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The University of Arizona M.S. 1985

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A COMPARISON OF COAGULATION VALUES OBTAINED BY TRADITIONAL VENIPUNCTURE AND INTRA-ARTERIAL LINE METHODS IN ADULT PATIENTS

by

Marylyn Kajs

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

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CAROLYN L. MURDAUGH
Assistant Professor of Nursing

5/6/85
Date

DEDICATION

To my best friend Kevin, whose continuous
love and long distance encouragement helped
me through those "trying times" --
I dedicate this thesis.

"The only limits are in the mind"

ACKNOWLEDGMENTS

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ABSTRACT

A descriptive study was conducted to compare coagulation values (specifically the activated partial thromboplastin time) obtained by the Traditional Venipuncture and Intra-Arterial Line Methods in adult patients. The convenience sample consisted of 24 adult patients in the medical, surgical and coronary intensive care units who were 18 years or older and had an intra-arterial line in place. Twenty-four pairs of blood samples were obtained. Group one consisted of 12 patients who had three milliliters of blood drawn and discarded prior to obtaining the APTT sample from the intra-arterial line. A second 12 patients had six milliliters of blood drawn and discarded. Activated partial thromboplastin time analyses were conducted on each sample and t-tests were used to compare the results between methods.

Findings revealed a significant statistical difference between the two methods. However, no significant differences were found between the group with the three milliliter discard and the group with the six milliliter discard.

CHAPTER I

STATEMENT OF THE PROBLEM

Introduction

Indwelling arterial catheters are commonplace in many operating rooms, recovery rooms, and intensive care units (Lamb, 1977). Because of increased utilization, the indwelling arterial catheter, also called an intra-arterial line, has become an integral part of the nursing care for the critically ill patient. The invasive intra-arterial line provides immediate and continuous information when used as a monitoring system for patients who are hemodynamically unstable or are receiving vasoactive drugs which require frequent blood pressure measurement (Kaye, 1983). Direct intra-arterial monitoring detects sudden changes in pressure and is a more accurate method of blood pressure determination than the indirect method of an occlusive blood pressure cuff (Nielson, 1977 and Aubin, 1979).

The intra-arterial line also provides an easy and quick access for obtaining laboratory blood samples (Lantiegne and Civetta, 1978). By utilizing the intra-arterial line, minimal discomfort occurs for the patient since frequent venous and/or arterial punctures are eliminated. Minimizing discomfort is especially relevant for the critically ill patient whose changing condition often warrants immediate and frequent analysis of arterial blood gases, blood chemistry, and/or hematological and coagulation studies (Smith, 1978 and Jastremski,

1982). This study will address the use of the intra-arterial line as an alternate method for obtaining blood for coagulation studies.

Overview of Problem

Blood for coagulation studies may be obtained by two different methods: withdrawing blood from a vein (venipuncture) or withdrawing blood from the intra-arterial line. The method is dependent on laboratory and/or nursing policy which varies from hospital to hospital, particularly in critical care units. As evidenced by a review of literature, limited scientific rationale exists on which is the most reliable and valid method. Secondly, most nurses are unable to state the rationale for the particular method followed in their hospital.

Controversy exists concerning which method is more reliable. Some physicians and laboratory personnel believe the traditional venipuncture method is more accurate than the intra-arterial line method. The strongest argument is that the heparin contained in the intra-arterial line flush-system might possibly cause false prolongation of coagulation values. False prolongation is possible for the activated partial thromboplastin time (APTT) since it is more sensitive to the effects of heparin than the prothrombin time (PT) (Thompson and Harker, 1983). The assumption, however, is based on personal experiences and documented incidences of prolonged APTT values in samples drawn from intra-venous lines which had been flushed with heparin at some time to maintain patency (Bark, 1970 and Czapek, 1974). Other factors suggested to possibly distort coagulation tests are adsorption of

the heparin by the wall of the catheter, protein interaction, and pooling of heparin solution around the catheter tip (Baer, 1983). None of these factors has been scientifically investigated.

The possibility of heparin producing prolongation of coagulation tests is well recognized and mentioned in many laboratory manuals and textbooks in reference to anticoagulant therapy. Possible heparin contamination during sampling from intra-arterial lines, however, is not cited (Colman et al., 1982 and Thompson and Harker, 1983). Limited research suggests that satisfactory blood samples for performing coagulation studies can be obtained from intra-arterial lines provided an adequate volume is removed prior to obtaining the sample (Merenstein, 1971 and Palermo et al., 1980). The problem addressed in the present study was the need for a scientifically tested method for withdrawing coagulation blood samples from intra-arterial lines.

Purpose

The purpose of this study was to compare two methods of obtaining blood for coagulation studies in critically ill patients for reliability of laboratory values. The APTT value drawn by venipuncture was compared with the APTT drawn by the intra-arterial line.

Significance of Proposed Research

Accurate laboratory values are crucial to the management of critically ill patients. Blood samples may be obtained by various methods; in some hospitals, the nurse decides which method to use. The intra-arterial line method may be chosen in an effort to minimize

the discomfort for the patient from frequent arterial and/or venipunctures. For example, discomfort can be a real problem for patients who are on anticoagulant therapy and require frequent blood samples for monitoring APTT and PT values (Gurewich, 1977).

Consensus does not exist, however, among hospital laboratory personnel, physicians, and nurses about the feasibility of the intra-arterial line for obtaining coagulation studies. Laboratory and/or nursing policy for procuring blood samples for coagulation studies varies from hospital to hospital. There is a need among hospitals for a standardized effective method for obtaining coagulation studies. The limited research which has been done points to the need for establishing a scientific basis for withdrawing coagulation blood samples from the intra-arterial line.

If the value of the activated partial thromboplastin time (APTT) drawn via the intra-arterial line is found not to significantly differ with the venipuncture method, nurses will be able to use the intra-arterial line already in place for obtaining blood samples. Critically ill patients who are subjected to many blood samplings to monitor their condition will benefit from the intra-arterial line method since they are already confronted with the effects of sensory deprivation which includes an increased sensitivity to painful stimuli, increased anxiety, and a decrease of tolerance for pain (McCaffrey, 1979 and Bourbonnais, 1981). By utilizing the intra-arterial line, unnecessary discomfort, pain and anxiety can be avoided for these

patients. The intra-arterial line method will also be beneficial for those patients who "don't have any veins" or who have bleeding tendencies.

Summary

An increased utilization of the intra-arterial line in critical care areas today has created an easy access for obtaining blood samples, thus minimizing patient discomfort, pain and anxiety from frequent, unnecessary arterial and/or venipunctures. One of the many questions with which the nurse is confronted in reference to the intra-arterial line is, specifically: Can coagulation studies such as the APTT be performed on blood withdrawn from the intra-arterial line? Presently, two methods are utilized for procuring blood samples for coagulation studies: withdrawing blood from a vein (venipuncture) and withdrawing blood via the intra-arterial line. Some hospital laboratory personnel and physicians believe the continuous heparin infusion found in the intra-arterial line causes false prolongation of the APTT and PT values. This one disagreement has led to inconsistency among hospitals in the method chosen to obtain blood samples for coagulation studies. The present study addressed the accuracy issue and began to establish scientific rationale for withdrawing coagulation blood samples from intra-arterial lines.

CHAPTER II

THE CONCEPTUAL FRAMEWORK

Introduction

Figure one depicts the conceptual framework on which this study is based. The construct level describes the relationship between physical stimuli and the stress response. The concept level describes two types of physical stimuli, two invasive procedures, used to obtain blood samples and their relationship to discomfort, pain and anxiety. The two methods of obtaining blood samples were compared, as this comparison was the basis of the present research.

Construct Level

Patients in acute care settings are exposed to various physical stimuli, such as procedures and treatments, throughout their hospitalization. Even though these events may be therapeutic or diagnostic in nature, they can be perceived as stressful and personally threatening to the patient. Patients undergoing surgical operations and diagnostic procedures have demonstrated that high levels of stress are experienced by patients before and during these events (Wilson-Barnett and Carrigy, 1978). The subjective state of stress may have more objective physiological signs caused by an activation of the sympathetic nervous system (Simon, 1980).

