Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia versus General Anesthesia for Cardiac Surgery.

By

Susan Mertin

A Thesis Submitted to the Faculty of Graduate Studies in Partial Fulfillment of the Requirements for the Degree of

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DEDICATION

This thesis is dedicated to the memory of my parents, Albert and Erna Steinwandt who both succumbed to heart disease before its completion. They inspired me to strive for success.

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I would like to gratefully acknowledge the individuals and the agency that assisted and supported me throughout this research process.

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ABSTRACT

Heart disease, including coronary artery disease and valvular heart disease, is a major cause of morbidity and mortality. While cardiac surgery is a viable treatment option, it is a potent physiological stressor. The surgical stress response (SSR) may result in patient decompensation and negative patient outcomes. The limited use of a novel anesthetic approach, which combines high spinal anesthesia with intrathecal morphine and general anesthesia (TSA), has been used to attenuate the SSR. Prior to this study, there had been no published evidence-based outcome evaluation of TSA.

The primary purpose of this retrospective, descriptive, correlational pilot study (N=70) was to describe and explore the cardiac surgery outcomes of TSA and to compare the outcomes with the "standard general anesthetic" (GA) technique. Although there were no statistically significant differences in complication rates between the two groups, TSA patients were more likely to be extubated in the operating room ($p<0.0001$); the TSA group also had significantly shorter overall duration of endotrachel intubation ($p<0.0008$). During the initial 24 hours after surgery, the TSA group received significantly less morphine ($p<0.0001$). The mean difference in postoperative hospital length of stay was clinically significant, with the TSA group being discharged 3 days earlier than the GA group.

The knowledge gained from these findings will enable the multi-disciplinary critical care team to anticipate TSA patient outcomes and to facilitate the development of appropriate and effective evidence-based, patient focused plans of care. This pilot study also establishes sound rationale for subsequent prospective cohort research of the TSA patient population.

Chapter 1: Introduction

Stress is a normal component of our daily lives. The majority of minor stressors are easily managed by our physiological stress response. In contrast, cardiac surgery is a potent physiological stress stimulus. The surgical stress response has the potential for systemic adverse effects. When the stressor is extreme and prolonged in relation to the resistance and strength of the patient, the physiological changes that occur in response to the stressor may prove to be maladaptive, eroding body mass and physiological reserve and leading to decompensation (Kehlet, 1987, 1989; Mitchell, Gallucci, & Fought, 1991; Weissman, 1990). It is probable that these negative systemic effects contribute to negative patient outcomes (Kehlet, 1991).

Striving to reduce the surgical stress response and to improve patient outcomes, clinicians have utilized various adjuncts to General Anesthesia (GA). Although previous research has provided a foundation of knowledge related to reducing the surgical stress response, limited nursing research studies have examined the effect of surgical stress reduction on patient outcomes.

Statement of the Problem

Heart disease, including coronary artery disease (CAD) and valvular heart disease is a major cause of morbidity and mortality in Canada. CAD is ranked as leading cause of mortality and hospitalization in Canada. The Heart and Stroke Foundation of Canada (2003) reported that in 2001, CAD was the leading cause of death among men aged 50 to 85+ and for women aged 70 to 85+. One in three deaths is the result of underlying cardiovascular disease (CVD). Hospitalization for CVD costs over 4 billion dollars annually. Since hospitalization rates increase with age, and the percentage of the

Canadian population over 65 years of age is increasing, hospital costs for CVD treatment are projected to increase in the future (Heart and Stroke Foundation of Canada, 2003). Thus, the ongoing challenge for Canada's health care system is to optimize patient outcomes, to provide the best quality of service possible, and to be cost efficient.

While cardiac surgery remains one of the treatment options for heart disease, it is not without risk of complications and adverse outcomes. Cardiac surgery is a potent physiological stressor that stimulates an exaggerated stress response (Hoar et al., 1980). This surgical stress response has been associated with negative patient outcomes (Mangano et al., 1992). With the goals of attenuating the surgical stress response, reducing morbidity, and improving patient outcomes, one Trevor W.R. Lee, MD, FRCPC, a cardiac anesthesiologist at Saint Boniface General Hospital (SBGH), initiated the use of a novel approach which combines total spinal anesthesia with intrathecal (IT) morphine and GA , hereafter referred to as TSA. The desired effects of TSA are to gain the benefits of attenuating the surgical stress response, while minimizing the risks of potential complications related to the anesthetic administration. To date, there has been no specific evidence-based evaluation of patient outcomes for this unique anesthesia method. The lack of research evidence related to postoperative outcomes may hinder the health care team's ability to anticipate the care needs of cardiac surgery patients and to provide optimal care. This, in turn, also impacts on the nursing resource requirements and allocation of nursing staff (Miller, Grindel, & Patsdaughter, 1998).

The primary purpose of this pilot study was to describe and explore the cardiac surgery outcomes of TSA and to compare these outcomes with the "standard cardiac anesthetic" (GA) technique. Previous anesthesia research supports the hypothesis that high spinal anesthesia, which is similar to TSA, blunts this response (Kowalewski, MacAdams, Eagle, Archer, & Bharadwaj, 1994; Lee, Grocott, Schwinn, & Jacobsohn, 2002). Building upon this previous research, the primary research hypothesis for this study was that attenuation of the surgical stress response via TSA for cardiac surgery improves patient outcomes.

The overall objective of this study was to complete an evidence-based TSA outcome evaluation that will enhance the ability of nurses to anticipate patient outcomes and to plan appropriate, effective, research-based, and patient focused nursing care. It is anticipated that this research will contribute to the collaborative goal of the perioperative team to optimize outcomes for cardiac surgery patients.

Background

Surgical Stress Response

The normal physiological response to stress occurs as a protective and adaptive mechanism that is designed to maintain homeostasis within the body (McEwan & Mendelson, 1993). Hans Selye (1946) pioneered the description and analysis of biological stress and was the first to describe the general adaptation system (GAS). He described the first two phases of the adaptation system as that of alarm and resistance. These two phases of the stress response are protective and adaptive; however, the third phase of the GAS is exhaustion, and results in pathophysiological responses toward decompensation (Mitchell et al., 1991; Selye, 1974).

Cardiac surgery is a potent physiological stressor, which initiates the release of a cascade of catecholamines and other stress hormones (Hoar, Stone, Faltas, Benedixen, Head, & Berkowitz, 1980; Lee et al., 2003). This surgical stress response has the potential to cause systemic adverse effects in the perioperative period, including: cardiac ischemia and hemodynamic instability (Lee et al., 2003; Liem, Booij, Hasenbos, & Gielen, 1992 a; Mangano, Siliciano, Hollenberg, Leung, Browner, Goehner, et al., 1992), pulmonary decompensation (Aun, St-John-Jones, Colvin, Savege, & Lewis,1985; Kehlet, 1993; Liu, Carpenter, & Neal, 1995), and increased catabolism (Kehlet, 1996; 91; Oppenheim, Williamson, & Smith, 1980). Other consequences of the surgical stress response include: impaired immune responses (Bach, Grundmann, Bauer, Buchinger, Soltsesz, Graeter, et al., 2002; Lin, Calvano, & Lowry, 2000; Page & Ben-Eliyahu,1997; Salo, 1992), paralytic ileus (Liu et al.,1996; Riddington et al., 1996; Wattwil, 1988), hypercoagulability syndromes (Liu et al., 1995; Rosenfeld, Beattie, Christopherson, Norris, Frank, Breslow, et al., 1993; Rosenfield, Faraday, Campbell, Dise, Bell, & Goldschmidt, 94), and pain (Kehlet, 1989; 96; Kilickan & Toker, 2001; Mangano et al, 1992).

Attenuation of Surgical Stress Response

The ongoing quest for a superior cardiac anesthetic technique has led to the use of various adjuncts to GA. These adjuncts have included the use of perioperative, high-dose, intravenous opioids (Liem, Booij, Gielen, Hasenbos, & Gilien, 1992b; Mangano et al., 1992), epidural anesthesia (Liem, Williams, Hensens, & Singh, 1998; Loick et al., 1999), and high-dose IT morphine (Aun, et al., 1985; Boulanger, Perreault, Choiniere, Prieto, Lavoie & Laflamme, 2002; Chaney, Furry, Fluder, & Slogoff, 1997; Vanstrum, Bjornson, & Ilko, 1988). All of the adjuncts to GA include the use of opioids for the management of pain. It follows that in order to critically review the literature related to anesthesia adjuncts, it is necessary to first comprehend the basic physiology of pain and the pharmacokinetics of opioids for pain management.

The neuroanatomy responsible for the sensation and perception of pain includes the afferent pathways, the central nervous system, and the efferent pathways. The afferent system is composed of pain receptors (nociceptors) located in the tissues. Afferent pathways end in the dorsal horn of the spinal cord (Huether & Leo, 2002). Opiate receptors are generally located in the brain stem, spinal cord, and gastrointestinal tract. The three major opioid receptor types include Mu, delta, and kappa receptors. At the presynaptic level on afferent pathways, opioid receptor activation closes ionic channels and inhibits the release of neurotransmitters including: anticholinesterase, norepinephrine, 5-HT, glutamate, and substance P (Trevor, Katzung, & Masters, 1998).

Opioid analgesics, such as morphine, exert their effects by acting as agonists at the opioid receptors located on both the primary afferent neurons and spinal cord pain transmission neurons (ascending pathways) and on the neurons in the midbrain and medulla (descending pathways), that function in pain modulation. Descending control of nociception, which may be involved in altering the reactivity to pain, is located in the cerebral cortex, limbic structures, hypothalamus, and basal ganglia. The Kappa receptor activation plays a role in spinal analgesia, which is the proposed mechanism for intravenous narcotics to attenuate the surgical stress response. Given intravenously, opioids are rapidly distributed and produce depressive effects on respiration, sensorium, and pain perception (Sullivan, 1995; Trevor, Katzung, & Masters, 1998).

Effects of opioids include the central effects of sedation and euphoria. Activation of mu and delta receptors contributes to both spinal and supraspinal level analgesia and to respiratory depression. Respiratory depression occurs as a result of opioid actions in the medulla, which leads to inhibition of the respiratory center and decreased response to carbon dioxide stimulus (Trevor et al., 1998). The administration of high dose opioids and the associated prolonged endotracheal intubation times, while once the norm, are no longer the standard of care (Chaney et al., 1997; Lee & Jacobsohn, 2000). High dose intravenous (IV) opioids are, however, not capable of completely attenuating the stress response to cardiopulmonary bypass (CPB) (Liem, et al., 1992b).

The ideal perioperative anesthetic and analgesic interventions should focus on prevention of the surgical stress response rather than on measures to control its adverse sequelae (Lubenow, Ivankowich, & McCarthy, 2001). Thoracic epidural anesthesia has been shown to reduce the stress hormone response to cardiac surgery. Epidural anesthesia refers to the injection of drugs into the epidural space, which lies between the ligamentum flavum and the dura mater. These drugs can include both opioids and local anesthetic agents. It is believed that local anesthetics and opioids act synergistically. Synergistic activity of these drugs permits therapeutic effects at reduced concentrations and dosages, which consequentially also serves to reduce potential side effects (Grichnik & Ginsberg, 2002). Drugs administered into the epidural space must pass through the myelin sheaths covering the nerve roots. The dura mater acts as a barrier to epidural drugs moving into the cerebrospinal fluid (CSF) (Sullivan, 1995). After epidural administration of an opioid, a small portion crosses the dura to enter the CSF and then penetrates spinal tissues. The remainder of the dose is systemically absorbed, adding to the analgesic effect as the drug is distributed to the central nervous system (Turner, Sibert, & Sinatra, 1992). Local anesthetic in the epidural space works to block sodium channels and the conduction of action potentials. This produces a slow onset, lower intensity inhibition of the sympathetic pathway (Trevor et al., 1998). However, in cardiac surgery, which requires anticoagulation for CPB, epidural anesthesia utilization has been questioned because the traumatic insertion of the larger epidural needle can increase the risk of neuraxial hematoma (Lee, et al., 2003; Rosen, Hawkinberry, Rosen, Gustaffson, Hogg, & Broadman, 2004; Scott et al., 2001; Vandermeulen, Van Aken, & Vermylen, 1994).This complication was first reported by Rosen et al. (2004).

In spinal anesthesia, the needle passes through the epidural space and the dura mater into the intrathecal (IT) space and CSF. Spinal anesthesia often combines the administration of both opioid (preservative free morphine) and local anesthetic agents. Because morphine is water soluble and highly ionized, it has a slow onset and a long duration of action in the IT space. The onset time of 30-60 minutes and a duration time of 18 to 24 hours make IT morphine a good analgesic choice for major surgeries (Gwirtz, 2002). IT local anesthetic is in direct contact with the nerve roots and produces a very rapid and intense blockade of sodium conducting ion channels and inhibition of impulse generation (Sullivan, 1995). Kowalewski et al. (1994) reported the use of spinal bupivicaine and morphine combined with GA for cardiac surgery and demonstrated that this technique could provide some of the benefits of thoracic epidural anesthesia (TEA), without a number of the potential risks. In a recent prospective, double blind, randomized controlled trial (N=38) of coronary artery bypass graft (CABG) surgery patients, Lee and associates (2003), compared the use of high-dose IT bupivicaine spinal anesthesia in combination with GA to GA alone.

In the experimental group, they reported decreased β-receptor dysfunction, as measured by maximal isproteronol, 50% isproterenol, sodium fluoride-stimulated activity, and zinterol stimulation assays of adenyl cyclase activity and β-adrenergic receptor density, and a lower stress hormone response, as measured by serum epinephrine, norepinephrine, and cortisol.

One cardiac anesthesiologist, Trevor W.R. Lee, MD, FRCPC, at SBGH in Winnipeg, Manitoba has modified this technique to combine total spinal anesthesia with IT morphine and GA (TSA: see Definition of Terms) for cardiac surgery patients. Based on the results of two previously published studies (Lee et al., 2003; Jacobsohn et al., 2005), the benefits of TSA are postulated to include the attenuation of the surgical stress response and prolonged analgesia. While the results are favorable anecdotally, there has been no formal evaluation of this combined technique.

In summary, the surgical stress response has been implicated in negative patient outcomes. In the ongoing quest for a superior cardiac anesthetic, the utilization of numerous anesthetic adjuncts has lead to the development of TSA. No research to date has explored the postoperative patient outcomes or the nursing care implications of the novel TSA technique.

Purpose of the Study

The primary purpose of this retrospective pilot study was to describe and explore the cardiac surgery outcomes of TSA and to compare the outcomes with "standard cardiac anesthetics" (GA). The primary research hypothesis was that TSA improves patient outcomes. The overall objective of this study was to establish evidence- based knowledge to enhance the ability of nurses to anticipate patient outcomes and to plan appropriate and effective research-based, patient focused, nursing care. It is anticipated that this research-based evidence will contribute to the overall goal of the perioperative team to maximize outcomes for cardiac surgery patients.

Significance of the Study

With the primary goals of optimizing patient outcomes and providing excellence in service and cost-efficiency, the development and utilization of anesthetic techniques that impact favorably on the perioperative course of cardiac surgery patients' recovery is paramount. In this time of increased demand for healthcare and the limited availability of resources, anesthetic techniques that optimize outcomes and increase efficiency are of interest to clinicians and researchers alike. The current dearth of TSA outcome research makes the anticipation of patient care resources difficult. Nursing managers who are responsible for allocation of patient resources such as healthcare personnel and critical care beds would also benefit from this outcome evidence (Miller et al., 1998).

