of ischemic changes in this sample. However, of the 14 patients who were classified as developing signs of impending limb ischemia all, except two, had a sheathed IABC in situ. This is consistent with findings of previous research, that is, there is a greater incidence of ischemic changes in patients who have the sheathed varieties of IABC inserted.

In summary, although the presence of the IABC in catheterized limbs resulted in statistically significant lower mean toe temperatures compared with the mean toe temperatures in non-catheterized limbs, and compared with mean toe temperatures following IABC removal, the temperature changes were not considered to be clinically significant. Therefore, it cannot be concluded that the presence of the IABC alone contributed significantly to any ischemic changes in this sample. It is possible that ischemic events are triggered by factors additional to and dependent on the presence of the IABC.

Differences Between Mean Toe Temperatures of Limbs in the Presence
and Absence of Signs of Impending Ischemia

In order to establish quantitative parameters of toe temperature
differences that would alert nurses to a deterioration in peripheral
perfusion and impending ischemia, mean toe temperatures in catheterized
and non-catheterized limbs, when they were showing signs of ischemia
were compared with mean toe temperatures when they were not showing
signs of ischemia. In reference to the theoretical framework this research
question examines relationships between the physiological concepts of
altered blood flow and temperature changes.

Stoner et al. (1991) found that skin temperature in the digits, palms
and toes can be confidently linked with perfusion. This finding was
supported in the present study, whereby the results of independent
samples t - tests for both catheterized and non-catheterized limbs showed
a significant difference between mean toe temperatures when limbs were
showing signs of poor perfusion and when they were not ($p < .001$).

The presence of signs of impending ischemia in non-catheterized
limbs was found to be related to events such as the harvesting of
saphenous veins from the limb during cardiac surgery, hypothermia,
presence of pre-existing PVD, or use of vasocontrictive agents, as
discussed above.

Mean toe temperatures of bilateral limbs when showing ischemic
changes were found to be more than 3°C lower than the mean toe
temperatures of limbs when not showing ischemic changes. Therefore, a
difference of >3°C was considered to be the clinically significant
temperature change, or critical parameter, which may indicate impending
ischemia in the sample of patients in this study. Since a temperature
probe can be used to monitor toe temperatures continuously, its value in

alerting the nurses to ischemic changes may therefore be a useful adjunct to conventional assessments of peripheral perfusion in the lower limbs of patients with an IABC. Further research using a larger sample size is required to firmly establish this assumption.

The Relationship Between Toe Temperatures Measured by Skin Probe and Nurses' Assessments of Peripheral Perfusion

Given the high inter-observer reliability score (16 out of 20 Phi coefficients significant at an alpha level of .05), it is logical to assume that bedside nurses in this study were consistent in their visual and tactile estimations of colour, warmth, CR and quality of pedal pulses, when assessing peripheral perfusion in this sample of patients. However, to date, only one study by Fagan (1988) has examined the relationship between nurses' qualitative observations of peripheral perfusion and a quantitative measurement of toe temperature by use of a skin probe. Fagan examined this relationship in a group of paediatric patients following cardiac surgery who did not have IABPs. Fagan makes no mention of having used a blinded design where the nurses' would be unaware of the actual toe temperature recordings as they carried out their conventional assessments. The current study may be the first to use a blinded design to determine the relationship between nurses' qualitative observations of peripheral perfusion and a quantitative method of measuring toe temperature in adult patients receiving IABP support.

The assumption arising from the conceptual framework is that the establishment of quantitative criteria for the assessment of peripheral perfusion may help nurses to intervene at an earlier stage to prevent the patient's lines of resistance being broken and complications arising from penetration of the body's core system.

Consistency in the relationship between all categories of nurses' observations of peripheral perfusion and mean toe temperatures was demonstrated in this study. This supports the findings by Fagan (1988) in her study of the relationship between nurses' observations of peripheral perfusion and toe temperatures in a group of paediatric patients post cardiac surgery. Throughout all categories of observations, toe temperatures corresponding to signs of good perfusion were significantly higher ($p < .05$), than those corresponding to signs of progressively poorer perfusion. Examination of individual data collection sheets, however, revealed that there were exceptions to these general findings. Events associated with these inconsistencies were not documented, but possible explanations may be, for example, incorrect methods of applying the skin probe to the toes, over-exposure of the feet to the environment, application of a warming blanket to the feet, or human errors in recording data. It was beyond the scope of this study to record these events and relate these to nurses' observations and toe temperature recordings. Inconsistencies in the timing of changes recorded by nurses and the skin temperature probe, prevented any conclusions being reached with regard to whether the nurses detected changes earlier or later than the skin temperature probe. Further research is required to establish the relationship in timing between nurses' observations and skin temperature probe recordings, and verify the usefulness of the skin probe as a valuable quantitative adjunct to nurses' conventional assessments of peripheral perfusion in patients receiving IABP therapy.