A certain amount of stress is attributed to all invasive stimuli. The construct stress refers to a multitude of physiological and

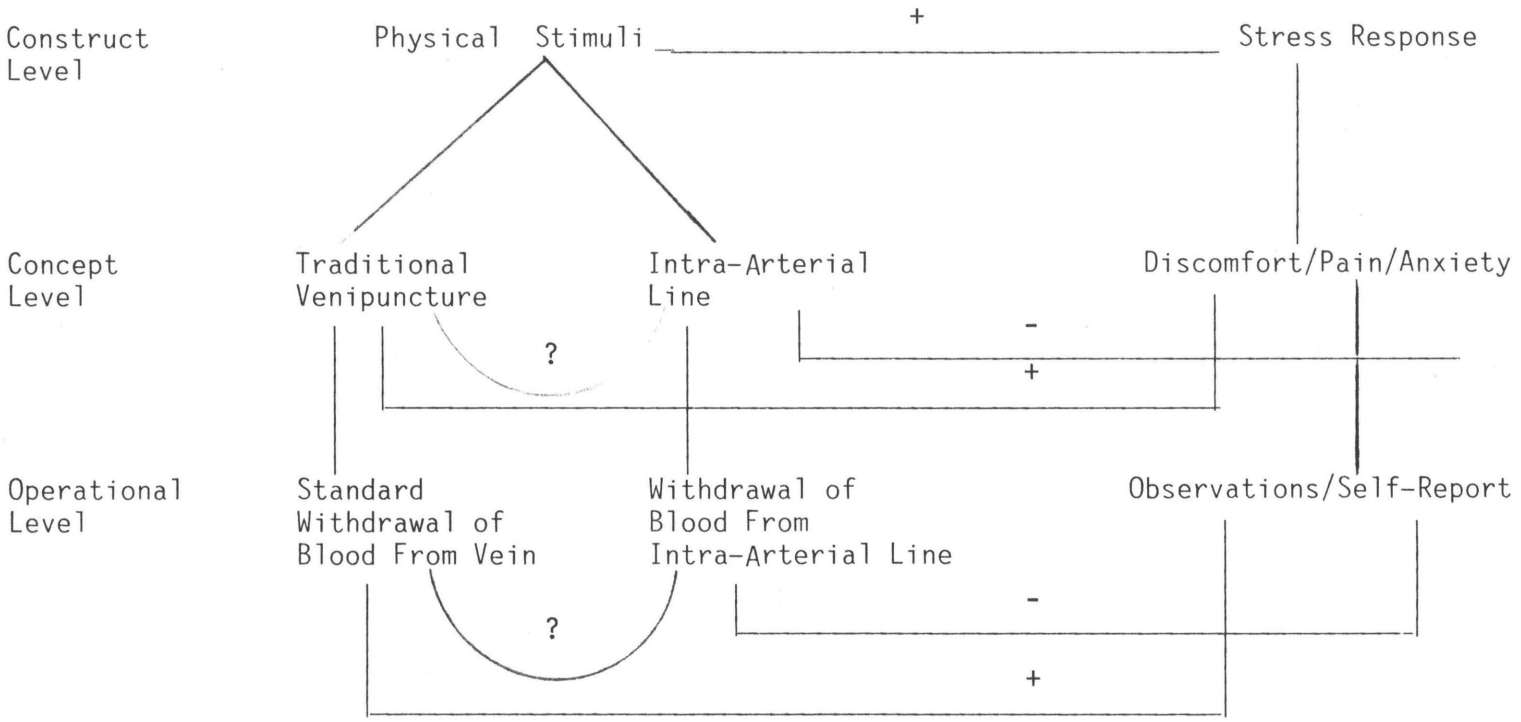

Figure 1. Methods of Obtaining Blood Samples and Stress Response: Conceptual Framework

psychological responses to stimuli that threaten the physical and emotional integrity of the individual (Soloman-Hast, 1981). Selye (1956) defined stress in physiologic terms and developed the general adaptation syndrome (GAS). According to Selye (1956), the body uses nonspecific adaptive responses in an attempt to deal with various systemic stressor agents. Adaptive responses or defense mechanisms are reflected in alterations in the individual's thoughts, feelings, endocrine and autonomic processes (Selye, 1956).

During the alarm stage of the general adaptation syndrome, the sympathetic and endocrine systems are activated. Typically, the cardiovascular system prepares itself to fight or flee by increasing the rate and force of the heartbeat, raising vascular tone and enhancing blood supplies to the heart and skeletal muscles. In addition, gastrointestinal motility generally decreases, the rate of respiration increases, the bronchioles dilate, the pupils dilate and perspiration begins (Stephenson, 1977 and Solomon-Hast, 1981).

Mason (1971) viewed psychological stimuli as also contributing to the sympathetic-endocrine response to stress. Emotional or physiologic arousal responses may be exhibited during the performance of various procedures which are considered personally threatening to the individual.

The interrelatedness of the physiological manifestations and psychological alterations as adaptive responses to stress has led to the conceptualization of stress as psychophysiological (Guzzetta and Forsyth, 1979). Critically ill patients, specifically, are confronted with a multitude of internal and external stimuli in their

environment which they perceive as threatening. The patient who is acutely ill, however, may be physically unable to cope with the environment of the critical care area and may become anxious (Solomon-Hast, 1981). External stimuli for the patient may include noises from the complex machinery used in the unit, other patients who are confused or in pain, and various activities of the critical care staff (Gardner and Parzen, 1980).

Studies have described the reactions of patients in the critical care area who had witnessed the performance of invasive procedures on other patients in the same unit. Increases in pulse rates were documented for patients witnessing resuscitation procedures, insertion of a Swan-Ganz catheter and temporary pacemaker, and cardioversion (Sczekall, 1973 and Vanson, et al., 1980).

Internal stimuli which may be considered threatening to the patient in the critical care area may arise from a "...disruption of psychological equilibrium found in the dehumanizing aspects of life support technology" (Lippincott, 1979, p. 1095). For example, the patient who requires hemodialysis treatment perceives the machine as a life-saving and life-protecting friend. However, dialysis also represents the life-long obligation of the patient to the invasive procedure and is tangible evidence of the lack of health and of impaired longevity. The stress produced by the procedure itself is often reflected in the presence of insomnia, a stress response to the stimulus, hemodialysis (Simon, 1980).

Studies have shown that therapeutic procedures such as surgery and various diagnostic procedures are stressful experiences for patients. Stressful experiences are those which are threatening, which require adaptive behavior, and may cause anxiety (Wilson-Barnett and Carrigy, 1978). Documentation of the stressful effects of surgery on patients involves studies which were conducted to determine the effects of teaching on reducing pre-operative stress and anxiety. Several studies have shown a strong relationship between physological preparation and support during the pre-operative period and reduction of stress. Patients' post-operative physiological responses were used as measures to show reduction of stress. Reduced stress responses included decreased post-operative vomiting, decreased amount of narcotics, analegesics and sedatives required; stable blood pressure, pulse and respirations; no evidence of urinary retention; increased ambulation after surgery; and decreased length of hospitalization (Dumas and Leonard, 1963; Egbert et al., 1964; Helay, 1968; Johnson, 1972; Lindeman, 1972; Lindeman and Van Aernam, 1971).

Johnson and Leventhal (1974) and Hartfield and Cason (1981) studied emotional responses of adults undergoing gastroendoscopic examination and barium enema procedures. Subjects who received sensation information before the procedure reported less stress as evidenced by more stable heart rates. The informed subjects also required less medication and exhibited less fear than those subjects who received no information.

Cardiac catherization and coronary cineangiography are also stressful procedures for most adult patients. The psychological stress of these invasive procedures is often due to stresses related to the procedure itself, involvement of the heart, a fear of the unknown, and fear of impending cardiac surgery (Finesilver, 1978).

