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A comparison of activated partial thromboplastin time obtained by two techniques in patients following percutaneous transluminal coronary angioplasty

Hobby, Deanna Jeanne, M.S.
The University of Arizona, 1987

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A COMPARISON OF ACTIVATED PARTIAL
THROMBOPLASTIN TIME OBTAINED
BY TWO TECHNIQUES IN PATIENTS FOLLOWING
PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

BY

Deanna Jeanne Hobby

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A Thesis Submitted to the Faculty of the
COLLEGE OF NURSING
In Partial Fulfillment of the Requirements
For the Degree of
MASTER OF SCIENCE
In the Graduate College
THE UNIVERSITY OF ARIZONA

1987
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APPROVAL BY THESIS DIRECTOR

This thesis has been approved on the date shown below:

Leanna J. Crosby
Assistant Professor

Nov. 17, 1987
Date
DEDICATION

I dedicate this thesis to my mother who has always given me encouragement and support in any endeavor I have pursued.
ACKNOWLEDGMENTS

Sincere gratitude and appreciation is extended to my thesis committee: Dr. Leanna Crosby, Chairperson, for the many hours spent in assistance and guidance, and to Dr. Joyce Verran and Dr. Carolyn Murdaugh for their valuable suggestions and contributions which helped to improve the quality of the final product.

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ABSTRACT

A descriptive study was conducted to test the null hypothesis: There will be no statistically significant difference between serum activated partial thromboplastin time (aPTT) obtained by two methods; venipuncture and large bore femoral arterial catheter. The convenience sample consisted of seventeen adults who had undergone percutaneous transluminal coronary angioplasty (PTCA) for the treatment of coronary artery disease. After the PTCA procedure, patients returned to an intensive care unit with a femoral intra-arterial catheter in place. Seventeen pairs of serum samples were obtained; one by venipuncture and one through the femoral intra-arterial catheter. Prior to obtaining the sample from the femoral intra-arterial catheter, 6.0 milliliters (3 times the deadspace of the catheter) of blood was withdrawn and discarded. aPTT samples were analyzed. T-tests were used to compare the results. Findings revealed that there was no statistically significant difference in the aPTT values when drawn from venipuncture versus the femoral intra-arterial catheter.
CHAPTER I

STATEMENT OF THE PROBLEM
AND CONCEPTUAL FRAMEWORK

Introduction

Percutaneous transluminal coronary angioplasty (PTCA) was introduced as a mode of treatment for coronary artery disease (CAD) in 1977 (Pollner, 1987). The purpose of the PTCA procedure is to increase blood flow through the coronary artery by decreasing the size of an intra-arterial stenotic lesion referred to more commonly as plaque. The number of individuals who were treated for CAD by PTCA, in 1983, was 32,000. The number in 1985 was 118,000 (Pollner, 1987). The dramatic increase in PTCA procedures is reportedly due to the effectiveness in treating CAD, minimal procedure discomfort, rapid convalescence, and relatively low cost (Block, 1985).

During the PTCA procedure a large bore catheter is inserted into the femoral artery. A deflated balloon, attached to a second catheter, is passed through the large bore catheter and threaded into the occluded coronary artery using fluoroscopy as a guide. Once appropriately located, the balloon is inflated, compressing the plaque against the arterial wall. At
the completion of the procedure, the balloon catheter is removed. However, the large bore femoral intra-arterial catheter remains within the femoral artery for approximately 6 to 12 hours in case the procedure must be repeated. The intra-arterial catheter may also be used as a continuous monitoring system by connecting the catheter to a transducer, thus providing immediate and continuous data relative to the patient's blood pressure. A dilute heparin solution of 500-1,000 units (U) per 500 milliliters (ml) of fluid is used to continuously flush the femoral catheter at a rate of 6-10 units per hour depending on the intraflow device used.

During the PTCA procedure, the patient receives 5,000-10,000 U of heparin to induce an anticoagulated state, thus reducing the chance of thromboemboli secondary to the presence of the catheter within the vascular space (Mabin et al., 1985). After the PTCA procedure, the effect of heparin is not reversed; that is, the patient's serum coagulation values are allowed to return to normal without therapeutic intervention. Prior to the removal of the intra-arterial catheter, an activated partial thromboplastin time (aPTT) is obtained to determine if the patient's coagulation status has returned to normal. This is a precautionary measure taken to avoid hemorrhage at the catheter site due to
the large bore size. The aPTT specimen has traditionally been obtained through a venipuncture.

The femoral catheter has not been used to obtain aPTT values. Some physicians and nurses have expressed concern that the aPTT, obtained through the intra-arterial catheter, may be prolonged as a result of the heparinized flush solution (Bark, 1970; Czapek, 1974; Kajs, 1986). The aPTT is sensitive to the affects of heparin (Thompson & Haker, 1983). However, Merenstein (1971), Palermo, Andrews, and Ellison (1980), Cannon, Mitchell, and Fabian (1985), and Molyneaux, Papciak, and Rorem (1987), concluded that the aPTT obtained through an intra-arterial catheter is accurate provided "adequate" amounts of blood are withdrawn and discarded prior to obtaining the aPTT specimens.

To date, however, empirical research has not evaluated the aPTT withdrawn by venipuncture versus through the large bore femoral intra-arterial catheter. Studies which have evaluated the accuracy of the aPTT drawn from heparinized intra-arterial catheters have assessed specimens from small bore catheters whose deadspace is 0.6-2.0 ml and the results have been conflicting (Merenstein, 1971; Palermo et al., 1980; Cannon et al., 1985; Kajs, 1986; Molyneaux et al., 1987).
Purpose

The purpose of this study was to compare aPTT obtained through a venipuncture versus aPTT obtained simultaneously through a large bore intra-arterial catheter, with a deadspace of 2 ml, to determine if there was a statistically significant difference between the aPTT values. The value of such research is that if indeed no difference exists between the two aPTT values, the patient can be spared a venipuncture which is painful.

Roy's Adaptation Model - Nursing Theory

Roy's Adaptation Model (1984) described person as an adaptive system that is in constant interaction with the internal and external environment. The hypothesized Adaptation Model is comprised of adaptive and/or ineffective responses. Adaptation is the person's response to the environment that promotes survival, growth, reproduction, and self-actualization. Ineffective response is the body's inability to maintain integrity. "Nursing aims to increase the person's adaptive responses and to decrease ineffective responses...An adaptive response is one that decreases the amount of energy needed to cope with a given situation and increase energy for other human processes" (Roy, 1984, p. 37).
Roy's Theory of Adaptation was applicable to this study in that patients who have undergone the PTCA procedure have been exposed to numerous physical and psychological stimuli, both prior to and during the procedure. Obtaining the aPTT specimen by venipuncture exposed the patient to additional physical and emotional stimuli. This may have occurred when the patient was less emotionally resilient and less able to adapt to stressors (Fisher & Moxham, 1984). Use of the femoral intra-arterial catheter to obtain the aPTT specimen had the potential of reducing the amount of energy expended by the patient by decreasing the pain, stress, or anxiety. This would have, perhaps, allowed additional energy to be available for other needs basic to living.

**Conceptual Framework**

The conceptual framework (Figure 1) for this study was similar to the one used by Kajs (1986). The construct level described the relationship between physical stimuli and the stress response. The concept level described the relationship between two methods of obtaining serum specimens. Each method resulted in a different physical stimulus with the potential for pain, stress, or anxiety. The operational level described the relationship between the withdrawal of blood using the two methods and the subsequent complaints by the
patients. This study tested only the difference in aPTT when drawn from a venipuncture versus a femoral intra-arterial catheter.
Figure 1. Conceptual Framework: Methods of Obtaining Serum Activated Partial Thromboplastin Times and the Stress Response. Adapted from Kajs, 1986.
**Construct Level.** Patients who are hospitalized for treatment of CAD are exposed to numerous physical and psychological stimuli not only due to the experience of being ill, but also the subsequent diagnostic studies which they endure. For example, prior to the PTCA procedure, patients are subjected to venipuncture procedures to obtain baseline electrolyte and hematocrit values. In addition, patients experience numerous radiologic and electrocardiographic studies. During the PTCA, the patient must lie on a relatively hard table, in a chilled room, for 2 to 4 hours while the physician conducts the procedure. While these diagnostic and therapeutic procedures are hopefully beneficial, the patient may perceive them as stressful and threatening. Stimuli resulting from diagnostic and therapeutic procedures are represented within the model as the Physical Stimulus. The result is an emotional and physical Stress Response.

Stress according to Solomon-Hast (1981) refers to "a multitude of physiological and psychological responses to stimuli that threaten the physical and emotional integrity of the individual" (p. 75). Selye (1956) demonstrated that factors perceived as stressful activate the autonomic nervous system resulting in a response of "fight or flight". The subsequent release of stress hormones, epinephrine and norepinephrine,
result in an increased heart rate and greater contractility of the myocardial muscles, as well as an increased respiratory rate, and increased blood supply to the skeletal muscles. Dilation of the pupils and bronchi, as well as increased glucose release from the liver, and decreased gastric motility result from the autonomic nervous system stimulation (Guzzetta & Forsyth, 1979; Solomon-Hast, 1981; Carrieri, Lindsey, & West, 1986).