An attempt was made, however, to eliminate individual patient characteristics which may have affected mean toe temperatures or nurses' assessment of peripheral perfusion. This was achieved by comparing mean toe temperatures with nursing observations only when the

categories of observations occurred together in the same patient. These comparisons helped to determine accurately any clinically significant temperature differences which occurred between one nursing observation and another, for example between the colours "pink" and "mottled". The establishment of criteria for significant temperature differences between signs of well perfused limbs and signs of poorly perfused limbs may help critical care nurses to detect limb ischemia earlier when assessing peripheral perfusion in patients with an IABP.

The relationship which was found between toe temperatures and nurses' conventional observations will now be discussed under each nursing observation category.

Mean toe temperatures and nurses' observations of colour.

A series of colour changes through "pink", "pale", "blue", and "mottled" to "white" occurs as limb blood flow and perfusion diminish (Hubner, 1988). Therefore lower toe skin temperatures are expected to occur as a limb progresses through these colour changes with deteriorating peripheral perfusion (Eberhart & Trezek, 1973). In the present study statistically significant higher mean toe temperatures corresponded to nurses' estimations of colours representing good perfusion, that is "pink" and "pale" than to those representing poor perfusion, that is "blue", "mottled" or "white"($p < .05$). The colour category "white" was an exception to this since it corresponded to a higher mean toe temperature than did the colour category "mottled", in both catheterized and non-catheterized limbs. However, the observation "white" was recorded in only one of the 30 patients and an electric warming blanket was being used over the lower limbs of this patient when the observations were being recorded. Since the limbs of this patient were

estimated by the nurses as being "white" and showing signs of limb ischemia, the warming device may have raised the surface toe temperature disproportionately.

There was a temperature difference of > 2°C between all paired colour categories in both limbs, except for when "pale" was paired with "mottled " in the non-catheterized limbs of two patients, the difference in this instance being minimal (1.53°C) but with a statistical significance of p < .005. In catheterized limbs larger differences in mean toe temperatures occurred between colour categories which indicated signs of well perfused limbs and those that indicated signs of limb ischemia, that is between "pink" and "mottled" (5.98°C), "pale" and "blue" (3.20°C), and "pale" and "mottled" (2.44°C). These findings, however, were based on very small numbers of observations. Unexpectedly, a clinically significant mean temperature difference of > 3°C (based on data collected from over 1000 observations on 16 patients), was found between the mean toe temperatures corresponding to the colours "pink" and "pale" in both limbs. In this study, both "pink" and "pale" were considered as signs of normal perfusion and therefore, the colour change from "pink" to "pale " was not classified as a sign of ischemia. The large temperature difference between "pink" and "pale" may indicate that the skin temperature probe was very sensitive to changes in perfusion which were undetected by the nurses' in their visual estimations of these two colour categories.

In summary, nurses in this study were consistent in their assessments of colour in the lower limbs of this sample of patients receiving IABP support.

Mean toe temperatures and nurses' observations of temperature by touch.

Results of this study showed that statistically significant higher mean toe temperatures corresponded to nurses' tactile estimations of "warm" and "cool" than to "cold" (p < .001). This consistency supports Fagan's findings in 1988, and assists in the validation of observations of temperature by touch of nurses in this study. As was found with the colour categories, larger differences between means lay in the categories which compared signs of good perfusion with signs of poor perfusion, that is between the categories "warm" and "cold" (> 6°C in bilateral limbs). However, as with nursing observations of colour, a large temperature difference (> 4°C) also occurred between categories of observations which were classified as signs of normal perfusion ("warm" and "cool"), and the change from "warm" to "cool" was not considered indicative of impending ischemia. The large temperature difference occurring between these two adjacent categories may indicate that the skin temperature probe was more sensitive in detecting small changes in temperature than were nurses in their estimations of temperature by touch. A temperature change of > 4°C was necessary before nurses were able to detect a temperature change from "warm" to "cool" by touch.

Mean toe temperatures and nurses' observations of pedal pulses.

The consistency which occurred between nurses' assessments of the quality of pedal pulses and mean toe temperatures, suggests that these observations were valid, in that mean toe temperatures were significantly higher when pulses were reported to be "palpable" than when they were "present on Doppler" and "absent on Doppler" (p < .05). As expected, small temperature differences (<1.40°C) existed between signs

indicating normal perfusion, that is, between "palpable" and "present on Doppler" and larger temperature differences (>3°C) existed between signs which indicated impending ischemia, that is, between "palpable" and "absent on Doppler". This finding applied to the DP and PT pulses in both limbs across the sample. These findings confirm that large temperature differences occurred when limbs changed from being well perfused to showing signs of impending ischemia, as evidenced by the disappearance of a pedal pulse.