In summary, several studies have been presented which describe the relationship between physical stimuli and the stress response. Therapeutic and diagnostic procedures have been related to various emotional and behavioral responses along with activation of the sympathetic-endocrine system.

Concept Level

Various invasive procedures have been associated with discomfort and pain. Fagerhaugh and Strauss (1977) state that a considerable proportion of work with and around patients involves the inflicting of pain. Inflicted pain is associated with a host of essential tasks: diagnosis, surgery, various therapies, regimens, and even the mechanics of giving adequate nursing care.

The pain response produces various physiological responses through an activation of the autonomic nervous system. Observable signs and symptoms of pain are divided into two groups: (1) those that are of sympathetic origin and (2) those primarily of parasympathetic origin. Sympathetic responses (which occur with pain of low to moderate intensity or superficial pain) include pallor, elevated blood pressure, dilated pupils, skeletal muscular tension and increased respiratory and heart rate. In contrast, a parasympathetic response

of decreased blood pressure and pulse, weakness and fainting, and nausea/vomiting can occur with pain of severe intensity or deep pain (McCaffrey, 1972; Storlie, 1978; Bourbonnais, 1981).

The patient's facial expression may be the first or only indication of pain. Common facial expressions are clenched teeth, wrinkled forehead, biting of the lower lip, and widely opened or tightly shut eyes (McCaffrey, 1972 and Bourbonnais, 1981). The patient may moan, cry or make other sounds indicating his/her discomfort. Body movements which may also accompany pain include taking a posture that minimizes pain (i.e. lying rigidly); purposeless movements (i.e. tossing and kicking in bed); protective movements (i.e. withdrawing when touched); and rubbing and rhythmic movements (McCaffrey, 1972).

Simon (1980) has identified various procedures in the acute care setting which may activate the stress response. Starting intravenous lines, giving injections and drawing blood all require the painful and often repetitive invasion of the patient's body with needles. Other procedures which may activate the stress response include surgery, venous cutdowns, thoracotomies, endotracheal intubation, and lumbar punctures.

Patients undergoing invasive cardiac catherization also experience discomfort and pain. Discomfort is experienced by remaining supine on the table during the procedure. Pain may also be at the catheter insertion site; numbness and cramping of the arm are common if the brachial approach is used. If the femoral approach is utilized, heavy, uncomfortable pressure is applied for approximately twenty minutes after removal of the catheter (Finesilver, 1980).

According to McCaffrey (1979), regardless of whether or not the procedures will actually cause pain, their strangeness may arouse anxiety and thereby contribute to pain. Invasive procedures also tend to be more anxiety provoking than those procedures which do not invade the body (i.e. exercise of a painful joint) (McCaffrey, 1979).

Researchers use anxiety as an index of psychological stress. Spielberger (1972) refers to anxiety as a sequence of cognitive, affective and overt-behavioral responses that occur as a reaction to some form of stress. According to Spielberger (1972), specific affective responses include feelings of being worried, nervous, tense, upset or over-excited. Overt-behavioral responses are seen to occur when the patient appears to be under stress during a procedure or treatment (Soloman-Hast, 1981). Overt-behavioral responses have been described as including restlessness, increased muscle tension, tremors, fatigue and the presence of a startle reaction (Stuart and Sundeen, 1979). Cognitive responses to anxiety have been identified as a reduced perceptual field, a distorted time sense with present-only focus, and selective inattention that serves to filter threatening stimuli that confront the patient (Stuart and Sundeen, 1979).

Anxiety may also produce physiological responses due to an activation of the sympathetic nervous system. Frequent signs evidenced are an increase in pulse rate, rapid breathing, cold sweating palms, transient increases in blood pressure, nausea/vomiting, increased frequency of urination, sleep disturbances, faintness, blushing or pallor (Simon, 1980).

Critically ill patients are subjected to frequent physical stimuli to monitor their acute condition. One such stimulus is blood sampling. Two types of procedures are employed to obtain blood samples: drawing blood from the vein (venipuncture) and drawing blood from an indwelling arterial catheter (intra-arterial line). Both methods are related to the stress response as the procedures are associated with discomfort, pain and anxiety. The intra-arterial line may decrease the potential for repeated patient discomfort, pain and anxiety by eliminating frequent, unnecessary arterial or venipunctures (Lamb, 1977).

Blood drawing is often a repetitive invasion of the patient's body with needles and produces a painful response (Simon, 1980). Many patients also get so anxious about the pain they anticipate during a venipuncture that they actually increase the likelihood of pain. Some patients develop vasomotor reactions that cause veins to constrict, making insertion of the needle more difficult. Extremely tense patients may suddenly pull away during the venipuncture, risking perforation of the vein with the tip of the needle (Friedman, 1981). Subcutaneous bleeding can occur and hematomas may form (Johnston-Early et al., 1981). Several venipunctures may be attempted in patients with "problem veins" to obtain blood samples. The patient is thereby subjected to repeated discomfort, pain and anxiety.

Invasive intra-arterial line placement in the critically ill patient is indicated for several reasons. Two major indications are to (1) continually monitor arterial pressure, and (2) obtain laboratory blood samples (Kaye, 1983 and Lantiegne and Civetta, 1978). One major

advantage of the intra-arterial line is the avoidance of discomfort and injury from frequent arterial and venous punctures (Kaye, 1983). A patient requiring frequent arterial blood gases will be more comfortable with a catheter in place then with repeated arterial sticks (Smith, 1978).

Insertion of the intra-arterial line results in one-time discomfort and anxiety for the patient. The catheter insertion itself is usually no more painful than an intravenous needle insertion and no undue discomfort occurs once the catheter is inserted (Lamb, 1977). Minimizing discomfort is necessary for the critically ill patient whose changing condition often warrants frequent analysis of arterial blood gases, blood chemistry, and/or hematological and coagulation studies (Smith, 1978 and Jastremski, 1982).

The amount of anxiety experienced by patients as a result of the intra-arterial line is considered minimal. Although the needle represents a temporary threat, the continuous monitoring offers the patient reassurance and security (Lamb, 1977). Arterial pressure wave observations demonstrate that the patient tends to relax quickly as soon as the catheter insertion has been accomplished. Interviews with patients several days after removal of the catheter also revealed that many were not able to distinguish the arterial catheter from intravenous catheters (Nielson, 1974).

In summary, physical stimuli, such as invasive procedures, and their stress response have been discussed. Specifically, two types of invasive procedures used to obtain blood samples for the

critically ill patient have been described along with their relationship to discomfort, pain and anxiety.

Comparability of Two Methods

Before utilizing the intra-arterial line for routinely obtaining coagulation studies, the Intra-Arterial Line Method must be compared with the Traditional Venipuncture Method to verify that drawing the blood sample from the intra-arterial line will produce as reliable laboratory values as the traditional venipuncture method. Thus, the present study only focused on the significant difference between the two methods (see Figure 2).

Few studies have attempted to determine the reliability of coagulation values of blood drawn from intra-arterial lines. Initial research on the effects of heparin on coagulation values was conducted on blood samples drawn from venous catheters. Bark (1970) reported a "coagulation nondisease" (false prolongation of APTTs) caused by obtaining blood samples from a central venous catheter flushed with heparin to maintain patency. The heparin effect, however, was eliminated by flushing the line with 50 milliliters of saline prior to obtaining the blood sample.

Merenstein (1971) demonstrated that passage of normal blood drawn by venipuncture through umbilical artery catheters flushed with heparin resulted in prolongation of the APTT of the blood leaving the catheter. The APTT returned to normal after four milliliters of blood had been withdrawn prior to obtaining the blood sample.