The nursing specialty of critical care has become increasingly science-based. The scope of critical care nursing practice enables nurses to provide nursing care to the extent of their education, training, skills, knowledge, experience, competence, and judgment. Nurses in expanded roles, such as the acute care nurse practitioner, strive to assess health risk factors, stabilize the patient, provide physical and psychological support, minimize complications, and facilitate restoration of health potential (Morse & Brown, 1999). Because the number of cardiac surgeries done with TSA is still small, nurses are unable to utilize previous clinical experience to guide the development of care plans for this population. The ability to anticipate the outcomes after TSA will enable nurses and physicians to work collaboratively to design appropriate and effective evidence-based clinical patient care plans, thus optimizing the TSA benefits for patients. It is also possible, that by maximizing the TSA benefits for cardiac surgery patients, the positive outcomes will translate into decreased use of hospital resources, such as intensive care unit (ICU) bed hours and overall hospital length of stays (LOS). As a pilot study, this project will establish the foundation for subsequent research in this area.

Assumptions

The primary assumptions of this descriptive, correlational study were that the surgical stress response negatively affects patient outcomes; that TSA effectively attenuates the surgical stress response by way of the ability of local anesthetic to achieve cardiac sympathectomy, and that combined with the benefits of IT morphine; TSA provides superior pain control than GA alone. The primary research hypothesis was that the utilization of TSA and the subsequent attenuation of the surgical stress response improves cardiac surgery patient outcomes.

Summary

Heart disease places a large burden on Canada's population, as well as its health care system. The challenges for administrators, clinicians, and researchers are to optimize patient outcomes and to provide the best quality of service possible, in a cost effective manner. To meet these challenges, the entire healthcare team must strive to collaborate in their efforts. Despite associated risks, cardiac surgery remains a viable treatment option for many patients with CVD. Current research has demonstrated that although the normal physiological response to stress occurs as a protective and adaptive mechanism, the surgical stress response to cardiac surgery has the potential to result in systemic adverse effects in the perioperative period, as well as overall negative patient outcomes. The search for innovative cardiac anesthetic techniques that can attenuate the surgical stress response, reduce morbidity, and improve patient outcomes has led to the development of TSA. To capacitate the optimal perioperative care of TSA patients, it is important for nurses to be actively involved in TSA outcome research. Accordingly, this research study was designed to explore the cardiac surgery outcomes of TSA and to compare the outcomes with the GA technique.

Definition of Terms

Analgesia can be described as the relief or absence of pain in response to stimulation, which would normally be painful (Retrieved April 11, 2006 http://shsskip.swan.ac.uk/Information/Pain%20Terms.htm).

Anesthesia is the loss of body sensation with or without consciousness to enable safe, painless surgical procedures (Sullivan, 1995).

Efficacy describes the ability of a technique to do more good than harm to those who are treated appropriately (Halpin, Barnett, & Beachy, 2003).

Efficiency describes the cost benefit in terms of measurable outcomes such as intubation times, symptom management, and LOS (Tugwell, Bennett, Feeny, Guyatt, & Haynes, 1986).

Epidural Anesthesia and Analgesia consists of the use of a continuous infusion of various local anesthetics, often in combination with opioid medications, via a catheter that is placed in the epidural space. The goal is to titrate the amount of local anesthetic used according to the needs of the situation. For surgical anesthesia, a high concentration of local anesthetic is used to provide a sensory and motor nerve block, which enables the surgery to be performed painlessly. In epidural analgesia, a lower concentration of local anesthetic is used and titrated to optimize analgesia while maintaining motor function. The patient remains awake and continues to breathe spontaneously. Unconsciousness is not the goal of this anersthetic procedure. The insertion of the epidural catheter is commonly achieved with the use of a 16 or 18-gauge epidural needle (Retrieved Nov 1, 2004, http://www.nda.ox.ac.uk/wfsa/html/u13/u1311_02.htm).

General Anesthesia (GA) is the induction of a state of unconsciousness and absence of pain through the administration of anesthetic drugs. The goals of GA include: anesthesia and amnesia for the patient and a still surgical field for the surgeon (Sullivan, 1995)

Intrathecal Opioid Analgesia consists of injection of an opioid into the subarachnoid space in order to provide postsurgical analgesia. The procedure can be performed with a needle as small as a 25 or 27-gauge spinal needle (Gwirtz, 1992; Sullivan, 1995).

Spinal Anesthesia consists of the temporary interruption of nerve transmission within the subarachnoid space. Successful spinal anesthesia effectively blocks pain sensation and the ability to move the target area. This is achieved with the injection of local anesthetic solution into the CSF. Spinal anesthesia is titrated to achieve a regional sensory and motor block while maintaining consciousness and spontaneous ventilation. The procedure can be performed with a needle as small as a 25 or 27-gauge spinal needle (Sullivan, 1995)

Total Spinal Anesthesia (TSA) as described in this research consists of the use of high spinal anesthesia, achieving a sensory and motor nerve block up to at least the cervical nerve level with bupivicaine local anesthesia combined with IT morphine and GA.

Because this high level block interrupts the ability to maintain spontaneous ventilation, the technique is combined with GA. The procedure can be performed with a needle as small as a 25 or 27-gauge spinal needle (personal communication, Dr. T.W.R. Lee, September, 2003).

Chapter II: Theoretical Framework

The use of theory offers structure and organization to nursing knowledge. Nursing theory should provide a systematic means of data collection to describe, explain, and predict nursing practice. The link of nursing theory to practice enhances the articulation and determination of the focus of nursing care from which specific goals and outcomes can be measured (McEwan, 2002). Accordingly, the Human Response to Health and Illness Model (HRM: Mitchell, Gallucci, & Fought, 1991) is a biopsychosocial model that serves to clarify nursing's domain as the patient's response to the health problem or stressor and not to the stressor itself. The multidimensional approach of the HRM, including the physiologic, pathophysiologic, behavioral, and experiential perspectives, provides organizational structure to the nursing science.

This chapter describes the background theories related to this research. The discussion of the HRM will include the historical evolution and research-specific adaptation of the model.

Background Theories

Theories evolve over time. Therefore, it is necessary to examine the foundational tenets on which new theories are built. Because the theories of stress and adaptation are central to the HRM, these concepts will be clarified and discussed within the context of the HRM development.

Stress Theory

To understand the response to stress, the concept of stress must first be clarified. Generally regarded as the father of stress research, Hans Selye (1946) was the first to describe and analyze the stress response. Selye (1974) defined stress as "the nonspecific response of the body to any demand made upon it" (p 27). It was from Hans Selye's general adaptation syndrome (GAS) that the common *fight or flight* phrase was brought into household language to describe the initial reaction to a stressor, or stage one of the GAS. The second stage is that of resistance, during which the individual attempts to cope with, or overcome the stressor. The third stage is the stage of exhaustion, during which the individual is overcome by the stressor and experiences negative outcomes (Selye, 1974). It is logical that once the stress response is understood, the next step of inquiry is focused on how to overcome or adapt to stress.

Adaptation Theory

Adaptation can be defined as the ability of the individual to physically and psychologically overcome the stressor and maintain homeostasis (McEwen & Mendelson, 1993). The inability or failure of efforts to adapt, (i.e. stage three/ exhaustion of GAS) results in illness and/or prolonged recovery. While Selye focuses on the physical response to stress, Lazarus' theory focuses on the person's psychological response and coping through appraisal and reappraisals of the threat or stressor. Lazarus defines coping as the process by which a person manages the appraisal. Adaptation is the result of successful coping (Lazarus& Folkman, 1984).

Adaptation theory serves as a foundation for the multidimensional HRM. Although it appears logical that Heitkemper and Shaver (1989) incorporated facets of previous adaptation theorists such as Sister Callista Roy; direct reference to these theorists are not included in their publications. However, Heitkemper and Shaver (1989) do discuss the components of their model such as, environment and person, under a heading of individual adaptations.

In summary, the application of stress and adaptation theories to nursing can provide a framework to assess the effects of physical and psychological stress on the individual, as well as the individual coping processes. It is important for nurses to consider the resources and support that the person has in coping with the stressor (Kuhns, 2002).

Specific to this project, the stress stimulus is the surgical procedure and the response to the surgical procedure is the surgical stress response. This research essentially evaluates the impact on the outcomes of the surgical stress response with the use of a clinical therapeutic intervention, namely TSA. Decreasing or attenuating the surgical stress response may decrease the severity and duration of the stressor and facilitate adaptation, thus preventing the progression to the stage three, exhaustion phase.

The Human Response to Health and Illness Model

Historical Evolution

Initially conceptualized by Shaver (1985) and further developed by Heitkemper and Shaver (1989), both of whom are associate professors of physiological nursing, University of Washington, the HRM was originally proposed to develop knowledge in the area of enteral nutrition (Heitkemper & Shaver, 1989). This early linear model visually defines the interactions between model components (see Figure 1). The three main concepts that are used to describe human function include: individual adaptations, environmental factors, and person factors.

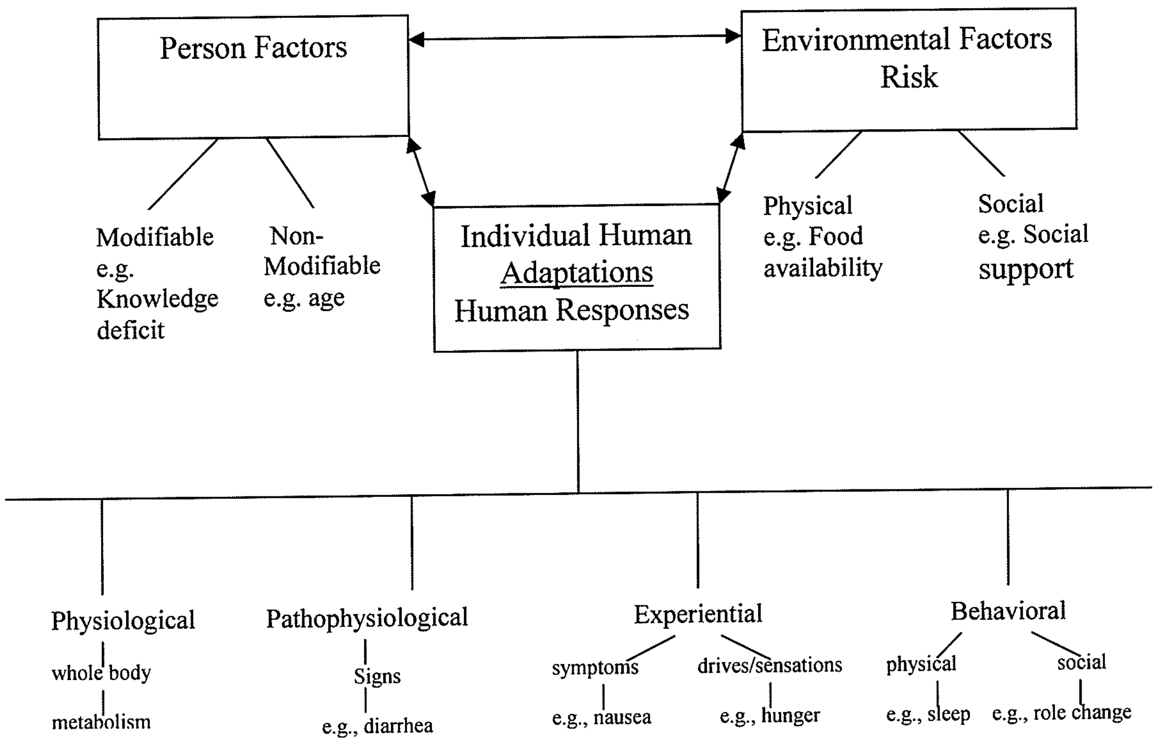

Figure 1. Framework for Human Response to Enteral Nutrition Therapy, 1989

From "Nursing Research Opportunities in Enteral Nutrition" by M.M. Heitkemper & J.F. Shaver, 1989, *Nursing Clinics of North America, 24,* p. 416.

Individual adaptations are divided into physiological and pathophysiological responses. Physiological responses are based on research evidence that describes normal function in healthy subjects or volunteers. Pathophysiological responses encourage the examination of studies conducted to determine the incidence or prevalence of pathophysiological responses to the clinical therapeutic therapy (e.g.enteral feeding) in clinical populations. Experiential responses encourage the exploration of experiential dimensions that are described as thoughts, emotions, sensations, or drives experienced by patients receiving the clinical therapeutic therapy. The behavioral perspective consists of measurable physical responses, (e.g. pain), that are communicated to the social environment.

The goal of the research utilizing the HRM is to provide information aimed at predicting which patients are most likely to develop problems. This goal leads to the need to study patients in relation to their environmental risk factors, as well as their person vulnerability factors. Environmental risk factors are identified as not being adequately researched and include factors such as the disruptive effects of noise on the ability to sleep. Person vulnerability factors are divided into non-modifiable factors, such as age, and modifiable factors, such as nutritional status, metabolism, anxiety, and tension.

Clinical nursing therapeutics often involves actions that promote normal physiological responses, alleviate pathophysiological responses, and promote adaptive behaviors. Heitkemper and Shaver (1989) utilized the initial HRM to guide research opportunities in enteral nutrition. For example, nursing therapeutics can be designed to manipulate environmental physical factors. An example of external environment manipulation is the timing of an intervention. Manipulation of environmental social factors may include studies of structuring the social environment, such as more family involvement. Alteration of person factors could include research related to how patient teaching can improve knowledge, influence compliance, and reduce psychological distress. Thus, this adaptation model provides directional guidance to the exploration of the effects of an illness or stressor.

In a separate schematic, Heitkemper & Shaver (1989) depicted the relationship between clinical nursing therapeutics and the human responses to enteral feeding (see Figure 2). Although separating the model into more basic depictions may have served to facilitate the understanding of the parts, the interrelationship of the concepts was not fully described.

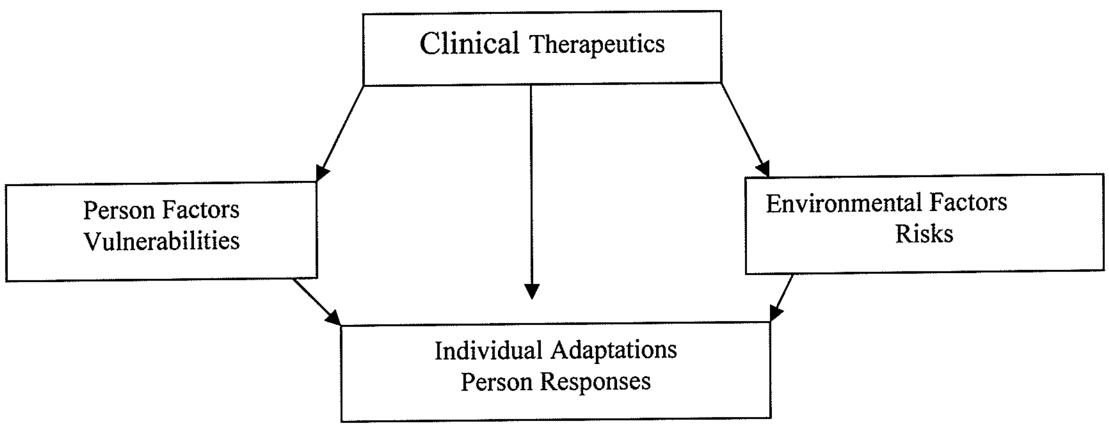

Figure 2. Clinical Nursing Therapeutics for Responses to Enteral Feeding Therapy, 1989

From "Nursing Research Opportunities in Enteral Nutrition" by M.M. Heitkemper & J.F. Shaver, 1989, *Nursing Clinics of North America, 24,* p. 417.

Mitchell, Gallucci, and Fought (1991) further developed the HRM by describing the four perspectives of the human responses, analyzing the value of the multiple perspectives for the study of nursing phenomena, and discussing the links among the perspectives. It is from this work that the circular depiction of the HRM was conceptualized (see Figure 3).