In summary, it is hypothesized that therapeutic and diagnostic procedures such as the PTCA may induce stress with a subsequent increase in the autonomic nervous system activity. The relationship between physical stimuli and the stress response has been described as it relates to this study.

Concept Level. As demonstrated within the model, two methods of obtaining blood were considered; the venipuncture method and the femoral intra-arterial catheter method. Each method may elicit different psychophysiologic responses. Carruthers, Taggart, Conway, Bates, and Somerville, (1970) demonstrated a positive correlation between venipuncture and increased serum epinephrine levels. They concluded that the pain associated with venipuncture contributed to the increased level of hormones associated with stress.
Clinical pain can be defined as a perception of an unpleasant stimulus arising from sensory alterations in association with a disease process and/or from therapeutic and diagnostic procedures (McGuire, 1984). Clinical pain may result from numerous procedures patients may be expected to endure during their hospital stay. One such procedure is venipuncture to obtain serum specimens.

Relative to stress and anxiety, Mason (1971) stated that emotional reactions to a threatening or unpleasant factor can also initiate the stress response. Psychological stimuli can be some of the most potent initiating factors which affect the adrenal cortical response (Mason, 1971). An individual's response depends on the person's perception of the stress factor, or how he/she has dealt with that stress factor in the past (Harlan, 1981; Baker & Cook, 1983; Pollock, 1984).

Anxiety can be defined as "an unpleasant emotional state related to the subjectively associated quality of fear which is directed toward the future...a response to what may happen" (Guzzetta & Forsyth, 1979. p. 30). Anxiety is an unspecific and vague apprehension. The anxiety response is commonly used as an index of psychological stress (Guzzetta & Forsyth, 1979).
Stress and anxiety may influence the degree of pain that is experienced by an individual. Melzack and Wall (1965) stated that anxiety may contribute to rapid cognitive evaluation and thus amplify the pain sensory input.

In summary, diagnostic procedures, such as obtaining serum specimens, may result in a response of pain, stress, or anxiety. Mason (1970) stated that psychological stress factors are potent activators of the autonomic nervous system. The method used to obtain the specimen may determine the level of response that occurs. In the proposed model, the Venipuncture Method is shown to produce a positive response of pain, stress, and anxiety. The Femoral Intra-arterial Catheter Method is shown to produce a negative or neutral response; that is, pain, stress, and anxiety are not experienced.

Operational Level. To obtain an aPTT specimen by venipuncture, 4.5 ml of blood must be withdrawn from the vein. To obtain an aPTT specimen through the femoral intra-arterial catheter, 10.5 ml of blood (6.0 ml deadspace volume plus 4.5 ml for aPTT specimen) must be withdrawn. A significant difference between the two methods is the pain that may occur with the venipuncture. The pain may be expressed verbally during the venipuncture, as well as complaints of tenderness at
the site when multiple venipunctures have occurred. Some patients may not verbalize their response to pain, but non-verbal responses such as grimaces, changes in respiratory pattern, and tensing of the body may indicate that pain is actually being experienced. Within the model, the withdrawal of blood from the vein produces a positive response of pain or discomfort either by verbal or non-verbal expressions. The withdrawal of blood from the femoral intra-arterial catheter results in an absent or neutral response; that is, no complaints of pain from the patient.

In summary, man viewed in a holistic fashion allows the individual to be assessed as a biopsychosocial unit which is influenced by physical and psychological stimuli or stress factors. From the time of hospital admission, a patient is subjected to numerous stress factors. These stress factors result from therapeutic and diagnostic procedures, change in health status, and loss of personal control. By decreasing the number and/or intensity of stress factors, the patient will be better able to mobilize energy sources for other needs. One way to eliminate the stress of venipuncture may be the use of the femoral intra-arterial catheter to obtain aPTT samples. This study assessed the difference in aPTT obtained by a venipuncture versus a femoral intra-arterial catheter.
Problem Statement

The question addressed by this study was: Is there a statistically significant difference in the aPTT value obtained through venipuncture versus withdrawal from a femoral intra-arterial catheter.

Definition of Terms

Percutaneous Transluminal Coronary Angioplasty (PTCA)-

Theoretical definition: PTCA is a therapeutic intervention for coronary artery disease.

Operational definition: PTCA involves the inflation of a balloon catheter within a coronary artery. This results in compression of the lesion, or desquamation of the superficial plaque elements and splitting the atheroma within the coronary artery, thus restoring circulation. (Bouman, 1984).
Activated Partial Thromboplastin Time (aPTT) -

Theoretical definition: aPTT is a serum laboratory test used to measure the adequacy of the procoagulant factors of the intrinsic and common pathways (Thompson & Harker, 1983). The aPTT is the coagulation test most sensitive to the effects of heparin.

Operational definition: The aPTT is defined as the time in seconds required for a fibrin clot to form in a serum sample (Dugdale, 1971).

Heparin -

Theoretical definition: Heparin is a highly negatively charged conjugated polysaccharide. Combined with antithrombin III heparin becomes a powerful anticoagulant (Guyton, 1986).

Operational definition: Heparin is defined as an anticoagulant that is added to normal saline or dextrose and water to provide a continuous flush solution for the intra-arterial catheter system.

Femoral Intra-arterial Catheter Method - The femoral arterial catheter method is defined as the method of withdrawing arterial blood from an indwelling large bore femoral arterial catheter which requires 6 ml of deadspace blood to be discarded prior to obtaining the specimen.
Venipuncture Method - The venipuncture method is defined as withdrawing blood from the vein utilizing a needle and syringe or needle and a Vacutainer.

Significance to Nursing

The decision of whether or not to remove an intra-arterial catheter following PTCA and anticoagulation therapy is based on the aPTT results. Within some hospital units, the nurses decide whether a venipuncture or femoral intra-arterial catheter sample is used to obtain the aPTT. This decision needs to be based on empirical research; however, these data are not available.

If there is no statistically significant differences in the aPTT values obtained by venipuncture or large bore intra-arterial catheter, nurses can use the femoral intra-arterial catheter knowing that the aPTT values accurately reflect the patient's coagulation status. Several aPTT specimens may have to be drawn before the aPTT returns to an acceptable level, \( \leq 35 \) seconds, and each aPTT will require a separate venipuncture. The use of the femoral intra-arterial catheter to obtain aPTT specimens would decrease potential venous trauma. In addition, patients would experience less pain and possibly less anxiety and
stress with the use of the femoral catheter. Often an intravenous (IV) drip must be interrupted in order to obtain a serum specimen by venipuncture. Use of the femoral intra-arterial catheter would eliminate the need to interrupt the IV therapy, thereby maintaining an adequate serum level of a therapeutic drug.

Nursing care must provide holistic, therapeutic interventions. This study focused on accomplishing this type of intervention. Invasive procedures such as withdrawing blood, either through venipuncture or through an indwelling catheter, can provoke anxiety, stress, and pain as well as introduce infection in a compromised host. This study was designed to investigate if there was a difference in aPTT values when two methods were used keeping in mind the biophysiologic and psychological needs of patients.
CHAPTER II

REVIEW OF THE LITERATURE

This chapter presents a review of available literature which examines the relationship between coagulation values and methods of obtaining serum coagulation specimens. The stress response to physical and psychological stimuli is also discussed as it relates to the stress of invasive procedures such as percutaneous transluminal coronary angioplasty (PTCA) and subsequent diagnostic procedures which include venipuncture.

Stress Response

Physical and psychological stimuli, known as stress factors, have been found to initiate a stress response. Selye (1956) described stress as the body's nonspecific physiologic response to any demand. Stress factors are those stimuli, either biophysiological or psychologic, internal or external, that upset an organism's homeostasis and demand some response (Harlan, 1981; Erickson & Swain, 1982; Fisher & Moxham, 1984). Furthermore, Selye (1956) noted that certain changes in the body's structural and chemical composition occurred as a result of stress. He proposed that such changes
represented the body's adaptive reactions. Selye (1956) identified man's response to stress factors as the general adaptation syndrome (G.A.S.). The course of the stress response is triphasic consisting of the alarm reaction, the stage of resistance, and the stage of exhaustion. The adaptive responses are represented by changes in the endocrine and sympathetic nervous system activity.

During the alarm stage, activation of the sympathetic nervous system causes a release of catecholamines including epinephrine and norepinephrine, resulting in an increased heart rate and increased contractile force of the heart, as well as increased respiratory rate, bronchial dilation, and dilation of the pupils. Adrenal cortex stimulation increases secretion of cortical hormones such as cortisol. If man survives the alarm stage, it is followed by a stage of resistance in which corticoid activity falls to a level only slightly above normal, thus the body attempts to resist the stress factor (Selye, 1956).