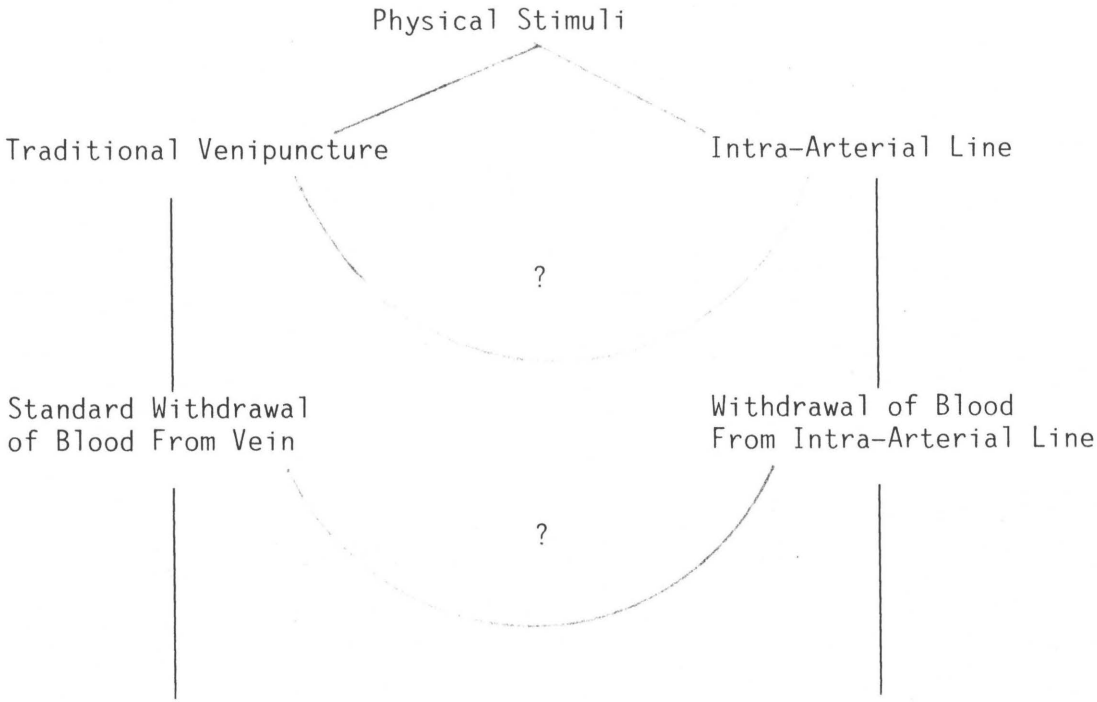

Figure 2. Comparability of Traditional Venipuncture Method and Intra-Arterial Line Method For Obtaining Coagulation Studies

Results suggested that withdrawing four milliliters of blood prior to sampling was sufficient to ensure accurate coagulation values.

Czapek (1974) also reported personal incidences of a nondisease state (iatrogenic prolonged APTT) in sampling from indwelling heparinized catheters. The type of indwelling catheters the blood was drawn from was not specified. Results indicated, however, that withdrawing as much as ten milliliters of blood prior to sampling did not obviate the heparin effect.

Palmero et al. (1980) reported markedly abnormal values of APTTs drawn from arterial and venous lines which were deliberately contaminated by inadequate clearing of the lines from the heparin flush solution. A significant change from the control value was observed until a volume of approximately two milliliters was withdrawn and discarded from the lines.

The use of the intra-arterial line as a site for obtaining coagulation studies has recently been studied. Research by Pryor (1983) on 50 patients indicated the venous and arterial PT and APTT values significantly correlated with one another for those patients who were on warfarin and subcutaneous heparin therapies. However, the APTT values of patients who received intravenous heparin therapy were altered considerably. A discard volume of six milliliters was used prior to obtaining the intra-arterial blood samples to decrease the chance of heparin effect.

Reports of a study done by Molyneaux (1984) showed prolongation of APTTs of arterial line samples by 0.3 to 10.6 seconds over the

venipuncture samples in 11 of the 14 patients studied. Conclusions indicated that some heparin effect still was present even with 1.6 cc of volume discarded.

Limited research suggests that satisfactory blood samples for performing coagulation studies can be obtained from intra-arterial lines provided an adequate volume is removed prior to obtaining the sample (Merenstein, 1971 and Palmero et al., 1980). The National Committee for Clinical Laboratory Standards (1981) states that in order to obtain accurate results from blood samples drawn from intra-arterial lines, attention must be paid to complete removal of "dead space" contents of the catheter and connectors prior to sampling. The Committee also states the volume of blood discarded depends on catheter size and length and the geometry of the catheter or connectors. Therefore, the volume to be drawn for discard must be determined for each system. More recent Committee Standards (1984) suggest a sample at least three times the volume of the line be removed and discarded before a specimen is obtained for analysis.

In summary, the relationship between physical stimuli and the stress response has been discussed. Various invasive procedures and their relationship to discomfort, pain and anxiety have also been presented. Lastly, studies have been presented which have compared coagulation studies of blood drawn from different indwelling lines and by venipuncture. Although results of studies and laboratory standards suggest that the heparin effect can be avoided by adequate removal of volume prior to sampling, controversial findings exist.

Hypotheses Tested

(1) Activated partial thromboplastin values (APTT) obtained by the Intra-Arterial Line Method will differ significantly from the APTT values obtained by the Traditional Venipuncture Method.

(2) Activated partial thromboplastin values following a 3 cc discard will differ significantly from the APTT values following a 6 cc discard.

Operational Definitions

The operational definitions were as follows:

1. Traditional Venipuncture Method: The Traditional Venipuncture Method is defined as a six-step method of blood withdrawal from the vein for laboratory analysis utilizing a needle and syringe or butterfly needle.

2. Intra-Arterial Line Method: The Intra-Arterial Line Method is defined as a 13-step method of arterial blood withdrawal from an indwelling arterial catheter which discards a certain amount of blood prior to obtaining the sample.

3. Activated Partial Thromboplastin Time (APTT): The APTT is defined as the time in seconds required for a fibrin clot to form in a plasma sample. The APTT is the coagulation test most sensitive to the effects of heparin contamination.

Summary

The chapter has described the development of a conceptual framework to describe the relationship between physical stimuli and the

stress response. The framework was based on a review of literature describing the relationship between various invasive procedures and the stress response of discomfort, pain and anxiety. Lastly, two types of invasive procedures used to obtain blood samples in the critically ill patient were discussed along with their relationship to discomfort, pain and anxiety.

CHAPTER III

METHODOLOGY

Introduction

The study was designed to investigate the difference between activated partial thromboplastin time (APTT) results obtained from two different methods of withdrawing blood for coagulation studies in critically ill adult patients. A discussion of the research design, sample and setting, and the protection of human rights is presented. The data collection protocol and analysis plan are also described in detail.

Research Design

A descriptive design was employed to study activated partial thromboplastin time (APTT) values obtained by two different methods. The APTT values obtained by the Intra-Arterial Line Method were compared with the APTT values obtained by Traditional Venipuncture Method.

Study Sample and Setting

The sample was comprised of 24 paired specimens of blood drawn from critically ill adult patients admitted to the cardiac, medical and surgical intensive care units of a southwestern teaching hospital. The specimens were obtained from 24 patients who had an intra-arterial line inserted and had available veins for venipuncture. No more than

one paired specimen was obtained per patient. Criteria for subject inclusion were:

1. Age 18 or older
2. An intra-arterial line inserted
3. Available veins for venipuncture
4. Standard heparin flush solution for the intra-arterial line

The rationale for the age of 18 or older was to ensure informed consent. The necessity of insertion of an intra-arterial line was determined by the attending physician or House Officer on duty. Available veins for venipuncture were necessary since the study required blood samples to be drawn via venipuncture for comparison with samples drawn from the intra-arterial line. Patients with "problem veins" could possibly necessitate withdrawal of blood by arterial puncture. The availability of the veins was determined by laboratory phlebotomists, as they withdrew the blood by venipuncture. A standardized intra-arterial line flush solution was necessary since the possibility of false prolongation of the APTT by heparin can depend on the amount of heparin infused (Czapek, 1974). A standardized amount of heparin in the flush solution, therefore, controlled for the potential problem.