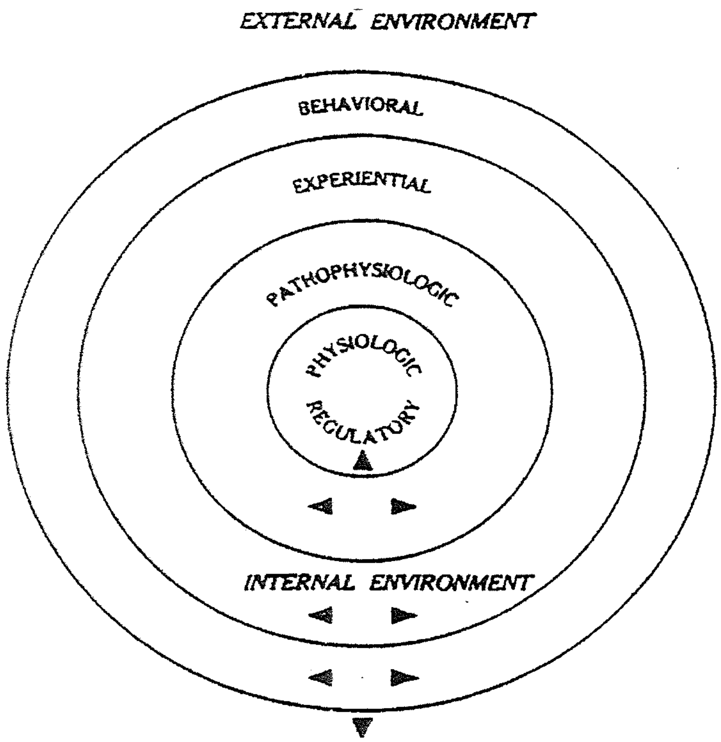

Figure 3. The Human Response to Health and Illness Model (1991).
From "Perspectives on Human Response to Health and Illness", by P.H. Mitchell, B. Gallucci, & S.G. Fought, *Nursing Outlook, 39, (4)*, p. 155.

The circular HRM depicts the relationships of the four perspectives on human responses to the internal and external environment. The arrows indicate the directions in which information can be communicated from all other perspectives. For example, the behavioral responses allow for communication of responses to the external environment. An important summary point made in their paper was that: "Learners begin to identify not only the usual responses to illness in the patient population with whom they practice, but also begin to predict, and therefore, act to decrease, prevent, or diminish, the full range of responses" (Mitchell, Gallucci, & Fought, 1991. p. 157).

Although it would appear that the HRM is an appropriate theoretical framework for research, few published studies have utilized this model. Heitkemper, Levy, Jarrett, and Bond (1995) used the HRM to provide a framework for reviewing the research literature on irritable bowel syndrome. Deane (1997) utilized the HRM as a basis for providing emotional support and information to patients who experience anxiety associated with pending breast biopsy procedures

While the circular depiction of the HRM adds insight by encouraging thought in multiple directions, the earlier, more linear and directional HRM, as depicted by Heitkemper and Shaver (1989) was chosen as the foundation for a conceptual framework for this research.

Adaptation of the Human Response to Health and Illness Model

The original HRM (Heitkemper & Shaver, 1989) was adapted for this research (see Figure 4). In the revised model, the arrows from the person and environmental factors to the clinical therapeutics are bidirectional. This was changed to reflect the fact that individual patient characteristics can impact the choice of clinical therapeutics. An example of this would be a person with severe anxiety who would not consent to a TSA.

The unidirectional arrows that connect the clinical therapeutics / TSA to environmental factors were also changed to bidirectional in the revised model to reflect the fact that there is currently only one anesthesiologist who performs TSA, as described in this study. The availability of this human resource was viewed as an environmental factor. Clinical therapeutics/TSA has a unidirectional arrow to the surgical stress response which, in turn, is also affected by person factors, such as age and environmental factors, such as lights. Person and environmental factors have unidirectional connecting arrows to individual adaptations and human responses; however, the surgical stress response has bidirectional connecting arrows, demonstrating the interdependent relationship.

The ability of the patient to adapt to this stress response depends on the severity and duration of the surgical stress response, their pre-existing person factors including, their physiological reserve and their psychosocial ability to cope. The bidirectional lines demonstrate the likelihood that the level of successful adaptation affects the physiological, pathophysiological, experiential, and the behavioral consequences of the surgical stress response. These manifestations of the surgical stress response may further deplete the ability to adapt to the prolonged stressor, eventually resulting in exhaustion.

The Revised Human Response to Health and Illness Model

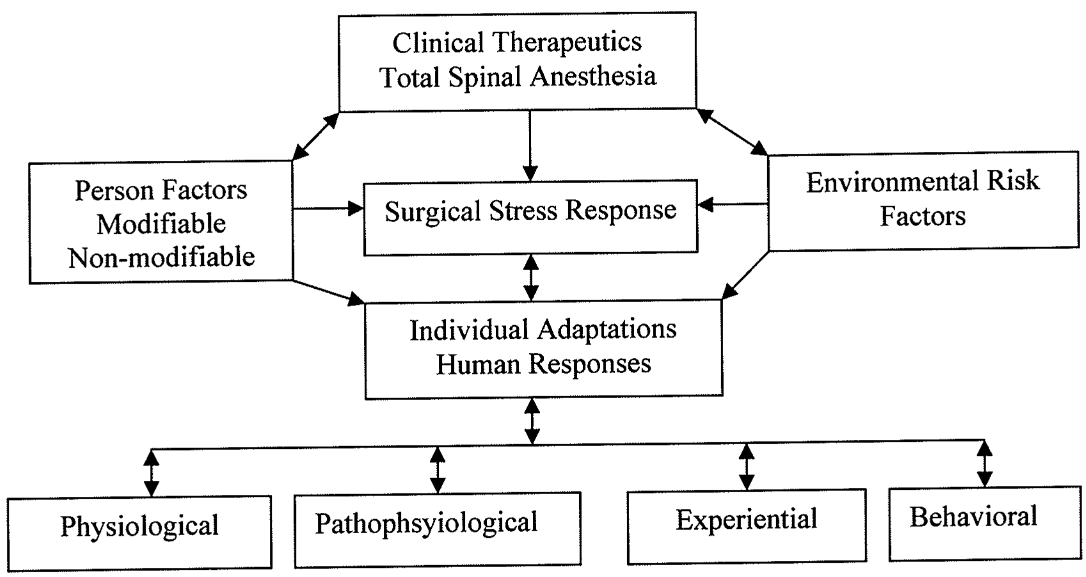

Figure 4. The Revised Human Response to Health and Illness

Adapted From "Nursing Research Opportunities in Enteral Nutrition" by M.M. Heitkemper & J.F. Shaver, 1989, *Nursing Clinics of North America, 24,* p. 416-417.

In summary, the original HRM was modified and utilized to guide this research. The revised model provided a framework in the planning, implementation, and evaluation of this research study.

Application of the Revised Human Response to Health and Illness Model

The multidimensional approach of the HRM, which includes physiologic, pathophysiological, behavioral, and experiential adaptive outcomes, provides organizational structure to nursing science (Mitchell et al., 1991).The description of the physiologic and pathophysiological responses establishes the background to the concepts to be studied. Physiologic responses describe the normative or biological functioning that occurs in response to a stressor or event. The goal of the physiologic response is to maintain the normative regulation of the body. Physiologic responses describe the effective regulatory efforts of the patient toward maintaining homeostasis (Mitchell et al., 1991).

Pathophysiological responses result from disordered or undesirable efforts of the individual to maintain homeostasis. Pathophysiological responses are those which move the patient toward decompensation and illness. Homeostasis is not achieved. The problem or target response for nursing interventions becomes apparent (Mitchell et al., 1991).

Assessment of the problem encompasses the behavioral and experiential perspectives, as well as the person and environment factors. The behavioral component of the HRM represents the observable and measurable components of assessment that can be used to identify, evaluate, and diagnose the specific response. Behavioral responses do not necessarily require the active involvement of the patient (Mitchell et al., 1991). In this study, the behavioral perspective provided guidelines for measurable outcome evaluation.

Experiential responses are unique to the patient's lived experience and are determined through self-report. Past experience, knowledge, and coping mechanisms will impact the perceived experience of the patient. Validation of the "lived experience" of the patient, which can only be achieved through verbalization of the experience, encompasses the concepts of introspection, personal experience and shared meaning (Mitchell et al., 1991). As this was a pilot project, with a restrospective design, the experiential perspective was not included in this research.

Person factors are normally included within the basic patient history. Therefore, person factors were gathered in the chart as part of the patient history and physical examination prior to cardiac surgery. Non-modifiable person factors included basic demographic data such as gender, age, and ethnicity. Smoking is an example of a modifiable person factor (Mitchell et al., 1991).

Environmental factors such as working in a coal mine or living with a smoker can have a profound effect on health. Other examples of environmental factors include the availability and accessibility of healthcare, which have a major role on health promotion and illness prevention. The accessibility and availability of the human resources of the one anesthesiologist who provides TSA for cardiac surgery can be considered an environmental factor. Specific to the hospital, the noise and lights of the intensive care unit affect the patient's level of anxiety and ability to rest and sleep (Mitchell et al., 1991).

Thus, the four perspectives of the HRM can be used to provide structure for research and guide practice. These perspectives are interrelated and thus cannot be viewed in isolation. The HRM encourages the analysis of multiple interacting facets of inquiry and understanding.

Mitchell et al. (1991) clearly outline the aims of the science of human responses to:

1. explain and understand the range of responses of individual humans to states of illness and to the demands of healthy living from at least four perspectives: physiologic, pathologic, experiential and behavioral;
2. understand the interrelationships of those responses with the social, cultural, and environmental context in which they occur;
3. predict the potential for change in health status when nursing therapies are applied to specific human responses;
4. measure the effectiveness of nursing therapies in promoting health responses, and preventing, modifying, or eliminating health-damaging human responses (p.156).

Summary

It is clear that the global nursing concepts of health, environment, and person are encompassed by the HRM and appear to be congruent with the philosophical bases of nursing models. Hence, the HRM was found to be applicable to the purposes of this pilot study. Person factors that may be predictive of outcomes were examined. The physiological, pathophysiological, and behavioral perspectives were explored. Subsequent research should consider incorporating the 'experiential' component of the model by integrating the 'lived experience' of patients, as well as exploring the environmental influence on patient outcomes.

Chapter III: Review of Related Literature

The revised HRM served to guide the literature review and to clarify the concepts that were studied. The goal of using a conceptual model is to provide guidance for nursing interventions. To this end, it was critical to have a basic understanding of the physiology and pathophysiology of the human response. The literature review, focusing on the physiology of stress and the pathophysiology of the surgical stress response, served to provide a foundation for the outcomes assessment. Anesthesia research is presented to provide the rationale for the development of TSA and the goals of its implementation. No previously published standard behavioral measurement data collection tools have been validated for use in similar cardiac research. The literature that supports and describes the process of the operationalization of the variables is presented.

Individual Adaptations/ Human Response

According to Mitchell et al. (1994), physiologic regulatory responses are based on the concept of normative or usual biologic function. Hans Selye (1974) pioneered the description and analysis of biological stress and the general adaptation syndrome (GAS). He described the first two phases of adaptation system as alarm and resistance.

The physiologic response to a stressor occurs as a protective and adaptive mechanism with the goal to maintain the homeostatic balance of the body (McEwen & Mendelson, 1993). Modern research has revealed that the stress response is very complex and has the potential to affect every bodily function. The efferent reflexes to surgical stress include the responses of the autonomic nervous system, the hormonal releases, the local tissue reactions, and vascular endothelial and single cell responses. The intensity and duration of surgical stress response is dependent on the severity and duration of the stimulus or stressor (Callahan, 1994). The responses to stress can be divided into responses of the sympathetic nervous system (SNS), the sympathetic-adrenal-medullary, the hypothalamic-pituitary, and the immune and inflammatory regulatory systems (Smelzer & Bare, 2004).

Sympathetic Nervous System Response

The SNS stress response is the body's immediate response to prepare for fight or flight. The purpose of the rapid and brief release of norepinephrine at nerve endings is to better perfuse vital organs, including the brain, heart, and skeletal muscles. Norepinephrine increases heart rate and causes peripheral vasoconstriction, which results in an increase in blood pressure (Smelzer & Bare, 2004).

Sympathetic-Adrenal-Medullary Response

The sympathetic-adrenal-medullary response is the second step of the stress response. The SNS stimulates the medulla of the adrenal glands to release catecholamines (i.e. epinephrine and norepinephrine), which produce a more prolonged response. The effect of the sympathetic-adrenal-medullary stress response is to increase heart rate, blood pressure, mental acuity, skeletal muscles tension, ventilation, and blood coagulability (Smelzer & Bare, 2004).

To fuel this prolonged stress response, increased circulating blood glucose is required (Smelzer & Bare, 2004). The initial release of epinephrine stimulates an increase in blood glucose levels through the process called glycogenolysis (i.e. the breakdown of the cell's stored glycogen to re-form glucose). Epinephrine activates the enzyme adenylyl cyclase, beginning the process of activation of the phosphorylase enzyme system, which ultimately converts glucose to glucose 6 phosphates. Glucose 6 phosphates are hydrolyzed in the liver and kidney cells to free glucose, which diffuses into the plasma and produces an increase in serum glucose (Callahan, 1994; Guyton & Hall, 2000). Epinephrine also stimulates activation of second –messenger molecules called cyclic adenosine monophosphate (cAMP) by the cells of the liver and muscle. cAMP is the initial link between the first signal hormone and the inside of the cell. In cardiac muscle, through a series of interactions, cAMP increases myocardial contractility (Piano & Huether, 2000).

Hypothalamic-Pituitary Response

Persistent stress stimulates the hypothalamic-pituitary response. Antidiuretic hormone (ADH) from the posterior pituitary and aldosterone from the adrenal cortex promote sodium and water retention. The release of ADH results in an increase in reabsorption of water from the renal collecting ducts and the distal tubules (Callahan, 1994). Aldosterone promotes sodium retention and potassium loss from the blood by stimulating the distal convoluted tubules to reabsorb sodium and excrete potassium. The retention of sodium increases blood volume and pressure. The control of aldosterone secretion is referred to as the renin-angiotensin-aldosterone system. Renin is an enzyme that is produced by the juxtoglomerular apparatus of the kidney in response to a low blood volume state and causes an increased production of angiotensin II. Angiotensin II vasoconstricts blood vessels and augments sympathetic nerve activity. In turn, this releases more epinephrine in the blood vessels. Angiotensin II also stimulates increased secretion of aldosterone (Van De Graaff & Fox, 1989). Pituitary release of growth hormone helps to mobilize energy stores by stimulating the uptake of amino acids, the release of free fatty acids, and an increase in blood glucose (Callahan, 1994; Smelzer & Bare, 2004).

The hypothalamus secretes corticotrophin releasing factor, which stimulates the anterior pituitary gland to produce adrenocorticotropic hormone (ACTH). ACTH stimulates the adrenal cortex to produce glucocorticoids. The primary glucocorticoid is cortisol. Cortisol stimulates the production of enzymes, resulting in protein catabolism, gluconeogenesis, and inhibition of glucose uptake (i.e. anti-insulin action) by cells other than those of the brain and heart. Protease enzymes increase hydrolysis of protein and increase the pool of free amino acids. Gluconeogenesis, the manufacture of glucose from protein, is an inefficient process that, at best, nets a 13% energy loss. The protease enzymes have a half life of six to twelve hours and so it may take up to several days after the stress hormones return to baseline before the enzymes return to homeostatic levels. It has been suggested that the most rational approach to control this response may be by attenuation of stress hormones (Callahan, 1994; Smelzer & Bare, 2004).

Immune and Inflammatory System Response

Since Hans Selye's early stress research, this field of inquiry has evolved to include the study of psychoneuroimmunology, which focuses on the interaction of the consciousness, brain, central nervous system, and immunology. Psychoneuroimmunology has established further evidence to support the complexity of the stress response (Shelby & McCance, 2002).