Mason (1971) stated that while Selye acknowledged that psychological stimuli can initiate the adrenal cortical response, he (Selye) did not suspect the true degree to which the pituitary-adrenal cortical response was sensitive to psychological influences. The psychological apparatus involvement in emotional
reactions to a threatening or unpleasant factor in a life situation may be a primary mediator to the pituitary-adrenal cortical response to stress. Mason concluded that psychological stimuli are among the most potent of all stimuli affecting the pituitary-adrenal cortical system. Subtle psychological stimuli of everyday life can be reflected in activation of the autonomic nervous system (Mason, 1971).

Stimulation of the sympathetic nervous system does not always prove beneficial to the individual. The increase in heart rate and contractility of the myocardial muscle also increases myocardial oxygen consumption. An increase in peripheral vascular resistance results in elevation of blood pressure. Increased myocardial oxygen consumption may decrease the individual's ability to preserve the ischemic area which results after a myocardial infarction.

Stress Associated with Hospitalization

During a hospital stay patients are subjected to numerous stress factors. Vanson, Katz, and Kerkeler (1980) evaluated patient responses following the witnessing of a therapeutic procedure on other patients within the critical care unit. Therapeutic procedures included insertion of a Swan-Ganz catheter, insertion of a temporary transvenous pacemaker, or cardioversion.
Thirty-six patients participated in the study. Eighteen patients witnessed the procedure performed on a patient in the same room. Eighteen patients witnessed the procedure performed on a patient in another room. Those patients that witnessed the procedure in the same room had a mean increase in their pulse rate from 81.4 to 89.2. The pulse rate in those patients who observed the procedure performed on a patient in another room remained essentially unchanged. The pulse rate patterns between the two groups was found to be statistically significant beyond the 0.001 level.

Poe (1982) evaluated post-myocardial infarction patients and found that even the transfer from the coronary care unit (CCU) to a general medical floor resulted in a stress response. Eight patients were assigned to the control group and eight patients were assigned to the experimental group. Patients in the experimental group were given pretransfer instruction the night before transfer from the CCU. A statistically significant difference (p<.05) was found between the two groups in relation to the psychological stress experienced as measured by the State-Trait Anxiety Inventory. The author concluded that the transfer from the CCU was stressful to the myocardial infarction patient. Some patients experienced difficulty sleeping and restlessness, while others experienced elevations in
their heart rate and blood pressure. Data for these disturbances was not included.

These studies illustrate that during a hospital stay patients are subjected to numerous stress factors, some of which are physical and others psychological. These stress factors may lead to the stress response as seen by changes in the endocrine and sympathetic nervous system.

An additional source of stress is the critical care unit to which patients will be returning following procedures such as the PTCA. Patients may not be able to cope with the environment in the critical care unit and feel overwhelmed by noise from complex machines, from patients who are confused or in pain, and from staff. The appearance of technical equipment as well as activities of the nursing and medical staff may be confusing. They may even witness death in the critical care unit (Vanson et al., 1980 and Solomon-Hast, 1981). Furthermore, loss of personal control in such units may be stressful to patients (Bouman, 1984).

Patients may also experience stress secondary to therapeutic and diagnostic studies. Included among these studies is the partial thromboplastin time (aPTT) obtained through venipuncture. In an effort to decrease these responses, the intra-arterial catheter is often used as an alternate method of obtaining various serum
specimens. Questions have arisen whether the heparin solution used to flush the intra-arterial catheter might cause the aPTT to be prolonged. However, studies to date have only compared aPTT values obtained from venipuncture with those obtained by small bore intra-arterial catheters.

**Venipuncture versus Indwelling Catheter**

Bark (1970) was the first to report partial thromboplastin time (PTT) obtained from a venipuncture versus an indwelling venous catheter. Wide variations in PTT results were observed in patients who did not demonstrate pathologic clinical symptoms, i.e., no excessive bleeding from wounds. In the course of evaluating the patients, it was discovered that PTT samples drawn from the venous catheter were consistently greater than 100 seconds. The amount of sample withdrawal from the catheter was not mentioned. Venipuncture samples yielded a normal PTT value. The patency of the venous catheter was maintained by continuous heparin flush. The concentration of the flush solution was 1,000 units (U) heparin per 1,000 milliliters (ml) solution.

A follow-up study was performed (Bark, 1970) in which normal citrated plasma (PTT of 40 seconds) was passed once through a section of tubing that was
routinely flushed with a solution of 1,000 U heparin per 1,000 ml of solution. He reported that plasma, exposed to heparin, consistently demonstrated PTT values in the range of 150 seconds. "After flushing the line with an additional 50 ml of saline, the heparin effect was eliminated" (p. 1214). However, PTT values were not reported following this procedure.

Merenstein (1971) studied the amount of blood needed to clear an in vitro umbilical artery catheter and eliminate the heparin effect. An umbilical artery catheter was flushed with a standardized heparin solution (one unit of heparin per one ml solution). Blood samples from adult subjects were collected in a syringe by venipuncture. The blood sample was passed through the catheter and subsequently collected. The aPTT time was found to be prolonged; however, the author did not provide actual data. The aPTT value returned to normal after a maximum amount of 3.2 ml of blood was passed through the catheter. Merenstein recommended that when blood for coagulation studies is obtained from a catheter exposed to heparin, 4.0 ml of fluid and blood (3.2 ml of blood, and 0.8 ml of deadspace fluid) be removed prior to obtaining the coagulation specimen. While representative results were discussed, the number of subjects and the number of
blood samples were not reported. Statistical analysis was also not included.

Peterson and Gottfried (1982) presented information about the effects of sample volume on prothrombin time (PT) and aPTT results. Sixteen subjects were evaluated in which blood was obtained by venipuncture. Total blood volumes ranged from 2.5 to 7.0 ml for the test samples. Results from the study demonstrated that with less than 4.0 ml of blood, PT and PTT values were prolonged while amounts greater than or equal to 4.0 ml were less likely to affect the results. The authors recommended that the specimen volume be at least 4.5 ml with blood volume representing 4.0 ml and sodium citrate, a standard preservative placed within blood collection tubes, being 0.5 ml.

Czapek (1974) reported data similar to those of Bark (1970), that is prolonged aPTT values were created using indwelling heparinized catheter to obtain specimens. While Merenstein (1971) demonstrated that the aPTT values were normal after 4 ml of blood had been removed prior to the specimen, Czapek reported that withdrawing as much as 10 ml of blood from the indwelling catheter, prior to obtaining the specimen, did not negate the heparin effect. Czapek recommended that aPTT samples be drawn through a new venipuncture
site whenever possible. However, data from the Czapek (1974) study did not include information as to the type of indwelling catheter or deadspace of the catheter used to obtain the specimen. Also, the amount of blood withdrawn for the aPTT samples was not specified, thus whether an adequate amount was withdrawn must be questioned.

A study similar to Merenstein's (1971) was conducted by Palermo, Andrews, & Ellison, (1980). To demonstrate that abnormal values can be produced if the heparin from the flush solution is not cleared prior to obtaining the aPTT sample, two patients had blood samples which were deliberately contaminated by inadequate clearing of the deadspace. Subsequent aPTT values of both patients were prolonged.

Twelve subjects scheduled for open heart surgery, with normal preoperative coagulation values, participated in the study. Subjects were divided into two groups. In one group, the flush solution contained 1 unit heparin per ml; in a second group, the flush solution contained 2 units heparin per ml. The control value of the aPTT was obtained by venipuncture. Subjects in each group had samples obtained from the arterial line with a deadspace [DS] equal to 1.79 and from the venous line with a DS equal to 1.50. Prior to obtaining the aPTT sample, four discard amounts were
obtained: DS + 0 ml, DS + 1 ml, DS + 2 ml, DS + 4 ml (Palermo et al, 1980).

Mean scores for each blood sample group were reported. As long as a volume equal to the deadspace of the catheter was withdrawn prior to obtaining the sample, no statistically significant differences between the control value obtained by venipuncture and the aPTT obtained via a catheter was demonstrated. The authors stated that discarding a volume equal to the deadspace volume of the catheter through which the specimen is being withdrawn is sufficient to negate the effect of heparin. However, they recommended that discard volume equal twice the deadspace of the catheter to be perfectly safe.

Cannon, Mitchell, and Fabian (1985) reevaluated the accuracy of the study by Palermo et al., referred to as (Method A), and compared it to a new method involving no blood loss (Method B). Fifty critically ill patients in an intensive care unit participated in the randomized study. Patients with an even unit number were assigned to Method A. Patients with an odd unit number were assigned to Method B. Patency of the arterial catheters was maintained by a heparin flush solution containing 1 unit heparin per ml.

