Rewarming After Induced Hypothermia With Cardiac Revascularization Surgery in the Diabetic Versus Nondiabetic Patient

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Dedicated to the memory of

Carol's father, Paul W. Pritchard and

Vickie's grandmother, Margaret V. Thomas

who passed away before this project was completed.

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ABSTRACT

TITLE: Rewarming After Induced Hypothermia with Cardiac Revascularization Surgery in the Diabetic Versus Nondiabetic Patient.

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Coronary artery disease occurs in approximately 42% of diabetics and is the most common cause of death in the adult diabetic. Peripheral neuropathy, often accompanied by autonomic neuropathy, is another common complication of long term disease. Diabetics with autonomic neuropathy who undergo cardiac revascularization surgery, during which patients are made hypothermic, may be at special risk for difficulty with rewarming in the early postoperative period. Neuropathic damage to microvascular and nerve structures can interfere with normal vasomotor responses (vasoconstriction, vasodilation) to changes in body temperature. The purpose of this quasi-experimental pilot study was to determine if postoperative rewarming after cardiac revascularization surgery differed between diabetic and nondiabetic patients in regard to (a) time required to reach initial and stable euthermia, (b) incidence and amount of temperature afterdrop, and (c) incidence of shivering.

The sample consisted of 8 diabetics and 8 nondiabetics with an age range of 51 to 74 years and a body mass index of 23.3 to 34.9 kg/m^2. Subjects were matched in pairs for age within 5 years and body mass index within 15%. The diabetics had a disease duration of 8 to 40 years, 5 had documented or self-reported peripheral neuropathy. Preoperative data collection included a brief chart review and interview related to medical history. Intraoperative data included surgical and cardiopulmonary bypass times, and pulmonary artery temperature at the end of cardiopulmonary bypass rewarming. Postoperative data were obtained at 15 minute intervals from admission to the cardiac recovery unit until

subjects reached stable euthermia, defined as a pulmonary artery temperature of at least 37°C for 1 hour. Physiologic variables included pulmonary artery temperatures, shivering, and amount of temperature afterdrop. Other variables included level of consciousness, use of blankets and active warming devices, medications, and ambient temperature. The two groups were compared using two-sample t-tests with quantitative variables and Fisher's exact test with categorical variables.

The diabetic and nondiabetic groups did not differ in regard to background variables that were accounted for, including patient factors, operative factors, and postoperative factors. The two groups did not differ in the mean time required to reach initial or stable euthermia. However, 3 diabetics did not reach stable euthermia within the 6 hour data collection period, as compared to only 1 nondiabetic. The two groups did not differ in the incidence or amount of temperature afterdrop, with all but two subjects experiencing it. Shivering occurred more often and more intensely in the diabetic group. Four diabetics shivered, 3 with visible tremors and 1 with. In contrast, only 1 nondiabetic shivered and only by palpable mandibular vibration. This pilot study suggests that diabetics with longstanding disease and thus greater likelihood to have autonomic neuropathy may be at greater risk to shiver during rewarming after cardiac revascularization surgery than nondiabetics. The study should be continued in order to improve statistical power and strengthen the findings.

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Chapter I

Introduction

Statement of Problem

According to the American Heart Association (1995), in 1993 almost 13.5 million Americans were afflicted with coronary artery disease (CAD). That same year, an estimated 485,000 people required cardiac revascularization surgery as an intervention for CAD, an increase of 150,000 over the number reported in 1986. The American Heart Association has identified diabetes as a contributor to the development of CAD. In 1993, 7.8 million diagnosed cases of diabetes were reported in the United States, with another 7 million undiagnosed cases estimated to exist (American Diabetes Association, 1996). According to the American Diabetes Association (1996) the incidence of CAD in diabetics is approximately 42%, the risk ratio for CAD in the diabetic population is two to twelvefold higher than in the nondiabetic population, and CAD is the most common cause of death (55%) in adult diabetics. However, the number of diabetic patients with CAD who have undergone cardiac revascularization surgery are uncertain.

Cardiac revascularization surgery is a procedure in which partially or totally occluded segments of the coronary arteries are bypassed to provide improved perfusion to the myocardium. After the chest is opened, the patient is placed on cardiopulmonary bypass as a mechanism to divert circulation from the heart and lungs, oxygenate the tissues, and cool the blood to induce a state of hypothermia (Holtzclaw, 1986). The purpose of induced hypothermia is to decrease metabolic activity, decrease oxygen

consumption, and preserve the myocardium (Philips & Skov, 1988). In general, a moderate range of hypothermia (28-32°C) is used (Weiland & Walker, 1986).

During surgery, hypothermia is a protective mechanism. However, prolonged hypothermia in the early postoperative recovery period has been shown to cause a number of deleterious effects such as shivering, acidosis, cardiac conduction disturbances, impaired cardiac contractility, hypercoagulopathy, accumulation of metabolic by-products, hyperglycemia, peripheral vasoconstriction, and prolonged drug actions (Williams, Davtyan, & Drazanova, 1995). After completion of the operative procedure, rewarming of the blood is begun before the patient is removed from bypass. Generally speaking, a goal of approximately 37°C for core body temperature is preferred before cardiopulmonary bypass is discontinued (Komer, 1991; Williams et al., 1995). However, the patient remains exposed to a cool ambient temperature in the operating suite following the termination of bypass while the operation is completed. At this time and in the early postoperative period, warmed blood from the central circulation flows through cold tissues where heat is lost from the blood. As a result of this cooling, core body temperature may fall and produce the phenomena of "afterdrop." The temperature may fall enough to place the patient back into a state of hypothermia. The continued presence of anesthetics or muscle relaxants can impair the normal thermoregulatory mechanisms of vasomotor activity, shivering, and chemical thermogenesis, further contributing to the problem of unstable rewarming from induced hypothermia. In the process of rewarming during the recovery period, patients are at risk of shivering as the body attempts to increase heat production to reach a stable state of euthermia--a core body temperature of about 37°C. If rewarming is too aggressive or

prolonged, however, the patient may experience a rapid rise in temperature which exceeds euthermia--a phenomena known as "overshoot" (Holtzclaw, 1990).

During rewarming, compensatory changes in heart rate, blood pressure, cardiac output, and systemic vascular resistance may accompany the vasoconstriction associated with hypothermia and afterdrop and the vasodilation associated with overshoot. A diminished cardiac output or blood pressure can potentially occlude the new coronary grafts, whereas an elevated blood pressure may loosen fresh sutures. Elevated systemic resistance or heart rate increases myocardial oxygen demands and myocardial workload.

Diabetics with the complication of neuropathy, specifically those with autonomic neuropathy, who undergo cardiac revascularization surgery may be at special risk for difficulty with thermoregulation in the early postoperative period. Neuropathies result in damage to microvascular and nerve structures. The damage may cause inefficient vasomotor responses that interfere with vasoconstriction and vasodilation mechanisms that normally occur in response to changes in body temperature. Development of neuropathy is more common as the duration of diabetes increases (Dyck et al., 1991).

In studies of diabetic patients exposed to heat and cold stressors, Greeson, Freedman, Levan, and Wong (1975) and Moorehouse, Carter, and Doupe (1966) demonstrated that some diabetic patients with neuropathy had slower and less complete vasomotor responses. In addition, Scott, Bennett, and McDonald (1986) found impairment of reflex vasoconstriction in the limbs of diabetic patients with neuropathy, resulting in the inability to conserve heat effectively during core cooling. Impairment of vasomotor control in diabetics with neuropathy may place them at special risk for

thermoregulatory problems after surgery under induced hypothermia. However, the pattern of rewarming in this group has not been examined.

Purpose

The purpose of this study was to determine if postoperative rewarming after cardiac revascularization surgery differed between diabetic patients and nondiabetic patients in regard to (a) the time required to reach initial and stable euthermic temperatures, (b) the incidence and amount of temperature afterdrop, and (c) the incidence and intensity of shivering.

Significance to Nursing

This study increases the body of knowledge regarding rewarming considerations for patients following induced hypothermia, specifically in the diabetic population about whom no previous research has been done. The knowledge gained could provide clinicians with information to support early intervention in this population and thereby reduce or prevent detrimental sequelae associated with hypothermia and prolonged rewarming, diminish the physiological and psychological burdens that can prolong recovery, and reduce the financial burden of an increased length of stay.

Chapter II

Review of Literature

This chapter will review the literature about temperature regulation, cardiopulmonary bypass and induced hypothermia, rewarming from induced hypothermia, shivering, diabetes mellitus, diabetic neuropathies, and diabetes and thermoregulation. The chapter also includes the conceptual framework of temperature regulation on which this study was based.

Temperature Regulation

Temperature is a thermodynamic property reflecting heat content (Holtzclaw, 1993). In humans, the internal body temperature is controlled by balancing heat loss and heat production to maintain a narrow range known as the "set point"--around 37°C. Heat continuously moves throughout body tissues from areas of higher temperature to areas of lower temperature via conduction and convection until the thermal gradient is diminished (Holtzclaw, 1990). The importance of maintaining a relatively constant body temperature is to ensure that living cells have an environment in which they can survive and perform metabolic and enzymatic functions (Roe, 1973). Fortunately, humans have a complex, yet efficient mechanism for thermoregulation.

Body temperature is regulated predominantly by feedback mechanisms which include peripheral and core thermoreceptors and the hypothalamus. The hypothalamus has both heat-sensitive and cold-sensitive neurons located in the preoptic area. It is believed they enable the hypothalamus to be an independent control for body temperature (Guyton & Hall, 1996). When the hypothalamus detects deviations from the set point, physiologic

and behavioral responses are initiated to promote gain or loss of body heat. A temperature below the set point initiates vasomotor activity (vasoconstriction, vasodilation, and resulting changes in blood flow), shivering, and chemical thermogenesis (Holtzclaw, 1993).

Vasoconstriction of the skin vessels reduces blood flow, diverting it to the core organs to conserve heat. Vasodilation of the vessels in muscle increases blood flow to the skeletal muscles to enhance their role in heat production (Blair, 1965). Shivering is not only heat producing but also facilitates regional shifts in heat as more blood perfuses the affected muscle groups (Holtzclaw, 1993). Chemical thermogenesis occurs as the body increases its rate of cellular metabolism, which produces heat, in response to the release of catecholamines and thyroxine (Roe, 1973; Guyton & Hall, 1996). Unfortunately, these thermoregulatory mechanisms become impaired in the patient undergoing cardiac revascularization surgery.

Thermoregulation is also influenced by circadian rhythmicity, age, and body mass index. The circadian rhythm of temperature is predominately initiated by an endogenous internal time keeping system but can be modified by exogenous factors such as environment and behavior. (Moore-Ede, Sulzman, & Fuller, 1982). Body temperature exhibits regular and predictable temporal variations in a circadian rhythm over an approximate 24 hour time period. Core temperature drops at onset of sleep reaching a trough at "midsleep" (the middle of a person's usual sleeping time) and begins to rise shortly before the usual waking time. An individual's temperature peaks in the latter part of the usual waking hours (Minors & Waterhouse, 1981; Reinberg & Smolensky, 1983;

Lanuza, 1993), about 11 to 15 hours after midsleep (Campbell, Gillin, Kripke, Erikson, & Clpoton, 1989). For example, a person who usually retires at 2200 and arises at 0600 will reach midsleep at 0200. Body temperature will begin rising prior to 0600, reaching a peak in the late afternoon or early evening hours.

Circadian rhythms can be influenced, but are not caused by, environmental factors such as alternation of day and night, heat and cold, and noise and silence (Minors & Waterhouse, 1981; Aschoff, 1984). In addition, individual differences in circadian rhythm are influenced by a person's morningness-eveningness preference. Morning types are fatigued in the evening, prefer to go to bed early, and arise early in the morning feeling refreshed. Evening types report feeling more alert in the evening, prefer to go to bed later, and arise later in the morning. In a study by Horne and Ostberg (1977), morning types (n = 18) exhibited a rapid rise in temperature upon waking, reaching a peak late in their customary waking period. The evening types (n = 20) had a steady rise in temperature upon waking which peaked about 70 minutes later than the morning types. In 1977, Horne and Ostberg developed a 19 item Morningness-Eveningness Questionnaire used to differentiate between morning and evening persons. More recently, the Short Assessment of Morningness-Eveningness, a one-question instrument, was developed and validated for use with elders (Felver & Hoeksel, 1996).