Mean toe temperatures and nurses' observations of circulatory return.

Nurses again demonstrated consistency in their assessments of CR. In catheterized limbs significantly higher mean toe temperatures corresponded to ≤ 4 seconds, than to > 4 seconds (p <.05), with a temperature difference of 1.87°C . In non-catheterized limbs, however, the temperature difference was negligible (0.45°C), and statistically insignificant.These small temperature differences may indicate either that nurses were very good at assessing CR in this sample of patients, and were able to discriminate between the two categories of CR within a very small temperature range, or that four seconds is an inappropriate parameter for the upper limit of a normal CR in critically ill patients with IABPs. Following the panel review, the upper limit of normal was raised from two to four seconds, as suggested by the review panel of clinical experts, based on findings by Schriger and Baraff (1988) who studied CR limits in different age groups of patients without IABPS. Since the assessment of CR has not been previously studied in patients receiving IABP therapy, further research would help to define parameters for normal

limits and support its value in the assessment of peripheral perfusion in this population of patients.

In summary, the relationship between all categories of nurses' conventional assessments of peripheral perfusion and mean toe temperatures measured by a skin probe, showed an overall consistency and accuracy for patients receiving IABP support in this study. This helps to validate the objectivity and reliability of nurses' clinical assessments of peripheral perfusion of patients receiving IABP therapy in this ICU.

Conclusion of the Discussion

This study has made a unique contribution to the body of knowledge about toe temperatures and nurses' assessments of peripheral perfusion in patients receiving IABP support.

It was considered beyond the scope of the study's purposes to control variables which may have contributed to the wide range of mean toe temperatures found across the sample, and because of the lack of previous research, results could only be compared with previous studies of toe temperatures in patients not receiving IABP therapy. In the sample of patients with IABP in the current study, the mean toe temperatures were found to be lower than those based on the findings of previous research for post-cardiac surgical patients without IABPs (Matthew, Meade and Evans, 1974a).

In this study, a mean toe temperature difference of > 3°C was considered clinically significant in terms of its relationship to signs of ischemic changes. This criterion was based on results of the differences between the mean toe temperatures of the catheterized limbs in patients who showed signs of ischemic changes and those who did not, and on the results of the differences in mean toe temperatures which corresponded

to nurses' observations that indicated good perfusion and those that indicated poor perfusion. Thus, although there was a statistically significant difference between mean toe temperatures in catheterized limbs and non-catheterized limbs, and between catheterized limbs with the IABC in and with the IABC out, these were not considered clinically significant, based on the above conclusions and on consideration of other factors which could not be controlled. Therefore, although the presence of the IABC may have contributed to lower mean toe temperatures compared with limbs without its presence, it cannot be concluded that the IABC alone caused a significant degree of altered perfusion in the sample of patients in this study. Further research could test the hypothesis that other triggering events, superimposed on the presence of the IABC, contribute to the onset of lower limb ischemia in patients receiving IABP support.

The relationship which was found between all categories of nurses' observations and mean toe temperatures shows that nurses in this study were accurate in their assessments of peripheral perfusion in patients receiving IABP. However inconsistencies in relation to timing of changes made it difficult to reach a conclusion as to whether nurses detected changes before or after the skin temperature probe. Further research would help to clarify this relationship.

Implications for Critical Care Nurses

Two major implications for nurses have arisen from this study: The skin temperature probe is a cheap, simple and non-invasive method of monitoring peripheral perfusion in patients with IABPs. The skin temperature probe may be more sensitive than nurses in detecting some minor changes in peripheral perfusion in the lower limbs, and as a

consequence may be a useful indicator of the effect on perfusion of therapeutic measures administered to patients.

Firstly, since measurement of toe temperatures by skin probe is simple, cheap, and non-invasive, with no hazards, and causes little disturbance to patients' sleep, critical care nurses may consider including it as a routine method of monitoring peripheral perfusion in patients receiving IABP support.

Secondly, although consistency was found between mean toe temperatures and nurses' conventional observations of peripheral perfusion, the skin probe thermometer was found to be more sensitive in detecting small changes in temperatures than were the nurses in assessing temperature of the lower limb by touch, or colour changes by vision. Matthews et al. (1974b) suggested that minor changes which could not be detected by hand, may indicate serious pathological processes or ischemic changes leading to subsequent pain and loss of limb function. This was also one of the assumptions of the study's theoretical framework (Neuman, 1989). Therefore, nurses must continue to be diligent in their observations of peripheral perfusion and be alert for early signs of limb ischemia occurring in patients receiving IABP therapy. Further research conducted on a larger scale, will assist in validating nurses' conventional observations.