Twenty-five samples were drawn by Method A (DS = 2.0 ml) which involved the withdrawal and discard
of 2.0 ml of blood from the heparinized arterial line prior to obtaining the PT and aPTT samples. Twenty-five samples were drawn by Method B which involved the use of two ports for blood withdrawal, a proximal port and a distal port with a deadspace of 4.5 ml. A volume of blood equal to the deadspace (4.5 ml) was withdrawn into a syringe connected to the distal port. The PT and aPTT specimen were withdrawn from the proximal port. The 4.5 ml of blood in the syringe connected to the distal port was reinjected back into the patient's vascular space. Venipuncture was performed simultaneously as arterial line specimens were obtained (Cannon et al., 1985).

Data analysis was completed using the Pearson product-moment correlation. Results obtained for aPTT by Method A, $r = .93$, and by Method B, $r = .84$ indicated a strong positive correlation between the sample obtained by venipuncture and the sample withdrawn from the arterial catheter. Results obtained for PT by Method A, $r = .95$, and by Method B, $r = .98$ also indicated a strong positive correlation between the sample obtained by venipuncture and the sample withdrawn from the arterial catheter (Cannon et al., 1985). Cannon et al. concluded that Method B had the advantage over Method A in that no loss of blood occurred when specimens were obtained from heparinized arterial lines.
Therefore, Method B, the use of two ports for blood withdrawal, was the preferred procedure.

A study by Pryor (1983) examined the use of the arterial catheter as a site for obtaining coagulation specimens. The study was expanded to include subjects who received warfarin and heparin therapy (intravenous or subcutaneous). Fifty pairs of blood samples were obtained from 49 acutely ill subjects, two of which were from the same patient. Six patients were receiving heparin therapy; four patients received 5,000 units of heparin subcutaneously (SQ) every 12 hours, one patient received 5,000 U of heparin intravenous push every 8 hours, and one patient received 1,000 U heparin per hour by intravenous infusion. One patient received 10 mg of warfarin daily. The arterial and venous catheters were continuously infused with 6 units of heparin per hour to maintain patency. A nurse withdrew and discarded 6 ml of blood prior to obtaining 4.5 ml of blood for the aPTT specimen. Simultaneously, a laboratory phlebotomist performed venipuncture on extremities not receiving intravenous infusions to obtain aPTT specimen.

Data analysis, using the Pearson product-moment correlation indicated that the venous and arterial PT values were perfectly correlated ($r = 1.00$). The venous and arterial aPTT values were also significantly
correlated \( r = .99 \). The warfarin and subcutaneous heparin therapies did not change the relationship between the venous and arterial aPTT. The aPTT values of two patients receiving intravenous heparin therapy were considerably altered. In one patient the arterial aPTT was 50.1 seconds (sec.) and the venous aPTT was 70.5 sec. In the second patient the arterial aPTT was 90.0 sec. and the venous aPTT was 80.2 sec (Pryor, 1983).

The investigator concluded that specimens drawn for PT and aPTT values can be drawn from intra-arterial lines if the patients are not receiving peripheral intravenous heparin therapy. Pryor recommended further study in subjects receiving intravenous heparin therapy. She did not mention the amount of deadspace in the arterial catheter.

Kajs' (1986) research study also compared coagulation values obtained by venipuncture and withdrawal from an arterial line. The population consisted of a convenience sample of 24 critically ill adults in an intensive care unit. Six units of heparin per hour continuously flushed the arterial line to maintain patency.

The investigator utilized two groups of patients. Twelve patients in Group 1 had 3 ml (five times the deadspace) of blood withdrawn and
discarded from the catheter prior to an aPTT specimen being drawn. Twelve patients in Group 2 had 6 ml (ten times the deadspace) of blood withdrawn and discarded prior to the aPTT specimen being drawn. Venipuncture specimens were obtained simultaneously with the specimen being withdrawn from the arterial line. In Group 1, seven patients were receiving some type of heparin therapy. In Group 2, four patients were receiving some type of heparin therapy.

Kajs (1986) tested two null hypotheses. The first null hypothesis stated that there would be no significant difference between aPTT values obtained by the arterial line and those obtained by venipuncture. The second null hypothesis stated that there would be no significant difference between aPTT values in blood obtained in the arterial line following the withdrawal and discard of 3 ml of blood versus the withdrawal and discard of 6 ml of blood.

Paired two-tailed t-tests were performed between the venous and arterial blood samples. Statistically significant differences in the aPTT values occurred between the two methods for each group at the 0.01 level of significance; Group I, $t = -1.95$, $p = <.08$, and Group 2, $t = -2.92$, $p = .03$. Thus, the first null hypothesis was rejected indicating that there was a statistically significant difference between aPTT values obtained by
the arterial line and those obtained by venipuncture. Independent two-tailed t-tests were performed between Group 1 (3 ml withdrawal and discard) and Group 2 (6 ml withdrawal and discard). The level of significance was set $p < .10$. There was no statistically significant difference between Group I and Group 2 when arterial ($t = 0.12, p = .90$) and venous ($t = 0.46, p = .65$) values were analyzed. The second null hypothesis was accepted indicating that both 3 ml and 6 ml discard prior to obtaining an aPTT sample were inadequate to eliminate the heparin effect.

Kajs (1986) concluded that both amounts of discard blood (3 ml and 6 ml) prior to obtaining samples for coagulation studies were inadequate to decrease the chance of heparin effect. She therefore recommended that the venipuncture method of withdrawing blood for coagulation studies be the method of choice, but also suggested was the need for further studies.

Recent research by Molyneaux, Papciak, and Rorem (1987) examined the relationship between aPTT samples obtained through an indwelling arterial catheter versus venipuncture. The convenience sample included 24 patients within a critical care unit who had indwelling arterial lines. The arterial lines were flushed with 6 U of heparin per hour in a continuous flow solution. Deadspace of the arterial line was 0.8 ml.
A venipuncture was performed on each subject to obtain a 4.5 ml venous aPTT specimen. Immediately following the venipuncture method, a 4.5 ml aPTT specimen was obtained from the arterial line after blood had been removed using one of the three discard volumes: 1.6 ml, 3.2 ml, or 4.8 ml.

The investigators utilized paired t-tests to analyze the data at the 0.10 level of significance. A significant difference ($p = .0025$) was found between the arterial line and the venipuncture samples in the group which had a discard volume of 1.6 ml. A significant difference .05 was found in the group which had a discard volume of 3.2 ml. No significant difference in aPTT values was demonstrated between the arterial line and venipuncture sample in the group which had a discard volume of 4.8 ml. In the group which had a discard volume of 4.8 ml, Pearson product-moment correlation between the venous and arterial aPTT values was significantly related ($r = .99$).

Five of the sample pairs in the group having a discard volume of 4.8 ml were receiving heparin therapy. Four were receiving subcutaneous (SQ) heparin therapy, and one was receiving heparin therapy from a continuous infusion. As with the Pryor (1983) study, Molyneaux et al. (1987) found that aPTT values obtained from the arterial line in patients receiving SQ heparin
were not significantly different from the aPTT obtained by venipuncture. However, unlike the Pryor (1983) study, the patient receiving intravenous heparin therapy did not exhibit a widely distorted aPTT value. However, the one subject did not provide sufficient data to support conclusions concerning the accuracy of aPTT drawn from an arterial line when the patient is receiving intravenous heparin therapy.

Molyneaux et al. (1987) recommended that a minimal discard volume of 6 times the deadspace volume of the catheter be withdrawn and discarded prior to obtaining an aPTT specimen from heparinized arterial lines. Further recommendations included repeating the study with subjects receiving intravenous heparin, using a larger sample size, and using arterial catheters having varying deadspace.

In summary, controversy exists over the use of the arterial catheter to obtain aPTT samples. Some authors have reported that the heparin in the flush solution may falsely prolong the aPTT value; therefore, the venipuncture method should be used to insure accuracy (Bark, 1970; Czapek, 1974; Kajs, 1986). Merenstein (1971), Palermo et al. (1980), Cannon et al. (1985), and Molyneaux et al. (1987) contended that if adequate amounts of blood were withdrawn from the arterial catheter prior to obtaining the aPTT sample,
the values would not be statistically different from samples obtained by venipuncture. These studies were conducted using catheters with a deadspace of 0.6 to 0.8 ml. Recommendations from these studies include replication with greater patient numbers, repeating the studies with patients receiving intravenous heparin, and using arterial catheters with varying deadspace volumes.

Review of the literature revealed that the studies which have attempted to determine if there is a statistically significant difference in the aPTT values of specimens obtained from venipuncture versus an indwelling arterial catheter have been conflicting. The studies to date have also been limited to small bore intra-arterial or venous catheters. This study attempted to determine if there was a statistically significant difference in the aPTT values obtained from venipuncture versus a large bore femoral intra-arterial catheter.
CHAPTER III

METHODOLOGY

Purpose

The purpose of this study was to determine if there was a statistically significant difference in the activated partial thromboplastin time (aPTT) when obtained by venipuncture versus femoral intra-arterial catheter. The research design, variables, sample, setting, and the protection of human rights are presented within this chapter. Also presented are data collection procedures and data analysis plan.