As humans age, they begin to experience decreased metabolic and vasomotor function. According to Morrison (as cited by Holtzclaw, 1990), a moderate reduction in metabolic heat can be discerned in patients over 65 years of age, and by age 80 the reduction is significant. Vaughan, Vaughan, and Cork (1981) found that following elective

general surgeries, patients 60 years of age and older had significantly lower temperatures upon arrival in the recovery room than patients less than 60 years of age. In addition, the older patients experienced a longer duration of hypothermia and lower body temperatures at discharge from the recovery room.

Heat is produced in proportion to mass and lost in proportion to surface area. Thin people have a higher ratio of surface area to body mass placing them at a high risk for heat loss (Brengelmann, 1989; Holtzclaw, 1990). Under normal conditions, adipose tissue acts as an insulator to conserve heat. In response to cold stress, however, obese people warm more slowly. Moors, Pickett, Woolman, Bethune, and Duthie (1994) studied 30 patients following cardiac revascularization surgery with induced hypothermia and found that the rate of rewarming was inversely related to body mass index (BMI), an index of weight in relation to height (kg/m^2). However, a study by Sladen (1985) which examined 73 patients undergoing cardiac surgery with induced hypothermia found no predictable relationship ($r < 0.3$) between the pattern of rewarming and age, body mass, or duration of cardiopulmonary bypass.

Conceptually, the body is composed of two thermal compartments, the "core" and the "shell" (Brengelmann, 1989; Guyton & Hall, 1996; Phillips & Skov, 1988). The core is composed of deep body tissues--the brain and the visceral organs--which are the predominant source of heat production and are less influenced by the environment than the shell (Holtzclaw, 1993; Guyton & Hall, 1996). The shell consists of skin and subcutaneous tissues and serves as a layer of insulation for core tissues (Brengelmann, 1989; Stevens, 1993). However, the shell thickness and insulative properties vary according to the

amount of cutaneous blood flow received by the tissues (Phillips & Skov, 1988). According to Brengelmann (1987), although core body temperature is a reflection of the temperatures of the deep body tissues and organs, the temperature is not uniform throughout the core area. In order to most accurately measure core body temperature, the clinician needs a measure of the thermal state of the body as a whole. Blood from the cooler periphery and warmer deep tissues returns and mixes together in the right heart. Therefore the pulmonary artery, which carries the mixed venous blood from the right heart to the lungs is an excellent site to measure core body temperature (Brengelmann, 1987; Holtzclaw, 1990; Stevens, 1993).

Cardiopulmonary Bypass and Induced Hypothermia

Cardiopulmonary bypass is a procedure that serves as a temporary substitute for the natural functions of the heart and lungs during cardiac revascularization surgery (Stephenson & Edmunds, 1991). It perfuses vital organs, ensures adequate oxygen transport, and provides the surgical team with a bloodless, motionless field in which to work (Weiland & Walker, 1986). One basic component of the cardiopulmonary bypass circuit is the heat exchanger where blood is cooled during the operative procedure, then later rewarmed as bypass is being discontinued.

During cardiopulmonary bypass, induced hypothermia enhances myocardial protection by decreasing metabolic demands. This allows longer periods of reduced circulation or no circulation to be safely tolerated during the surgery (Stephenson & Edmunds, 1991). Because blood viscosity is increased during hypothermia, patients are given fluids to dilute the blood to a hematocrit of 20 to 25% (Hall, Thomas, & Hug, 1995)

in order to improve capillary perfusion and prevent sludging of red blood cells in the cardiopulmonary bypass circuit (Weiland & Walker, 1986). The introduction of hypothermia and hemodilution have improved oxygen delivery and organ perfusion during cardiopulmonary bypass. As temperature decreases, oxygen is bound more tightly to hemoglobin causing a less efficient release of oxygen to the tissues (Komer, 1991). Because the solubility of gases in liquid is inversely related to temperature, more oxygen is carried in physical solution in the blood under hypothermic conditions (Mitchell & Casthley, 1991).

During surgical procedures such as cardiac revascularization, patients are given general anesthetics which can impair the body's ability to maintain a stable body temperature. Anesthesia eliminates the physiologic responses that attempt to correct hypothermic core temperatures, resulting in a temporary poikilothermic condition in which body temperature varies with the ambient room temperature (Roe, 1973; Rodriquez et al., 1993). In a study of women having microscopic surgery of the fallopian tubes, Holdcroft and Hall (1978) found a large decrease in skin temperature during the transfer from the operating room to the recovery room despite the beginning of patient activity and maintenance of environmental temperature at 24°C in the operating suite. Only after recovery from anesthesia can thermoregulatory reflexes reappear with gradual restoration of body temperature (Goldberg & Roe, 1966). In cardiac revascularization surgery, recovery from anesthesia and induced hypothermia can prolong the time of rewarming.

Aging and obesity can affect drug responses during both the intraoperative and postoperative periods. The physiologic changes of aging can affect drug absorption,

distribution, metabolism, and excretion (Schlesinger, 1992). A decreased total body water content, decreased cardiac output, poor nutrition, and extremes of body weight can affect the distribution and transport of many drugs. Metabolism and excretion of drugs are influenced by both diminished blood flow to the liver and kidneys as well as impaired organ function. The amount of adipose tissue can also affect drug absorption and distribution throughout body tissues which can subsequently prolong metabolism and excretion time. Therefore, both older patients and patients with a large body mass who undergoing surgical procedures are at risk for slower recovery from anesthesia and sedatives.

Rewarming from Induced Hypothermia

Hypothermia is the lowering of core body temperature to a generally accepted value of less than 37°C (Philips & Skov, 1988; Holtzclaw, 1990, 1993; Whitman, 1991; Stevens, 1993). Significantly, a fall in body temperature of even 0.5°C can cause the resting rate of energy expenditure to double due to thermogenesis (Roe, 1973). A resulting increase in oxygen consumption increases myocardial oxygen demand and may place patients with poor cardiac reserve at risk for developing cardiac arrhythmias, heart failure, or even myocardial infarction (Tølløfsrud, Gundersen, & Andersen, 1984). All 38 patients in the study by Giuffre, Heidenreich, and Pruitt (1994) experienced a large afterdrop from the time cardiopulmonary bypass was discontinued in the operating room until arrival in the intensive care unit. In addition, pulmonary artery temperature in 12 patients continued to drop after the institution of rewarming in the surgical intensive care unit.

Mild hypothermia induces muscular shivering, vasoconstriction, tachycardia, and hyperventilation. Vaughan et al. (1981) found that 60% of 198 patients undergoing elective general surgeries arrived in the recovery room with tympanic temperatures less than 36°C. Hypothermic patients shivered significantly more often than normothermic patients in the first 30 minutes following admission. A study of patients following major intra-abdominal or intrathoracic surgery by Rodriquez et al. (1983) confirmed that shivering as a result of hypothermia increased oxygen consumption and carbon dioxide production. Their data demonstrated that suppression of shivering with neuromuscular blockade resulted in lower oxygen consumption, heart rate, myocardial oxygen consumption, and mean arterial blood pressure. This suggests that control of shivering during rewarming prevents a rise in the metabolic demands placed on a potentially compromised myocardium. Frank et al. (1995) found that a decreased core temperature was associated with higher norepinepherine levels and, concurrently, greater vasoconstriction and higher arterial blood pressure. A retrospective chart review of 82 post-cardiac surgery patients by Marelli, Chiu, Fleiszer, and Brown (1988) found that 50% arrived in intensive care with a pulmonary artery temperature less than 35.5°C despite being rewarmed as cardiopulmonary bypass was discontinued. Those with hypothermia had a significantly lower cardiac output and a trend toward higher systemic vascular resistance.

Shivering

Shivering is a normal physiologic response to increase heat production in response to a lowered body temperature (Stolewijk, 1977). Although shivering can generate large

amounts of heat, the muscle movements create convective air currents which interfere with heat conservation. Since heat production increases the metabolic rate, it also places an increased burden on cardiac and respiratory functions. Hemingway (1963) found the rate of oxygen consumption increased two to five times with shivering. According to Bay, Nunn, and Prys-Roberts (1968) oxygen consumption increased by 135 to 486% in patients who shivered. However, Horvath, Spurr, Hutt, and Hamilton (1956) reported that shivering had only an 11% efficiency rate in protecting against heat loss. They also found that oxygen consumption, respiratory minute volume, and respiratory quotient significantly increased with cold exposure and shivering. Zwischenberger, Kirsch, Dechert, Arnold, and Bartlett (1987) found significant differences between shivering and nonshivering patients: the shivering patients had increased oxygen consumption, increased carbon dioxide production, lower systolic blood pressure, and lower mixed venous oxygen saturation while nonshivering patients did not.

Diabetes Mellitus

Diabetes mellitus is a disease characterized by the body's inability to properly metabolize glucose. Of several clinical classes of diabetes, the two most prevalent are insulin-dependent diabetes mellitus (IDDM), commonly referred to as type I, and noninsulin-dependent diabetes mellitus (NIDDM), referred to as type II. IDDM accounts for less than 10% of all cases of diabetes mellitus in the United States, while NIDDM accounts for 90 to 95% of cases (American Diabetes Association, 1996).

IDDM is distinguished by low or unmeasurable levels of endogenous insulin. Individuals afflicted with this class of diabetes are dependent on insulin therapy to prevent

development of ketoacidosis and sustain life. The onset of IDDM occurs predominately before the age of 30, but can occur at any age. The onset is usually abrupt and patients present with symptoms of excessive thirst, frequent urination, and significant weight loss at the time of diagnosis (Harris, 1995). The development of IDDM can occasionally be associated with or follow viral infections. In addition, genetic factors may also have a causal role in its development (Brown & Asbury, 1983).

In contrast, insulin levels of individuals with NIDDM may be normal, depressed, or elevated. Typically, high insulin levels are present, indicating insulin resistance due to decreased tissue sensitivity. However, patients often develop low levels of insulin as the disease progresses, necessitating insulin therapy. The onset of NIDDM can occur at any age, but typically occurs in people over 40 years of age. These individuals can be asymptomatic for years before diagnosis and frequently present with neuropathic symptoms at time of diagnosis. The prevalence of NIDDM increases with age, is slightly higher in women than men, and varies substantially by race and ethnicity. There also appears to be a genetic predisposition to NIDDM, and in the United States, diabetes is clearly more prevalent in blacks, Hispanics, and American Indians as compared to whites (Kenny, 1995; American Diabetes Association, 1996).

Diabetic Neuropathies

People with diabetes are prone to develop both acute and long term complications such as metabolic disturbances, vision disorders, kidney disease, coronary artery disease, peripheral vascular disease, and neuropathic disease. The most common neuropathy affecting diabetics is peripheral symmetrical somatic polyneuropathy (peripheral

neuropathy), which is often accompanied by autonomic neuropathy. Although the causes of diabetic neuropathies remain largely a mystery, the most common causes are believed to be metabolic abnormalities and microvascular ischemia.

In peripheral neuropathy a progression of nerve fiber loss, nerve atrophy, and nerve injury manifest as deteriorating neural function and worsening sensory-motor deficit (Vinik et al., 1992). The specific symptoms that occur depend on the type of nerve fiber affected. Small nerve fiber damage usually precedes large nerve fiber damage and presents first in the lower limbs. Symptoms associated with small fiber damage include loss of thermal sensitivity and reduced light-touch and pin-prick sensation. Symptoms of large nerve damage include reduced vibratory sensation and depressed deep tendon reflexes (Green, Sima, Stevens, Feldman, & Lattimer, 1992). Most studies of diabetic neuropathy have been performed on subjects with IDDM and report consistent findings in which the progression of nerve damage and nerve loss is related to the degree or duration of hyperglycemia or both (Dyberg, Benn, Christiansen, Hilsted, & Nerup, 1981; Sundkvist, 1981; Brown & Asbury, 1983; Boulton, Knight, Drury, & Ward, 1985). More recent findings from the Diabetes Control and Complications Trial (Greene et al., 1988) found an association between male gender, age, clinical peripheral neuropathy, and abnormal somatic and autonomic nerve function tests even when duration of diabetes was not considered.

Autonomic defects in diabetic neuropathy are a consequence of small nerve fiber damage which can cause failure in both sympathetic and parasympathetic nerve fibers. Early autonomic nerve dysfunction has been attributed to vagal nerve damage with

manifestations appearing in many organs. Cardiac defects attributable to autonomic damage can include tachycardia at rest, abnormal heart-rate response to the Valsalva maneuver, loss of beat-to-beat variability in heart rate, and loss of immediate heart-rate response to standing (Vinik et al., 1992). Sympathetic failure results in loss of vasomotor control, increased peripheral blood flow, and a loss of peripheral and splanchnic vasoconstriction and is believed to follow parasympathetic damage. However, in a review article by Watkins and Edmonds (1983), sympathetic damage in diabetic neuropathy was noted to be much more common than previously suspected with sympathetic defects likely to develop in parallel with parasympathetic damage. Symptoms of these defects include postural hypotension, sweating disturbances, and hypoglycemia unawareness (Vinik et al. 1992).