Finally, the skin temperature probe may prove to be a sensitive indicator of the effectiveness or otherwise of therapeutic measures, such as inotropic agents, administered to patients with IABP. Although this aspect was beyond the scope of the present study, it has opened avenues for further research which may help nurses in their overall assessment and management of critically ill patients receiving IABP support. Therefore, the use of a skin probe thermometer may be a valuable

addition to clinical monitoring of patients before, during and after receiving IABP therapy, and may alert nurses earlier to changes in peripheral perfusion.

Limitations of the Study

The sample size was small because relatively few patients (three to five per month in this ICU) require IABP support and it was not possible within the time frame available to access a larger sample size. Given the small sample size and short time frame available for this study, it was not considered feasible or advisable to address all the variables which may have affected toe temperatures and influenced the findings. This prevents any generalisation to the wider population of patients receiving IABP therapy. The study also has limited generalizability because it was conducted in one hospital in a specific geographical location. With the availability of a larger sample of patients from multiple centres, and a longer time frame, generalization of the findings would be feasible.

Another limitation is that, although the importance of movement and sensation in the assessment of peripheral perfusion is acknowledged in the literature (Chenevey & Sexton-Stone, 1988), these observations were not included in the research, since they are considered difficult to assess in the patient population under study, the majority of whom are unconscious and sedated for a considerable length of time.

Recommendations for Further Research

This study has described mean toe temperatures measured by skin probe in a small sample of patients receiving IABP support and examined the relationship between nurses' conventional observations of peripheral

perfusion and skin probe toe temperatures. The limits placed on this study give direction to further avenues of research.

Firstly, there is a need to identify haemodynamic events such as a fall in blood pressure, or a deterioration in cardiac indices which may occur simultaneously with a change in toe temperatures. Secondly, the identification of how specific drugs, such as vasoactive agents affect toe temperatures would be a useful contribution to the ongoing management of patients with an IABP. Thirdly, in the relationship between nurses' conventional assessments of peripheral perfusion and toe temperatures measured by skin probe it may be useful to determine which event occurs first, that is a change in temperature, as monitored by the skin probe, or a change in peripheral perfusion as noticed by a nurse. The usefulness of the skin probe in the diagnosis of ischemia would then be firmly established. Fourthly, it is not known whether the range of mean toe temperatures found in this sample of patients is typical for IABP supported patients after cardiac surgery, or typical for all post cardiac surgical patients with potential for haemodynamic instability. Further study would be useful in the comparison of toe temperatures in a group of patients following cardiac surgery who are receiving IABP support and a control group who are not. It might also be useful to establish baseline parameters of mean toe to core temperature gradients of patients with IABPs, and to compare these with the mean gradients of patients without IABPs. Finally, studies could be conducted to determine parameters for normal and delayed CR in patients who are critically ill and receiving IABP support.

The potential of opportunities for further research in this area is extensive and would contribute to the prevention of ischemia and ongoing management of critically ill patients who are receiving IABP support.

In conclusion, this study has been important since it may assist critical care nurses to understand the concepts of a theoretical framework relevant to critically ill patients who require IABP support. In addition, the study appears to be the first to address a number of issues related to monitoring of perfusion in patients receiving IABP support. Firstly it has related qualitative and quantitative methods of assessing peripheral perfusion in adult patients requiring IABPs, and therefore it has helped to validate nurses' conventional assessments of peripheral perfusion. Secondly the study has evaluated the usefulness of the skin temperature probe as a valuable accessory in the monitoring of peripheral perfusion of patients with IABPs. Thirdly, It has established baseline parameters of toe temperatures which would alert nurses to impending ischemia in patients with an IABC in situ. Finally, it has opened up avenues for further research to examine the wide spectrum of events which may influence great toe temperatures of patients requiring IABP support.

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APPENDIX A

PROTOCOL FOR ASSESSMENT OF CIRCULATORY RETURN (CR)

1. Using your forefinger and thumb apply firm pressure to the nail bed of the great toe.

2. As soon as blanching of the nail bed occurs, release the pressure.

3. Time the circulatory return from the release of pressure until flushing or return to original colour is seen in the nail bed.

4. Record 'normal' if flushing, or return to original colour occurs within 4 seconds (≤ 4 secs.).

5. Record 'delayed' if flushing or return to original colour occurs later than 4 seconds (> 4 secs.).

IABP RESEARCH

DATA COLLECTION SHEET

Please do not discard this document

Return to IABP Research Box - Front Desk SICU

Thank you: Jacqueline Hawkrigg, Clinical Nurse, ICU
Phone: Work: 224 2727
Phone: ███████████

IABP RESEARCH

INTRODUCTION

1.   Please complete Section One as soon as possible after insertion of the intra-aortic balloon catheter (IABC).

2.   Please record hourly observations in Section Two.

3.   Please complete Section Three only if limb ischemia occurs.

4.   Please complete Section Four as soon as possible after removal of the IABC.

GUIDELINES

1.   <u>PERCUTANEOUS INSERTION</u>

      Catheter is inserted into the femoral artery through the skin and threaded over a guide wire.