Protection of Human Rights

The research proposal and consent form was presented to the University of Arizona Human Subjects Committee for approval (see Appendix A). To assure subject anonymity and confidentiality, both the subjects and the specimens were assigned a code number.

Data Collection Procedures

Subjects who had an intra-arterial line inserted were aproached by the investigator and asked to participate in the study. After informed consent was obtained, demographic data such as age, sex, diagnosis and type of anticoagulant therapy the patient was receiving (if applicable) were collected. When coagulation studies (specifically the APTT) were ordered, the Traditional Venipuncture Method as well as the Intra-Arterial Line Method were used to obtain the blood samples. The venipuncture method consisted of obtaining blood from the vein of a patient's extremity, utilizing a needle and syringe or butterfly needle. Venous blood specimens were not collected from extremities receiving intravenous infusions.

The Intra-Arterial Line Method involved drawing blood from a three-way stopcock which was connected to six inches of plastic tubing and an inch and a half to two inch arterial catheter. The "dead space" contents of the catheter and tubing for the system was 0.6cc. The intra-arterial line system consisted of a flush device which allowed for a continuous infusion of heparinized solution of approximately three milliliters per hour (six units of heparin per hour) to maintain patency. For the first 12 patients, three milliliters (3cc) of blood were drawn and discarded prior to obtaining a sample from the intra-arterial line. The 3cc amount of blood for discard was the laboratory standard set by a local medical, coronary, and surgical intensive care unit for obtaining other laboratory tests (i.e. electrolytes, arterial blood gases). The three milliliter

aliquot allowed for clearing of "dead space" volume between the arterial catheter and the stopcock which in turn decreased the chance of heparin contamination from the heparinized solution (National Committee for Clinical Laboratory Standards, 1981). The second group of patients (N=12) had six milliliters of blood drawn and discarded prior to obtaining the coagulation sample from the intra-arterial line. The multiple of the 3cc discard was used because recent tentative guidelines from the National Committee for Clinical Laboratory Standards state that a larger volume of blood for discard decreases the chance of heparin contamination of coagulation blood samples drawn from the intra-arterial line (National Committee for Clinical Laboratory Standards, 1984).

A laboratory phlebotomist performed the venipuncture as the investigator simultaneously withdrew a sample from the intra-arterial line from all 24 patients. A description of the two methods are as follows:

Specimen A: Traditional Venipuncture Method

1. Locate vein and cleanse venipuncture site with alcohol.
2. Apply tourniquet.
3. Perform venipuncture using needle and syringe or butterfly needle.
4. Withdraw 3.0 milliliters (ml) of blood from patient's vein.
5. Place 3.0 ml of venous blood in blue-topped tube containing 0.3 ml of sodium citrate.
6. Label as Specimen A.

Specimen B: Intra-Arterial Line Method

1. Place 3.0 ml or 6.0 ml syringe at stopcock port.
2. Turn stopcock "OPEN" to patient and "OFF" to fluid source.
3. Withdraw 3.0 ml or 6.0 ml of blood and fluid.
4. Turn stopcock position halfway between present position and syringe to ensure that no flush solution dilutes the arterial blood.
5. Remove syringe with blood and fluid from stopcock and discard.
6. Place 3.0 ml syringe at stopcock port.
7. Turn stopcock "OPEN" to patient and "OFF" to fluid source.
8. Aspirate 3.0 ml of blood for coagulation test analysis.
9. Turn stopcock back to original (neutral) position.
10. Remove 3.0 ml syringe with 3.0 ml of arterial blood.
11. Flush the line with heparinized solution with intra-flow device.
12. Place 3.0 ml of blood into blue-topped tube containing 0.3 ml of sodium citrate.
13. Label as Specimen B.

The investigator carried both specimens to the hospital's hematology laboratory for immediate coagulation analysis. Both samples were analyzed on the same machine by the same technician and the patient was charged only for the routinely ordered APTT analysis

(Specimen A). The laboratory results were then recorded on the data collection sheet by the investigator (see Appendix C).

Data Analysis Plan

The demographic data for each group of patients were analyzed using descriptive statistics. Frequencies, means, and standard deviations were calculated for age, sex, diagnosis, and type of anticoagulants.

The two null hypothesis tested were as follows: (1) There is no significant difference between APTT values obtained by the Intra-Arterial Line Method and APTT values obtained by the Traditional Venipuncture Method; and (2) There is no significant difference between APTT values obtained following a 3cc discard and APTT values obtained following a 6cc discard.

Correlated t-tests were performed between the two methods of blood withdrawal, and independent t-tests were performed between the two groups of patients (Group 1 = 3cc discard; Group 2 = 6cc discard). A significance level of 0.10 was set to decrease the likelihood of a 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 two groups.

Summary

The chapter has described the methods employed to investigate the difference between APTT values drawn by the Traditional Venipuncture

Method and the Intra-Arterial Line Method in critically ill adult patients. An explanation of the study sample, setting, protection of human rights, data collection protocol and data analysis was included.

CHAPTER IV

PRESENTATION AND ANALYSIS OF THE DATA

Introduction

Results of analysis of the data are presented in this chapter. Characteristics of the sample are described as well as results of hypotheses testing.

Characteristics of the Sample

A convenience sample of 24 patients participated in the study. Simultaneous venipuncture and intra-arterial line specimens were collected. Two groups of patients were used. Group one consisted of 12 patients who had three milliliters of blood drawn and discarded prior to obtaining the APTT blood sample from the intra-arterial line (Group one = 3cc discard). The second group of 12 patients had six milliliters of blood drawn and discarded (Group two = 6cc discard). One paired specimen was obtained per patient, making a total of 24 pairs of blood samples.

The ages of the patients in Group one ranged from 19 to 76 years. The mean age was 54.4 years (standard deviation 20.1 years). Seven patients (58 percent) were female and five patients (42 percent) were male. Eight patients (66 percent) were admitted under the surgical service. Three patients (25 percent) were admitted under the medical service, and one patient was admitted under the cardiology service.

The type anticoagulants the patients were receiving (if applicable) was also recorded. Four of the patients (33 percent) received heparin in the form of 800 units-1000 units per hour by intravenous infusion, one patient received 5000 units of heparin subcutaneously every 12 hours, and two patients (16 percent) received 100 units of heparin intravenous push every eight hours.

In Group two, the patients' ages ranged from 24 to 76 years with a mean age of 56.0 years (standard deviation 18.0 years). Seven patients (58 percent) were male and five patients (42 percent) were female. Eight patients (66 percent) were admitted under the surgical service. Two patients (17 percent) were admitted under the medical service, and two patients (17 percent) were admitted under the cardiology service.

In reference to anti-coagulant therapy, two patients in Group two (17 percent) received 5000 units of heparin subcutaneously every 12 hours. One patient received 3000 units of heparin per hour by intravenous infusion, and one patient received 100 units of heparin by intravenous push every eight hours. Table 1 presents the characteristics of the two groups of patients in the sample.

The diagnoses of the patients in both groups varied. Group one included patients admitted for vascular surgery, cardiac problems, head trauma, abdominal surgery, respiratory problems, multiple vehicle accident, cerebral bleed, bladder surgery, liver surgery, head trauma, respiratory problems, and sepsis. The diagnoses of the two groups are listed in Table 2.