Several studies have examined the prevalence of neuropathy in diabetes within certain subgroups. The Rochester Diabetic Neuropathy Study was a population-based, cross-sectional survey followed by a longitudinal followup study of diabetic neuropathy in 870 subjects in Rochester, Minnesota. Forty-three percent of the subjects underwent detailed study for neuropathy, of whom 278 had NIDDM and 102 had IDDM. Although the duration of diabetes was not evaluated, the frequency distribution of neuropathies was similar for both NIDDM and IDDM (Dyck at el., 1991). The San Luis Valley Study specifically looked at patients with NIDDM in a geographically based, case-control study and found the prevalence for peripheral neuropathy was associated with age and duration of diabetes. The prevalence of neuropathy was lowest in those under 45 years of age and highest in those 65 to 74 years of age. Duration of diabetes was positively correlated with

prevalence of neuropathy, ranging from 33% in those with diabetes for 10 to 14 years to 50% for a disease duration greater than 25 years (Franklin, Kahn, Baxter, Marshall, & Hamman, 1990).

Measuring the prevalence of autonomic neuropathy is difficult, in that patients with autonomic involvement are often asymptomatic. The prevalence has been reported anywhere from 17 to 40% (Vinik et al., 1992), with most studies conducted with patients with IDDM. Most literature on the prevalence of autonomic neuropathy concurs that clinical symptoms (e.g., gustatory sweating, orthostatic hypotension) increase with duration of diabetes and that asymptomatic abnormalities are not uncommon after 10 to 15 years duration of diabetes (Dyberg et al., 1981).

A study by Veglio et al. (1990), which was specifically designed to assess the prevalence of autonomic neuropathy among people with NIDDM, found autonomic impairment was higher in the NIDDM group than in people with IDDM. However, no correlation was found between duration of diabetes or metabolic control and development of autonomic neuropathy. The difficulty in accurately establishing the duration of diabetes in patients with NIDDM was addressed by using the date of diagnosis as the starting point.

Diabetes and Thermoregulation

Studies on alterations in peripheral blood flow in response to the application of cold and heat stressors found that most vasomotor responses (i.e., vasoconstriction, vasodilation) were slower and less complete in diabetic versus nondiabetic patients. Under most conditions, blood flow through the skin acts primarily as a means of heat exchange.

Therefore, inappropriately high flow rates result in excessive heat loss. Moorehouse et al. (1966), using digital temperatures as an indicator of blood flow, examined reflex vasomotor responses in diabetic and nondiabetic patients to body heating and cooling, as well as local vasomotor responses to direct heating and cooling. Body warming caused rapid and sustained vasodilatation in normal healthy subjects, while cooling produced prompt vasoconstriction. However, in some diabetic patients with neuropathy, the vasomotor responses were slower and less complete. When local cooling was applied to the limbs of nondiabetics, vasoconstriction could be inhibited by heating the trunk. However, in diabetic patients with absent vasomotor reflexes, the limbs remained vasoconstricted even in the presence of body heating. Similar findings were reported by Almér, Sundkvist, and Lilja, (1982) in both short-term diabetics (mean 11 years) with autonomic neuropathy and long-term diabetics (mean 35 years), irrespective of presence or absence of cardiac autonomic neuropathy.

Only one study by Scott et al. (1986) has compared the response of diabetics, both with and without neuropathies, and individuals without diabetes to hypothermic conditions. In this study, 12 diabetics without neuropathy, 11 diabetics with autonomic neuropathy, and 12 nondiabetics were evaluated first in the supine position wearing a liquid-perfused coverall over the trunk and legs. Core temperature was measured aurally; metabolic rate was measured by indirect calorimetry; and forearm, calf, and foot blood flows were measured by plethysmography at 34°C. One foot was wrapped in an electric blanket and maintained at 34°C. Once blood flows were stable, the suit was perfused at 16°C for up to 45 minutes. Before cooling, blood flows were similar in each group.

However, diabetics with neuropathy had regional differences in blood flow in response to cooling. In particular, foot blood flow was significantly higher in diabetics with neuropathy than the other two groups. Core temperature decreased in three of the diabetics with neuropathy, a contrast to the normal response to cooling (vasoconstriction) which usually produces a transient increase in core temperature. Shivering was induced in half of the neuropathic patients, while none of the diabetic patients without neuropathy or the nondiabetic patients shivered. Metabolic rates rose significantly higher in the subjects who shivered than in those who did not. These findings suggest that autonomic neuropathy resulted in impaired heat conservation on exposure to cold. No research studies have examined the response of diabetic patients to body cooling in clinical situations such as induced hypothermia for cardiac revascularization surgery.

Conceptual Framework

The conceptual framework for the study is shown in Fig. 1. In order for the thermoregulatory system to function normally, core and peripheral thermoreceptors, sensory and motor nerve fibers, hypothalamic integrative abilities, and microvascular vasomotor responses must be intact. A patient who has received anesthesia and undergone induced hypothermia is at risk for disruption of the normal pathway for thermoregulation. The normal compensatory mechanisms to counteract hypothermia include behavioral activities, cutaneous vasoconstriction, increased chemical thermogenesis, and shivering. According to Sessler (1993), during ordinary circumstances behavioral activities are more likely to be a factor in the maintenance of core body temperature than autonomic

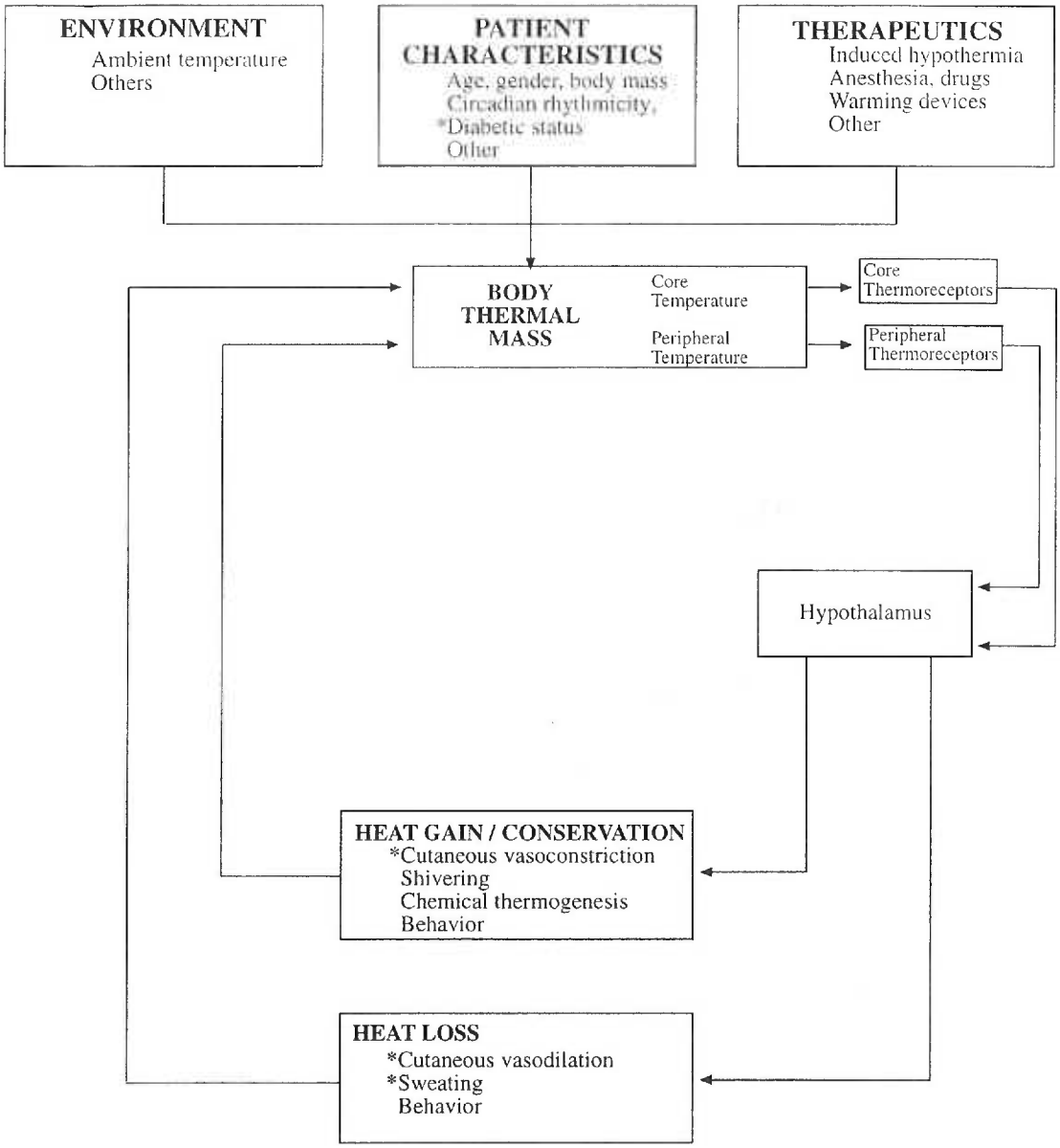


Figure 1. Conceptual framework. Asterisks (*) indicate the location in the normal thermoregulatory pathway where major defects occur in diabetics with autonomic neuopathy.

regulation. Because behavioral activities cannot occur while the patient is anesthetized or sedated, the patient must rely on autonomic functions and therapeutic interventions by providers to reach a state of euthermia.

Diabetic patients are at increased risk to develop peripheral and autonomic neuropathies as time progresses. In the diabetic with autonomic neuropathy, both sympathetic and parasympathetic nerve fibers can be damaged. However, the damage to sympathetic nerve fibers is responsible for interfering with the vasomotor response to body cooling, impairing the diabetic's ability to vasoconstrict as a mechanism to conserve heat during rewarming from induced hypothermia. This defect may cause a greater amount of afterdrop, prolong the time required to reach stable euthermia, and increase the likelihood of shivering as a mechanism to enhance metabolic heat production.

Chapter III

Methods

This chapter presents the design of the study, sample and setting, human subjects considerations, and a description of the variables. The section on variables includes operational definitions, how the variables were measured, information related to the instruments that were used, and data collection procedures. The chapter concludes with a description of the data analysis procedures.

Design

This study used a quasi-experimental, two-group comparison design. Diabetics with at least a 10-year history of either IDDM or NIDDM disease, and therefore an increased likelihood of neuropathy, were compared to nondiabetics in regard to variables associated with rewarming from cardiac revascularization surgery. This was an exploratory study, as no previous research had examined the issue of rewarming in diabetic patients after cardiac revascularization surgery.

Subjects and Setting

The subjects were a convenience sample of female and male patients 45 to 75 years of age who had cardiac revascularization surgery. Diabetic subjects had a diagnosis of IDDM or NIDDM with either a minimum duration of 10 years or documented or reported peripheral neuropathy. Control subjects did not have a diagnosis of diabetes. Exclusion criteria for both groups included adrenal, pituitary, or thyroid disorders; Raynaud's disease; and neuropathic disease not attributable to diabetes. All subjects had a pulmonary artery catheter placed prior to the start of the operative procedure. Subjects had a BMI

that fell within the range of 20 to 34.9 kg/m^2. Subjects in the two groups were matched by pairs for age within 5 years and BMI within 15%.

The study setting was a 452-bed tertiary, nonprofit hospital in Portland, Oregon. An average of 120 patients per month undergo open heart surgical procedures. Patients were recovered in a 16-bed cardiac recovery unit immediately following surgery.

Potential subjects were identified from the tentative operating room schedule which was released at 1700 for the following day. The list was obtained on a daily basis from the unit secretary on the cardiac recovery unit at the study hospital. One of the two investigators screened the preoperative medical records for patients who fit the initial inclusion criteria of age, presence or absence of diabetes, and BMI. Patients who met the criteria were approached by one of the investigators to determine interest in participating in the study. The study was explained verbally and in writing to the patients, and written informed consent was obtained (Appendix A). At that time, the investigator proceeded with a short preoperative interview (Appendix B).