      <u>SURGICAL INSERTION</u>

      Catheter is inserted through a surgical incision made directly into the femoral artery.

2.   <u>CORE TEMPERATURE</u>

      Please record in degrees centigrade from the pulmonary artery catheter via the Sieman's bedside monitor.

3.   <u>SKIN TEMPERATURE = SKIN TEMPERATURE OF THE GREAT TOE</u>

      The skin probe will be attached to the great toes by the research assistants who will also obtain strip recordings of the toe temperatures from the Siemen's monitor.
      (See Protocol for Attachment of Skin Temperature Probe).

4.   <u>CIRCULATORY RETURN = C.R.</u>

      (see Protocol for the procedure).

5.   <u>LIMB ISCHEMIA</u>

      Defined as the loss of Doppler signals from the dorsalis pedis (DP) and posterior tibial (PT) pulses.

6.   <u>ROOM TEMPERATURE</u>

      Please record <u>four</u> hourly in degrees centigrade.

IABP RESEARCH
SECTION ONE - BASELINE DATA

Code No.

PLEASE CIRCLE CORRECT RESPONSE

Presence of Palpable Pedal Pulses Pre-op

(DP = Dorsalis Pedis)
(PT = Posterior Tibial)

DP Left	Yes	1
	No	2
DP Right	Yes	1
	No	2
PT Left	Yes	1
	No	2
PT Right	Yes	1
	No	2
	Not known	3

Date and Time of
Insertion of IABC _____

_____

Reason for Insertion: _____

_____

Method of Insertion
(See guideline No. 1)

Percutaneous	:	1
Surgical	:	2

Catheter Type

Sheathed	:	1
Unsheathed	:	2
Catheter Size	:	_____

Site of Insertion

R. Femoral Artery	:	1
L. Femoral Artery	:	2
Other (Specify)	:	3

_____

Saphenous Vein Graft Taken From Catheterized Limb?

Yes	:	1
No	:	2

IABP RESEARCH
SECTION 2 - 24 HOURS OBS CHART

Record observations <u>one</u> hourly whilst IABC <u>insitu</u>, and <u>one</u> hourly for 24 hours post-removal.
Identify catheterized limb by circling right foot or left foot column. Indicate time when IABC is removed.

PERIPHERAL PULSES		**COLOUR**		**WARMTH**		**CIRCULATORY RETURN (C.R.)**	
Palpable	1	Pink	1	Warm	1	> 4 secs 1	Please indicate in appropriate
Not palpable	2	Pale	2	Cool	2	≤ 4 secs 2	column which number most
Present only		Blue	3	Cold	3		closely fits description. If 'other'
on Doppler	3	Mottled	4	Other	4		please specify.
Absent on		White	5				
Doppler	4	Other	6				
		(i.e. Ethnic Variations)					

DATE	TIME	CORE T°	RIGHT FOOT					LEFT FOOT					4 HOURLY ROOM T°
			DP	PT	COLOUR	WARMTH	C.R.	DP	PT	COLOUR	WARMTH	C.R.	
	01												
	02												
	03												
	04												
	05												
	06												
	07												
	08												
	09												
	10												
	11												
	12												
	13												
	14												
	15												
	16												
	17												
	18												
	19												
	20												
	21												
	22												
	23												
	24												

IABP RESEARCH
SECTION THREE - COMPLICATIONS

CODE NO.

Limb Ischemia Diagnosed?   YES   1
(see guideline No. 5)   NO   2

Action taken on detection of Limb Ischemia

Nil   1

Removal of balloon sheath   2

Premature removal of IABC   3

Embolectomy   4

Fasciotomy   5

Amputation   6

Other: (please specify) _____   7

IABP RESEARCH
SECTION FOUR - IABP REMOVAL

CODE NO.

Date & time of removal:

_____

Duration of IABP support:

_____

Method of removal:	Surgical	1
	Direct Pressure	2
Method of Pressure:	Clamp	1
	Manual	2
Duration of Compression:	30 minutes	1
	Other (Specify)	2

APPENDIX C

CODE NO.