The immune system is connected to the neuroendocrine and autonomic nervous systems. For example, lymphoid tissue is supplied by autonomic nerves. These nerves can release a number of different neuropeptides and byproducts of the SNS, including: CRF, ACTH, endorphins, substance P, epinephrine, NE, dopamine, serotonin, histamine, GH, vasoactive intestinal hormone, β-endorphins, methionine-enkephalin, leucine-enkephalin, and somatostatin (Dunn, 1989; Friedman & Irwin, 1995; Jankovic, 1989; Rabin, et al, 1989). All of these substances can directly influence immune system functioning, leukocyte regulation, and the inflammatory response (Shelby & McCance, 2002). For example, neuroendocrine hormones can inhibit or stimulate leukocyte function. Catecholamines have been shown to increase the numbers of T cytotoxic and natural killer lymphocytes circulating in the blood (Robin, 1999). Further research is needed to clarify the relationship between the immune system and the stress response.

Summary

The purpose of the stress response is to enable the threatened individual to adapt and survive. The stress response is a complex process that affects all systems of the body. The stress response has evolved over millions of years and includes components of value to the surgical patient (Kehlet, 1991). The major hormonal changes that occur in the physiological stress response cascade are summarized in Table 1.

Table 1.

Major Hormonal Changes of the Stress Response

Hormone	**Effects**
↑ Epinephrine	Preparation for "fight or Flight" response ↑skeletal muscle tension Mobilization of stored energy (glycogenolysis) ↑serum glucose and fatty acids ↓insulin release from pancreas
↑ Cortisol	Mobilization of energy stores (gluconeogenesis) ↑serum glucose, amino acids, and fatty acids Inhibits inflammatory and immune responses
↑Glucagon (alpha cells of pancreas) ↓ Insulin (beta cells of pancreas)	↑ serum glucose and fatty acids Response to insulin is impaired
↑Growth Hormone(mild stress)	↑blood glucose level, release of free fatty acids, and cellular uptake of amino acids (phase 1).
↓Growth Hormone(more severe stress)	↓cellular uptake of amino acids and ↓protein synthesis (phase 2).
↑Renin- angiotensin ↑Aldosterone	Conserve salt and water, vasoconstriction Salt retention promotes increases plasma volume
↑Antidiuretic hormone(vasopressin)	↑arteriolar vasoconstriction, thus maintaining or elevating blood pressure Reduces excretion of urine (↑reabsorption of water from renal collecting ducts and distal tubules)

The Pathophysiologic Surgical Stress Response

Although the nursing literature substantiates nurses' awareness of stress, the majority of nursing research has focused on the psychologically-stimulated stress response and the ability of the coping mechanisms to facilitate adaptation (Frazier et al., 2003; Ulmer, 1996). However, a significant amount of nursing research has explored specific components of the surgical stress response, such as pain (Gates, 1998; White, Pokrupa, & Chan, 1998). While many of the reviewed research studies focused on acute pain, the links between unresolved acute pain and the neural, autonomic, and immune systems are only briefly mentioned (Good, 1999; Page & Ben-Eliyahu, 1997).

There is an abundance of research on the surgical stress response in the medical literature. In an effort to better understand the surgical stress response and develop techniques to attenuate this response, surgeons and anesthesiologists are very interested in surgical stress research. As new techniques are developed, it is imperative that their outcomes are evaluated. There has not been any medical or nursing research that explores the influence of TSA on surgical stress and patient outcomes.

The medical and physiology literature includes very specific descriptions of the surgical stress response, as well as outcomes research which incorporate the more comprehensive definition of the surgical stress response. The HRM provided structure for the following literature review, focusing on the pathophysiologic consequences to the surgical stress stimulus.

Pathophysiologic responses produce decompensatory outcomes that are manifestations of the inability to adapt to stress (Mitchell et al., 1991). The third phase of Selye's general adaptation syndrome is exhaustion. The surgical stress response can be described as the endocrine, metabolic, immune, and inflammatory response to injury and is composed of a variety of physiological changes that may prove to be maladaptive, eroding body mass and physiological reserve (Kehlet, 1987, 1989; Weissman, 1990).

This global surgical stress response has the potential for systemic adverse effects in the perioperative period, including: cardiac ischemia and hemodynamic instability, renal failure, pulmonary decompensation, increased catabolism, impaired immune response, paralytic ileus, hypercoagulability syndromes, and pain (Lubenow, Ivankovich, & M^cCarthy, 2001). The following is a comprehensive review of the research that has been conducted to examine these pathophysiological surgical stress responses.

Cardiac Ischemia and Hemodynamic Instability Response

The sustained surgical stress response and the consequent release of catecholamines from the sympathetic nerve endings and the adrenal medulla, combined with release of aldosterone and cortisol from the adrenal cortex, and activation of the renin-angiotensin system, can have a direct burdening effects on the cardiovascular system. Angiotensin II causes vasoconstriction. Catecholamines increase HR, myocardial contractility, and systemic vascular resistance. This cascade of events may result in hypertension, tachycardia, and dysrhythmias and may lead to myocardial ischemia in susceptible patients (Lubenow et al., 2001).

Patients who undergo major surgery such as cardiac surgery are susceptible to the sustained surgical stress response. Previous research suggests that myocardial ischemia is most severe during the first eighteen hours post CPB (Knight et al., 1988; Leung et al., 1989; Smith, Leung, & Mangano, 1991). Mangano et al. (1992) identified the need to perform therapeutic trials to suppress postoperative ischemia, because of its association with adverse cardiac outcomes. Their primary research question was whether the application of an intensive perioperative analgesic regimen would decrease the incidence and/ or severity of postoperative ischemia. In their prospective randomized trial of 106 patients undergoing elective myocardial revascularization surgery, participants were given either (minimal) morphine sulfate boluses or (intensive) sufentanil infusions of 1mcg/kg/hr for a postoperative period of eighteen hours. Using continuous Holter electrocardiographic (ECG) monitoring, they concluded that the severity of ischemic episodes following cardiac surgical revascularization can be diminished by prolonged use of intensive analgesia.

In a prospective study, Hoar et al. (1980) analyzed plasma catecholamine concentrations in conjunction with hemodynamic measurements in 15 coronary artery bypass graft (CABG) patients. Plasma norepinephrine, epinephrine, dopamine, and plasma renin levels were measured during preoperative, anesthesia induction, operation, closure of sternotomy, and the immediate post-sternotomy phases of the surgery. The stimulus of surgical incision doubled the norepinephrine and elevated the epinephrine levels from the preoperative/awake levels. This surgical stress response correlated significantly with deterioration of the circulatory status, as measured by elevated preload pressures and cardiac index depression. The authors concluded that sympatho-adrenal activation is reflective of the stress response and is a potential cause of ischemic injury.

Renal Decompensation Response

Multiple organ failure is often the ultimate failure of two or more organ systems following an uncontrolled systemic inflammatory and stress response that are characterized by hypermetabolic and hyperdynamic states (Baldwin & Morris, 2002). Acute renal failure (ARF) is often one component of multi-organ failure and may be a part of low cardiac output syndrome and sepsis (Bahar et al., 2005). A variety of underlying causes of ARF post cardiac surgery have been identified including: low cardiac output, acute tubular necrosis, multiple blood transfusions, renovascular emboli, preoperative contrast agents, nephrotoxic drugs, and prolonged cardiopulmonary bypass (CPB) time (Bahar et al., 2005; Finkelmeier, 1995).

ARF is a serious complication of cardiac surgery. ARF is characterized by a sudden decrease in glomerular filtration rate and renal function with retention of fluid, decreased urine output, and retention of nitrogenous waste (Bahar et al., 2005). The incidence of post-cardiac surgery ARF varies in the literature from 1.16-15.1% (Bahar et al., 2005; Zanardo et al., 1994). Unfortunately, the occurrence of postoperative ARF carries a high mortality and morbidity. In a large retrospective study (N=14,437) of consecutive patients undergoing cardiac surgery from 1991-2001, Bahar et al. (2005) reported a mortality rate of 79.7%.

There is a paucity of research literature that directly examines ARF in the context of anesthetic advances such as TEA or TSA. However, in a prospective study to determine the potential benefits of TEA in cardiac surgery patients, Scott et al.(2001) identified that TEA was associated with a significant ($p= 0.031$) reduction in renal failure, as defined by a twofold increase in preoperative serum creatinine level. This is a promising finding that supports the use of TEA.

Pulmonary Decompensation Response

Atelectasis, pneumonia, pulmonary edema, and pulmonary emboli are the most common postoperative pulmonary complications. Absorption atelectasis results from removal of air from obstructed or hypoventilated alveoi and is often combined with the negative effects of inhaled high oxygen concentrations and anesthetic agents (Rothers, Sporre, Wegenius, Reber, & Hedenstierna, 1995). Inadequate or excessive administration of pain medications is a contributor to pulmonary decompensation (Brooks-Brunn, 1995; Brooks, 2001). In a review article, Brooks (2001) identified depressed level of consciousness, immobilization and supine positioning, and pain as contributing factors to nosocomial pneumonia. Furthermore, postoperative pain related to sternal incisions and chest tubes causes patients to hypoventilate and to resist position changes and ambulation, and consequently, to develop respiratory complications. Hypoventilation reduces ciliary clearing of secretions, stasis of surfactant, and discourages collateral ventilation through the pores of Kohn, which only open during deep breathing (Brashers, 2002). Hypoventilation causes both decreased alveolar oxygen content and increased carbon dioxide gas content. Diffusion of oxygen through the alveolar capillary membrane is impaired by pooled secretions and inflammatory changes within the lung that are triggered by surgical manipulation. The resulting ventilation/perfusion mismatch is called shunting (Brashers, 2002). Hypoxemia stimulates the drive to produce increased minute ventilation. Prolonged efforts to increase the minute ventilation result in fatigue and respiratory failure. In this manner, atelectasis, dyspnea, and hypoxia exacerbate the effect of inadequately managed pain and the cycle continues, thus substantiating the need for adequate early pain management (Lubenow et al., 2001). It follows that effective analgesia may reduce pulmonary decompensation and improve patient outcomes.

It has been suggested that epidural analgesia has the ability to reduce pulmonary morbidity through the provision of superior analgesia, improved diaphragmatic function, and reduced frequency and severity of postoperative hypoxia (Liu, Carpenter, & Neal, 1995). Liu et al. (1995) published a research review of current knowledge of the effects of epidural anesthesia and analgesia on postoperative morbidity. They reviewed and synthesized experimental and clinical evidence from 379 studies, and organized the results by physiologic systems. They concluded that postoperative pulmonary dysfunction can be attenuated by the use of epidural anesthetics and that continuation of epidural analgesia into the postoperative period may maintain optimal pulmonary function.

Increased Catabolism Response

Prolonged surgical stress leads to a catabolic state during which insulin hormones decline and catabolic hormones including: epinephrine, glucagon, cortisol, and growth hormone increase (Callahan, 1994; Kehlet, 1996; Ouelette, 1998). The hormonal response can be divided into two phases, which are stimulated simultaneously (Callahan, 1994).

Phase one is the catecholamine phase. It can be described as short and rapid in its biochemical effect. Epinephrine released from the adrenal medulla stimulates the liver and muscle cells to produce cyclic adenosine monophosphate. Through a complex process of mobilizing glycogen and producing fatty acids, serum glucose increases and ketone acids and free fatty acids are produced, which, in turn, lower ph, resulting in a metabolic acidosis (Shelby & McCance, 2002). With the cessation of epinephrine release, phase one is easily terminated (Callahan, 1994).

Phase two of the hormonal response to surgical stress occurs after glycogen has been depleted and protein becomes the source of glucose production. The production and activation of the extra enzymes required to convert protein to glucose is time consuming. The hormones of phase two, including growth hormone, ACTH, and cortisol, stimulate enzymes which cause protein breakdown and reversal of the glycolytic process (Shelby & McCance, 2002). Protease enzymes, which increase over the course of a few hours, hydrolyze proteins and increase the availability of free amino acids. Gluconeogenesis depletes amino acids and is an inefficient system of energy production; even if the system is perfectly functioning, it results in a 13 % loss of caloric energy. Gluconeogenesis utilizes proteins for fuel and depletes their availability for cellular structure, function, repair, and replication. Depleted plasma protein and albumin decrease capillary osmotic pressure, which contributes to the development of interstitial edema. Anaerobic metabolism results in the buildup of toxic waste products such as ammonia, pyruvic acid, and urea. Pyruvic acid is the starting point for gluconeogenesis. These waste products further disrupt cellular function and membrane integrity (Baldwin & Morris, 2002). Phase two enzymes take a relatively long period of time to be manufactured and they have a half life of 6-12 hours, independent of stress hormones. Once nitrogen excretion exceeds nitrogen intake, this negative nitrogen balance becomes resistant to efforts to control the situation, with infusion of proteins, fats, and carbohydrates, insulin, or any combination of hormones or nutrients having only a minimal effect. Therefore, it is necessary to strive to minimize or prevent phase two from occurring (Callahan, 1994).

Impaired Immune and Inflammatory Response

Although the stress response is designed to maintain homeostasis within the body, an exaggerated surgical stress response can negatively effect the immune and inflammatory systems which may delay recovery and contribute to exhaustion (Bach et al., 2002; Lin et al., 2000).). For example, cytokines are polypeptides or glycoproteins produced by cells at the site of injury and by systemic immune cells. Cytokines play an important role in intercellular communication and have been called the hormones of the immune response (Rote, 2002).

Although cytokines are necessary messengers, which can direct the inflammatory response to the site of infection or injury, exaggerated production of pro-inflammatory cytokines can manifest systemically as metabolic derangements that result in muscle wasting, or the hemodynamic instability of septic shock (Lin et al., 2000).

In a prospective, randomized study of patients scheduled for elective CABG surgery, Bach et al. (2002) investigated whether dopexamine infusion or continuous epidural anesthesia with bupivicaine would attenuate the inflammatory response as a result of the proposed ability of these medications to improve splanchnic blood flow. Procalcitonin, tumor necrosis factor, soluble tumor necrosis receptor, human soluble intercellular adhesion molecue-1, C-reactive protein, and leukocyte counts were measured as parameters of inflammation. Results indicated that all parameters were significantly increased after CPB and that increases of procalcitonin, tumor necrosis factor, and leukocyte counts were significantly attenuated in both experimental groups, although at different time points. Neither splanchnic blood flow nor oxygen delivery and consumption were different when compared to the control group. Bach et al. (2002) concluded that a mechanism other than an improved splanchnic blood flow by dopexamine or continuous epidural bupivicaine may be responsible for the anti-inflammatory effects.

The high levels of cortisol produced by the adrenal cortex, in response to tissue trauma, result in the inhibition of protein synthesis; this includes a reduction in the synthesis of immunoglobulin and consequent immunosupression (Saspolsky, Romero, & Munck, 2000). High levels of cortisol inhibit the immediate local inflammatory reaction to injury; this, in turn, results in less dilation of the capillaries and an inhibition of the endothelial cell membrane changes that normally increase microvascular permeability and enhance the trapping of circulating leukocytes at the site of injury (Berne, Levy, Koeppen, & Stanton, 2004). Cortisol also inhibits fibroblast proliferation and function at wound sites, which may negatively affect wound healing and increase susceptibility to infection (Shelby & McCance, 2002).

In a small, non-randomized, prospective study (N = 25), Lanuza (1995) compared the cortisol levels of CABG surgery patients (n = 9) with patients who had automatic cardioversion defibrillator (ICD) insertions (n=16) to ascertain the impact on the circadian rhythm. The Lanuza study concluded that elevated postoperative cortisol levels and altered circadian rhythms may contribute to increased vulnerability to infections in both patient groups. Although this study achieved its goal, it did not analyze many factors that could have influenced the cortisol levels, such as pain or anxiety levels, nor did it recommend any strategies to reduce cortisol levels.