Study approval was obtained from the institutional review boards at both Oregon Health Sciences University and the study hospital. The nursing department and the cardiothoracic surgery, cardiology, and anesthesiology groups at the study hospital extended support to the study. All data were kept confidential by use of identification numbers on each study data form. The forms were kept in a locked cabinet at the School of Nursing, and data entry was done on a computer with a restricted password.

Variables

The independent variable in this study was the diabetic status of the subjects. The dependent variables included rewarming times, afterdrop, and shivering. All temperature data were obtained from the digital display on a Siemens Sirecust® bedside monitor (Model No. 1281) (Fig. 2) using the Siemens LIM (Large Integrated Multiparameter) cartridge (Fig. 3) (Siemens Medical Systems, Inc., Danvers, MA). In addition to pulmonary artery temperature, the monitor also continuously displayed a variety of measures and calculations of hemodynamic variables such as heart rate, arterial blood pressure, pulmonary artery pressure, cardiac index, and systemic vascular resistance.

An intraoperative data sheet developed for the study (Appendix C) was used by the circulating nurse to record pulmonary artery temperatures and identify the primary intraoperative care providers between the time the patient entered and exited the operating room. A postoperative data sheet (Appendix D) was used by the investigators to collect data on the dependent variables during the immediate postoperative recovery phase in the cardiac recovery unit. Postoperative data collection was done only by the two investigators. Data collection began immediately upon subjects' arrival in the cardiac recovery unit. Subjects were observed until they reached a state of stable euthermia for one hour or a maximum of six hours, whichever occurred first. Routine postoperative care was provided by the assigned staff nurse or nurses. The investigators did not participate in any direct or indirect care with the exception of setting and maintaining the ambient room temperature between 21.1 and 23.3°C (70 and 74°F). The data collection protocol is shown in Appendix E. All invasive lines and monitoring equipment used during

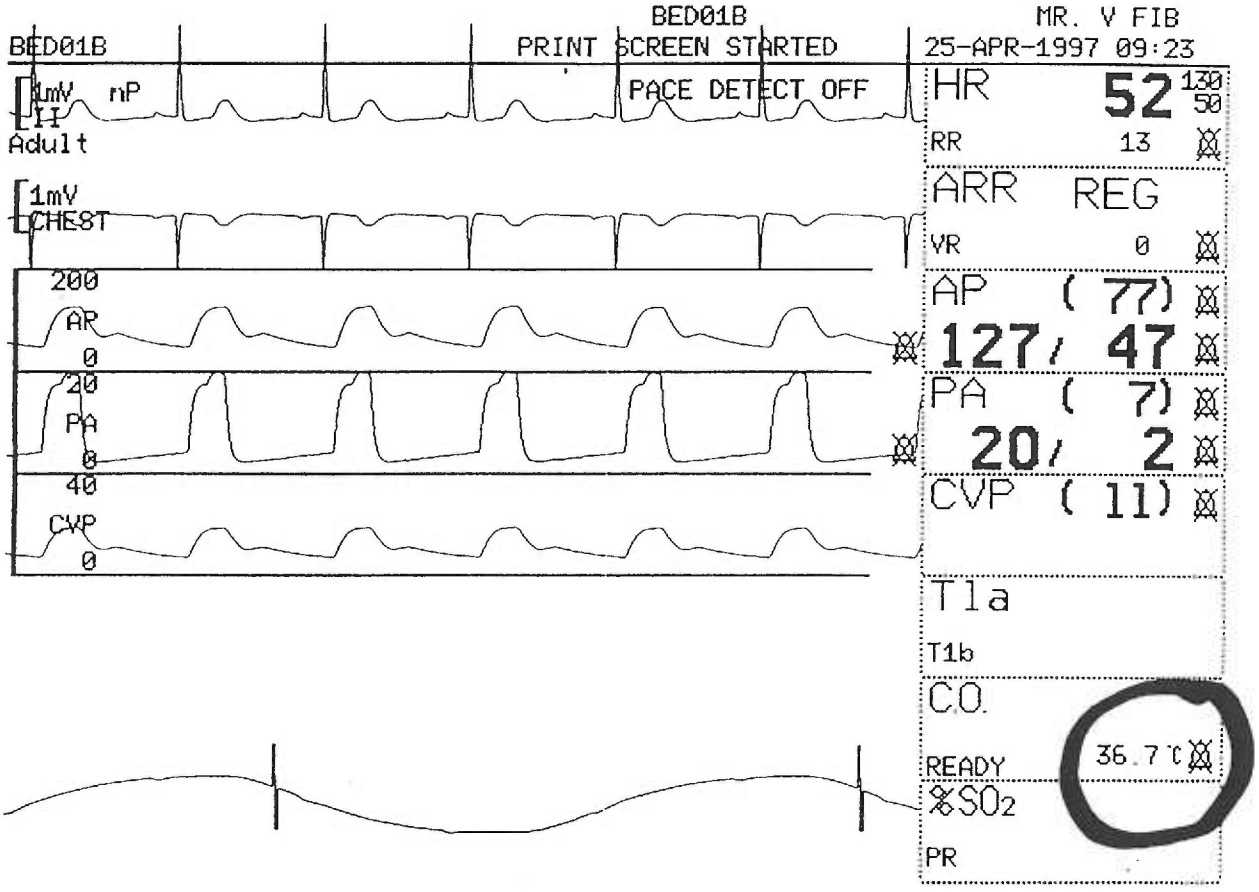


Figure 2. Display on the Siemens Sirecust® bedside monitor. Note pulmonary artery temperature reading in the lower right corner which has been circled.

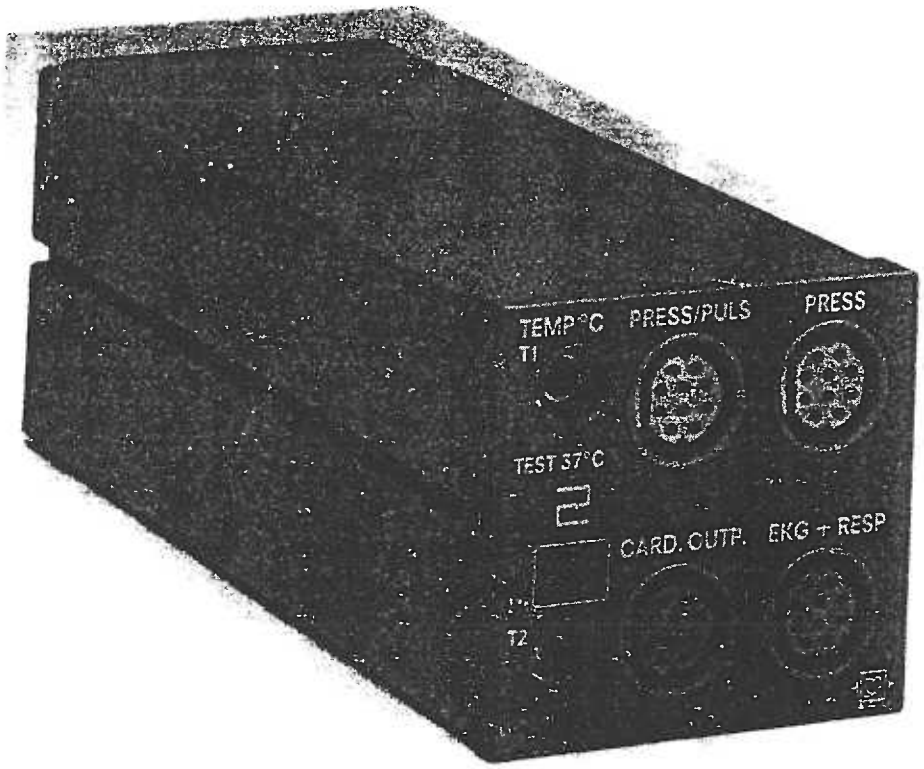


Figure 3. Siemens LIM cartridge used in processing body temperature and hemodynamic measurements.

the study were usual and customary practice for the operative and recovery phases following cardiac revascularization surgery. No new or different practices or procedures were implemented for purposes of this study.

Prior to the study, information explaining the purpose and procedures of the study were presented to the nursing staff of the Cardiac Recovery Unit, Cardiovascular Operating Room, Interventional Cardiovascular Recovery Unit, and Cardiology floor. Prior to actual data collection one patient was studied to test the protocol (Appendix E) and determine interrater reliability between the investigators. Reliability was verified at 98% agreement on the major outcome variables.

Temperature measurement. Euthermic and hypothermic body temperatures have been described by a wide variety of ranges. Euthermia has been reported in the literature as approximately 37, 37.6 to 37.4, and 36.7 to 37°C (Brengelmann, 1989; Whitman, 1991, Guyton & Hall, 1996). Hypothermia has been reported as being 32 to 37, 34 to 36.5, and less than 36°C (Holtzclaw, 1990; Whitman, 1991; Stevens, 1993). For this study, euthermia was defined as a core temperature of 37°C or greater measured in the pulmonary artery, considered the gold standard for core temperature measurement (Brengelmann, 1987). Hypothermia was defined as a pulmonary artery temperature less than 37°C. Afterdrop was defined as any fall in pulmonary artery temperature of 0.5°C or greater after the termination of cardiopulmonary bypass. A stable state of euthermia was defined as a pulmonary artery temperature which remained at 37°C or greater for at least one hour after the subject was admitted to the cardiac recovery unit.

Pulmonary artery temperature was recorded at designated stages of the intraoperative period including the start and end times of surgery, cardiopulmonary bypass, and rewarming on cardiopulmonary bypass, and the last temperature prior to leaving the operating room. In the recovery period, pulmonary artery temperature was recorded every 15 minutes.

Pulmonary artery temperature was measured from a 4-lumen or 5-lumen Torque-Line™ Thermodilution Catheter (Model No. 41239-01 or 41237-01, Abbott Critical Care Systems, Mountain View, CA). A thermistor bead located near the distal end of one "lumen" of the catheter continuously measures the temperature of the blood flowing past it. The manufacturer guarantees accuracy specifications of the pulmonary artery catheters within ± 0.5°C. However, when similar pulmonary artery catheters were tested in previous research (Erickson & Kirklin, 1993), they demonstrated mean error of 0.03 to 0.07°C. Accuracy of the LIM cartridge is reported to be ± 0.1°C over a range of 30 to 50°C.

Shivering measurement. Shivering was defined as palpable or visible fasciculations or tonic muscle contractions. A 1985 pilot study by Holtzclaw (cited in Holtzclaw, 1986) validated the use of a grading scale which rated shivering from 0 to 4; 0, no visible or palpable shivering; 1, palpable mandibular vibration; 2, visible fasciculation of head or neck muscles; 3, visible fasciculation of pectorals and trunk; and 4, generalized shaking, teeth chattering. Every 15 minutes during the postoperative period, the investigators palpated the masseter muscles for a mandibular vibration for 10 seconds. In addition, the subjects were continually observed and graded for visible fasciculations. The use of any

interventions by the staff nurse to treat shivering was documented on the postoperative data collection tool.

Other Background variables

A number of other factors that were known or suspected to have a potential effect on thermoregulation were also measured. Subject factors included age, BMI, ethnicity, concurrent disease states, level of consciousness, and extubation. To help identify each individual's circadian status for body temperature, the time of midsleep was calculated from subjects' reported bed times and rising times and their preference as an early, late, or no preference person was determined using the one-item Short Assessment of Morningness-Eveningness (Felver & Hoeksel, 1996). Data were recorded on the Chart Review and Subject Interview Data Sheet (Appendix B) during preoperative interviews with subjects and review of hospital records.

Therapeutic factors included use of blankets, thermal hats, and active warming devices; administration of vasoactive drugs, analgesics, and anxiolytics. The environmental factor was ambient room temperature. Therapeutic and environmental factors were observed by the investigators and recorded on the Postoperative Data Sheet.

Ambient room temperature was measured using an Omega® digital thermometer (Model No. HH22) with a type K thermocouple probe (Omega Engineering, Stamford, CT) placed at the head of the subject's bed. Accuracy specifications from the manufacturer are reported at ± 1 °C. Temperatures were recorded from a digital display every 15 minutes in the first hour, and hourly thereafter.

Data Analysis

The diabetic and nondiabetic groups were initially compared for equivalence in regard to background variables and then the main study variables. For quantitative variables, group means were compared with two-sample t-tests. Categorical variables were all analyzed as 2 x 2 comparisons with the Fisher exact test (Daniel, 1995). Multiple comparisons between groups increased the risk of finding significant results on the basis of chance (Type I error). Since this was an exploratory study however, no corrections were made for multiple tests. Although a p-value of .05 was used as the level for statistical significance, p-values up to .20 were considered to be of interest because of the small sample size and limited statistical power (Jonathan B. Fields, personal communication, April 14, 1997).