IABP RESEARCH

TOE TEMPERATURE RECORDING CHART
PROCEDURE FOR OBTAINING TOE TEMPERATURE RECORDING

1. Select Mode 'A" on Siemens monitor.
2. Ensure T1a is recording left big toe and T1b is recording right big toe.
3. Please circle balloon pumped limb right or left below.
4. Select 'Trend' on Siemens monitor.
5. Select 'page 2'.
6. Move cursor (L) to time when the toe T° recordings were commenced, or to the hour after the last toe T° was recorded.
7. Move cursor slowly (R) to get recording each hour up to current time, record each hour below.
8. Circle time when IABC is removed.
9. Continue recording until 24 hours after IABC is removed.

| DATE	TIME	T1a LEFT	T1b RIGHT	DATE	TIME	T1a LEFT	T1b RIGHT

APPENDIX D

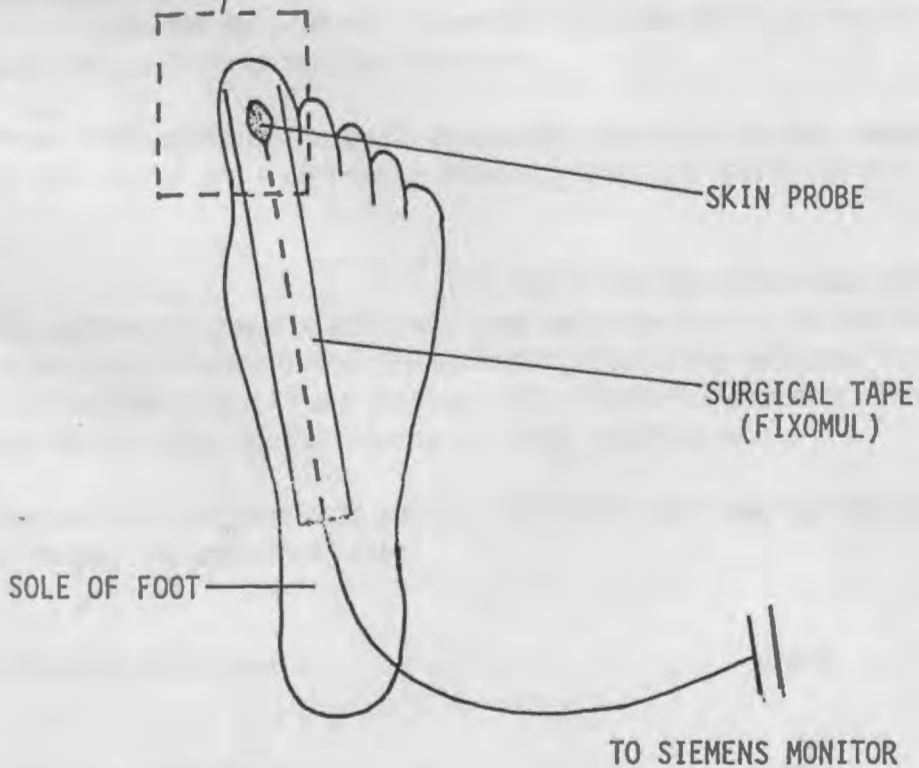## PROTOCOL FOR THE APPLICATION OF THE SKIN TEMPERATURE PROBE

1. Skin temperature probes are kept in packages in IABP Research Box (front desk SICU).

2. Attach a skin probe to the plantar (under surface) of each great toe.

3. Seal the skin probe with a 2cm x 2cm piece of waterproof adhesive tape (See diagram A).

4. Secure the probe to the toe and also to the sole of the foot with surgical tape (See diagram B.)

5. Connect the thermistor probes to the temperature slots in the Siemen's Monitor - T1a slot (left toe probe); T2b slot (right toe probe).

6. Select Display Mode "A" - mask the display with tape.

7. Obtain hourly recordings of toe temperatures at end of each shift whilst the IABC is in situ, and for 24 hours following its removal.

8. Staple the recording strip to Patient Data Collection Sheet.

9. After use, please do not discard the skin temperature probes - clean and place in completed IABP Research Box (front desk SICU) for re-packaging.

DIAGRAM A

SKIN PROBE

SURGICAL TAPE
(FIXOMUL)