Research Design

A descriptive research design was used to assess the difference between activated partial thromboplastin time (aPTT) obtained by venipuncture versus femoral intra-arterial catheter. The independent variables in this study were: The methods of obtaining aPTT specimen, that is, venipuncture versus femoral intra-arterial catheter. The dependent variable was the aPTT obtained for each method of sample withdrawal.
Null Hypothesis

The null hypothesis was tested at the 0.10 level of significance.

$H_0$ There will be no statistically significant difference serum aPTT values obtained by venipuncture and aPTT values obtained from a large bore femoral intra-arterial catheter.

Setting

The sample was comprised of seventeen paired specimens of blood drawn from seventeen adult patients who had been admitted to two intensive care units following percutaneous transluminal coronary angioplasty (PTCA). The intensive care units were located within two tertiary care hospitals in the southwestern United States.
Subjects

The subjects included in this study were selected based on the following criteria:

1) Male or female
2) Twenty-one years of age or older
3) Had undergone a PTCA during the past 4 to 36 hours
4) A functional femoral arterial catheter within the femoral artery
5) Physiologically stable; systolic blood pressure (BP) >90 millimeters (mm) Hg, heart rate <125 beats per minute, but >45 beats per minute
6) A hematocrit >30 mg/dl or a hematocrit >20 mg/dl for chronic dialysis patients
7) Able to read, write, speak, and understand English

Internal Validity

At Hospital 1 the investigator, along with research assistants, obtained the serum samples from the femoral intra-arterial catheter. In an effort to minimize random error, the method used by the investigator and research assistants was the same for each subject following "Guidelines for Obtaining
Serum aPTT-Femoral Arterial Catheter Method" (see Appendix A). The investigator collected all femoral intra-arterial samples at Hospital 2 following the stated guidelines. The venipuncture and intra-arterial catheter specimens were drawn simultaneously. Both aPTT specimens were analyzed using the same optical fibrometer by the same laboratory technician.

Procedure

The day before the PTCA procedure, the investigator or research assistant obtained a listing of patients scheduled for a PTCA. The evening prior to the procedure, the purpose and method for obtaining the two different blood specimens was explained to the patient and written consent obtained. Those patients who were admitted the morning of the PTCA procedure were visited following their return to the intensive care unit (ICU) and the consent was signed after the half life of the intraoperative narcotic had lapsed.

After the PTCA procedure had been completed, the subjects returned to an intensive care unit and resided overnight for physiologic monitoring. The femoral intra-arterial catheter remained in place. Prior to the removal of the catheter, two aPTT specimens were drawn. A laboratory technician performed the venipuncture and
simultaneously, the investigator or research assistant obtained a serum specimen via the femoral intra-arterial catheter. The entire procedure did not exceed 5 minutes. Both specimens were obtained per standardized guidelines (see Appendix A).

**Instruments**

The activated partial thromboplastin time (aPTT) was analyzed for clot formation by use of an optic fibrometer. One-tenth ml of the lactic reagent/phospolipid was added to 0.1 ml of the patient's serum samples, one obtained by venipuncture and one obtained from the large bore femoral intra-arterial catheter. Samples were incubated at 37 degrees centigrade for 3-5 minutes. One-tenth ml of .025 mole CaCL was added to the blood and reagent samples and the timing in seconds began. When clot formation occurred, there was a change in the optical density and timing was stopped. This method of obtaining aPTT results was the same at both hospitals.

**Data Analysis**

Demographic data for each patient was analyzed using descriptive statistics. Frequency counts, means, and standard deviations were calculated for age, sex, types of anticoagulant received pre-procedure, amount of heparin received during the procedure, amount of heparin
received after the procedure, and time of last heparin dose.

Correlated t-tests (two-tailed) were performed to determine if there were any significant differences between the two aPTT values. The significance level of \( \alpha = 0.10 \) had been selected to decrease the likelihood of Type II error. The alpha level of 0.10 provided for a more conservative test when attempting to support the null hypothesis and therefore reduced the probability of accepting a false hypothesis of no difference between the groups. The power was set at .80 to detect significant difference. The sample size of N=17 was selected to insure power of .80 with alpha = .10 and an effect size of 0.80 (Cohen, 1978).

Assumptions

The assumptions in this study included:

1) The aPTT value is an accurate indication of the patient's coagulation status.

2) The venipuncture specimen which is utilized as a control is an accurate indication of the patient's activated partial thromboplastin time.
3) Test analysis by the same laboratory technician using the same optical fibrometer will increase the likelihood that the aPTT obtained truly reflect the values of each specimen; error introduced by different machines would be negated.

4) The results of the aPTT obtained by two different methods will not be influenced by any medications received prior to specimen collection.

**Limitations**

The following limitations have been identified:

1) A small sample size (N = 17) was obtained.

2) Sample groups had different concentrations of heparin in the flush solution.

3) The investigator did not analyze each sample, but had to rely on laboratory personnel which were not consistently the same person.

4) The study is generalizable only to patients following elective PTCA with femoral intra-arterial catheters that are continuously flushed with a heparinized solution.
Risk/Benefit Ratio

There was a minimal risk of infection occurring as a result of the femoral catheter being utilized to obtain serum specimens. This was minimized by the investigator's use of aseptic technique when obtaining each specimen. The potential benefits included elimination of unnecessary venipuncture and decreased venous trauma from multiple venipuncture.

Protection of Human Subjects

The research proposal and consent form was presented to Human Subjects Review Committee for the College of Nursing, University of Arizona and to the Human Subjects Committee for the Arizona Health Sciences Center for approval (see Appendix B).

Prior to participation in the study, the patient was visited by the investigator or research assistant. The patient was informed of the purpose of the study, the methods of obtaining the blood specimen, and the potential risks involved. Questions were encouraged. If the patient agreed to be a participant in this study, a consent form (see Appendix C) was signed. Prior to obtaining the intra-arterial specimen, the patient was encouraged to ask any questions that may have arisen after the initial visit.
The patient was assured that refusal to participate in this study would not affect the medical or nursing care that he/she received. The patient was also informed that he could withdraw from the study at any time.

To assure patient anonymity and confidentiality, the patients and serum specimens were assigned a code number and all data was coded accordingly.
CHAPTER IV

PRESENTATION OF DATA ANALYSIS

Introduction

The purpose of this study was to determine if there was a statistically significant difference in the activated partial thromboplastin time (aPTT) when obtained by venipuncture method versus femoral intra-arterial catheter method.

The study was conducted within two tertiary hospitals in the southwestern United States. A convenience sample of seventeen patients who had undergone a percutaneous transluminal coronary angioplasty (PTCA) procedure participated in the study.

Following the PTCA procedure, patients were returned to the intensive care unit (ICU) with a large bore femoral intra-arterial catheter in place. The femoral catheter remained in place following the PTCA procedure because the patients were in an anticoagulated state from heparin received during the PTCA procedure. To maintain patency, the femoral intra-arterial catheters were continually flushed with a heparinized solution at a rate of 3 cubic centimeters (cc) per hour. Paired aPTT samples were collected simultaneously; one
venipuncture sample was collected by the laboratory phlebotomist and one arterial sample was collected by the investigator or a research assistant through the use of the femoral intra-arterial catheter. Prior to obtaining the aPTT sample from the femoral intra-arterial catheter, 6cc of fluid-blood mixture were withdrawn and discarded. The aPTT obtained by venipuncture served as the control.

Seventeen patients participated in the study. Fifteen of the 17 patients had one set of paired aPTT samples drawn while two patients had two sets of paired samples drawn due to the first aPTT being greater than 200 seconds (sec.) for both the venous and arterial samples. According to standard procedure, the second paired sample for these two patients was obtained several hours later. The time lapse between the first and second paired samples allowed the aPTT value to decrease to a measurable level that could be analyzed. Only the second sample was included in data analysis.

**Characteristics of the Sample**

Of the 17 patients who qualified for this study, 14 (82.4%) were males and 3 (17.6%) were female. The mean age of the 17 patients was 57 years, with a range of 40-76 years and a standard deviation of 9.5 years. Ten (58.8%) patients were in Hospital 1 and 7 (41.2%)
patients were in Hospital 2. Tables 1 and 2 present the gender and age characteristics of the patients according to hospital.
Table 1.

**Gender Distribution of Percutaneous Transluminal Coronary Angioplasty Patients; Hospital 1 and Hospital 2, N=17**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7</td>
<td>70</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>HOSPITAL 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Female</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2.

**Age Range, Mean, and Standard Deviation of Percutaneous Transluminal Coronary Angioplasty Patients; Hospital 1 and Hospital 2, N=17.**

<table>
<thead>
<tr>
<th>Age range (years)</th>
<th>Mean (years)</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL 1</td>
<td>40-69</td>
<td>56.1</td>
</tr>
<tr>
<td>HOSPITAL 2</td>
<td>50-76</td>
<td>58.6</td>
</tr>
</tbody>
</table>
All patients received intravenous (IV) heparin during the percutaneous transluminal coronary angioplasty (PTCA) procedure. The amount of heparin received ranged from 1000 units (U) to 20,000 U.