Chapter IV

Results

Characteristics of Study Sample

The sample consisted of 16 men and women prescheduled for cardiac revascularization surgery. As shown in Table 1, subjects included 11 men and 5 women who ranged in age from 51 to 74 years with a BMI of 23.3 to 34.9 kg/m^2. Thirteen subjects were Caucasian and three were noncaucasian. No subjects had thyroid, pituitary, or adrenal disorders; Raynaud's disease; or neuropathy not associated with diabetic disease. The subjects had a calculated midsleep range of 0030 to 0600 hours. Nine subjects reported an early preference of morningness-eveningness, three reported a late preference, and four reported no preference. All subjects had cardiac revascularization surgery with two to five bypass grafts. The total operative time on cardiopulmonary bypass ranged from 36 to 115 minutes. All subjects were admitted to the cardiac recovery unit following surgery where ambient room temperature was controlled between 21.1 and 23.3°C (70 to 74°F). Subjects were studied until they reached stable euthermia or a maximum of six hours, whichever came first.

Comparison of Study Groups

The subjects comprised two study groups, eight diabetics and eight nondiabetics. Pairs of subjects, one in each group, were matched for age within five years and BMI within 15%. As shown in Tables 1 and 2, the diabetic group included four males and four females with a mean age (± standard deviation) of 63.5 ± 6.4 years (range 53 to 74 years) and a mean BMI of 30.0 ± 4.0 kg/m^2 (range 23.7 to 34.9 kg/m^2). One subject had IDDM

Table 1

Characteristics of Individual Subjects

Subject	Age	BMI (yr)	Gender (kg/m²)	Ethnicity	Mid-sleep	SAM-E	Number of grafts	Bypass time (min)
				Diabetic group				
101	61	30.0	Female	Caucasian	0200	NP	2	58
102	61	34.9	Female	Caucasian	0130	LP	3	71
103	53	32.9	Female	Caucasian	0245	EP	3	53
104	63	33.7	Male	Caucasian	0215	NP	2	47
105	74	27.4	Male	Caucasian	0245	EP	5	84
106	67	25.8	Male	Caucasian	0300	NP	3	74
107	69	23.7	Male	Black	0215	EP	2	75
108	60	31.4	Female	Caucasian	0600	LP	5	115
				Nondiabetic group				
201	57	28.1	Male	Hispanic	0145	EP	2	39
211	61	31.5	Male	Caucasian	0030	EP	3	67
206	51	32.8	Male	Caucasian	0115	EP	3	51
210	67	31.2	Female	Caucasian	0115	EP	4	80
208	73	27.5	Male	Caucasian	0215	LP	4	66
204	65	27.5	Male	Caucasian	0215	NP	3	54
207	72	23.3	Male	Caucasian	0230	EP	3	36
203	60	29.1	Male	Asian	0200	EP	3	63

Note. BMI = body mass index, SAM-E = Short Assessment of Morningness-Eveningness, EP = early person, LP = late person, NP = no preference. The nondiabetic subjects are listed in the order in which they match a diabetic subject for age and BMI.

Table 2

Disease Related Characteristics of Diabetic Subjects

Subject	Diabetes type	Duration (years)	Reported neuropathy	HbA_1C (%)	Type of control		
					Diet	Oral	Insulin
101	NIDDM	22	Yes	7.8	No	No	Yes
102	IDDM	40	No	8.1	Yes	No	Yes
103	NIDDM	15	No	7.8	No	Yes	Yes
104	NIDDM	8	Yes	9.2	No	No	Yes
105	NIDDM	8	Yes	---	No	No	Yes
106	NIDDM	11	No	7.9	Yes	Yes	No
107	NIDDM	16	Yes	8.3	No	Yes	No
108	NIDDM	10	Yes	11.0	No	Yes	No

Note. IDDM = insulin dependent diabetes mellitus, NIDDM = noninsulin dependent diabetes mellitus, HbA_1C = glycosylated hemoglobin.

with a 40-year duration of disease. The other seven subjects had NIDDM with a duration 8 to 22 years. Five of the diabetic subjects had documented or self-reported peripheral neuropathy, though none had documented autonomic neuropathy. Four subjects used insulin for glucose control, three used oral agents, and one used both insulin and an oral agent. Only two patients reported consistent use of a therapeutic diet as part of their regime. Seven subjects had a glycosylated hemoglobin (HbA_1C) level obtained during this hospitalization with a mean value of 8.6 ± 1.2% (range 7.8 to 11.0%). Since the normal reference range for HbA_1C at this hospital was 4.5 to 5.9%, the lab values indicated that these diabetics had fair to poor glucose control. This was not an unexpected finding considering glycemia is a factor that may mediate the increased risk of CAD in diabetics (American Diabetes Association, 1996). The nondiabetic group included seven males and one female. They had a mean age of 63.3 ± 7.5 years (range 51 to 73 years) and mean BMI of 28.9 ± 3.0 kg/m^2 (range 23.3 to 32.8 kg/m^2).

Table 3 shows the comparison of the diabetic and nondiabetic groups in regard to selected personal, intraoperative, and postoperative background variables. No statistically significant differences were found for any of the variables except agitation ($p = .03$), which was noted in five nondiabetics but in no diabetics.

Other intraoperative and postoperative background variables that were accounted for included use of medications, volume expanders, blood products, and mechanical ventilation. Intraoperatively, all subjects received anesthesia with isoflurane, fentanyl, and midazolam; all but one subject received one or more neuromuscular blocking agents (pancuronium bromide, vecuronium bromide, succinylcholine chloride); and nine

Table 3

Comparison of Background Characteristics of the Study Groups

Variable	Diabetic	Nondiabetic	Test statistic	p value
	Patient Factors			
Age (yr)	63.5 ± 6.4	63.3 ± 7.5	t = 0.07	.94
BMI (kg/m^2)	30.0 ± 4.0	28.9 ± 3.0	t = 0.62	.54
Gender			Fisher's	.28
male:female	4:4	7:1		
Ethnicity			Fisher's	1.00
Caucasian	7	6		
Noncaucasian	1	2		
Morningness-Eveningness			--	--
Early person	3	6		
Late person	2	1		
No preference	3	1		
	Operative Factors			
Number of grafts	3.1 ± 1.2	3.1 ± 0.6	t = 0.00	1.00
2	3	1		
3	3	5		
4	0	2		
5	2	0		
Thermal hat (yes:no)	5:3	8:0	Fisher's	.20
Average OR ambient temperature (°C)	18.7 ± 1.1	18.6 ± 0.6	t = 0.27	.80
OR times				
Total	201 ± 33	184 ± 25	t = 1.16	.26
Surgery	162 ± 32	148 ± 20	t = 1.07	.30
Bypass	72 ± 21	57 ± 15	t = 1.64	.12
Rewarming	21 ± 5	17 ± 4	t = 1.70	.11

(table continues)

Variable	Diabetic	Nondiabetic	Test statistic	p value
	Postoperative Factors			
Thermal hat (yes:no)	5:3	8:0	Fisher's	.20
Light blanket (yes:no)	1:7	4:4	Fisher's	.28
Heavy blanket (yes:no)	7:1	7:1	Fisher's	1.0
Active warming device (yes:no)	2:6	2:6	Fisher's	1.0
Agitation (yes:no)	0:8	5:3	Fisher's	.03
HAMS to baseline CRU measurements (decimal hours)	9.4 ± 1.6	10.7 ± 2.9	t = -1.13	.28
Baseline temperature (°C)	36.0 ± 0.4	36.0 ± 0.4	t = 0.65	.52
Average CRU ambient temp (°C)	22.3 ± 0.3	22.9 ± 0.5	t = 1.0	.33
Staff			Fisher's	.62
Investigator	5	3		
Investigator 2	3	5		

Note. BMI = body mass index, OR = operating room, HAMS = hours after mid sleep, CRU = coronary recovery unit, Fisher's = Fisher's exact test.

subjects received the anesthetic propofol. Three nondiabetic subjects received warmed blood products intraoperatively. During the postoperative period the most commonly used medications were morphine sulfate as a bolus or continuous drip (n = 15), nitroprusside sodium (n = 14), nitroglycerine (n = 13), and midazolam (n = 9). Other drugs more sparsely utilized in the postoperative period included propofol, meperidine hydrochloride, dobutamine, dopamine, nifedipine, and enalapril. Seven diabetic subjects required a continuous insulin infusion at a dose determined by bedside glucose monitoring. Six diabetics and seven nondiabetics received albumin or hetastarch for volume expansion during the postoperative period. All subjects had an in-line heat-moisture exchanger in place of externally warmed, humidified inspired ventilatory gases. Only one diabetic was extubated during the postoperative study period as compared to five nondiabetic subjects. Fisher's exact test was performed on each set of these intraoperative and postoperative nominal data sets. No statistically significant differences between the two groups were present.

Comparison of Rewarming Variables

Euthermia. The two groups were compared in regard to the length of time required to reach initial and stable euthermia using two-sample t-tests. The three subjects (two diabetics, one nondiabetic) who did not reach initial euthermia within the 6-hour study limit were assigned a maximum value of 360 minutes for the calculations. Similarly, the four subjects (three diabetics, one nondiabetic) who did not reach stable euthermia were assigned a maximum value another 60 minutes longer (420 minutes).

As shown in Table 4, the diabetic and nondiabetic groups did not differ in the time

Table 4

Comparison of Rewarming Variables in Diabetic and Nondiabetic Subjects

Variable	Diabetic (n = 8)	Nondiabetic (n = 8)	Test statistic	p value
	Rewarming Times (minutes)			
To euthermia (37°C)	211 ± 131	214 ± 85	t = -0.05	.96
To stable euthermia	269 ± 133	274 ± 85	t = -0.09	.93
To 36.8°C or greater	173 ± 116	150 ± 38	t = 0.52	.62
To stable 36.8°C or greater (minutes)	242 ± 129	216 ± 37	t = 0.55	.60
	Afterdrop			
Occurrence			Fisher's	.47
Yes	6	8		
No or data missing	2	0		
Temperature-loss (°C)	1.9 ± 0.6 (n = 6)	1.6 ± 0.7 (n = 8)	t = 1.00	.34
	Shivering			
Occurrence (yes:no)	4:4	1:7	Fisher's	.28
Level				
None	4	7		
Palpable-Mandibular	1	1		
Visible-head/neck	2	0		
Visible-pectoral/trunk	1	0		
Generalized	0	0		

required to reach either initial ($p = .96$) or stable euthermia ($p = .93$). Diabetics required a mean time of 211 ± 131 minutes (range 44 to 360 minutes) to reach a temperature of at least 37°C, and nondiabetics required a mean time of 214 ± 85 minutes (range 102 to 360 minutes). Temperature stability at this level for an hour was achieved at a mean time of 269 ± 133 minutes for diabetics (range 104 to 420 minutes) and 274 ± 85 minutes for nondiabetics (range 162 to 420 minutes).

Afterdrop. All subjects except two diabetics experienced temperature afterdrop. The extent of afterdrop was similar ($p = .34$) in the diabetic and nondiabetic groups with means of 1.9 ± 0.6°C (range 0.9 to 2.5°C) and 1.6 ± 0.7°C (range 0.5 to 2.5°C), respectively.

Shivering. Shivering occurred more often and more intensely in the diabetic group. Four diabetics shivered, three with visible tremors and one with palpable mandibular vibration. In contrast, only one nondiabetic shivered and only at a level of palpable mandibular vibration. In addition, all four of the diabetics who shivered had peripheral neuropathy. As might be expected, the difference did not reach statistical significance with the small sample size.

Background Variables

Correlation coefficients were calculated to identify associations between the rewarming variables and background factors of age, BMI, hours after midsleep, extubation, and agitation (Table 5). Age had a positive, significant correlation with the time required to reach both initial ($r = .56$, $p = .02$) and stable euthermia ($r = .56$, $p = .03$). That is, the older the subjects, the longer their rewarming period was likely to be. A small,

Table 5

Correlations between selected background variables and study variables

Study Variable	Age	BMI	HAMS	Extubate	Agitation
Rewarming time to initial euthermia n = 16 (minutes)	.56 (.02)	-.36 (.17)	.40 (.13)	.47 (.07)	-.03 (.91)
Rewarming time to stable euthermia (minutes) n = 16	.55 (.03)	-.35 (.19)	.41 (.11)	.47 (.06)	-.02 (.93)
Amount of afterdrop (° C) n = 14	.17 (.55)	-.48 (.08)	-.34 (.24)	-.16 (.59)	-.52 (.06)
Incidence of shivering n = 16	-.22[a] (.41)	.28[a] (.30)	.03[a] (.92)	-.33 (.21)	-.26 (.33)

Note. Correlations are Pearson's r except Spearman's rho[a] . Values in parenthesis are p-values. BMI = body mass index, HAMS = hours after midsleep to stable euthermia.

negative correlation was found between BMI and the times to initial ($r = -.36$, $p = .17$) and stable euthermia ($r = -.35$, $p = .19$) and a moderate, negative correlation between BMI and the extent of temperature afterdrop ($r = -.48$, $p = .08$). That is, subjects with a smaller BMI took longer to rewarm and had a larger temperature afterdrop. No apparent association was found between the circadian temperature cycle, as measured by hours after midsleep, extubation, or agitation and any of the rewarming variables.