Page and Ben-Eliyahu (1997) reviewed research studies and review articles pertaining to immunity, immune function, stress, and the immunosuppressive nature of pain and concluded that postoperative pain not only results in suffering, but is also a pathogen that produces immune suppression. The implications for nursing practice are that adequate pain relief may not only be a primary concern for patient comfort, but may also be a matter of physiological necessity.

Paralytic Ileus Response

Paralytic ileus can be described as the inhibition of gastrointestinal motility. This response can occur as a result of hyperactivity of the SNS and the stress response (Watwill, 1988). Paralytic ileus delays oral intake and may contribute to postoperative morbidity. Stechmiller, Treloar, and Allen (1997), reviewed 66 medical and nursing studies on the intestinal response to critical illness and the implications for early enteral stimulation and nutrition. They determined a need for nurses to have a better understanding of the normal defense mechanisms of the gut and alterations associated with ischemia-reperfusion injury, risk of infection, and the link to multiple organ dysfunctions. They expanded on the risks of short-term paralytic ileus and identified the risk of the prolonged surgical stress response, which may subject the gut to inflammation, ischemia- reperfusion injury, capillary leak syndrome, and hypo-albuminemia which, in turn, may cause intestinal edema, decreased peristalsis, bacterial stasis and overgrowth, and possibly increased gut permeability to pathogenic bacteria. Septic shock and multiple organ failure can occur as a result of this sequelae or the surgical stress response cascade.

Riddington and associates (1996) completed a prospective, observational study of 50 patients undergoing cardiac surgery and ten patients awaiting elective cardiac surgery.

They used chromium 51 as a marker of intestinal permeability, continuous gastric tonometry to measure intramucosal pH, a pulmonary artery catheter to measure systemic oxygen delivery and consumption variables, arterial blood sampling for plasma endotoxin, and blood and urine sampling for excretion of chromium 51. The results indicated that there was a significant increase ($p<.001$) of urine chromium 51 excretion in the cardiac surgery group. Post CPB, the intestinal pH declined from a median of 7.45 to 7.10. Endotoxin was detectable in 21 patients (42%). They concluded that cardiovascular surgery is associated with increases in gut permeability, which precedes gut mucosal ischemia.

Based on their review of the related literature, Liu, Carpenter, and Neil, (1995) noted that anesthetics or analgesic techniques that reduce postoperative ileus have the potential to substantially reduce postoperative morbidity, duration of hospitalization, and medical costs. Based on the experimental evidence, they concluded that local epidural anesthetics can reduce postoperative ileus in a number of ways, including: the relief of pain; systemic absorption of local anesthetics, which increases gastrointestinal blood flow; blockade of sympathetic innervations of the bowel; and reduction of requirements for systemic opioids which decrease gastric motility.

Hypercoagulability Syndrome Response

There is consistent research evidence that surgery causes changes in hemostasis, which leads to a hypercoagulable state; this is manifested by increased circulating coagulation proteins, increased platelet reactivity, decreased circulating coagulation inhibitors, and decreased fibrinolysis (Liu et al., 1995; Rosenfeld et al., 1993). Increases in perioperative coagulation are associated with vaso-occlusive and thromboembolic events, such as deep vein thrombosis, pulmonary embolus, myocardial infarction, and stroke. These complications contribute to a substantially to postoperative morbidity and mortality (Liu et al., 1995).

In a clinical trial of 95 patients scheduled for elective lower extremity vascular reconstruction, Rosenfeld et al. (1993) randomized patients into either epidural anesthesia followed by epidural fentanyl infusion or GA followed by intravenous morphine. Results of the study demonstrated that 17 of the GA group had postoperative arterial thrombosis compared to 5 of the epidural group. Pre-operative fibrinogen levels were similar in both groups, remained unchanged over the first 24 hours, and increased equally over the first 72 hours postoperatively. In the postoperative period, GA group plasminogen activator inhibitor (PAI) increased from 13.6 ± 2.1 activity units to 20.2 ± 1.4 activity units at 24 hours and returned to baseline within 72 hours. In contrast, in the epidural group, PAI concentrations remained unchanged over time. The authors concluded that epidural anesthesia combined with epidural analgesia appears to prevent postoperative inhibition of fibrinolysis and may decrease the risk of arterial thrombotic complications.

While the research evidence supports the contention that the postoperative increase in hemostatic function is attenuated in surgical patients who have received regional anesthesia, the mechanism of action of this effect of regional anesthesia has not been completely explained.

Rosenfeld and associates (1994) designed a prospective, randomized study of 12 healthy volunteers to test the hypothesis that neuroendocrine hormone release causes changes in homeostasis. Rosenfeld et al. (1994) concluded that stress hormone infusion causes changes that resemble those seen postoperatively, but does not recreate the postoperative decrease in fibrinoytic activity. They also suggested that cytokines and tissue thromboplastins may be additional components of the hypercoagulable state. It can be hypothesized that determining the mechanism of action with which regional anesthesia attenuates the postoperative increase in hemostatic function could lead to improved therapeutic management of altered postoperative hemostatic function.

Pain Response

Pain can be defined as a subjective and multidimensional phenomenon (Puntillo, 1988). The stress response to pain is influenced by physiological, pathophysiological, emotional, psychological, cognitive, environmental, and social factors (Holdcroft & Power, 2003). However, this response elicits a consistent and well defined metabolic response, involving the release of neuroendocrine hormones and cytokines, and has the potential to result in detrimental multi-systemic effects (Weissman, 1990). Postoperative cardiac surgery pain can arise from numerous sources which including surgical incisions, chest tubes, endotracheal tubes, and cannulation sites (Ferguson, Gilroy, & Puntillo, 1997).

The potential pathophysiological responses to pain are summarized in Table 2.

Table 2.

Pathophysiological Sequelae of Pain and Surgical Stress Response

Organ System	**Clinical Effect**
Cardiovascular ↑myocardial workload mediated from catecholamines and angiotensin II	Dysrhythmias, angina, cardiac ischemia, myocardial infarction, congestive heart failure
Respiratory ↑ skeletal muscle tension ↓ total lung compliance	Hypoxemia, hypercapnia, atelectasis,
Endocrine	Protein catabolism, hyperglycemia Salt and water retention, vasoconstriction, ↑heart rate, ↑myocardial contractility (see Table 1)
Immunologic	↓immune function and resistance to infection, sepsis ↑inflammation
Gastrointestinal	Paralytic ileus, ↑sphincter tone, ↓smooth muscle tone
Renal/Genitourinary	Urinary retention, ↑sphincter tone, ↓smooth muscle tone
Coagulation Effects	↑incidence of thromboembolic events
Central Nervous System (cognitive)	Insomnia, anxiety, feelings of helplessness

While pain is the initial, and perhaps the most potent stimulus for the surgical stress response, the pathophysiological sequelae of untreated or poorly managed pain can further potentiate pain and, in turn, exacerbate and prolong the surgical stress response. Hence, pain can act as both the stimulus and the response. An example of this cyclic positive feedback system is the pain that a postoperative cardiac surgery patient experiences during deep breathing. The sternal incision, chest tube, and lung changes caused by the surgical procedure, elicit pain. Pain stimulates the SNS response, but also causes splinting and immobilization, which potentiates atelectasis, hypoxia, and perhaps pneumonia. The resulting dyspnea exacerbates the pain response and the cycle continues (Lubenow et al., 2001).

The literature is replete with evidence that postoperative pain has negative consequences on patient outcomes. The literature review describing the pathophysiological consequences of the surgical stress response has been previously focused on cardiac ischemia and hemodynamic instability, renal decompensation, pulmonary decompensation, increased catabolism, impaired immune and inflammatory function, paralytic ileus, and hypercoagulability. Pain can act as both the stimulus and the response. Effective pain management is central to the ability to minimize the stress response and improve patient outcomes.

Presumably, the majority of health care providers, armed with the knowledge that pain has deleterious effects, would ensure that patients had adequate pain control. Unfortunately, a large body of research evidence supports the fact that pain remains poorly managed for many patients. For example, Puntillo and Weiss (1994) observed pain management in a convenience sample of (N=98) patients who had undergone either cardiac or abdominal surgery. These patients reported moderate postoperative pain intensity that did not decrease over the immediate three day postoperative period. Relatively small and decreasing amounts of analgesia were given over the three days and patients reported that the amounts were not enough to minimize the intensity of their pain. Puntillo and Weiss (1994) also found that patients with greater pain intensity had a significantly higher incidence of atelectasis.

In a descriptive correlational study of patients recovering from CABG surgery, Ferguson, Gilroy, and Puntillo (1997) found that patients can experience significant pain, which is not always effectively managed. While patients' pain intensity increased over the 48 hour time frame of the study the amount of analgesia actually decreased during that period. The researchers concluded that effective management of pain in CABG surgery patients is not a universal practice and presents a challenge to nurses.

In a large survey of acute care surgical and medical hospitalized patients (N=5150), Bruster et al. (1994) determined that 61% of patients identified suffering from pain at some point during their hospital stay and that 33 % reported suffering from pain during the majority of their hospital stay. Similarly, in a pain management study of cardiac surgery patients (N=102), Yorke, Wallis, and McLean (2005) identified that 92% of patients experienced severe pain in their sternal incisions and fewer than half of the patients always told the nurses that they were in pain. Simpson, Armstrong, and Mitchell (1989) identified pain and sleeplessness as the major problems that patients (N = 59) recalled about their critical care experience.

The state of the knowledge of pain control and comprehension of the importance of mediation of the surgical stress response may not be adequate in nursing practice. In an educational review article, Callahan (1994) identified the need for surgical nurses to understand the responses to surgical injury and the manifested stress response. She explained the basic physiology and pathophysiolgy of the response to surgery and summarized her article by stating the following:

> It is clear that uncontrolled hormonally mediated stress responses may be deleterious to the intraoperative and postoperative course of patients undergoing

> surgery and anesthesia. Knowledge of the mechanisms and timing of metabolic stress responses plus the knowledge of the effects of the anesthetic techniques utilized allows the anesthesia personnel to more effectively assess and diagnose the needs of the patient during the immediate postoperative period. (Callahan, 1994.p.135)

Although Callahan's article described the benefits of understanding the surgical stress response, there is still a gap in the research-based evidence. Unfortunately, while some of the nursing literature focuses on aspects of the surgical stress response, there is a paucity of nursing research that incorporates the more comprehensive definition of the surgical stress response. A better understanding of the physiology and pathophysiology of the surgical stress response could enable the collaborative healthcare team to anticipate the care needs of the cardiac surgery patient.

Summary

The literature review of the pathophysiology of the surgical stress response describes the potential decompensation that can negatively affect patient outcomes. Multiple systems can be affected in the perioperative period including: cardiac ischemia and hemodynamic instability, acute renal failure (Bahar et al., 2005; Zanardo et al., 1994), pulmonary decompensation, and increased catabolism. Other adverse systemic effects of the surgical stress response that have been researched include: impaired immune responses, paralytic ileus, hypercoagulability syndromes.

Pain is also a stimulus for the surgical stress response. If the pain stimulus is not adequately managed, the pathophysiological surgical stress response has the potential to elicit negative surgical outcomes through over activation and stimulus of the cardiac, renal, respiratory, metabolic, immune and inflammatory, gastrointestinal, and coagulation systems. Thus, prolonged surgical stress can result in negative surgical outcomes. It is necessary for nurses to understand the implications of the surgical stress response. In order to improve surgical outcomes and patient well-being, the healthcare team needs to strive to improve pain management and thereby intercept the cyclic nature of pain (Callahan, 1994).

Thus, there are numerous, often interrelated consequences of the pathophysiological surgical stress response, which can have a significant impact on surgical outcomes. Examination of the adverse effects of pain, in particular, reaffirms the importance of effective perioperative pain management.

Person Factors: Susceptibility to the Surgical Stress Stimulus

According to the HRM, person factors are vulnerabilities or influencing factors that are present within the person and may influence the patient's response to the therapeutic strategy (Heitkemper, Faan, Levy, Jarrett, & Bond, 1995). Knowledge of indicators and predictors of postoperative morbidity and other negative surgical outcomes assists nurses to anticipate which patients have increased postoperative risks. It would be beneficial for nurses to be able to predict which patients may be more likely to be adversely affected by the surgical stress response. This knowledge could enable the collaborative health care team to develop a plan of care to minimize the occurrences and anticipate the treatment of these morbidities.

Person factors are categorized as modifiable and non-modifiable (Heitkemper & Shaver, 1989; Heitkemper, et al., 1995). Modifiable person factors, such as obesity and smoking, have been identified as significant predictors of increased vulnerability to adverse surgical outcomes. Non-modifiable person factors including, basic demographic data such as age, gender, and concurrent co-morbidities can serve to predict vulnerabilities and outcomes. Advanced age is generally associated with increased fat mass and decreased muscle mass. The capacity for muscle mass to be catabolized may diminish the physiologic strength necessary for basic respiratory effort and vital muscle function. The prevalence of cardiovascular and pulmonary disease increases with age and is manifested by changes that alter arterial compliance, vasoconstriction, autonomic function, sensitivity to catecholamines, and baroreceptor sensitivity (Smith, Austen, & Souba, 2001).

Kim et al. (2001) studied the effect of postoperative atrial fibrillation on LOS after cardiac surgery. During their research, they identified several additional preoperative clinical variables that were associated with increased LOS. These preoperative variables included: male gender, advanced age, need for temporary pacing, ejection fraction <40%, proximal right coronary artery stenosis, hypertension, smoking, mitral regurgitation, unstable angina, and preoperative treatment with βeta blockers, digoxin, and calcium channel blockers. Multivariate analysis revealed that the occurrence of atrial fibrillation contributed an additional one to one and a half days to the LOS.

Person factor predictors of susceptibility to surgical stress encourage further research designed to more specifically delineate those patients who are at high risk for negative outcomes. Thus, there is sound rationale for the exploration of clinical therapeutics that have the potential to reduce the surgical stress response in the cardiac surgery population.

Clinical Therapeutics: Surgical Stress Response Reduction

The desire to improve surgical outcomes has led researchers and clinicians to focus attention on the surgical stress response. Pain management, pain prevention, and interruption or blocking of the pain response is the focus of the healthcare team efforts to attenuate this response. To achieve this goal, anesthesiologists have been striving for the ideal cardiac anesthetic technique that would have the following abilities: provision of hemodynamic stability without myocardial depression or constriction; ease of administration; lack of toxicity; elimination independent of lung, liver, and kidney; rapid emergence with residual analgesia; and titratable effects (Hall, 1993). The following literature review describes and critiques anesthesia research that preceded the development of the TSA technique and the current research project.

Previous anesthesia research that has focused on the reduction or attenuation of the surgical stress response has included studies on intravenous (IV) opioids, intrathecal (IT) opioids, and thoracic epidural anesthesia (TEA). The following review will focus on the effectiveness of each method in achieving surgical stress response reduction.

Intravenous (IV) Opioids

In a prospective, randomly-selected sample of 106 elective CABG patients Mangano et al. (1992), compared two groups who received either; low dose morphine sulfate or high dose sufentanil infusion at 1 μg/kg, every 30 minutes. They concluded that the severity of myocardial ischemic episodes can be diminished by the use of prolonged, intensive analgesia. Duration of tracheal intubation and mechanical ventilation and length of ICU stay were not provided.

The use of high dose IV opioids has fallen out of favor due to negative outcomes, including prolonged intubation times, which for numerous reasons is no longer the standard of care (Lee & Jacobsohn, 2000). As well, decreased gastrointestinal motility and postoperative ileus are common sequelae of high dose opioid use (Smeets, Kiveit, Dulfer, & van Kleef, 1993; Wattwil, 1988). It has been postulated, but not proven that high dose IV opioid use may also contribute to neuropsychiatric dysfunction (Vanstrum, Bjornson, & Ilko, 1988).