Thirteen (76%) patients received additional heparin by IV infusion after returning to the intensive care unit (ICU). The amount of the heparin infusion ranged from 800 u per hour to 1,000 U per hour. The patency of the femoral intra-arterial catheter was maintained by a heparinized flush solution. In Hospital 1 the standardized flush solution consisted of four units of heparin per cc of normal saline (NS) solution. In Hospital 2, the standardized flush solution consisted of 1 unit heparin per cc dextrose and water. The intravenous fluids were infusing through the femoral intra-arterial catheter at a constant rate of 3cc per hour, the standardized flush rate for arterial lines in the ICU at both hospitals in which the study was conducted. Table 3 presents the amount of heparin the patient received during the procedure and within the ICU, as well as the number of hours the heparin had been discontinued prior to obtaining the aPTT sample.
Table 3.
Heparin Therapy Received During PTCA Procedure, Within ICU Unit, and Number of Hours Intravenous (IV) Heparin Discontinued Prior to aPTT Sample Obtained (N=17).

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Heparin (in units)</th>
<th>IV Heparin Infusion Rate (units per hour)</th>
<th>Number of Hours IV Heparin Discontinued Received within ICU Prior to aPTT Sample Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15,000</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>10,000</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>3</td>
<td>5,000</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>4</td>
<td>15,000</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>5</td>
<td>15,000</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>6</td>
<td>15,000</td>
<td>1,000</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>20,000</td>
<td>1,000</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>15,000</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>9</td>
<td>8,000</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>12,500</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>Hospital 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>8,000</td>
<td>1,000</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>8,000</td>
<td>1,000</td>
<td>1</td>
</tr>
<tr>
<td>13</td>
<td>9,500</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>14</td>
<td>1,100</td>
<td>800</td>
<td>0+</td>
</tr>
<tr>
<td>15</td>
<td>8,000</td>
<td>1,000</td>
<td>0+</td>
</tr>
<tr>
<td>16</td>
<td>1,000</td>
<td>1,000</td>
<td>2</td>
</tr>
<tr>
<td>17</td>
<td>8,000</td>
<td>900</td>
<td>0+</td>
</tr>
</tbody>
</table>

† = IV Heparin Therapy infusing at the time the aPTT sample obtained
**Hypothesis Testing**

The following null hypothesis was tested at the $\alpha = .10$ level of significance:

$H_0$: There will be no statistically significant differences between serum aPTT values obtained by venipuncture and aPTT values obtained from a large bore femoral intra-arterial catheter. Correlated t-tests were performed between the aPTT samples obtained by venipuncture and those obtained by use of the femoral intra-arterial catheter. Table 4 presents these data. No statistically significant difference in the aPTT values was found between the venipuncture sample and the femoral intra-arterial catheter sample ($t = -1.43$, $p = .17$). Thus, the null hypothesis was accepted.
Table 4.

Correlated t-tests of Venipuncture aPTT Sample and Femoral Intra-arterial Catheter aPTT Sample; N=17.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (Sec.)</th>
<th>Standard Deviation (Sec.)</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT Venipuncture</td>
<td>56.3</td>
<td>29.5</td>
<td></td>
</tr>
<tr>
<td>aPTT Femoral Intra-arterial Catheter</td>
<td>67.2</td>
<td>42.8</td>
<td>-1.43</td>
</tr>
</tbody>
</table>

* p ≤ .10
Comparison of Samples from Study Sites

The total sample (N=17) was subsequently divided into two groups according to hospital. Once divided, each group's mean values for venous aPTT and femoral intra-arterial catheter aPTT were assessed for statistically significant differences through the use of correlated t-tests. Tables 5 and 6 illustrate these data. No statistically significant difference was found in the aPTT values of either group when assessed according to Hospital 1 (t= 0.99, p= .35) and Hospital 2 (t=-1.45, p= .20).
Table 5.

Correlated t-tests of Activated Partial Thromboplastin Time: Venipuncture Method and Femoral Intra-arterial Catheter Method: Hospital 1. (N=10)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (Sec.)</th>
<th>Standard Deviation (Sec.)</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT Venipuncture Method</td>
<td>47.0</td>
<td>24.6</td>
<td></td>
</tr>
<tr>
<td>aPTT Femoral Intra-arterial Catheter Method</td>
<td>47.7</td>
<td>24.5</td>
<td>-0.99</td>
</tr>
</tbody>
</table>

* p ≤ 0.10

Table 6.


<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (Sec.)</th>
<th>Standard Deviation (Sec.)</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>aPTT Venipuncture Method</td>
<td>69.5</td>
<td>32.6</td>
<td>-1.45</td>
</tr>
<tr>
<td>aPTT Femoral Intra-arterial Catheter Method</td>
<td>95.1</td>
<td>49.5</td>
<td></td>
</tr>
</tbody>
</table>

* p ≤ 0.10
To determine if there was a statistically significant difference between the two hospitals, plans were made to conduct independent t-tests on the difference between the venous aPTT and the arterial aPTT obtained at the two hospitals. Reviewing the data revealed, however, a PTT standard deviation for Hospital 1 of 2.0 seconds, and a PTT standard deviation for Hospital 2 of 46.8 seconds. Since the standard deviation for samples based on hospital site varied so greatly, the independent t-tests were not conducted.

As illustrated in Table 7, five subjects (50%) in Hospital 1 had arterial values greater than the venous values. The differences between the arterial and venous values ranged from 0.1 sec. to 4.5 sec. with a mean difference of 1.5 sec. and a standard deviation of 3.3 sec.

Six subjects (86%) within Hospital 2 had arterial values greater than the venous value. Two subjects were considered outliers: subject number 14 with a venous value greater than the arterial value and subject number 17 with a difference between the venous and arterial value of 102.7 seconds. One questions whether mislabelling occurred in the paired samples of subject number 14 in which the venous value was greater when the results were entered into the laboratory computer.
At Hospital 2, a large difference between venous and arterial values was noted as compared to the difference between venous and arterial values obtained at Hospital 1. The differences between the arterial and venous values at Hospital 2 ranged from 11.5 sec. to 102.7 sec. with a mean difference of 40.6 sec. and a standard deviation of 29.7 sec. The mean difference between the arterial and venous values in Hospital 2 was 27 times greater than the mean difference in Hospital 1. The standard deviation in Hospital 2 was 9 times greater than Hospital 1.
Table 7.
Results of Serum Activated Partial Thromboplastin Times Obtained by Venipuncture Method and Femoral Intra-arterial Catheter Method (N=17)

<table>
<thead>
<tr>
<th>Subject Number</th>
<th>Venipuncture Method</th>
<th>Femoral Intra-arterial Catheter Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>98.3</td>
<td>97.2</td>
</tr>
<tr>
<td>2</td>
<td>57.3</td>
<td>56.7</td>
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<tr>
<td>3</td>
<td>53.1</td>
<td>54.8</td>
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<td>4</td>
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<td>5</td>
<td>25.8</td>
<td>24.3</td>
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<td>6</td>
<td>27.2</td>
<td>26.8</td>
</tr>
<tr>
<td>7</td>
<td>24.1</td>
<td>22.8</td>
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<tr>
<td>8</td>
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<td>81.0</td>
</tr>
<tr>
<td>16</td>
<td>33.6</td>
<td>45.1</td>
</tr>
<tr>
<td>17</td>
<td>97.3</td>
<td>200.0</td>
</tr>
</tbody>
</table>
Summary

Seventeen patients had paired venous and arterial aPTT samples drawn. A laboratory phlebotomist obtained the venous sample by venipuncture. The investigator, or research assistant, obtained the arterial sample from the femoral intra-arterial catheter. Sample values were obtained by use of an optic fibrometer. Correlated t-tests were performed between the aPTT values obtained by venipuncture and those obtained by use of the femoral intra-arterial catheter. The data indicated no statistically significant difference between the aPTT values when serum samples were drawn by venipuncture or from the femoral intra-arterial catheter.

The total sample was subsequently divided into two groups according to hospital. Data analysis indicated no clinically or statistically significant difference between the venous and arterial aPTT values at Hospital 1. In addition, data indicated there was no statistically significant difference between the venous and arterial aPTT values at Hospital 2. However, consideration must be given to the fact that two outliers were included in the data analysis. A larger subject population may have indicated a statistically significant difference. While the difference was not
statistically significant at Hospital 2, it was judged by this investigator to be clinically significant.
CHAPTER V

DISCUSSION AND CONCLUSIONS

Introduction

This chapter presents a discussion of the results generated following hypothesis testing. Included also are limitations of the study as well as implications for nursing practice and recommendations for future research.