Graphic charts of each subjects' 15-minute pulmonary artery temperature readings were plotted and visually examined in relation to the estimated circadian temperature cycle for each individual. The hypothetical circadian temperature curve was based on customary midsleep time and morningness-eveningness preference. No subject was rewarming at a time in the temperature cycle beyond the expected peak temperature. Therefore, minimal if any physiologic interference with rewarming would be expected.

Chapter V

Discussion

Induced hypothermia during cardiac revascularization surgery is a protective mechanism. However, hypothermia during the immediate postoperative period may represent a significant clinical risk for patients with cardiopulmonary compromise. In addition, because diabetics with autonomic neuropathy have impaired vasomotor tone causing inefficient vasoconstriction, they may be at greater risk for detrimental outcomes when exposed to cold stress. The purpose of this pilot study was to determine if postoperative rewarming after cardiac revascularization surgery differed between diabetic and nondiabetic subjects in regard to the times required to reach initial and stable euthermia, risk for afterdrop, and incidence of shivering.

Rewarming

Mean rewarming time to initial and stable euthermia and the incidence and amount of afterdrop were not measurably different between the two groups. However, the diabetic group had considerably more variability in the individual times to reach both initial and stable euthermia. This variability could possibly be explained by the occurrence of shivering, increased chemical thermogenesis (e.g. higher epinephrine level), or a higher amount of residual anesthesia. However, epinephrine levels and residual anesthesia were not analyzed.

In this study, of the five subjects who shivered, four were diabetic. The three diabetics who shivered with the highest intensity warmed to stable euthermia within a short time period (105 to 180 minutes). In contrast, two diabetic subjects, including one

who had only two brief incidents of palpable shivering, never reached initial euthermia within the 360 minute study limit. Another diabetic who did not shiver, but was treated with an active rewarming device within 15 minutes of admission to the cardiac recovery unit just reached initial euthermia at 360 minutes. In contrast, rewarming time tended to be more similar among the nondiabetic subjects. Most rewarmed to stable euthermia within 210 to 270 minutes. Only one nondiabetic subject warmed quickly, reaching stable euthermia in 165 minutes and only one did not reach initial or stable euthermia within the 6-hour study limit (Figure 4).

Rate of temperature rise was not a variable originally included in the design of this study. However, because the three diabetics subjects with visible shivering rewarmed so rapidly, correlations between rate of temperature rise and several other study variables were calculated. When the rate of temperature rise was calculated as total temperature change divided by time to stable euthermia, no apparent correlation was found between the rate of rise and age, BMI, shivering, amount of temperature afterdrop, agitation, or extubation.

Shivering

The higher incidence of shivering in diabetic subjects with documented or reported neuropathy in this study is consistent with findings by Scott et al. (1986) that half (n = 6) of their diabetic subjects with neuropathy (two with peripheral neuropathy and 10 with peripheral and autonomic neuropathy) shivered when exposed to moderate cooling as compared to none of the diabetics without neuropathy (n=11) or subjects without diabetes (n = 12). Their findings suggest that diabetics with autonomic neuropathy, and therefore

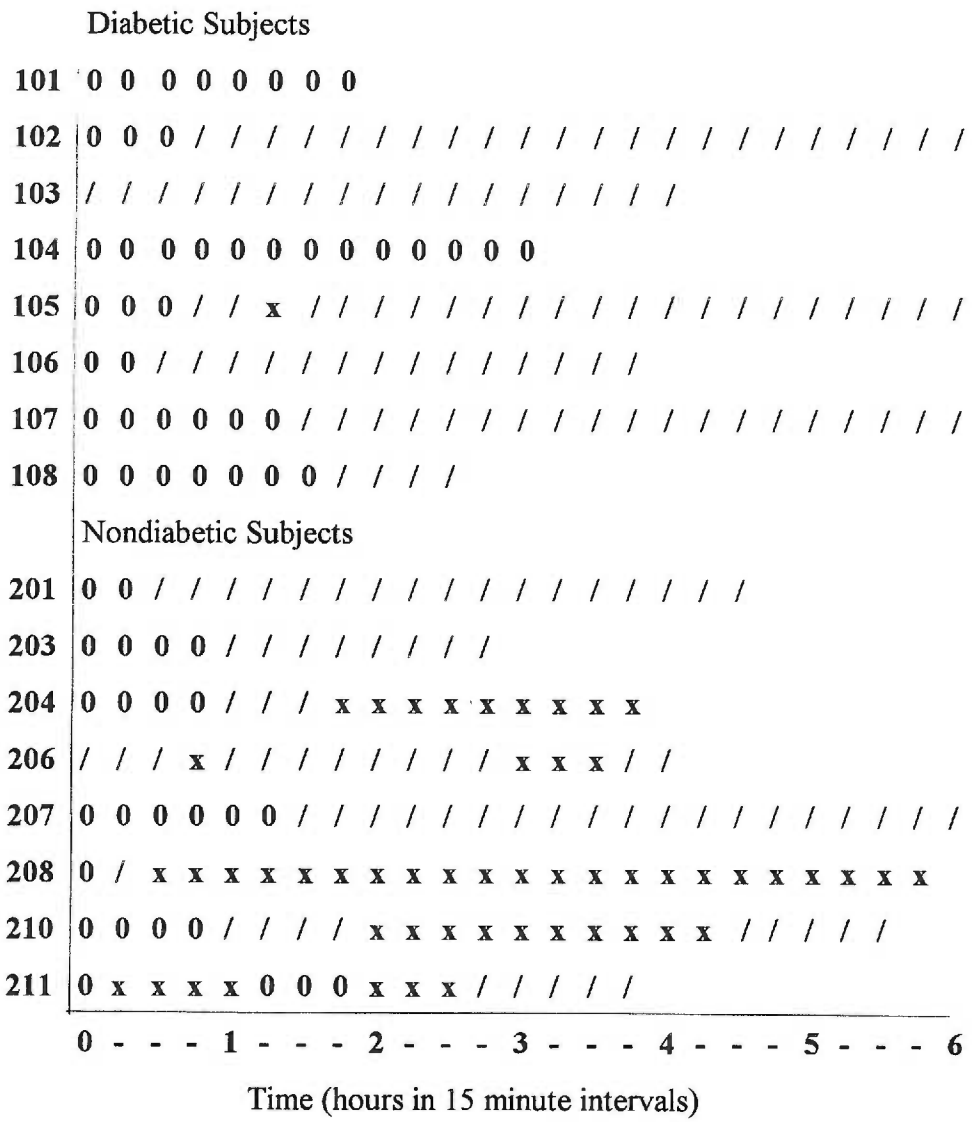


Figure 5. Level of consciousness evaluated in 15 minute intervals and individual rewarming times to stable euthermia. As shown in diagram, the nondiabetic subjects had considerably more agitation than the diabetic subjects as indicated by the "x" symbol. In constrast, the diabetic had longer periods of sedation as indicated by the "0" symbol.

likely to have an impaired vasoconstriction response to cold stress, are more likely to thermoregulate by shivering. Although none of the diabetic subjects in this study had documentation of autonomic neuropathy in their inpatient hospital record, two of the diabetic shiverers had preoperative findings highly suspicious of autonomic neuropathy, including one subject with a permanent pacemaker and one with renal failure. However, all of the diabetics who shivered reported having peripheral neuropathy, which often precedes the development of autonomic neuropathy (Greene et al., 1988; Vinik et al., 1992). In addition, of the four diabetics who did not shiver, only one reported neuropathy.

Shivering associated with postoperative rewarming is an undesired physiologic stress. Although this study was not designed to directly investigate hemodynamic variables or oxygen consumption, other researchers have found that the increased metabolic demands of shivering cause increased oxygen consumption, heart rate, blood pressure, and cardiac index. The adverse physiologic effects of shivering during postoperative rewarming have been documented numerous times in research. Studies by Bay et al. (1968), Macintyre, Pavlin, and Dwersteg, (1987) and Zwischenberger et al. (1987) found significant increases in both carbon dioxide production and oxygen consumption in subjects who shivered. Frank et al. (1995) found that oxygen consumption increased 38 to 125% above basal levels in shivering subjects. In contrast, Rodriguiz et al. (1983) found that the suppression of shivering with neuromuscular blockade resulted in decreased carbon dioxide production, oxygen consumption, heart rate, and mean arterial blood pressure.

In a 1993 review of thermoregulation during general anesthesia, Sessler discussed

many research studies which found that general anesthesia impairs the body's ability to maintain temperature. Therefore, when investigating postoperative shivering, anesthesia must be considered a major confounding variable since it suppresses the normal thermoregulatory mechanisms--vasoconstriction, shivering, and behavior--which conserve heat and increase heat production. The presence of residual anesthetic agents during the early postoperative period cannot be identified without sophisticated metabolic analysis and would be difficult to quantify. Residual anesthesia may therefore have been a factor in the inhibition of the shivering response of some subjects in this study.

The cause of the tremulous muscular movement seen during postoperative rewarming is controversial (Vaughan et al., 1981; Macintyre, et al., 1987; Crossly, 1992). Opinions vary as to whether shivering represents a response to lowered body temperature or the recovery of normal neuronal activity following general anesthesia. A study by Pozos, Israel, McCutcheon, Wittmers, and Sessler (1987) was undertaken to compare muscular activity in two groups using an electromyogram (EMG). One group (n = 9) was placed in an environmental chamber at 0°C for 30 to 45 minutes, while the other group (n = 9) had either elective laparoscopy or laparotomy with general anesthesia in a warm operating room (22.6 ± 0.8°C). The findings indicated that the EMG signal patterns in the postoperative group were markedly different from those in the cold stressed group. In a recent study by Spaniol, Bond, Brengelmann, Savage, and Pozos (1994), the EMG patterns of the subjects who shivered (n = 10) following cardiac surgery with induced hypothermia suggested that true thermogenic shivering had occurred. Although numerous studies, including the present one, have used a physical assessment scale to grade levels of

shivering, the grading does not distinguish between thermally induced shivering and tremors associated with residual anesthesia as would be possible with an electromyogram.

Subject Characteristics.

Gender. The results of this study are consistent with research which has shown that diabetic women lose their gender advantage against developing heart disease (Gordon, Castelli, Hjortland, Kannel, & Dawber, 1977; Heyden, Heiss, Bartell, & Hames, 1980; Seeman, Mendes de Leon, Berkman, & Ostfeld, 1993) and may be at even greater risk than diabetic men (Barrett-Connor, Cohn, Wingard, & Edelstein, 1991). In this study, half of the diabetic subjects were female as compared to only one female in the nondiabetic group. Although the factors causing increased risk of heart disease are controversial, research suggests that favorable lipoproteins, specifically high-density lipoprotein (HDL) cholesterol, are lower in diabetic women than in diabetic men (Kannel & McGee, 1979; Walden, Knopp, Wahl, Beach, & Strandness, 1984).

Age. Findings in the present study are consistent with the well known relationship between age and postoperative hypothermia: older subjects take longer to rewarm (Goldberg & Roe, 1966; Roe, Goldberg, Blair, and Kinney, 1966; Vaughan et al., 1981; White, Thurston, Blackmore, Green, & Hannah, 1987; Frank et al., 1995; Nathan & Polis 1995). Subjects 65 years of age and older (n = 7) in this present study took longer to reach both initial and stable euthermia than did younger subjects. Three of the four subjects who required an active warming device were in the older group. In addition, three of four subjects who did not reach stable euthermia within the 360 minute observation limit were 69 years of age or older.

Body mass index. A moderate correlation ($r = -0.48$, $p = .08$) was found between BMI and the amount of temperature afterdrop. Smaller subjects had greater afterdrop: of the eight subjects with a BMI of less than 30 kg/m^2, the three smallest had the largest amounts of afterdrop (2.5, 2.3, and 2.5°C). Although other studies which looked at rewarming patterns following induced hypothermia included body mass as a factor in data analysis, no specific mention of BMI in relation to temperature afterdrop was found.