Intrathecal (IT) Opioids

Several researchers have focused their efforts to reduce the surgical stress response on the use of high dose IT opioids. Boulanger et al. (2002) studied sixty-two elective cardiac surgery patients in a prospective, randomized, partly-blinded study. Standardized anesthesia was provided to all subjects. Patients were randomized into three groups. Patients were assigned to receive either IT morphine followed by patient controlled analgesia (PCA), IT placebo followed by PCA morphine, or nurse-administered subcutaneous morphine injections. The IT dosage of morphine was 0.2-1.0 milligrams per kilogram (mg/kg) of isobaric morphine. The standardized anesthesia given to all patients in this study included pre-medication of intramuscular morphine 0.1mg/kg and intramuscular midazolam 0.1 mg/kg plus a narcotic induction of sufentanyl (maximum 3 micrograms/kg) and midazolam 0.5 mg/kg (maximum 0.1 mg/kg). Patients were given pancuronium or vecuronium; isoflurane was administered as needed. At the onset of CPB, sufentanyl and midazolam were stopped and a propofol infusion was initiated and maintained. After surgery, the propofol infusion was maintained for one to four hours in the ICU until specific criteria were met.

During the first and second postoperative days, the IT morphine group required less morphine than the control group. There was, however, a tendency for prolonged intubation in the IT morphine group compared to the other groups. The hemodynamic profile before, during and after surgery was similar for the groups. No statistical difference was found the day before surgery, 24, or 48 hours post extubation between the group pulmonary function tests. As well, there were no significant differences between the groups in time to first ambulation and hospital LOS. Specific to patient satisfaction, in the IT morphine group, 92% reported that they would choose the same method, compared to 89 and 90 percent for the IT placebo and PCA and the nurse-administered subcutaneous morphine injection groups respectively.

The researchers concluded that considering the cost and risk of IT morphine, they did not recommend the use of IT morphine if early extubation is planned. However, it should be noted that all three groups received narcotics throughout their surgery and propofol infusions postoperatively. It could be hypothesized that the relatively large dosages of narcotics and propofol given in conjunction with the IT morphine negated the potential benefits of the IT morphine and may have contributed to the tendency for longer intubation times for the IT morphine group.

Jacobsohn et al. (2005) examined the efficacy of low-dose IT morphine on extubation times and pain control after cardiac surgery. This study was a prospective, randomized, double-blinded placebo (saline injection) controlled trial of 43 patients. The authors concluded that low dose IT morphine did not delay early endotracheal extubation, but improved postoperative analgesia, as measured by visual analogue scales at rest and with deep breathing. During the first 24 postoperative hours, the IT morphine group had lower IV morphine requirements, higher forced expiratory volumes, and higher vital capacities. Analgesic satisfaction and overall hospital satisfaction scores were high with no significant differences between the groups.

Chaney, Smith, Barclay, and Slogoff (1996) postulated that aggressive pain control during the immediate postoperative period after cardiac surgery was associated with decreased catecholamine levels and could serve to decrease morbidity and mortality. Sixty patients were randomized to receive either 4.0 mg. of IT morphine or a placebo. Postoperative pain management included standardized patient control analgesia. One patient in the IT morphine group experienced persistent somnolence that delayed tracheal extubation. There were no statistically significant differences in norepinephrine or epinephrine levels between the groups. The authors concluded that large dose IT morphine provides reliable postoperative analgesia but does not reliably attenuate the surgical stress response.

Unfortunately, the use of high dose IT opioids has not been successful in completely blocking the surgical stress response. High dose IT opioids have been associated with prolonged extubation times (Boulanger et al., 2002; Chaney et al., 1997), which is no longer the standard of care for cardiac surgery patients. A prospective, randomized controlled clinical trial of CABG patients (N=120), designed to compared morbidity outcome in early versus conventional tracheal extubation after CABG, demonstrated that early extubation is safe and does not increase perioperative morbidity (Cheng, Karski, Peniston, Asokumar, Raveendran, Carroll, et al., 1996 a).

Early extubation has been associated with significant financial cost savings. In a random controlled trial of CABG patients (N=100), Cheng, Karski, Peniston, Raveendran, Asokumar, Carroll, et al. (1996 b) concluded that early extubation reduced ICU costs by 53% and total costs per CABG patient by 25%. In this time of limited resourced and waiting lists, perhaps the most significant finding of their research was that early extubation significantly reduced cancellation of elective cases ($p<0.002$). Due to incomplete attenuation of the surgical stress response, delayed extubation, and the potential that IT administration of morphine may add to the complication risk, simple administration of IT morphine has fallen from favor.

Thoracic Epidural Anesthesia (TEA)

Thoracic epidural anesthesia (TEA) has been shown to effectively decrease the stress hormone response to cardiac surgery, reduce myocardial oxygen consumption, ischemia, and intraoperative and postoperative arrhythmias, and improve analgesia, pulmonary function, and hemodynamic stability.

Liem et al. (1992 a) investigated the response of high-dose sufentanil-midazolam anesthesia and high TEA combined with general anesthesia during CABG surgery. In their randomized, prospective study of 54 patients undergoing CABG, data was collected during surgery in the pre-CPB, during CPB, and post CPB periods and terminated at the end of surgery. After induction of epidural anesthesia, stroke volume index increased significantly; during the pre-CPB period, fewer inotropes and vasopressors were required. Evidence of pre-bypass ischemia in four GA patients necessitated nitroglycerine treatment. More antihypertensive therapy was required for the GA group during CPB. The authors concluded that there was improved hemodynamic stability in high TEA with bupivicaine and sufentanil combined with GA group compared to a control GA group. Liem et al. contend that lower than baseline heart rates combined with vasodilatory effects of TEA on stenosed arteries may explain the finding that none of the TEA patients developed ischemic ECG changes during the pre CPB period. The authors speculate that TEA may be more effective in achieving hemodynamic stability during CABG due to the blockade of the cardiac accelerator fibers (T1-T5) and the sensory blockade, which prevents hemodynamic response to noxious stimuli.

In a prospective, randomized controlled study of male patients (N=30) undergoing CABG surgery, Stenseth et al. (1994) investigated the hemodynamic benefits of TEA. Three groups: high dose fentanyl, high dose fentanyl and TEA, and high dose fentanyl and TEA with bupivicaine were compared, based on measurements of adrenalin, noradrenalin, and systemic vascular resistance (SVR), glucose, cortisol, lactate, and free fatty acids during the operation and for 20 hours postoperatively. Significant results included comparatively lower levels of adrenalin, noradrenalin, and SVR in the TEA group. Significant increases in glucose and cortisol levels were noted in all three groups; however the increase was delayed in the TEA group. Results suggest that TEA more effectively blocks endocrine metabolic response to CABG surgery. Although a limitation of this study was its small sample size, it did provide a foundation of inquiry for future research.

Loick and associates (1999) evaluated whether high spinal (C6-T10) TEA or IV clonidine, in addition to GA, affects the CPB and surgery associated stress response and the incidence of myocardial ischemia. In their prospective, randomized trial (N=70), 25 patients had TEA prior to induction with GA, 24 received IV clonidine as a bolus of 4ug/kg before the induction of GA and then by continuous infusion. The remaining control group of 21 patients underwent routine GA. Hemodynamics, plasma epinephrine and norepinephrine, cortisol, troponin-T, and other cardiac enzymes were measured preoperatively and postoperatively. During the preoperative night and for 48 hours postoperatively, continuous five lead electrocardiogram monitoring was used to detect ischemia. Results supported that both TEA and clonidine significantly reduced the postoperative heart rate compared to the control group, without an associated decrease in cardiac output or perfusion pressure; plasma epinephrine increased significantly less in the TEA group; changes in plasma cortisol levels increase was non-significant. TEA appeared to attenuate the release of troponin-T, an indication of myocardial ischemia. New ST elevation and depression occurred in 70% of the control group, 40% of the clonidine group and in 50% of the TEA group. Loick and associates (1999) concluded that TEA combined with GA attenuates the myocardial SNS response to CPB and cardiac surgery.

Liu et al. (2004) completed a Meta analysis of MEDLINE and other databases, including randomized controlled trials of patients undergoing CPB, who were randomized into either GA, GA plus TEA or GA plus IT analgesia. Fifteen trials were included for a total of 1178 patients, for the period of 1966 to January 1, 2004. Their results indicated that TEA significantly reduced the risk of dysrhythmias (odds ratio [OR] = 0.52), and pulmonary complications (OR =.41). TEA also decreased tracheal intubation by 4.5 hours and visual analog pain scores at rest. There were no significant differences in mortality or MI between the three groups.

Scott and associates (2001) completed a non-blinded, prospective, randomized, controlled study (N = 420) of the effects of sympathetic blockade produced by continuous TEA on morbidity after routine CABG. The covariates included age, weight, height, ejection fraction, gender, New York Heart Association class of angina, smoking, hypertension, diabetes, previous respiratory disease, and previous MI. The methodology and measurement of major organ complications were well described.

All patients received a standardized GA. One group received TEA through a catheter inserted the day before surgery in the T2-3 or T3-4 interspace. Bilateral neuraxial blockade was established from T1 to T10 with an initial bolus of bupivicaine 0.5% followed by another bolus after 10 minutes. TEA infusion continued postoperatively for a period of 96 hours. The control group received a target controlled infusion of alfentanil for 24 hours post operatively, and then converted to patient controlled IV morphine pump analgesia for a period of 48 hours.

Systemic complications were recorded for the first five postoperative days. Pulmonary complications were divided into lower respiratory infections, and respiratory failure requiring tracheal reintubation. Arrhythmias were classified as supraventricular, ventricular, or conduction defects. Supraventricular arrhythmias were specified as either atrial flutter or fibrillation. Ventricular arrhythmias were further specified as tachycardia, fibrillation or multiple ventricular ectopics, Conduction defects were specified as first, second or third degree block. Postoperative MI was diagnosed with a combination of ECG analyses, and serum creatinine kinase levels. Renal failure was defined as an increase in serum creatinine level to more than twice the preoperative level. A cerebral vascular accident (CVA) was defined as any new motor and sensory deficit. Confusion was described as the inability to cooperate or communicate and disorientation to time and place for more than eight hours after extubation and discontinuation of propofol.

Significant bleeding was defined as bleeding necessitating treatment with blood products and/or a surgical re-operation to control bleeding.

Results of the study were supportive of multi-system advantages of TEA. Significant findings included improved pulmonary function, as measured by maximal lung volume ($p<0.0001$), and earlier extubation ($p<0.001$) in the TEA group. In the TEA group, 51 of 206 were extubated within the first 4 postoperative hours compared to 11 of 202 in the GA group. In the TEA group, the incidence of new supraventricular arrhythmias (SVT) that required rescue therapy was significantly lower. New SVT occurred in 21 of 206 of the TEA group (10.2%) versus 45 of 202 (22.3%) of the GA patients. There was a significant difference in the rate of postoperative acute renal failure in the TEA group versus the GA group (i.e. 4 of 206, versus 14 of 202 in the GA group; $p=0.016$). As well, there were significantly less patients with postoperative confusion in the TEA group, with an incidence of 3 out of 206 versus 11 out of 202 ($p= 0.031$). There were also fewer patients in the TEA group with CVA. However, due to a small number of incidences of CVA (i.e., 2 out of 206 in the TEA group, versus 6 out of 202 in the GA group), statistical significance was not achieved. Fewer patients in the TEA group than the GA group (i.e. 23 versus 35) had postoperative bleeding requiring either blood transfusion or chest reopening, however, this difference was not statistically significant.

Scott and associates (2001) concluded that continuous TEA significantly improved the quality of recovery after CABG surgery compared with conventional narcotic analgesia. They suggested that the reduction in postoperative supraventricular arrythmias was probably a result of sympathetic blockade. Although MI rates were not significantly different between the two groups, the researchers cited evidence from previous studies that cardiac sympathectomy results in lower heart rates, reduced afterload, and thereby reduced oxygen consumption, which should theoretically reduce MI rates. Scott and associates state that compared to the literature rate of 10 to 25% for postoperative CABG MI, their rate of 4 % was low. It could be postulated that the methods of MI diagnosis were not specific enough. More recently, creatinin kinase-MB and cardiac troponin T measurement have been found to be more accurate indicators of myocardial damage and ICU LOS (Baggish et al., 2004; Januzzi et al., 2002; Lehrke et al., 2004; Lyon et al., 2002). As well, in another similar study, Loick et al, (1999) reported that TEA attenuated the release of troponin T.

A review of one hundred TEA research studies by Hahnenkamp, Herroeder, and Hollman (2004) concluded that there is increasing evidence that TEA improves patient outcomes after major surgical procedures. Based on the research evidence that TEA significantly improves recovery outcomes, the reluctance of the 'mainstream' use of TEA for cardiac surgery is questioned. Scott and associates (2001) alluded to one answer to this question when they reported the incidence of one TEA patient waking up with lower limb flaccidity. Although, subsequent investigations ruled out the feared complication of an epidural hematoma, the significance of the potential complication of a thoracic epidural hematoma will be explored.

Neuraxial Hematoma

TEA requires the insertion of a large bore, 16-18 gauge, epidural needle and catheter. Anesthesiologists question the safety of epidural anesthesia for cardiac surgery because of the concern that the traumatic insertion of the large bore epidural needle and catheter may increase the risk of neuraxial hematoma subsequent to full heparinization, which is a requirement of cardiac surgery (Baron, LaRaja, Rossi, & Atkinson, 1987; Ho, Cung, & Joynt, 2000; Lee et al., 2003; Scott et al., 2001; Vandermeulin et al.,1994).

In a retrospective analysis of surgical case reports on the National Library of Medicine's MEDLINE system, Vandermeulen et al. (1994) reviewed 61 cases of epidural and/or subdural hematoma between 1906 and 1994. Of the 61 cases, 42 occurred in association with the use of anticoagulant drugs or the presence of clotting disorders. Multiple, difficult, and/or bloody punctures were noted in several cases associated with spinal hematoma. In 53 of the cases, at least one of either clotting disorder or puncture difficulty was mentioned. Long term indomethacin or cortisone therapy and spinal tumors were also associated with the risk of spinal hematoma.

Although the review focuses on the occurrence reports of spinal hematoma after both epidural and subarachnoid anesthesia, the article also provides a review of a large case series, with patient numbers totaling 200,000 that were done without spinal hematoma complications dating from 1952 to 1989. The authors concluded that knowledge of the pharmacological properties of the different anticoagulants in combination with strict patient selection, and awareness of the risks should enable enhanced safety of anesthetic practice without withholding anesthetic techniques from patients who would benefit from them.

Ho, Chung, and Joynt (2000) reviewed the literature of epidural and subarachnoid anesthesia and/or analgesia up to and including 1999 for cardiac surgery patients. In non-cardiac surgical cases, the incidence of epidural hematoma has been estimated at <1 in 150,000, and the incidence of spinal hematoma in spinal anesthetics as <1 in 220,000. Using the data from cardiac surgical cases reported in the literature, Ho and associates

(2000) mathematically estimated that the risk of a rare adverse event (i.e.neuraxial-induced hematoma) with a 95% confidence to be between 1: 150,000 and 1:500 for epidural blockade, and between 1:220,000 and 1:3,600 for spinal blockade. They stated that the acceptance of any technique into routine practice ultimately depends on the evidence that its associated risks can be justified in improved outcome measurements. They concluded that in the case of neuraxial hematoma due to regional blockade for cardiac surgery, there may be a sufficiently acceptable risk/benefit ratio to justify a large scale study on selected patients.

Rosen et al. (2004) were the first to report the occurrence of an epidural hematoma related to epidural anesthesia in a patient who underwent cardiac surgery. They reported that an eighteen year old man had a T9-10, 20-gauge epidural catheter inserted preoperatively, prior to aortic valve replacement with a bioprosthetic valve. TEA was continued postoperatively. Neither the anesthesiologist nor the surgeon was notified of the intensive care physician's decision to institute thrombo-prophylaxis for the prosthetic aortic valve at 49 hours postoperatively.