Background and Purpose of the Research Study

The number of individuals undergoing percutaneous transluminal coronary angioplasty (PTCA) as a means to treat coronary artery disease (CAD) has dramatically increased over the last four years. At the completion of the procedure, patients return to the Intensive Care Unit with a femoral intra-arterial catheter in place. This catheter may be used to obtain serum samples for ordered laboratory tests.

To prevent blood from coagulating within the femoral intra-arterial catheter, the catheter is usually flushed with a heparinized solution at a rate of 6-10 units of heparin per hour depending on the intra-flow device used. Some physicians and nurses have expressed concern that the aPTT obtained through the
intra-arterial catheter may be prolonged as a result of the heparinized flush solution. They state that aPTT samples should be obtained by the traditional venipuncture method.

To date, nursing studies which have evaluated the accuracy of the aPTT obtained from heparinized intra-arterial catheters have assessed samples drawn from small bore catheters (Palermo, Andrews, and Ellison, 1980; Cannon, Mitchell, and Fabian, 1985; Kajs, 1986; Molyneaux, Papciak, and Rorem, 1987). Empirical research has not evaluated the aPTT withdrawn by venipuncture versus through the large bore femoral intra-arterial catheter which has a deadspace of 2.0 ml. The purpose of this study was to determine if there was a statistically significant difference between the aPTT values obtained by the venipuncture method versus aPTT values obtained simultaneously by the femoral intra-arterial catheter method.

A convenience sample of 17 adults who had undergone the PTCA procedure as a means to treat CAD participated in the study. Patient participants were obtained from two tertiary care hospitals in the southwestern United States.

After the PTCA procedure, all patients were taken to an intensive care unit (ICU). Prior to the removal of the femoral intra-arterial catheter, aPTTs
were obtained. While the phlebotomist obtained the aPTT sample by venipuncture, the investigator or research assistant simultaneously obtained the aPTT sample from the femoral intra-arterial catheter. Four milliliters of blood were obtained by each method for the aPTT sample. Prior to obtaining the aPTT sample from the femoral intra-arterial catheter, however, 6ml of blood were withdrawn and discarded. Samples were appropriately labeled and taken to the laboratory for analysis.

Discussion

The null hypothesis tested in this research was: There will be no statistically significant differences between serum aPTT values obtained by venipuncture versus aPTT values obtained from a large bore femoral intra-arterial catheter. Correlated t-tests were performed on the aPTT values obtained by both methods. T-tests indicated that there was no significant differences between serum aPTT values obtained by venipuncture versus by the femoral intra-arterial catheter. The null hypothesis, therefore, was accepted. The investigator proposes that accurate aPTT samples may be obtained from the large bore femoral intra-arterial catheter providing a volume of 3 times the deadspace of the catheter is withdrawn and discarded.
prior to obtaining the sample based on the data from Hospital 1.

When reviewing the aPTT values obtained in this study, it was noted that there was a rather dramatic difference in the mean arterial and venous aPTT values of patients according to hospital. In Hospital 1, the mean value of the venous aPTT was 47.0 seconds (sec.) and the mean of the arterial aPTT was 47.7 sec. In Hospital 2, however, the mean venous aPTT value was 69.5 sec. and the mean arterial aPTT value was 95.1 sec., a difference of 25.6 sec. One venous value in Hospital 2 was 52.7 sec. greater than the paired arterial value. One questions whether mislabelling occurred in this paired sample when results were entered into the laboratory computer.

Within group t-test values for Hospital 1, (n=10), demonstrated no statistically significant difference in aPTT values obtained by venipuncture versus those obtained by the femoral intra-arterial catheter (t= -.99; p= .35). Within group t-test values for Hospital 2, (N=7), also demonstrated no statistically significant difference in the aPTT values obtained by venipuncture versus those obtained by the femoral intra-arterial catheter (t= -1.45; p= .20). This was unexpected since the mean difference between the venous and arterial aPTT values was 40.6 seconds.
However, this may have been the result of the small sample size at Hospital 2 and the inclusion of outliers in the data analysis.

When investigating the discovered differences between the two Hospital groups, it was found that the patients in Hospital 1, after returning from the PTCA procedure, received 6-12 units of heparin per hour through the femoral intra-arterial catheter flush solution. The patients in Hospital 2, after returning from the PTCA procedure, received 3-6 units of heparin per hour through the femoral intra-arterial catheter flush solution. Patients in Hospital 1 received 2-4 times the amount of heparin via the femoral intra-arterial catheter flush solution than did the patients in Hospital 2. The amount of heparin received from the femoral intra-arterial catheter flush solution, therefore, does not account for the difference found between the two hospital groups when venous and arterial aPTT samples are compared.

Following additional investigation, it was found that both hospitals used identical aPTT analysis techniques and the same brand and model of optic fibrometer. However, different reagents were used to conduct the analysis. The laboratory personnel in Hospital 2 stated that one year ago they had changed to a new brand of reagent, and since that time, the aPTT
values had been more prolonged than in the past. This may account for the disparity in values between Hospital 1 and Hospital 2. It may also account for the disparity between venous and arterial values in Hospital 2. One questions whether the reagent used in Hospital 2 may be more sensitive to minute amounts of heparin present in the aPTT sample drawn from the femoral intra-arterial catheter.

In a previous comparison study by Pryor (1983) 50 pairs of aPTT values were drawn, however, only two patients were receiving continuous peripheral intravenous heparin therapy (PIVHT). Likewise, Molyneaux et al. (1987) evaluated 24 patients and only one was receiving continuous PIVHT. In this study, thirteen (76%) of the patients were receiving continuous PIVHT at a rate of 800-1000 units per hour. The values of patients receiving continuous PIVHT were compared to those patients not receiving continuous PIVHT. For example, patients at Hospital 1 who had received continuous PIVHT after their PTCA procedure had a mean difference between their venous and arterial aPTT value of 1.7 sec.; patients not receiving continuous PIVHT had a mean difference between their venous and arterial aPTT value of 1.5 sec. At Hospital 2, patients who received continuous PIVHT after their PTCA procedure had a mean difference between their venous and
arterial aPTT value of 40.0 sec.; the patient who did not received continuous PIVHT had a difference between the venous and arterial aPTT value of 44.4 sec. Thus, the aPTT values obtained did not appear to be affected by the use of continuous PIVHT.

**Conclusions**

The results of this study have indicated that there is no statistically significant differences between aPTT values obtained by venipuncture versus those obtained from the femoral intra-arterial catheter. However, in view of the disparity in findings within Hospital 2, further investigation in obtaining aPTT samples by venipuncture versus by the femoral intra-arterial catheter is needed. Accurate laboratory data that truly reflects the patients physiologic status must be provided to the medical and nursing staff for safe and effective patient care to be provided.
**Recommendations**

Recommendations for further nursing research include:

1. Replication of the study with a larger sample size from more than one institution.
2. Replication of the study in which sample groups receive different heparin flush concentrations.
3. Utilization of a smaller amount of blood for discard, i.e. 3cc.

**Limitations**

The following limitations have been identified:

1. A small sample size was obtained.
2. Sample groups had different concentrations of heparin in the flush solution.
3. The investigator did not analyze each serum sample, but had to rely on laboratory personnel which were not consistently the same person.
4. The study is generalizable only to patients following PTCA with femoral intra-arterial catheters that are continuously flushed with a heparinized solution.
Implications for Nursing

In some hospitals, nurses are asked to decide whether aPTT samples should be drawn by venipuncture or from the femoral intra-arterial catheter. The method chosen must be based on knowledge that the aPTT are accurate.

Heparin received during and possibly after the PTCA procedure results in prolongation of the aPTT. Several aPTT samples may be needed before the aPTT returns to an acceptable level (<35 seconds) and before the femoral intra-arterial catheter can be safely removed. Each aPTT sample requires a separate venipuncture. Difficulty in entering the vein may result in multiple punctures to obtain one sample. In addition, the infusion of an intravenous drip usually eliminates a limb from being used to obtain a serum sample. Reduction of venipuncture sites results in the individual having serum samples repeatedly obtained from one limb and may lead to potential venous trauma.

Venipuncture may increase the anxiety level of a patient resulting in an increase in sympathetic response. Sympathetic responses increase the work of the heart in patients who have previously experienced a myocardial infarction or who have some form of coronary artery disease. The femoral
intra-arterial catheter provides direct access for needed serum samples. Use of the femoral intra-arterial catheter would decrease the number of unnecessary venipunctures, thereby decreasing the amount of discomfort and anxiety experienced by the patient.