A study by Sladen (1985) found no consistent relationship between BMI and postoperative rewarming following induced hypothermia. Even though this study found a small correlation between BMI and rewarming times to initial and stable euthermia, considerable variability was noted in both the diabetic and nondiabetic groups. Confounding factors such as shivering and use of active warming devices must also be considered. Of the eight subjects with a BMI of less than 30 kg/m^2, three (one on an active warming device) reached stable euthermia in 240 minutes or less. Five took more than 240 minutes, two of whom never reached initial euthermia and three of whom (two on an active warming device) never reached stable euthermia. Of the eight subjects with a BMI of 30 kg/m^2 or greater, six reached stable euthermia in 240 minutes or less, three of whom had the highest levels of shivering and one of whom was on an active warming device. Of the two who took longer to rewarm, the one with the largest BMI did not reach initial or stable euthermia during the 6-hour study limit.

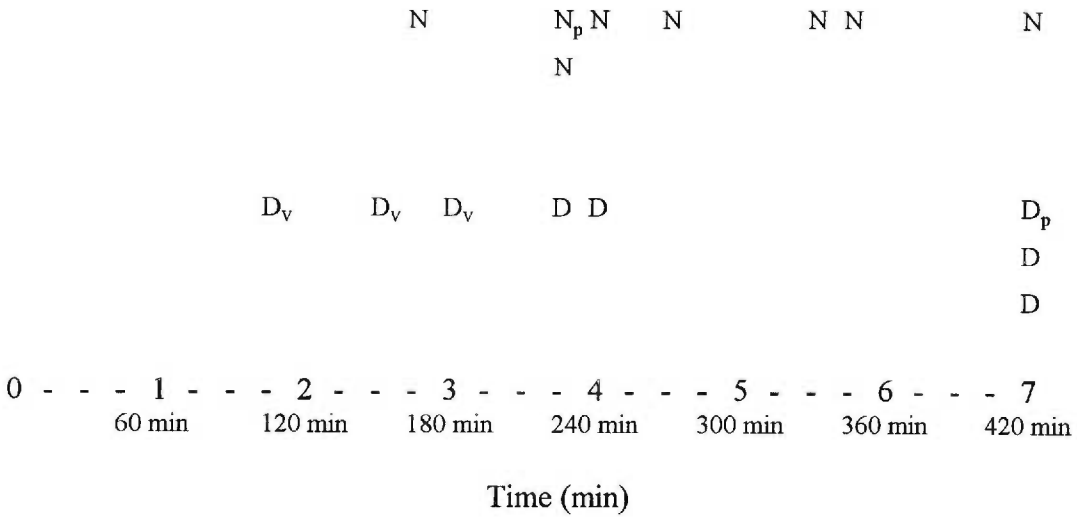
Circadian temperature rhythm. This study found no relationship between circadian timing, as indicated by hours after midsleep and morningness-eveningness preference, and the times to reach initial and stable euthermia. This was not unexpected because the

subjects were between 6.9 and 14.6 hours after midsleep. Since temperature is expected to peak approximately 11 to 15 hours after midsleep (Campbell, 1989) subjects were likely to have been rewarming at a time in their temperature cycle when body temperature would be expected to be rising and no physiologic interference would be anticipated. When looking at the three preference groups--early, late, and no preference--only three subjects in the early preference group were near or at the hypothetical peak of their temperature curve. All other subjects were in the rising phase of their temperature curve.

Agitation and Extubation.

Agitation. A serendipitous finding in this study was a significant difference in the presence of agitation between the diabetic and nondiabetic groups, although no relationship was found between agitation and rewarming times (Figure 5). Four diabetic subjects remained sedated (no response to verbal or tactile stimuli) for 75 minutes or longer after admission to the cardiac recovery unit, as compared to only one nondiabetic subject. Two diabetics remained sedated during their entire study periods of 105 and 180 minutes. The only diabetic who was agitated exhibited this kind of behavior for just 15 minutes. In contrast, five nondiabetic subjects were agitated, four of whom were treated with an intravenous infusion of propofol. Three subjects were continuously agitated for 135, 150, and 315 minutes respectively, while the other two each had two periods of agitation lasting 15 to 60 minutes.

Although all subjects received several of the same anesthetic agents (isoflurane, fentanyl, and midazolam) and most of them received one or more neuromuscular blocking agents (pancuronium bromide, vecuronium bromide, succinylcholine chloride), this study



N = Nondiabetic subjects
D = Diabetic subjects
$_v$ = Visible shivering
$_p$ = Papable shivering

Figure 4. Individual times to stable euthermia showing the greater variability in the diabetic subjects.

was not designed to quantify medication use. Therefore, it is possible that the difference in agitation between the two groups was affected by variations in the dose of pharmacologic agents received during the intraoperative period, their rate of metabolism, and residual anesthesia in the postoperative period.

Extubation. In the course of this study six subjects were extubated, five nondiabetics and one diabetic. Criteria for extubation in the cardiac recovery unit included a stable trial on continuous positive airway pressure, with oxygen saturation maintained at 93% or greater, and a cardiac index of 2.1 L/min or greater. All extubation was done prior to initial euthermia, with one subject each at pulmonary artery temperatures of 36.4, 36.7 and 36.8°C and three at 36.9°C. No specific relationship between extubation and rewarming times were apparent.

Therapeutic Interventions

There was no consistent practice among nursing staff in the cardiac recovery unit in regard to use of an active warming device, the number or thickness of cloth blankets, and the pulmonary artery temperature at which thermal hats were removed. Although four subjects (two diabetic, two nondiabetic) who arrived in the cardiac recovery unit with a pulmonary artery temperature less than 36°C were placed on an active warming device, another five were not. Some variation in the use of an active warming device could be explained by the lack of a written protocol. It might also be explained by the Hawthorne effect: knowing they are included in a study may change people's usual behavior in such a way as to obscure the effect of the variable of interest (Polit & Hungler, 1995). In this case, some members of the nursing staff may have changed their customary practice in

regard to the use therapeutic rewarming interventions knowing their patient was enrolled in a study.

Another uncontrolled variable, medications, could have influenced the results. Vasodilators such as nitroprusside sodium and intravenous nitroglycerine are commonly used in the immediate postoperative period to prevent hypertension and dilate coronary arteries. However, vasodilation redistributes the centrally warmed blood more evenly to the periphery, therefore interferes with heat conservation and promotes heat loss (Stevens, 1993). All but one subject in each group received a continuous infusion of nitroprusside sodium, and seven diabetics and six nondiabetics received continuous infusion of nitroglycerine. Medications administered that affect the central nervous system such as morphine sulfate, meperidine hydrochloride, midazolam, and propofol may interfere with sensory and motor functions which are necessary to conserve or generate heat (Holtzclaw, 1990). All subjects received either morphine sulfate or meperidine for pain control. Nine subjects received midazolam and five subjects received propofol for restlessness or agitation. Use of each of these drugs were evenly distributed between the diabetic and nondiabetic groups.

Implications for Nursing

This study examined rewarming, temperature afterdrop, and shivering in the immediate postoperative period following induced hypothermia during cardiac revascularization surgery in diabetic and nondiabetic subjects. Although the study sample was too small to detect statistically significant differences between the two groups in regard to the study variables, there was a higher incidence and higher level of shivering in

the diabetic group. The only apparent similarity between the diabetic shiverers was the presence of reported or documented peripheral neuropathy. This finding suggests that nursing staff should assess for the possible presence of diabetic neuropathies through chart review and patient interview prior to surgery. Although a definitive diagnosis of diabetic autonomic neuropathy requires specialized physical assessment skills, disease duration of 10 or more years or the presence of peripheral neuropathy suggests the likelihood that the patient could also have autonomic neuropathy (Greene et al., 1988; Vinik et al., 1992). Therefore the nurse should be especially alert to the possibility these patients may be at greater risk for shivering during the immediate postoperative period.

Shivering was assessed every 15 minutes in the study subjects both by palpating the mandible and by visual observation. Only one subject exhibited visible shivering not preceded by a palpable mandibular vibration. Holtzclaw's (1986) shivering assessment tool is simple to learn and easy to implement in the clinical setting. By using palpation as well as visual observation, nurses may detect shivering more quickly, allowing for more prompt intervention. It is therefore recommended that nurses be taught to use this tool. The shivering assessment tool should be considered a "vital sign" and incorporated in the frequent assessment of patients recovering from induced hypothermia during at least the first two hours of the immediate postoperative period.

This study supports the plethora of research which has found that older subjects take longer to rewarm from induced hypothermia. The findings also suggest that subjects with a smaller BMI may have a larger temperature afterdrop. Therefore, nurses should be prepared to intervene with appropriate warming therapies in older and smaller patients. In

addition, a protocol for the use of an active warming device should be implemented to provide a consistent method for rewarming the hypothermic patient.

Limitations

The absence of statistically significant findings in this study may largely be a result of an insufficient sample size. In the time available for data collection, 19 patients met the study criteria, 16 of whom were matched in diabetic and nondiabetic pairs.

Although the incidence of autonomic neuropathy increases with duration of diabetes and is more likely to occur in the presence of peripheral neuropathy, neither can identify the actual presence of diabetic autonomic neuropathy. The inability to identify diabetic subjects with a definitive diagnosis of autonomic neuropathy for inclusion in this study is another limitation.

The accuracy of secondary data collection is well recognized as a limitation. In this study, intraoperative data were not collected on two diabetic subjects. In addition, several other subjects had incomplete intraoperative data collection. Although the investigators were able to extrapolate some of the data from the anesthesiology and cardiopulmonary bypass records, not all of the necessary data could be retrieved. In order to assess interrater reliability, the investigators collected postoperative data on one patient for 4.5 hours. Although a 98% agreement was attained on the study variables, the subject did not shiver, therefore interrater reliability for the shivering scale between the two investigators was not tested.

Although the accuracy of monitoring equipment is a vital component to the integrity of a physiologic study such as rewarming, due to time constraints, independent

testing was not done to verify accuracy of the temperature measuring system in this study. Instead, the accuracy, range, and sensitivity of the monitoring equipment and pulmonary artery catheter thermistor was obtained either from the manufacturer's specifications or previous research.

A variety of confounding factors that were not controlled which may have an effect on the rewarming variables include total cardiopulmonary bypass time, cardiopulmonary bypass rewarming time, intraoperative and postoperative medications, and differences in nursing practice in regard to use of warming interventions such as blankets and active warming devices.

Recommendations for Future Research

This study should be continued or replicated in order to improve statistical power and strengthen the findings. In addition, several design modifications are suggested. A sample size of 26 subjects per group would be required to have an 80% chance, or power, of detecting a 100-minute difference in rewarming time between groups at the .05 significance level, given the variability in rewarming time (SD = 120 minutes) found in the study (Cohen, 1988). To detect a 60 minute difference in rewarming with the same power and significance, a sample size of 64 subjects per group would be required.

The premise of this study was based on the concept that diabetics with autonomic neuropathy cannot effectively vasoconstrict to conserve heat in the presence of hypothermia; diabetics may rewarm more slowly or be at a greater risk to shiver. More diabetic subjects did in fact shiver, but the shivering assessment tool used in this study simply graded the level of shivering and did not distinguish the physiologic cause of

shivering. Although using a physical assessment tool to detect shivering in the clinical setting is practical, the assessment tool cannot differentiate between shivering which occurs as a thermoregulatory mechanism and shivering which occurs in response to anesthesia. Therefore, the use of an electromyogram in addition to the physical assessment tool is recommended in future research.

Chemical analysis to determine serum levels of residual anesthesia and sedatives is a complex and costly procedure. However, standard chemistry panels include blood urea nitrogen (BUN), creatinine, lactic dehydrogenase (LDH), alanine aminotransferase (SGPT), gamma-glucamyl transferase/transpeptidase (GGT/GGTP), and serum glutamic oxaloacetic transaminase (SGOT). These tests could provide a rudimentary analysis of renal and liver function, both of which have a direct influence in the metabolism and excretion of pharmacological agents. It is therefore recommended that these laboratory tests be included in preoperative data collection.

Within the 6-hour maximum study limit, three subjects did not reach initial euthermia and four subjects did not reach stable euthermia. For the purpose of data analysis, an artificial value was assigned to these data points. Therefore, the analysis somewhat underestimated the mean rewarming times and may have contributed to the lack of statistically significant findings. It is recommended that future studies duplicating this research collect data on all subjects until they reach stable euthermia.