At 53 hours after surgery, the patient's peripherally-inserted central venous catheter (PICC) became dysfunctional and each of the two lumens was flushed with the thrombolytic drug alteplase. At hour 57, the patient complained of intense back pain and blood was noted in the epidural catheter and at the insertion site. The intensive care physician ordered the removal of the epidural catheter. At that time, the partial thromboplastin time (PTT) was 87.4. On removal of the catheter, there were neurological symptoms of numbness and weakness distal to T9; five hours later, surgical evacuation of the hematoma was performed. Within a six week time frame, the patient's neurological status had returned to normal.

Rosen and associates (2004) concluded that the case report documents the occurrence of a postoperative epidural hematoma in a postoperative cardiac surgery patient whose coagulation system was further altered postoperatively by heparin infusion and thrombolytic alteplase injection. Postoperative thrombocytopenia further contributed to the derangement of the patient's coagulation system. The removal of the epidural catheter in the presence of impaired hemostasis may have contributed to further increase the bleeding. Although this case report highlights the possible complication of an epidural hematoma, several questionable clinical judgments are likely to have contributed to this occurrence.

Summary

High dose IV analgesia has fallen from favor and is associated with prolonged intubation and ICU LOS. High dose IT morphine has been shown to provide reliable analgesia; however, it does not consistently attenuate the surgical stress response and it has been associated with prolonged extubation times. Research-based evidence suggests that TEA blunts the stress hormone response to CABG surgery, reduces myocardial oxygen consumption and intraoperative/ postoperative arrhythmias, and improves analgesia, pulmonary function, and hemodynamic stability. However, the utilization of TEA for cardiac surgery patients has been questioned due to the risk of neuraxial hematoma, which could result from traumatic insertion of the large bore epidural catheter in a patient who is subsequently fully heparinized. Thus, the quest for a superior cardiac anesthetic technique has been ongoing. Total spinal anesthesia may be able to provide the benefits of TEA and provide a safer alternative to the epidural catheter.

Evolution of Total Spinal Anesthesia (TSA)

TSA can be performed with a small bore needle and without the need to thread a catheter. The use of IT morphine has been reported in a number of studies, in large numbers of patients, without any reported adverse neurogenic consequences (Chaney et al., 1997; Fitzpatrick & Moriarty, 1988; Goldstein et al., 2001; Loick et al., 1999; Scott et al., 2001;Vanstrum et al., 1988).

Kowalewski et al. (1994) reported favorable clinical results of their anesthetic technique of GA combined with IT bupivicaine and IT morphine for CABG surgery. The purpose of adding a local anesthetic to the IT injection was to provide sympathetic blockade. After receiving GA, selected patients were given a lumbar level spinal anesthesia using hyperbaric bupivicaine (23-30 mg) and lidocaine (150 mg) with morphine (0.5-1mg). The stated goals of the use of this anesthetic regimen were to provide a stable hemodynamic course, to decrease opioid requirement, and to obtain the benefits of cardiac sympathectomy, such as decreased myocardial oxygen demand and enhanced blood flow to ischemic myocardium.

This retrospective chart review study included 18 patients who had their elective or urgent CABG surgery at the Foothills Hospital in Calgary, Alberta. Kowalewski et al. (1994) reported a minimal hyperdynamic response to surgery and achievement of cardiac sympathectomy with their technique. Their novel procedure included supplementation with subarachnoid bupivicaine and morphine. They stated that the controlled hemodynamic response to their anesthetic administration and surgery may be an advantage of their technique. In addition, they reported that postoperative analgesic requirements were minimal, and in half of the patients, extubation occurred on the same day as surgery. Limitations of this research included the small sample size, lack of a randomized control group, and the retrospective nature or the research; however, the favorable evidence did serve as a stimulus for further interest and inquiry.

In a subsequent randomized, double blinded, controlled study of cardiac surgery patients (N=38), Lee et al. (2003) examined the ability of high dose bupivicaine spinal anesthesia combined with GA on atrial β-adrenergic receptor (βAR) function, the stress response, and hemodynamics during CABG surgery. One of the assumptions of the research was that βAR desensitization may be a contributing factor to decreased myocardial performance. They compared one group who received 37.5 mg of IT bupivicaine (ITB) to the control group who received subcutaneous local anesthetic (placebo effect). Atrial adenylyl cyclase activity and βAR density were measured before and after CPB by right atrial biopsy. Serum epinephrine, norepinephrine, and cortisol samples were obtained at six standardized points. Hemodynamic measurements were taken at 13 standardized points.

Results indicated that, in patients with CPB times in excess of one hour, the ITB group had significantly less β receptor dysfunction. Results also revealed that serum epinephrine, norepinephrine, and cortisol levels were significantly lower in the ITB group, independent of CPB times. The ITB patients had a higher cardiac index and lower pulmonary vascular resistance in the post- CPB time period. In the pre- CPB period, the ITB group had significantly lower mean arterial pressures and SVR indexes. A significant finding was that the ITB group had improved regional wall motion in the post intubation and the pre-CPB periods. There was a trend for improved left ventricular wall motion in the post-CPB period. The authors discussed the significance of this finding as being in keeping with previous work that reports the benefits of cardiac sympathectomy, which include: relieved angina, improved ST segment depression, improved oxygen supply and demand ratio in ischemic myocardium, increased diameter of stenotic epicardial coronary arteries, and improved left ventricular function (Blomberg, Emanueslsson, & Ricksten, 1989; Blomberg, Emanuelsson, Kvist, Lamm, Ponten, Waagstein, & Ricksten, 1990; Klassen, Bramwell, Bromage, & Zborowska-Sluis, 1980; Kock, Blomberg, Emanuelsson, Lomsky, Stomblad, & Ricksten, 1990). The authors concluded that high-dose IT bupivicaine, combined with GA in CABG surgery patients, resulted in less β-receptor dysfunction and a lower surgical stress response.

In summary, with the goals of minimizing patient risk and maximizing therapeutic benefits of surgical stress response reduction, the rationale for further research related to TSA has been established.

Summary

The review of the literature, guided by the HRM, has provided clarification of the concepts of the physiological and the pathophysiological responses to surgical stress. Support has been established that the reduction of the surgical stress response would positively affect patient outcomes and reduce morbidity and mortality. The dearth of nursing research related to the surgical stress response highlights the need for nurses to be more actively involved in the collaborative efforts to improve cardiac surgery patient outcomes.

The evolution of varied clinical therapeutics and their ability to attenuate the surgical stress response have been discussed. Associated risks, including TEA hematoma have been reviewed. The search to develop an anesthetic technique that would best achieve attenuation of the surgical stress response, without exposing the cardiac surgery patient to unacceptable risks, is ongoing. The addition of a local spinal anesthetic to the IT injection of morphine appears to provide the benefits of surgical stress response attenuation and may provide the benefits of TEA without many of the associated risks. The combination of regional spinal anesthesia with low dose IT morphine may provide superior analgesia without the sedative properties of large dose IT opioids. Further evaluation of TSA in the cardiac population is central to achieving the goal of optimal outcomes for cardiac surgery patients.

Chapter IV: Methodology

This chapter presents the overall plan for addressing the research questions and the primary hypothesis. Description and explanation of the research design, sample and setting, and instrumentation will be provided. Data collection procedures and methods of data analysis will be reviewed. Ethical considerations for the study will be discussed.

Research Hypothesis

Cardiac surgery is a potent physiological stress stimulus that elicits the cascade of the surgical stress response. The surgical stress response can have adverse effects on patient recovery. With the goals of attenuating the stress response, reducing morbidity, and improving patient outcomes, (TSA) is being utilized.

Although the results appear favorable, there has been no evidence-based outcome evaluation of this specific procedure.

The primary research hypothesis was that TSA improves patient outcomes. The overall objective of this study was to establish evidence-based knowledge that will enhance the ability of nurses and other members of the collaborative health care team to anticipate patient outcomes and to plan appropriate and effective, research-based, patient focused, nursing care that can be utilized to further enhance patient outcomes.

Accordingly, the following research questions were developed to address the hypothesis:

1. What are the person factors of the study cohort?
2. Are the person factors predictors of surgical outcomes?
3. What are the perioperative pathophysiological surgical stress response outcomes of TSA and standard GA in cardiac surgery patients?

4. What is the efficacy of TSA compared to standard GA alone for cardiac surgery

5. If there is a difference in the pathophysiological surgical stress response outcomes between the TSA and standard GA, is the difference predictive of efficiency?

Research Design

The objectives of this pilot study incorporated the HRM to describe and explore the outcomes of the TSA technique and compared these outcomes with a matched control sample who received GA. To achieve these goals, a retrospective, descriptive correlational design was employed. The charts of cardiac surgery patients who had their surgeries between September, 2003 and May, 2005, and who provided written consent to participate in this research were reviewed.

This non-interventional design provided an outcome evaluation of TSA technique, guidance for care of patients who receive TSA, and the foundation for further research.

The retrospective design was selected for two reasons. Although TSA was initiated at SBGH in September of 2003, the total number of cardiac surgery patients who had their anesthesia via the TSA method was, at study onset, approximately 50. This was a relatively small sample size. Although a prospective cohort would have been the ideal, delaying research outcome evaluation through attempts to recruit participants and conducting the research over a prolonged period of time prospectively would have impeded progress or changes that could be made in the current TSA protocol. The second reason that this retrospective design was utilized was that the provision of care has been completed on these subjects and there was no possibility of this research biasing or altering the standard care.

A descriptive correlational design enables the researchers to describe relationships among variables, without necessarily seeking to establish causal relationships (Polit, Beck, & Hungler, 2001). To answer the research questions, it was necessary to establish the strength of the relationships between the variables.

Therefore, the first step of this research was to describe the TSA outcomes for cardiac surgery patients. To analyze the independent effect of TSA, matched pair comparisons were made with the GA cardiac patient outcomes.

The independent variables in this study were the TSA and GA techniques. Because this was a pilot project, a large number of dependent variables were included to determine their significance as predictors of surgical outcomes. Variables that may be indicators of the surgical stress response were also analyzed.

The Setting and Sample

St. Boniface General Hospital (SBGH) is a tertiary care institution located in Winnipeg, Manitoba, Canada. Approximately 746 cardiac surgeries were performed at SBGH in 2005. Six cardiovascular surgeons operated during the study time period. The TSA study population included all TSA cases done at SBGH from September, 2003 to May, 2005. Approximately 50 cardiac surgery patients had received the TSA at the time of the research design phase. Hence, the potential sample included approximately 100 subjects. The actual consented sample size was 70, with 35 patients per group. Adequacy of sample size was determined using the data from Liem et al. (1992 b), regarding extubation after CABG. They indicated that a sample size of 25 patients/group would provide an 80% power in detecting a 27% reduction in extubation time in the TSA group ($p = 0.05$). Accordingly, the goal of the current research was to achieve a minimal sample size of 25 subjects per group. TSA is currently being done by only one cardiac anesthesiologist at SBGH. The advantage of a one anesthesiologist and one facility setting is that the data collection conditions were relatively homogeneous.

To achieve a matched sample, a randomly selected group of equal size to the TSA group (n= 35), controlling for pertinent demographics and morbidity including: age (within 10 years), gender, previous cardiac surgery, type of CABG versus valve replacements, surgeon, no contraindications to TSA and approximate date of surgery (within 3 months), was obtained from the Operating Room Scheduling Office System (ORSOS) computer system at SBGH. The decision to match for the above variables was based on previous research studies which demonstrated that these variables had the potential to confound the results. Controlling for the most important intrinsic variables was a deliberate strategy to add strength to the research results and eliminate possible extraneous influences on the dependent variables. The paired matching was done to enable a better description of the true relationship between the independent and dependent variables. Surgeon matching was done to control for factors that may impact on patient outcomes, such as surgeon experience, surgical technique and duration of CPB time. Research by Glance, Dick, Osler and Mukamel, (2005) of 36,930 patients undergoing isolated CABG surgery, suggested that surgeons performing a high volume of CABG procedures have significantly lower risk adjusted mortality rates among their patients compared to those performing a very low volume, and a medium volume of CABG procedures ($p<0.006$). Subsequent research by Wen, Tang, Lin, Tsai, Chen, and Li (2006), utilizing the Taiwan National Health Insurance Research Database with a sample of 9,895 CABG patients and 316 surgeons, concluded that the skill and experience of the individual surgeons is a more critical factor for patient outcomes than either hospital equipment or surgical teams.

The type of procedure was matched to attempt to control for severity of disease, duration of CPB and general surgical risk. It is well reported in the literature that valve replacements and combined valve replacements with CABG surgery have higher mortality rates than CABG surgery. In a prospective study of cardiac surgery patients (N=818), Aggarwal et al. (2006) reported 2003 mortality rates as: CABG 2.3%, valve replacement or repair 5.9%, and combined procedure 5.7%. In previous research, age has been shown to influence cardiac surgery outcomes; for example, in one study, octogenarians were found to have higher co-morbidities and mortality even after controlling for 16 potential confounding variables (Johnson, Smith, Woods, Hendy, & Hiratzka, 2005).

In a study of (N=300) cardiac surgery patients (N=300), Miller (1998) reported that women experienced postoperative complications such as myocardial infarctions, low cardiac output syndromes, and respiratory dysfunction more frequently than men. Miller and Grindel (1999) reviewed the literature and identified differences in symptom presentation, gender bias in referral for treatment, and altered preoperative profile which included more co-morbidities as factors that negatively effect female gender cardiac surgery outcomes. Thus, because gender was thought to be a potential influencing factor on the outcomes, it was included as a controlled variable.

Efforts were made to match the surgeries for date of procedure. The reason for this matching was to control for possible confounders, such as changes in equipment or other procedures.

Exclusion criteria for the study included all of the same exclusion criteria used for potential TSA recipients: emergency surgery, previous cardiac surgery; coagulopathy, as defined by platelet count less that 100 $x10^9$ /litres or abnormal clotting parameters, or any anticoagulant medication other than acetylsalicyclic acid; administration of ticlopidine, clopidigrel, or dipyridamole within 14 days prior to the surgery; administration of other potent antiplatelet agents, such as abciximab (ReoPro); administration of unfractionated heparin IV within six hours and PTT > 45 seconds; administration of fibrinolytic agents, such as tissue plasminogen activator or low dose subcutaneous heparin within 72 hours; infection or inflammation at the lumbar puncture site; serum creatinine greater than 180μmol/litre; and other hematological derangement, such as multiple myelmoma.

Instrumentation

The literature review highlighted the variety of measurements that can be used to operationalize the complex surgical stress response. Operational definitions of variables require the clarification and definition of the variables that will be observed and measured because there are multiple methods for measuring most variables (Polit et al., 2001). The HRM and the reviewed literature provided a framework for the data collection and rationale for the study variables. The following section will describe the process of operationally defining the relevant concepts within the context of the key research questions.

Person Factors

Questions One and Two

1. What are the person factors of the study cohort?
2. Are the person factors predictors of surgical outcomes?

The review of previous research studies on cardiac surgery patients and their surgical stress response outcomes led to the identification of the person factor variables for this research. Person factors were therefore operationalized as the preoperative factors (see Table 3) and intraoperative factors (see Table 4) that may influence the postoperative outcomes.

Table 3.