2 X 2CM
WATERPROOF ADHESIVE
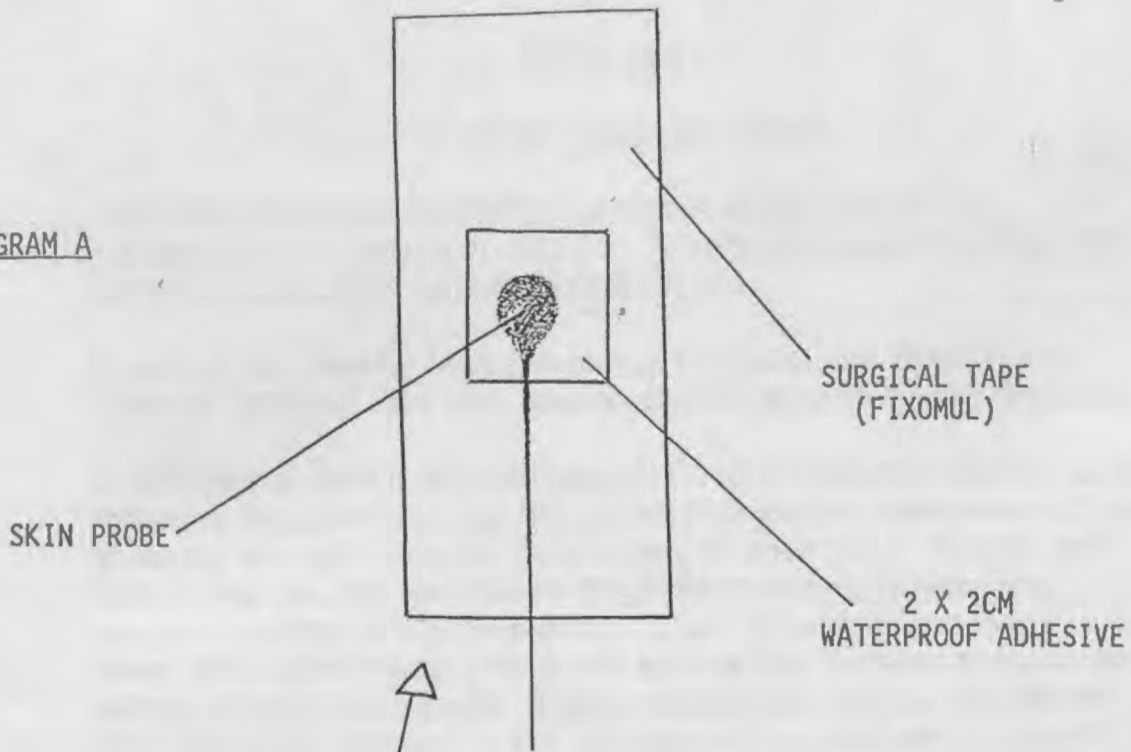
INSERT ENLARGEMENT

DIAGRAM B

SKIN PROBE

SURGICAL TAPE
(FIXOMUL)

SOLE OF FOOT

TO SIEMENS MONITOR

DIAGRAMS OF APPLICATION OF SKIN PROBE

APPENDIX E

PATIENT CONSENT FORM

THE RELATIONSHIP BETWEEN NURSES' ASSESSMENT OF PERIPHERAL PERFUSION AND TOE TEMPERATURES IN PATIENTS WITH INTRAAORTIC BALLOON PUMPS.

A study undertaken by Jacqui Hawkrigg, Clinical Nurse, Royal Perth Hospital, Intensive Care Unit, Masters Student at Edith Cowan University.

During your surgery it was necessary to insert an intraaortic balloon pump through a large artery in your leg. A potential problem associated with the presence of a balloon pump is impairment of blood flow to the legs and feet. It may be possible to detect this problem earlier, by recording temperatures from the surface of the big toe. Your participation in this study will involve attaching small skin surface thermometers to the under surface of both your big toes. These should not cause you any pain or discomfort, nor incur any risks or interfere with your care and treatment. A nurse will record the temperature of your toes from these surface thermometers and will carry out other routine observations of the blood flow to your feet, such as feeling for your foot pulses.

Upon your agreement, a nurse will also collect some information about your medical condition from your records. This will remain confidential, and your identity will be concealed by a code when the details are entered into a computer for analysis. You will not be identifiable in any reports or publications arising from this research.

Your participation in this study is entirely voluntary, and you have the right to withdraw at any time without affecting your care and treatment.

I, ... have read the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this study, realising that I may withdraw at any time. I understand that if I have any concerns or further questions I may contact the people listed on the information sheet given to me.

I agree that research data gathered from the study may be published provided I am not identifiable.

Signature of Patient: .... Date: ....

Signature of Nurse: .... Date: ....

Thank you for participating.

APPENDIX F

PATIENT INFORMATION SHEET

THE RELATIONSHIP BETWEEN NURSES' ASSESSMENTS OF
PERIPHERAL PERFUSION AND TOE TEMPERATURES IN PATIENTS WITH
INTRAAORTIC BALLOON PUMPS.

A study undertaken by Jacqui Hawkrigg, Clinical Nurse, Royal Perth Hospital, Intensive Care Unit, Masters Student at Edith Cowan University.

During your surgery, it was necessary to insert an intraaortic balloon pump. This is a device which is inserted temporarily into a major artery close to your heart. It assists the function of the heart in situations such as after a severe heart attack or during the stress of cardiac surgery.

The balloon pump is introduced through a large artery in your leg, and a potential problem associated with the presence of a balloon pump is impairment of blood flow to the legs and feet. It may be possible to detect this problem earlier by recording temperatures from the surface of the big toes to monitor blood flow to legs and feet.