Table 1. Descriptive Characteristics of the Two Groups of Patients in the Sample (Group 1: N=12, Group 2: N=12)

Patient Number	Sex	Age in Years	Service	Type of anticoagulant
Group 1= 3cc discard				
01	male	19	surgical	Heparin 100U IVP every 8 hrs
02	female	44	surgical	Heparin 100U IVP every 8 hrs
03	female	69	surgical	none
04	male	21	medical	none
05	male	66	cardiology	Heparin infusion, 900U/hour
06	female	64	medical	Heparin infusion, 1000U/hour
07	male	76	surgical	Heparin 5000U subq every 12hrs
08	female	64	surgical	none
09	female	31	surgical	none
10	female	65	medical	Heparin infusion, 800U/hour
11	female	69	surgical	Heparin infusion, 800U/hour
12	male	65	surgical	none
Group 2= 6cc discard				
13	female	24	surgical	none
14	male	57	cardiology	Heparin 5000U subq every 12hrs
15	male	40	cardiology	Heparin 100U IVP every 8 hrs
16	male	55	medical	Heparin 5000U subq every 12hrs
17	male	71	surgical	none
18	male	70	surgical	Heparin infusion, 3000U/hour
19	female	75	surgical	none
20	male	75	surgical	none
21	female	56	surgical	none
22	male	32	surgical	none
23	female	42	surgical	none
24	female	76	medical	none

Table 2. Diagnoses of the Two Groups of Patients in the Sample (Frequencies) (N=24)

Diagnosis	N
GROUP ONE:	
Vascular surgery	4
Cardiac problems	2
Head Trauma	1
Abdominal surgery	1
Respiratory problems	1
Multiple vehicle accident	1
Cerebral bleed	1
Gastrointestinal bleed	1
TOTAL	12
GROUP TWO:	
Cardiac problems	3
Multiple vehicle accident	2
Cerebral bleed	2
Bladder surgery	1
Liver surgery	1
Head trauma	1
Respiratory problems	1
Sepsis	1
TOTAL	12

In Group one, the majority of patients (75 percent) had a radial catheter in place as part of the intra-arterial line system. Two patients had a brachial catheter and one patient had a pedal catheter. All 12 patients in Group two had a radial catheter in place as part of the intra-arterial line system.

As previously stated, only patients with a standardized intra-arterial line flush solution (1000U of heparin in 500cc of Dextrose in Water) were used to control for the possibility of false prolongation of the APTT values by the amount of heparin in the line. Two other intervening variables were also controlled for by the simultaneous drawing of the blood samples by the investigator and the laboratory technician: the order of the method to draw the blood samples, and the length of time to allow between drawing the two blood samples.

Hypotheses Testing

The two null hypotheses tested were: (1) There is no significant difference between APTT values obtained by the Intra-Arterial Line Method and APTT values obtained by the Traditional Venipuncture Method; and (2) There is no significant difference between APTT values obtained following a 3cc discard and APTT values obtained following a 6cc discard. Correlated t-tests were performed between the two samples for the APTT values on the first group of patients (Group one = 3cc discard as well as the second group of patients (Group two = 6cc discard). Significant differences in the APTT values were found between the two methods for each group [Group one: $t=-1.95$ ($p=.077$); Group 2: $t=-2.92$ ($p=.014$)] (see Tables 3 and 4). Correlated t-tests were

Table 3. Significance of Differences Between Traditional Venipuncture Method and Intra-Arterial Line Method on APTT Values: Correlated t-tests (Group One = 3cc Discard, N=12)

GROUP A = Traditional Venipuncture Method

GROUP B = Intra-Arterial Line Method

Variable	Mean (Secs)	Standard Deviation Secs)	t
APTT A (Venous)	26.3	11.15	
			-1.95*
APTT B (Arterial)	32.9	17.74	

* $\alpha \leq .10$

Table 4. Significance of Differences Between Traditional Venipuncture Method and Intra-Arterial Line Method on APTT Values: Correlated t-tests (Group Two = 6cc Discard, N=12)

GROUP A = Traditional Venipuncture Method

GROUP B = Intra-Arterial Line Method

Variable	Mean (Secs)	Standard Deviation (Secs)	t
APTT A (Venous)	24.1	9.55	
			-2.92*
APTT B (Arterial)	29.0	12.04	

* $\alpha \leq .10$

repeated between the two samples in Group one after one APTT value which was considered an outlyer was deleted from the statistical calculations. Even after the deletion, a significant difference still existed in the APTT values between the two methods in Group one [t=-2.20 (p=.052)] (see Table 5). Thus, the first null hypothesis was rejected.

The two groups (Group one = 3cc discard, Group two = 6cc discard) were also compared. Independent t-tests were performed between Group one and Group two to ascertain if any significant differences existed between a 3cc discard and a 6cc discard. In comparing the APTT arterial and venous samples of each group as well as the difference between the arterial and venous samples, no significant differences were found between the two groups [venous t-Value = .51 (p=.615); arterial t-Value = .62 (p=.542); arterial-venous t-Value = -.44 (p=.615)] (see Table 6). Thus, the second null hypothesis was accepted.

In describing the two groups, Group one had nine (75 percent) arterial values which were greater than the venous values, two (17 percent) of the arterial values were less than the venous values and one arterial and venous value were identical. The differences between the arterial and venous values ranged from 0.0 to 9.0 seconds, but it was 12.3 seconds for one patient, and 40.2 seconds for another patient (mean difference = 6.63 seconds, standard deviation = 11.75 seconds).

Group two had nine (75 percent) arterial values which were greater than the venous values and three (25 percent) of the arterial

Table 5. Significance of Differences Between Traditional Venipuncture Method and Intra-Arterial Line method on APTT Values: Correlated t-tests (Group one = 3cc Discard, N=11)

GROUP A = Traditional Venipuncture Method

GROUP B = Intra-Arterial Line Method

Variable	Mean (Secs)	Standard Deviation (Secs)	t
APTT A (Venous)	26.1	11.68	
			-2.20*
APTT B (Arterial)	29.7	14.66	

*$\alpha \leq .10$

Table 6. Significance of Differences Between Traditional Venipuncture Method and Intra-Arterial Line Method on APTT Values When Comparing the Two Groups: Independent t-tests (Group one= 3cc Discard, N=12; Group two=6cc Discard, N=12)

Venous = Traditional Venipuncture Method

Arterial = Intra-Arterial Line Method

Variable	Mean (Secs)	Standard Deviation (Secs)	t
(APTT) Venous:			
Group 1	26.0	11.14	
Group 2	24.1	9.55	.51
(APTT) Arterial:			
Group 1	32.9	17.74	
Group 2	29.0	12.04	.62
Arterial-Venous:			
Group 1	6.6	11.75	
Group 2	4.9	5.89	-.44

$\alpha \leq .10$

values were less than the venous values. The differences between the arterial and venous values ranged from 0.1 to 6.3 seconds, but it was 11.8 seconds from one patient, 14.3 seconds from another patient, and 16.0 seconds from another patient (mean difference = 4.95, standard deviation = 5.89 seconds).

Independent t-tests were also performed between Group one and Group two after the APTT value from one patient which was considered an outlyer was deleted. Table 7 depicts the results of the statistical analyses. Even after this deletion, Group one and Group two were shown not to be significantly different when comparing the venous values [t=.46 (p=.650)], arterial values [t=.12 (p=.904)], and the difference between the arterial and venous samples [t=.58 (p=.565)]. Looking at Tables 6 and 7, one can conclude that increasing the amount of discard prior to obtaining the APTT arterial sample (from 3cc to 6cc) did not make any significant difference on the values obtained.

Summary

In conclusion, a comparison of APTT values drawn by two different methods on adults resulted in significant differences in the laboratory values obtained with the two methods. Specifically, t-tests were performed on the APTT values obtained by the Traditional Venipuncture Method and the Intra-Arterial Line Method on two groups of patients (Group one = 3cc discard, Group two = 6cc Discard). A significant difference was also found between the two methods after the

Table 7. Significance of Differences Between Traditional Venipuncture Method and Intra-Arterial Line Method on APTT Values When Comparing the Two Groups: Independent t-tests (Group one= 3cc discard, N=11; Group two=6cc discard, N=12)

Venous = Traditional Venipuncture Method

Arterial = Intra-Arterial Line Method

Variable	Mean (Secs)	Standard Deviation (Secs)	t
(APTT) Venous:			
Group 1	26.1	11.68	
Group 2	24.1	9.55	.46
(APTT) Arterial:			
Group 1	29.7	14.66	
Group 2	29.0	12.04	.12
Arterial-Venous:			
Group 1	3.6	5.40	
Group 2	5.0	5.89	.58

$\alpha \leq .10$

deletion of one APTT value from Group one which was considered an outlyer. When Group one and Group two were compared, t-Values showed that there was no significant difference in the arterial samples, venous samples, and the difference between the arterial and venous samples obtained by each group.