Scientific testing of a method, however, is necessary prior to implementation into clinical practice. Replication of research studies is needed to substantiate findings. Nursing research studies conducted by Palermo, Andrews, and Ellison (1980), Cannon, Mitchell, and Fabian (1987), and Molyneaux, Papciak, and Rorem (1987) have concluded that aPTT values obtained from samples withdrawn from an intra-arterial catheter have no statistically significant differences from those obtained by venipuncture providing "adequate" amounts of blood are withdrawn and discarded prior to obtaining the laboratory sample. However, Kajs (1986) reported statistically significant differences between aPTTs obtained by venipuncture and use of the intra-arterial catheter when 6cc of blood was withdrawn and discarded prior to obtaining the aPTT sample. The hospital and laboratory that participated in Kajs' study was the same as in this study labeled as Hospital 2.
In summary, this study has investigated a scientific basis for rationale of obtaining aPTT from large bore intra-arterial catheters versus venipuncture. The findings of this study based on results from Hospital 1 indicate that an aPTT drawn from the femoral intra-arterial catheter is not statistically different from aPTT samples drawn from venipuncture when 6cc of blood are discarded from a catheter, with a deadspace of 2cc, prior to obtaining the aPTT sample. Even though there was no statistically significant difference between the venous and arterial aPTT value at either hospital, it must be noted that at Hospital 2 a clinically significant difference between the two values did occur. Further research on the use of the large bore femoral intra-arterial catheter to obtain aPTT values needs to be conducted and results disseminated within the nursing community in order that research be utilized within practice.
APPENDIX A

GUIDELINES FOR OBTAINING SERUM ACTIVATED PARTIAL THROMBOPLASTIN TIME
Guidelines for Obtaining Serum Activated Partial Thromboplastin Time:

Specimen A: Venipuncture Method

1. Locate vein and cleanse site with alcohol.
2. Apply tourniquet.
3. Perform venipuncture using needle and syringe.
4. Withdraw 4.5 ml of blood from the patient's vein.
5. Apply pressure at the puncture site.
6. Place venous specimen in a blue-topped tube containing 0.5 ml of sodium citrate.
7. Label: Specimen A.
Guidelines for Obtaining Serum Activated Partial Thromboplastin Time:

Specimen B: Femoral Arterial Catheter Method

1. Wash hands with antiseptic soap.
2. Obtain two sterile 6.0 ml syringes.
3. Remove stopcock cap from the femoral catheter and place in a sterile container.
4. Place the first 6.0 ml syringe at the stopcock port.
5. Turn the stopcock valve "OPEN" to the patient and "OFF" to the flush solution.
6. Withdraw 6.0 ml of blood from the catheter.
7. Turn the stopcock position halfway between the "OPEN" and "OFF" position to prevent the flush solution from contaminating the blood in the catheter.
8. Remove the syringe containing the blood and discard.
9. Place a second 6.0 ml syringe at the stopcock port.
10. Turn the stopcock "OPEN" to the patient and "OFF" to the flush solution.
11. Withdraw 4.5 ml of blood for the aPTT test.
12. Turn the stopcock to the original "OPEN" position.
13. Remove the syringe containing the aPTT specimen.
14. Flush the catheter with heparinized solution using the intra-flow device until clear.
15. Replace the sterile cap on the stopcock port.
16. Place the 4.5 ml of blood into a blue-topped tube containing 0.5 ml of sodium citrate.
17. Label: Specimen B.
Dear Ms. Hobby:

We have received your project, "A Comparison Study of Activated Partial Thromboplastin Time Obtained by Two Different Techniques in Patients following Percutaneous Transluminal Coronary Angioplasty", which was submitted to this Committee for review. The procedures to be followed in this study pose no more than minimal risk to participating subjects. Regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)] authorize approval of this type project through the expedited review procedures, with the condition(s) that subjects' anonymity be maintained. Although full Committee review is not required, a brief summary of the project procedures is submitted to the Committee for their endorsement and/or comment, if any, after administrative approval is granted. This project is approved effective 21 April 1987.

Approval is granted with the understanding that no changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research-related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

cc: Departmental/College Review Committee
May 7, 1987

Deanna Hobby
3555 N. First Avenue #J-3
Tucson, AZ 85719

Dear Ms. Hobby:

It is a pleasure to approve the request to conduct the study, "A Comparison Study of Activated Partial Thromboplastin Time Obtained by Two Different Techniques in Patients Following Percutaneous Transluminal Coronary Angioplasty" at the University Medical Center on 6-West, the Cardiac Intensive Care Unit. Jayne Matte, Nurse Manager, will serve as your contact person.

Please let me know if you have any questions. We look forward to having you share your results with the nursing staff and administration.

Sincerely,

Ada Sue Hinshaw, Ph.D., R.N., F.A.A.N.
Director of Nursing Research
University Medical Center
& Professor, College of Nursing
University of Arizona

Imh
June 9, 1987

Deanna Hobby, RN, BSN
3555 N. 1st Avenue, J-3
Tucson, Arizona 85719

Dear Dee:

This letter is to officially inform you of the St. Luke's Nursing Research Committee's approval of your research proposal entitled, "A Comparison Study of Activated Partial Thromboplastin Time Obtained by Two Different Techniques in Patients Following Percutaneous Transluminal Coronary Angioplasty". Your proposal will also need to be approved by the Medical Research Committee.

Upon completion of your study, we request that you report your findings in the way of a presentation to the Nursing Research Committee and present St. Luke's with a bound copy of your thesis to be kept in the Medical Library. In addition, St. Luke's reserves the right to approve or disapprove the use of its name prior to any publication of the study results.

Congratulations as you move on to the next step of the research approval process. If you have questions, please do not hesitate to contact me.

Sincerely,

Rebecca Kuhn, RN, MS, CCRN
Chairperson
Nursing Research Committee
June 26, 1987

Deanna Hobby, R.N.
3555 N. 1st Avenue
J-3
Tucson, Arizona 85719

Dear Ms. Hobby:

I am pleased to inform you that upon recommendation of the Institutional Review Committee at its June 19, 1987 meeting has approved your protocol for the study of "A Comparison Study of Activated Partial Thromboplastin Time Obtained by Two Techniques in Patients Following PTCA".

The Institutional Review Committee has assigned the following file number to your protocol: (87-6/87). Please use the number in all future correspondence and/or revisions to the protocol.

During the study you are required to report all adverse reactions to the committee immediately. You are also required to submit to the committee an annual summary of your research, as well as a final report upon completion of the projects.

Sincerely,

Mark G. Kastub, M.D.
Chairman
Institutional Review Committee
APPENDIX C

SUBJECT CONSENT FORMS
SUBJECT CONSENT FORM
A Comparison Study of Activated Partial Thromboplastin (aPTT) Values Obtained by Two Different Techniques: Venipuncture and Intra-arterial Catheter Method

The purpose of this study is to determine if activated partial thromboplastin (aPTT) values obtained from a catheter in your groin vessel compare to those obtained from a needle stick in your vein. The catheter is presently used in some hospitals to obtain serum aPTT samples, a test for blood coagulation. Use of the femoral intra-arterial catheter may reduce the potential discomfort, pain, and anxiety by eliminating the need to puncture your veins to obtain blood samples.

Adults over 21 years of age whose catheter is in place after having undergone percutaneous transluminal coronary angioplasty (PTCA) are being recruited. You will be excluded from this study if your blood pressure or pulse rate is abnormal. Your physician has approved this study. The sample will be drawn in the intensive care unit following the procedure.

If you agree to participate in this study, the investigator will obtain an additional 10.5 ml or approximately 2 1/2 teaspoons of blood from your groin catheter at the same time a technician draws a blood sample (approximately 1 1/4 teaspoons) from your vein. You should feel no discomfort when the sample is obtained from your groin catheter. Some discomfort may be felt when the needle is inserted into your vein to obtain the venipuncture sample. No more than five minutes will be required to obtain the sample. This research study will be conducted during the months of May, June, July and August. The results of the aPTT obtained from the groin catheter will be compared to the results of the aPTT obtained by venipuncture. You will not be charged for the cost of the additional laboratory test.

To protect your confidentiality, all results will be coded. The results may be published in medical and/or nursing literature; however, your identity will not be revealed. The only known risk in obtaining blood via the groin catheter is the possible chance of infection. Although this chance is highly unlikely, this may result in an infection in the blood. To prevent this from happening, the investigator will use aseptic technique when obtaining the blood samples. In the event of any signs of infection, your physician will be notified and appropriate actions will be taken immediately. If infection should occur, financial compensation for cost of medical care must be borne by you.
If you decide not to participate in this study, it will in no way affect your relationship with the institution, your physicians, nurses, or the quality of care you receive. You are free to withdraw from the study and to ask questions at any time.

"I have read the above 'Subject's Consent.' The nature, demands, risks, and benefits of the project have been explained to me. I understand that I may ask questions and that I am free to withdraw from the project at any time without incurring ill will (or affecting my medical care). I also understand that this consent form will be filed in an area designated by the Human Subjects Committee with access restricted to the principal investigator or authorized representatives of the particular department. A copy of this consent form will be given to me."

Subject's Signature ___________________________ Date ______

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the subject signing this consent form understands clearly the nature, demands, benefits, and risks involved in participating in this study. A medical problem or language or educational barrier has not precluded a clear understanding of his/her involvement in this project.

Investigator's/Research Assistant's Signature ___________________________ Date ______

Phone Number: (602) 888-3179
REFERENCES