In summary, although this pilot study was inconclusive in regard to rewarming times and temperature afterdrop, the findings suggest that diabetics with longstanding disease and thus greater likelihood to have autonomic neuropathy may be at a greater risk

to shiver during rewarming after cardiac revascularization surgery than nondiabetics. Shivering increases metabolic rate therefore placing an additional burden on cardiac and respiratory function of an already compromised population. The continuation or replication of the present study may provide nurses with valuable information to identify a population at risk for shivering and the knowledge to provide early intervention to prevent or suppress shivering.

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APPENDIX A

INFORMED CONSENT

PHS IRB#96-122 Approved 12-31-96
OHSU IRB# 4317 Approved 1-2-97

Informed Consent

TITLE
"Rewarming after induced hypothermia with cardiac revascularization surgery in the diabetic versus the nondiabetic patient."

INVESTIGATORS
Vickie L. Gloeckner, RN, BSN, CCRN, OHSU Graduate Student (503) 494-1289
Carol J. Morones, RN, BSN, CDE, OHSU Graduate Student (503) 494-1289
Roberta S. Erickson, PhD, RN, OHSU Faculty (503) 494-3726

PURPOSE
You are invited to participate in a research study because you are scheduled to have open heart surgery. The study is being conducted by investigators from Oregon Health Sciences University and patients at the study hospital are being asked to participate.

During open heart surgery your body temperature will be cooled a few degrees to help make the surgical procedure easier and faster to do. The purpose of this study is to compare the time required to rewarm the body to its normal temperature after surgery is completed in people who have diabetes and people who do not have diabetes. It is also a purpose of this study to observe and report other physiologic observations such as shivering, heart rate, and blood pressure during the rewarming process. Diabetics often develop a complication known as neuropathy which can affect the ability of blood vessels to properly dilate or constrict in response to temperature changes. We believe this may cause the diabetic patient to rewarm more slowly. A delay in rewarming can place additional stress on body systems at a time when a patient is already experiencing the stress of recovery from a major operation.

PROCEDURES
The study involves an interview before your surgery that lasts 15-20 minutes and observation of your monitoring devices and hospital chart in the cardiac recovery unit for 4-6 hours after you return from surgery. In the interview, we will ask you a few questions about your medical history and sleep habits. During surgery a nurse in the operating room will write down information about your body temperature for the study. After surgery we will collect information from your chart about your body temperature, blood pressure, heart functions, breathing, and medications from your chart and the routine monitoring devices used in your care. All of this information will be evaluated to see if patients who have diabetes and are undergoing open heart surgery take longer to rewarm after surgery than do patients who do not have diabetes.

RISKS AND DISCOMFORTS

The study includes a short interview and observation. The interview may involve some inconvenience. No physical risks or discomforts are anticipated from participating in this study.

BENEFITS

You will not personally benefit from participating in this study. However, by serving as a subject, you may contribute new information which may benefit diabetic patients in the future.

ALTERNATIVES

The alternative is to not participate in this study.

CONFIDENTIALITY

Information you provide to the investigators will be kept strictly confidential, Neither your name not your identity will be used for publication or publicity purposes. Study records will be identified only by a code number. We will keep the coded data indefinitely and may use it in future related research. The study hospital review board will also have access to the coded study information.

COSTS

There is no cost or compensation to you for participating in this study.

LIABILITY

The Oregon Health Sciences University, as a public institution, is subject to the Oregon Tort Claims Act, and is self-insured for liability claims. If you suffer any injury from this research project, compensation would be available to you only if you establish that the injury occurred through the fault of the University, its officers, or employees. If you have further questions, please call the Medical Services Director at (503) 494-8014.

Should you suffer any injury as a result in taking part in this research activity, all of the necessary medical facilities are available for treatment, insofar as is reasonably possible. The study hospital is not the sponsoring agency of this project and will not assume financial responsibility for such treatment, or provide financial compensation for such injury.

You do not waive any legal rights by agreeing to participate in this study and signing this consent form.

PARTICIPATION

Vickie Gloeckner or Carol Morones, (503) 494-1289, have offered to answer any questions you may have about this study. If you have any questions about your rights as a research subject, you may contact the Oregon Health Sciences University Institutional

Review Board at (503) 494-7887 or the study hospital review board at (503) 216-6512. Your participation in this study is voluntary. You may refuse to participate or you may withdraw from this study at any time without affecting your relationship with, or treatment at, the study hospital. Your signature below indicates that you have read this form and agree to participate in this study. You will receive a copy of this consent form.

Subject	Date
Investigator	Date
Witness	Date

APPENDIX B

CHART REVIEW & SUBJECT INTERVIEW DATA SHEET

6TH FLOOR & CCU: CVOR has requested these sheets be placed in the front of the chart - thanks!

DATA SHEET

Intraoperative Data Sheet

Study ID _____ Date _____ # grafts _____

Thermal hat Y N OR data collector _____

Surgeon _____ Anesthesiologist _____ Perfusionist _____

Time into OR _____/OR ambient temp _____

Time surgery started _____

Time bypass started _____

Time rewarming started/PA temp _____/_____

Time rewarming ended/PA temp _____/_____

Time bypass ended _____

Time surgery ended _____

Time of last temp in OR/PA temp _____/_____

Time leaving OR _____/OR ambient temp _____

Warmed IV fluids N Y

Warmed blood products N Y (Cell Saver is assumed on all patients)

****

CVOR STAFF - You DO NOT need to collect the information which is in **bold** print or the back of this sheet. We can get that information from the various OR records.

THANKS!!

PLEASE DO NOT STAMP.
THIS STUDY USES ONLY
OUR ASSIGNED NUMBER.

Total OR time _____ Total surgical time _____ Afterdrop_____

Time out Time done Temp @ end rewarm

Time in Time started Lowest CRU Temp

Total bypass time _____ Total rewarming time _____

Time off Time done

Time on Time started

In OR: medications

_____

_____

_____

_____

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_____

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_____

APPENDIX D

POSTOPERATIVE DATA SHEET

Postoperative Data Sheet

Study ID _____ Date _____ Room Temp _____ Time of arrival in CRU _____ Covers _____ Thermal hat Y N

Time	PA Temp	Heart Rate	ABP S/D	PA S/D	CVP	Room Temp	Vent Temp	CO /CI	SVR	Rx	Rx	Rx	Rx	Rx	Rx	Shiver	Comments

PA = pulmonary artery
ABP = arterial blood pressure
S = systolic
D = diastolic
Vent = ventilator

CO = cardiac output
CI = cardiac index

SVR = systemic vascular resistance

PVR = pulmonary vascular resistance

Rx = medication drips
Tr = tridil

Np = nipride
Dp = dopamine

Db = dobutamine
Epi = epinepherine

MS = morphine
Dem = demerol

Prop = propofol
Shivering scale 0 - 4

0 = no palpable or visible vibration

1 = palpable mandibular vibration or EKG artifact

2 = visible fasciculations of head or neck

3 = visible fasciculations of pectorals and trunk

4 = generalized shaking of entire body

APPENDIX E

DATA COLLECTION PROTOCOL

Rewarming Study

DATA COLLECTION PROTOCOL

Vickie L. Gloeckner
Carol J. Morones

Identify Potential Subjects

1. Contact the Cardiovascular Recovery Unit (CRU) unit secretary after 1700 daily to obtain a list of patients scheduled to undergo revascularization surgery the following day. All patients are anticipated to have a pulmonary artery (PA) catheter placed at the beginning of surgery.

2. Review inpatient charts on the unit to which the patient has been admitted (Interventional Cardiovascular Recovery Unit, Coronary Care Unit, Cardiology floor) for eligibility as a participant in study. Inclusion factors:
   A. Age between 45 and 75 years.
   B. Either diabetic (experimental group) or nondiabetic (control group).
   C. No documented adrenal, pituitary, thyroid disorders; Raynaud's disease; or neuropathy not associated with diabetes.
   D. Body mass index between 20 and 34.9 kg/m^2.
   E. Less than 5 days of hospitalization.

Consent and Preoperative Interview

Obtain informed consent and collect background data. Record obtained data on the Chart Review and Subject Interview Data Sheet.

1. Introduce self to patient and explain the study something like:

   "Hello, (name). I'm (name), a registered nurse in graduate school at OHSU.My partner (name) and I are gathering information for a research study about rewarming after open heart surgery. I'd like to tell you about the study and ask if you would consider participating."

   "You're scheduled for open heart surgery tomorrow. During surgery you will be purposely cooled then rewarmed at the end of surgery. After surgery when you come to the cardiac recovery unit, you'll have a routine monitoring line in place that can measure your internal body temperature. We want to obtain information about your body temperature and other types of measurements that are routinely made by the regular nursing staff. We will only be looking at the first 4 - 6 hours of your recovery. The information we gather will not interfere with your care or make any changes your usual care. We will merely obtain information from the monitoring equipment in your room and from your chart."

   "In addition to the information we collect during your recovery, we would also like to ask you a few questions now about your medical history and sleeping habits that will help us analyze the information we gather. This will only take about 15-20

minutes. Would you be willing (or: would you be willing for your wife/husband) to be in this study and to talk with me briefly at this time?"

2. Obtain written consent: "I'd like you to read (or: I'd like to read) the study consent form.Then I'll ask you to sign two copies, one for you to keep and the other for the study records."After the patient (or representative) signs, investigator and a witness will sign the consent form.

3. Interview the patient for the following information:
   A. If diabetic:
      a. "When were you first diagnosed with diabetes?"
      b. "How is your diabetes being controlled?"
      c. "Do you know what neuropathy is?"
      d. "Do you know if you have any neuropathy from diabetes or for any other reason?"
   B. For all patients:
      a. Determine presence of neuropathy as from above.
      b. "Do you have any of the following":
         Diabetes
         Adrenal disorders
         Thyroid disorders
         Raynaud's disease
         Pituitary disorders
      c. "What time do you usually go to bed?"
      d. "What time do you usually get up?"
      e. Determine morningness/eveningness.

4. Assign a study ID number to each consenting subject and obtain the following information from their medical record:
   Date of admission, gender, age, ht/wt, admission vital signs, ethnicity, hemoglobin A_1C (diabetics).

Collection of Intraoperative Study Data

1. Identification of study subjects to the operating room (OR) personnel.
   Subjects chosen for inclusion in the study will be identified by placing a brightly colored intraoperative data collection sheet attached to the operative consent form.

2. The following information will be obtained during surgery by designated OR nurses and recorded on the Intraoperative Data Sheet.
   A. Surgeon, anesthesiologist, perfusionist, and RN data collector.
   B. Time into and out of OR.
   C. Length of surgery time, bypass time, and rewarming time.

D. The following temperatures and times:
   a. PA temp at start and end of bypass.
   b. PA temp at start and end of rewarming on bypass.
   c. Last PA temp in OR.
E. Presence or absence of thermal hats.

Collection of Postoperative Study Data

1. Check equipment and supplies.
   A. Forms:
      a. Data collection protocol
      b. Data collection sheet
      c. Consent form
   B. Ambient temperature thermometer
   C. Supplies:
      a. Pen
      b. Wrist watch
      c. Calculator

2. Attire

   Appropriate street attire with lab coat and OHSU name tag.

3. Record postoperative data on the Postoperative Data Sheet.
   A. Obtain the following information from the bedside monitoring equipment:
      a. In 15 minute increments: PA temperature, heart rate, arterial blood pressure (systolic & diastolic), PA pressures (systolic & diastolic),central venous pressure, ambient room temperature for the first hour.
      b. In hourly increments: ambient room temperature.
      c. As performed by the bedside nurse: cardiac output, cardiac index, and systemic vascular resistance.
   B. Palpate for a mandibular vibration every 15 minutes for 10 seconds (grade 0-4).
   C. The following information will be obtained by observations and from the medical record:
      a. Arrival time into CRU.
      b. Observed shivering (record time and grade 0-4 scale) and treatment if any (record time and dosage).
      c. Vasoactive drugs, analgesics, muscle relaxants or paralytic drugs (record time, dosage).
      d. Number of blankets on arrival and any additions or deletions throughout the study period.
      e. Presence of thermal hat on arrival and time of removal if applicable.
      f. Use of active warming devices.

g. Administration of blood products (record time, volume, specify type of product).
h. Blood glucose.

D. Review Anesthesia Record and record muscle relaxants, analgesics, and vasoactive drugs administered during OR on the back side of the Intraoperative Data Collection Sheet.