CHAPTER V

CONCLUSIONS AND IMPLICATIONS

Introduction

In the final chapter, the results of the data analysis are discussed. Conclusions drawn from the results are presented along with implications for nursing practice. Limitations of the study and recommendations for further nursing research are suggested.

Conclusions

The two null hypotheses tested were: (1) There is no significant difference between APTT values obtained by the Intra-Arterial Line Method and APTT values obtained by the Traditional Venipuncture Method; and (2) There is no significant difference between APTT values obtained following a 3cc discard and APTT values obtained following a 6cc discard. The first null hypothesis was rejected as the findings indicated that the APTT values did indeed differ significantly between methods. The second null hypothesis was accepted because there was no difference found in the APTT values following a 3cc and 6cc discard. Therefore, if blood is drawn from intra-arterial lines for APTT values using a 3cc or 6cc discard nurses need to know that the APTT values obtained may significantly differ from the APTT values drawn from the vein as occurred in this sample. Since the purpose of this study was to compare the two methods for reliability of laboratory values,

the investigator must conclude that the Traditional Venipuncture Method is the method of choice for withdrawing blood in adult patients for coagulation studies.

The Traditional Venipuncture Method, which consists of withdrawing blood from a vein for coagulation studies, has been considered by some physicians and laboratory personnel to be more accurate than the Intra-Arterial Line Method. The strongest argument is that the heparin contained in the intra-arterial line flush system might possibly cause false prolongation of coagulation values. The assumption, however, is based on personal experiences and documented incidences of prolonged APTT values in samples drawn from heparinized intra-venous lines (Bark, 1970 and Czapek, 1974). Limited research suggested that satisfactory blood samples for performing coagulation studies could be obtained from indwelling heparinized lines provided an adequate volume was removed prior to obtaining the sample (Mernestein, 1971 and Palermo et al., 1980).

Pryor (1983) supported use of the intra-arterial line as a site for obtaining coagulation studies in patients not receiving intravenous heparin therapy. The venous and arterial PT and APTT values significantly correlated with one another for those patients who were on warfarin and subcutaneous heparin therapies. Pryor's study, however, did not test for statistically significant differences between the two methods. Only descriptive statistics were used to analyze the data (Pearson correlation coefficients). Pryor also advocated the use of the intra-arterial line to decrease patient discomfort, pain and anxiety associated with unnecessary and repeated venipunctures.

The results of the present study, however, found a statistically significant difference between the two methods for the APTT values. The Intra-Arterial Line Method appears to provide a statistically different APTT value from the sample drawn by the Traditional Venipuncture Method. If the venous and arterial values were not identical, it was expected that the arterial value would be greater than the venous value since the intra-arterial line flush system contained heparin. The finding, however, was not consistent with two of the paired samples in Group one and three of the paired samples in Group two. Two possible explanations could account for the paradoxical values: first, an error in sample labeling may have occurred, or second, an error in withdrawing the arterial samples may have happened.

When conducting coagulation studies, one must keep in mind that reliable laboratory tests are essential to the safety and efficacy of anticoagulant therapy (Gurewich, 1977). For example, prior to institution of heparin treatment, it is important to perform an accurate APTT test as well as four hours following any adjustment in dosage and daily during maintenance therapy (Thompson and Harker, 1983). Czapek (1974) stated that patients who require frequent APTT determinations for control of heparin or other therapy can be subjected to multiple venipunctures. He goes on to say that it is only natural for the physician or nurse to wish to minimize the patient's discomfort and pain by obtaining samples in the easiest manner possible (i.e., through an indwelling catheter). However, one must be aware of the

error that can be introduced. Also, additional time, effort, discomfort, cost and concern to the patient often will need to be expended in determining the cause of the abnormal laboratory value that may result. In the critically ill adult patient, a difference in the APTT values may influence adjustments in dosage which might falsely lead to under-treatment or to over-treatment, with a potential for hemorrhage.

The National Committee for Clinical Laboratory Standards (1981) stated that in order to obtain accurate results from blood samples drawn from intra-arterial lines, attention must be paid to complete removal of "dead space" contents of the catheter and connectors prior to sampling. Molyneaux (1984) found that utilizing a discard volume of 1.6cc (twice the dead space of the system) was not enough to clear the line of the heparin effect as 11 of the 14 pairs of arterial samples were prolonged over the venipuncture samples. In the present study, even with the removal of the 0.6cc dead space calculated in the intra-arterial line system utilized, different results existed. The Committee Standards (1981) also suggested that a sample at least three times the volume of the line be removed and discarded before a specimen is obtained for analysis. For the first group of patients in the study who had 3cc of blood discarded (five times the dead space) and the second group of patients who had 6cc of blood discarded (ten times the dead space) the APTT values were still found to be significantly different. The investigator concluded that both amounts of discard used prior to obtaining the blood samples for coagulation

analysis were not adequate enough to decrease the chance of heparin effect. The possibility of heparin pooling at the catheter tip as well as adhering to the catheter wall and tubing must be considered.

When the patients in Group one (3cc discard) were compared with the patients in Group two (6cc discard), no significant differences were found between the arterial and venous values, and the difference between the two values for each group. The investigator is unable to explain why a multiple of the 3cc discard (6cc) did not produce different results than the lesser volume of discard especially since recent tentative guidelines from the National Committee for Clinical Laboratory Standards (1984) state that a larger volume of blood for discard decreases the chance of heparin contamination. In view of the above findings, one can conclude that increasing the amount of discard prior to obtaining the APTT arterial sample (from 3cc to 6cc) did not make any significant difference in the results obtained.

In summary, based on the findings of the study, the investigator concludes the Intra-Arterial Line Method is not the method of choice to withdraw blood in adult patients for coagulation analysis. Further investigations are needed, specifically utilizing a larger discard amount prior to obtaining the sample, before the method can be implemented as a clinically useful and accurate method.

Implications for Nursing Practice

An implication for nursing practice learned from this study is the necessity for scientifically testing a method prior to implementation and standardization into clinical practice. Since limited research existed on withdrawing coagulation blood samples from intra-arterial lines, this study began to establish a scientific basis for the procedure.

The National Committee for Clinical Laboratory Standards (1984) stated that the volume of blood discarded from the intra-arterial line prior to obtaining a sample depends on catheter size and length and the geometry of the catheter or connectors. They also suggested the volume drawn for discard needs to be determined for each system. This study determined that a 3cc or 6cc amount of discard was not enough for the particular intra-arterial line system utilized in the present study (0.6cc dead space = $1\frac{1}{2}$-2 inch catheter, six inch tubing) as different laboratory values were obtained with the intra-arterial method.

Another implication for nursing practice is the need to replicate research to substantiate previous findings. A case in point is the study by Pryor (1983) where the intra-arterial line system utilized in the comparison with the venipuncture method was similar to the system utilized in the present study (amount of discard and dead space). However, the two studies had very different results. Thus, the findings of this study need to be published not only to disseminate the findings for clinical utilization, but to alert nurses

to question the rationale for different procedures. This investigator intends to inform the intensive care units where the study was conducted of the findings of this study.

Finally, the present study addressed the fact that often methods of withdrawing blood for analysis are chosen based on patient comfort. The ultimate well-being of the patient, however, depends on reliable laboratory results. Therefore, accuracy must take priority over immediate patient comfort especially when substantiated evidence exists.

Limitations

The following possible limitations have been identified:

1. A small sample size was obtained.

2. Laboratory technicians and techniques of withdrawing the blood by the Traditional Venipuncture Method varied according to the idiosyncrasy of the technician (utilizing a needle and syringe versus a butterfly needle).