Small skin surface thermometers (temperature probes) are attached by sticky tape to the under surface of your big toes. These should not cause you any pain or discomfort, nor incur any risks or interfere with your care and treatment. A nurse will record the temperature of your toes from these surface thermometers, and will carry out other routine observations of the blood flow to your feet, such as feeling for your foot pulses. A nurse will also collect some information about your medical condition from your records. This will remain confidential, and your identity will be concealed by a code when the details are entered into a computer for analysis. You will not be identifiable in any reports or publications arising from this research.

The Ethics Committee at this hospital and at Edith Cowan University, and the doctor in charge of the Unit have given approval for this study. Although you may not benefit directly from participating, the results of the research may provide nursing and medical staff with valuable information on how to detect early problems with blood supply to the legs.

Your participation in this study is entirely voluntary and you are free to withdraw at any time without affecting your care and treatment. If you have any concerns about this study, or if you require further information, please do not hesitate to contact either Jaqui Hawkrigg, Clinical Nurse, Royal Perth Hospital, Phone: 224 2727 or Gavin Leslie, Clinical Nurse Specialist, Royal Perth Hospital, Phone 224 2244 page 2035.

If so desired correspondence regarding any concerns about this project can be directed to Dr J M White, Chairperson, Ethics Committee, c/o Medical Administration, Royal Perth Hospital, Wellington Street, Perth 6000.

Thank you for participating in the study.

APPENDIX G

The Means And Ranges of Toe Temperatures and the Toe to Core
Temperature Gradiants (Degrees Celsius)

Patient	No. Observations	Toe Temperature M (Range)		
		Non-Catheterized Limbs	Catheterized Limbs	M difference
1	65	33.84 (26.80 - 36.60)	33.93 (27.00 - 37.00)	.09*
2	120	29.14 (25.10 - 34.40)	29.98 (24.80 - 35.80)	.84*
3	39	30.23 (24.60 - 36.40)	29.27 (24.00 - 36.20)	.96
4	50	30.13 (23.00 - 36.60)	29.12 (23.80 - 36.40)	1.01
5	63	30.70 (23.60 - 35.70)	28.38 (23.20 - 34.00)	2.32
6	64	30.97 (24.20 - 34.60)	29.18 (24.00 - 33.20)	1.79
7	69	26.23 (22.40 - 33.20)	25.43 (22.20 - 33.40)	.80
8	36	29.39 (23.60 - 33.40)	29.91 (24.00 - 34.40)	.52*
9	50	31.22 (25.40 - 33.80)	30.22 (25.00 - 33.30)	1.00
10	80	30.06 (25.60 - 34.60)	30.29 (25.40 - 34.40)	.23*
11	45	29.29 (24.40 - 35.40)	28.02 (24.60 - 34.60)	1.27
12	41	30.39 (23.80 - 34.40)	29.71 (24.00 - 34.80)	.68
13	66	33.23 (23.20 - 37.20)	33.67 (23.00 - 37.00)	.44*
14	32	29.47 (25.80 - 33.40)	27.13 (24.00 - 30.80)	2.34
15	40	26.32 (22.40 - 31.80)	26.65 (23.40 - 33.00)	.33*
16	46	26.85 (24.60 - 32.00)	27.61 (24.60 - 33.80)	.76*
17	27	25.80 (23.80 - 32.20)	24.63 (22.40 - 27.20)	1.17
18	64	28.80 (24.60 - 34.80)	26.88 (23.60 - 36.00)	1.92
19	88	30.79 (22.80 - 36.00)	30.00 (23.00 - 36.20)	.79
20	73	33.33 (24.40 - 36.70)	32.70 (24.60 - 36.70)	.63
21	78	29.92 (23.20 - 36.40)	31.00 (22.80 - 36.80)	1.08*
22	73	33.48 (28.00 -36.40)	32.14 (24.00 - 36.70)	1.34
23	63	28.48 (23.00 - 35.20)	29.55 (22.80 - 36.40)	1.07*
24	42	26.14 (23.20 - 37.40)	26.45 (23.40 - 37.00)	.31*
25	41	30.37 (23.80 - 34.20)	29.71 (24.00 - 34.80)	.66
26	86	27.14 (23.90 - 33.20)	26.57 (23.60 - 32.40)	.57
27	61	24.86 (22.00 - 31.20)	24.33 (22.20 - 28.20)	.53
28	90	28.38 (23.40 - 32.00)	28.33 (23.40 - 32.40)	.05
29	52	33.04 (24.80 - 36.40)	30.74 (25.70 - 35.20)	2.30
30	62	31.50 (25.20 - 35.20	29.00 (23.80 - 33.60)	2.53

* Toe temperature of catheterized limbs higher than in non-catheterized limbs.