3. The length of time the intra-arterial line was in place prior to withdrawing the sample was not documented to account for the increased possibility of pooling of the heparin and adhering to the catheter and tubing wall.

4. The actual number of patients who were on anticoagulants was too few to be able to ascertain if the anticoagulant therapy the patients were receiving had any effect on the results.

5. The investigator did not analyze each sample and had to rely on a laboratory technician who varied according to the time of day the specimens were drawn.

Recommendations

Recommendations for further nursing research include:

1. Replicate the study with a larger sample size.

2. Utilize a larger amount of blood for discard (9cc).

3. Include more patients who are on anticoagulants.

4. Replicate the study analyzing the PT values along with the APTT.

5. Standardize the technique utilized by the laboratory technician for withdrawing the blood sample from the vein.

Summary

In conclusion, the study examined the results between APTT values obtained by two different methods. Twenty-four pairs of blood samples were obtained from two groups of patients. Group one consisted of 12 patients who had 3cc of blood drawn and discarded prior to obtaining the APTT blood sample from the intra-arterial line. Group two had 6cc of blood drawn and discarded. Significant differences were found between the two methods for each group. No significant differences were found when comparing the two groups. Implications for nursing practice were presented. Limitations of the study were recognized and recommendations were made for further study.

APPENDIX A

APPROVAL FORMS

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

UNIVERSITY HOSPITAL

October 29, 1984

Marylyn Kajs, RN
College of Nursing, Box 99
University of Arizona
Tucson, AZ 85721

Dear Ms. Kajs:

It is a pleasure to approve your request to conduct your study entitled "A Comparison of Coagulation Studies Obtained by Venipuncture and Intra-arterial Line Methods in Adult Patients" with patients at University Medical Center, Arizona Health Sciences Center. The abstract of your study has been reviewed by the two critical care Head Nurses of 6WS/N and 5WN. Both Jeanne Thrush (6WS/N) and Shelly Singer (5WN) have given their approval for the conduct of your study.

The two head nurses have raised several questions which I would like for you to address with them before proceeding with your data collection. Ms. Singer has particularly raised an issue whether the unit assistants can be the individuals on the nursing staff who are trained to contact you when needed. In addition, Ms. Singer has raised the question of whether there is additional cost to the patient for the blood sample that you will be drawing or the tests that will be conducted. Ms. Thrush asks that you put together an abstract of your project which can be shared with the physicians on 6WN/S as well as 5WN so that the medical staff will be informed about the project that you are conducting. Please let her know how you plan to contact the physicians and which ones with whom you have had an opportunity to discuss the project. Both head nurses have raised the issue of whether you will be able to coordinate the drawing of blood at the same time that other lab sample bloods are done - would like to see this done in order to not have the procedure conducted twice but only once. You have spoken to this in your proposal and may wish to reassure them of your plans in this area.

As you commence with your data collection, if I can be of further help to you, please don't hesitate to let me know. Your contact people for the study will be the two head nurses that have been cited above. We will look forward to having a report of your project and the staff will appreciate your discussing the results with them verbally.

Sincerely,

Ada Sue Hinshaw

Ada Sue Hinshaw, PhD, RN, FAAN
Associate Director of Nursing for Research

ASH/fp

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

HUMAN SUBJECTS COMMITTEE
1609 N. WARREN (BUILDING 220), ROOM 112

TELEPHONE: (602) 626-6721 or 626-7575

26 October 1984

Marylyn Kajs, R.N., B.S.
College of Nursing
Arizona Health Sciences Center

Dear Ms. Kajs:

We are in receipt of your project, "A Comparison of Coagulation Values Obtained by Venipuncture and Intra-Arterial Line Methods in Adult Patients", which was submitted to this Committee for review. The procedures to be followed in this study pose no more than minimal risk to the 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 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 information and comment, if any, after administrative approval is granted. This project is approved effective 26 October 1984.

Approval is granted with the understanding that no changes or additions will be made to either the procedures followed or 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 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

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

MN/jm

cc: Ada Sue Hinshaw, R.N., Ph.D.
College Review Committee

APPENDIX B

CONSENT FORMS

CONSENT FORM

A Comparison of Coagulation Values Obtained By Venipuncture and Intra-arterial Line Methods in Adult Patients

The purpose of this study is to examine the accuracy of coagulation tests (clotting constituent of the blood) drawn by an alternative method from a catheter in your artery (intra-arterial line). This method is presently being used for drawing blood for other kinds of laboratory tests. However, the medical and nursing professions do not know if the coagulation tests obtained by the intra-arterial line method and by the venipuncture method (withdrawing blood from a vein) are comparable. This alternative method may reduce the potential for repeated discomfort, pain and anxiety for you by eliminating frequent punctures of the veins and/or arteries.

Adults 18 and older who have an intra-arterial line in place are being recruited. Your physician has approved this study which will take place in the intensive care unit.

If you agree to participate, the investigator will obtain an additional 7.5 ml or approximately $2\frac{1}{2}$ teaspoons of blood from the catheter in your artery while the amount ordered by your physician is obtained from your vein. No more than one sample from the intra-arterial line will be obtained from you in a 24-hour period. The results of the blood tests drawn by the alternative method will then be compared with the results of the present method being used in the intensive care unit. No cost for this laboratory analysis or equipment will be included by participating in this study. You will receive no money for participating in this study.

To protect your confidentiality, all results will be coded. The results may be published in group form, but your identity will not be revealed. The only known risk to the study is that a possible chance of infection may be introduced when obtaining the blood from the catheter in your artery. Although highly unlikely, this may result in blood infection. Careful attention will be paid to ensure that sterile technique is used to obtain the blood. 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 are free to withdraw from the study and to ask questions that you may have at any time.

"I have read the above '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 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 representatives of the particular department. A copy of this consent form will be given to me."

Subject _____ Date _____

Parent or Guardian
(if appropriate) _____ Date _____

Witness _____ Date _____

CONSENT FORM

A Comparison of Coagulation Values Obtained By Venipuncture and Intra-Arterial Line Methods in Adult Patients

The purpose of this study is to examine the accuracy of coagulation tests (clotting constituent of the blood) drawn by an alternative method from a catheter in your artery (intra-arterial line). This method is presently being used for drawing blood for other kinds of laboratory tests. However, the medical and nursing processions do not know if the coagulation tests obtained by the intra-arterial line method and by the venipuncture method (withdrawing blood from a vein) are comparable. This alternative method may reduce the potential for repeated discomfort, pain and anxiety for you by eliminating frequent punctures of the veins and/or arteries.

Adults 18 and older who have an intra-arterial line in place are being recruited. Your physician has approved this study which will take place in the intensive care unit.

If you agree to participate, the investigator will obtain an additional 9.0 ml or approximately $2\frac{1}{2}$ teaspoons of blood from the catheter in your artery while the amount ordered by your physician is obtained from your vein. No more than one sample from the intra-arterial line will be obtained from you in a 24-hour period. The results of the blood tests drawn by the alternative method will then be compared with the results of the present method being used in the intensive care unit. No cost for this laboratory analysis or equipment will be included by participating in this study. You will receive no money for participating in this study.

To protect your confidentiality, all results will be coded. The results may be published in Group form, but your identity will not be revealed. The only known risk to the study is that a possible chance of infection may be introduced when obtaining the blood from the catheter in your artery. Although highly unlikely, this may result in blood infection. Careful attention will be paid to ensure that sterile technique is used to obtain the blood. 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 are free to withdraw from the study and to ask questions that you may have at any time.

"I have read the above '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 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 representatives of the particular department. A copy of this consent form will be given to me."

Subject _____ Date _____

Parent or Guardian
(if appropriate) _____ Date _____

Witness _____ Date _____

APPENDIX C

DATA COLLECTION SHEET

DATA FORM

ID. NO.							
DATE							
TIME							
SPECIMEN A APTT							
SPECIMEN B APTT							
DIAGNOSIS							
ANTI-COAGULANT THERAPY							
AGE							
SEX							

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