Preoperative Person Factors

Person Factor Variables	**Operational Definition (Type of Measurement)**
Age	Years at time of surgery (Continuous)
Height	In centimeters (Continuous)
Weight	In kilograms (Continuous)
Body mass index	$\frac{\text{Weight in kilograms}}{\text{Height (HT) in meters}^2}$ (Continuous)
Gender	Male or female (Nominal)
Hypertension	Diagnosed yes or no preoperative blood pressure reading on SBGH history (Nominal)
Diabetes	Type 1 or Type 2 (Ordinal)
Serum Glucose	Preoperative non fasting lab value (Discrete)
Hemoglobin	Lab value

	(Continuous)
Partial Thromboplastin time	Lab value (Continuous)
International normalized ratio (INR)	Lab value (Continuous)
Platelet level	Lab value (Continuous)
Angina Severity	New York Heart Association Angina Class 1,2,3,or 4 (Ordinal)
Congestive heart failure	Yes or no (Nominal) New York Heart Association Class Dyspnea 1,2,3, or 4 (Ordinal)
Ejection fraction	From coronary angiogram report, echocardiogram or MIBI scan (Ordinal)
Preoperative myocardial infarction	Diagnosis yes or no (Nominal) If yes, the time from day of infarct to day of surgery (Interval)
History of arrhythmia	Atrial fibrillation Atrial flutter Ventricular fibrillation Arrhythmias requiring pacemaker/ other (Nominal)
Valvular heart disease	Significant history and type of disease (Nominal)
Psychiatric history	History of psychiatric illness requiring medical treatment (Nominal)
Cerebral vascular accident (CVA)or transient ischemic attack (TIA)	With deficit or without deficit (Nominal)

Other vascular disease	Carotid stenosis Peripheral vascular disease (Nominal)
Other neurological disorders	Dementia, neuromuscular disorder (i.e. Multiple sclerosis) (Nominal)
Renal disease	Renal insufficiency Chronic renal failure (Nominal) Serum creatinine level (Continuous)
Asthma	Yes or no (Nominal)
Chronic obstructive pulmonary disease	Yes or no (Nominal)
Preoperative pulmonary function	FEV1 (Continuous)
Smoking history	Yes or no (Nominal)
	Number of pack years history (Discrete)
Current smoker	Yes or no (Nominal)
Preoperative medications	Drugs and dosages Beta adrenergic blockers Digoxin Amiodorone Other anti arrhythmic agents Calcium channel blockers Angiotensin converting enzyme inhibitors Angiotensin II receptor blockers Oral prednisone Inhaled bronchodilator Inhaled steroid

	Diuretic Other anti arrhythmic agents Insulin Oral antidiabetic agents-sulfonylureas, biguanides, thiazolidinediones, glucoseidase inhibitors meglitidines Lipid lowering agents (Nominal)

Table 4.

Intraoperative Person Factors

Person Factor Variables	**Operational Definition (Type of Measurement)**
Surgical procedure	CABG Number of grafts 1,2,3,4,5 (Discrete)
Surgical graft procedure	Left internal mammary artery Right internal mammary artery Bilateral internal mammary artery Radial artery harvest (Nominal)
Surgical procedure	Type of valve repair or replacement (Ordinal)
Cardiopulmonary bypass time	Recorded in minutes from perfusionist record (Continuous)
Aortic cross clamp time	Recorded in minutes from perfusionist record (Continuous)

The Behavioral Response

The HRM identifies the behavioral perspective as what is measurable or observable (Mitchell, 1991). Because the surgical stress response is a complex concept, measurement of the response is also complex. The effects of the surgical stress response are perhaps still not fully understood and therefore, the measurement of the surgical stress response effects is not fully validated. No specific tools that have been developed and verified as the 'gold standard' of surgical stress response evaluation. Therefore, for the purposes of this study, the behavioral response was encompassed within the context of operationalizing the pathophysiological responses.

Pathophysiological Perspective

Question Three: What are the perioperative pathophysiological surgical stress responses of TSA and standard GA in cardiac surgery patients?

The pathophysiological perspective was operationally defined as the variables that measure decompensation (Mitchell et al., 1995). A review of related literature, as well as the knowledge and experience of the researcher and thesis committee, was utilized to operationally define the variables of this study. The retrospective nature of this research made it necessary to rely on the written records of each subject. Therefore, variables were sought that would most likely be consistently recorded. Logical reasoning guided variable inclusion. A systematic physiological approach was used to organize the operationalizing of the pathophysiological variables.

Cardiovascular decompensation is a measurable component of the surgical stress response. The necessity for vasopressor, antihypertensive, or inotropic pharmaceutical support in the intraoperative and postoperative period indicates the inability of the patient to independently compensate for the surgical stressor. The type and amount of volume expansion given during the anesthetic period, as well as the volume given postoperatively is an indicator of blood loss, fluid shifts, and hemodynamic instability. The presence of cardiac arrhythmias indicates the failing ability of the heart to maintain homeostasis. The requirement for an intra-aortic balloon pump indicates severely depressed cardiac function.

Based on previous research evidence, creatinine kinase-MB and cardiac troponin T measurements are considered to be accurate indicators of myocardial damage, as well as strong predictors of ICU LOS (Baggish et al., 2004; Januzzi et al., 2002; Lehrke et al., 2004; Lyon et al., 2002). Research by Loick et al, (1999) reported that TEA attenuated the release of troponin T theoretically by decreasing myocardial ischemia. At SBGH, serum troponin T and creatinin kinase-MB levels are routinely measured on arrival in the surgical and at 0600 hours the following day.

Prolonged duration of endotracheal intubation and the need for endotracheal reintubation are indicators of the inability of the respiratory system to effectively manage the stress of surgery. This data is quite reliably documented and available in patient charts.

Elevated serum glucose is an indicator of the effects of the surgical stress response on altering metabolism (Smelzer & Bare, 2004;Weissman, 1990). Random serum glucose levels are routinely measured preoperatively, as part of the preoperative preparation for surgery. Immediately postoperatively, and at 0600 hours the following day, random glucose levels are measured in the surgical intensive care unit (SICU). Insulin infusions are also recorded.

Acute renal failure after cardiac surgery remains a relatively frequent and serious complication. It has been hypothesized that TSA and attenuation of the surgical stress response may decrease the occurrence of acute renal dysfunction. Serum creatinine is measured routinely preoperatively and at various times throughout the patient stay. An elevation of serum creatinine to twice the preoperative level, is an indicator of some renal failure (Scott et al., 2001). The research reflects considerable variation related to the definition of acute renal failure (Kuitunen, Vento, Suojaranta-Ylinen, & Pettila, 2006). For the current study a 50% peak increase in serum creatinine was determined to be a measure of renal decompensation.

Surgical complications were operationally defined by factors that indicate the decompensation of the patient. The literature review was used to determine complications for the analysis, and included documented: re-operation for bleeding, sternal dehiscence, mediastinal wound infection, reintubation for respiratory failure/decompensation, pleural effusion, diagnosis of perioperative MI, stroke, prolonged postoperative confusion, incisional leg infection, epidural hematoma, and postoperative ileus (Chaney et al., 1996; Halpin et al., 2003; Rosen et al, 2004). These complications impact on surgical patients' recovery and on overall surgical outcomes.

In summary, pathophysiological surgical stress responses are indicators of patient decompensation and are linked to the need for emergency treatment in the care of the critically ill patient. Knowledge about the potential occurrence of these responses enables the collaborative healthcare team to anticipate their occurrence and to provide optimal patient care. For the purposes of this study, the pathophysiological variables were operationalized as outlined in table 5.

Table 5.

Pathophysiological Response Variables

Pathophysiological Response	**Operational Definition (Type of Measurement)**
Hemodynamic instability Myocardial damage/ischemia	Arrhythmia: type and treatment (Nominal) Drug and dosage in minutes from time off bypass (Nominal and Continuous) Hypotension: Vasopressor treatment (Nominal) Drug and dosage in minutes from time off bypass (Continuous) Volume expansion given: type and amount (Nominal and Continuous) Decreased myocardial contractility: Inotropic drug, dosage and duration (Nominal and Continuous) Requirement for intra-aortic balloon pump (Nominal) Hypertension: Antihypertensive drug, dosage and duration (Nominal and Continuous)
Myocardial damage/ischemia	Troponin T levels Creatinine kinase Creatinine kinase-MB (Continuous)
Renal dysfunction	Creatinine level (Continuous) Calculated in percentage increase from preoperative value (Continuous)

Blood loss	Hemoglobin and hematocrit levels (Continuous) Blood product administration/ type and amount (Nominal and Continuous) Chest tube losses over first 6 hour period Pericardial, mediastinal, pleural, pleural Total losses (Ratio) Chest tube removal times Times calculated from sternal dressing time (Continuous)
Altered respiratory function	Endotracheal extubation time calculated from end surgery time to time of tracheal extubation documented in chart (Continuous) Reintubation for resp. failure-yes or no (Nominal)
Hyperglycemia	Blood glucose level on arrival to surgical intensive care unit (Continuous) Administration of insulin-type, amount and duration (Continuous)
Complications	Occurrence of: Re-operation for bleeding Sternal dehiscence Reintubation for respiratory failure Pleural effusion requiring treatment Documented perioperative myocardial infarction Cerebral vascular accident Prolonged postoperative confusion Incisional leg infection Paralytic ileus Renal failure necessitating dialysis Diagnosed neuraxial hematoma (Nominal)

Question Four: What is the efficacy of TSA compared to standard GA alone for cardiac surgery at SBGH?

Efficacy is defined as the ability of a technique to do more good than harm to those who are treated appropriately. Efficacy describes the therapeutic potential of a technique (Tugwell, Bennett, Feeny, Guyatt, and Haynes, 1986). Efficacy is operationalized to reflect the individual patient perspective. This question can be partially answered by examining the potential group differences in the pathophysiological variables outlined in Table 5.

Enhanced patient comfort is an indicator of efficacy. Opioids are commonly used as analgesics in the perioperative period. The amount and type of postoperative analgesia is based upon both the nurses' pain assessment and the experience of the patient. The types, as well as the amount of opioids used throughout the patient stay are measurable indicators of analgesia provided to cardiac surgery patients. One of the goals of the TSA is to attenuate the surgical stress response, which can be triggered by pain stimuli. Accordingly, it was postulated that subjects in the TSA group may require less postoperative analgesia.

Question Five: If there is a difference in the pathophysiological surgical stress response outcomes between the two samples, is the difference predictive of efficiency?

Efficiency describes the cost benefit in terms of measurable outcomes such as LOS (Halpin, Barnett, & Beachy, 2003). Efficiency is measured by variables that are relevant to the broader perspective, including the external environment of the hospital and healthcare system. Variables that were operationalized to describe efficiency included duration of endotracheal intubation, LOS in the SICU, and postoperative LOS in hospital.

The duration of endotracheal intubation is a measurable outcome that indicates the ability of the patient to overcome a number of factors involved in the surgical stress response. At SBGH, tracheal extubation is achieved once the patient is cognitively awake enough to breathe, and has adequate pain control, satisfactory arterial blood gas results, minimal blood loss, and a reasonable level of hemodynamic stability. Time to endotracheal extubation can be easily calculated from the end surgery time, as recorded on the operating room record to the time of tracheal extubation documented in the chart. These times were chosen because they are quite reliably/consistently recorded.

Chart records of duration of LOS, in the SICU and overall hospitalization are also quite reliably documented in the patient charts.

Measurement

A designed template using EXCEL software was developed for the purpose of data collection (see Appendix D). Demographic data and relevant indicators of surgical stress were incorporated into this tool.

Procedures

Data Collection

Data collection was initiated following ethical approval from the Education and Nursing Research Ethics Board (ENREB), and approval for access by the Research Ethics Review Committee of SBGH. In accordance with the Personal Health Information Act (PHIA) of Manitoba guidelines, an application was also be made to the Department of Health Records of SBGH to access the patient sample for the retrospective chart review. Procedures for the retrieval of personal health information from the charts followed the guidelines of PHIA.

A list of potential TSA subjects and approval/agreement to proceed with the proposed research was obtained from the primary cardiac anesthesiologist. Letters of support confirming awareness of the study and agreement from both the Cardiac Sciences Section and the Department of Anesthesia and Perioperative Medicine at SBGH were obtained (see Appendix A & B). A memorandum explaining the proposed research and a copy of the ENREB application were sent to all cardiac anesthesiologists and cardiac surgeons; this provided them with the opportunity to have their questions answered and the option to have their patients excluded from the study (see Appendix C).

The names of the subjects were forwarded directly to Health Records Department of SBGH, where the addresses of the potential participants were obtained. The Office of Clinical Research at SBGH completed the mail-out process of the invitation to participate (see Appendix D) and the research subject information and consent form (see Appendix E). The PHIA certified research nurse made follow-up telephone calls to potential participants one week after mail-out to verify that the mail-out was received and to answer any questions that the potential participant might have. Initially, the mail-out was sent to TSA patients only. Upon receipt of signed consents, the matched control group was determined. The random, matched selection for the control group was done by drawing random numbers that correspond to surgical cases in the ORSOS data bank. Prior to inclusion into the study, charts were analyzed by a PHIA trustee, or a research assistant approved by the PHIA trustee to assess for inclusion/exclusion criteria and to enable matching. The same procedures for obtaining addresses, mail-outs, and follow-up telephone calls were utilized for this group as was used for the TSA group.

Only the research nurse and researcher, who are both employees of SBGH and PHIA certified, as well as experienced with providing critical care nursing care to cardiac surgery patients, and thus have a familiarity with the required data, collected the data from the charts. Confidentiality was maintained by having each data entry in the electronic spreadsheet numerically-coded to protect the subject's identity. The paper data files were kept in a locked drawer, in the office of the researcher. Only the researcher has access to this data file.

After a period of no more than ten years from project completion, data will be destroyed at SBGH consistent with the standard confidential document disposal guidelines (shredding).

Description of Cardiac TSA Procedure

This was a retrospective study and therefore did not have any impact on the care that was provided to patients. However, it was important to understand the process of the TSA procedure.

The general risk of the procedure was explained to the patients by the primary anesthesiologist prior to the procedure. Patients were pre-medicated with diazepam 2.5-5.0 mg, orally, 90 minutes preoperatively. Further sedation was given in the operating room, as required, with midazolam 0.5-1.0mg. IV. Fluid loading with pentaspan 500 ml IV was given via a large bore peripheral IV. Prior to induction, peripheral arterial access was established. The TSA was administered with the patient in the lateral position. The dose range for intrathecal bupivicaine was between 37.5 and 45 mg depending on the patient's body habitus, but generally 45 mg was used. Between 200 and 300 mcg of spinal morphine was used. The patient was then placed supine in a Trendelenberg position of five degrees for five to seven minutes until at least a T1 block was demonstrated. After pre-oxygenation, anesthesia was induced with propofol (1-2mg/kg IV) and rocuronium (0.6-1.0 mg/kg IV). IV narcotics were not used for induction in this technique. Blood pressure was maintained with small IV boluses of ringer's lactate and titrated boluses of ephedrine in the range of 2.5-5.0 mg. To maintain an adequate mean arterial pressure, small boluses of phenylephrine were used if necessary in the range of 0.5- 1.0 mcg/kg IV. The patient was intubated in the usual fashion and an 8.5 French internal jugular line was inserted. Transesophageal echocardiography was routinely performed. General anesthesia was maintained with propofol (50mcg/kg/min) IV and isoflurane (minimum end-tidal concentration of 0.6%) or desflurane (minimum end-tidal concentration of 2.0%).

Parasternal marcaine was administered by the surgeons; post-procedure, a sternal dressing was applied and whenever possible, the patient was extubated in the operating room. Morphine IV was administered prior to extubation, if necessary, and titrated to respiratory rate in the range of 18-22 breaths per minute. No IV narcotics were administered during the case prior to this point. In the absence of contraindications, prior to transfer to the SICU, the patient received rectal acetaminophen 650 mg. Patients were then admitted to the SICU for routine postoperative care and received small doses of IV morphine for pain until they were able to take oral acetaminophen with 30 mg of codeine. In the absence of contraindications, one dose of rectal naprosyn was administered in the SICU two to four hours post admission.

Description of Routine Cardiac General Anesthesia Procedure

The following description provides an approximation of the routine cardiac general anesthetic administered to patients at SBGH. This is by no means an exhaustive description and is meant to provide a general framework for comparison only. Patients were pre-medicated with diazepam 5.0 – 10 mg, orally, or morphine 5.0 – 10.0 mg IM, with scopolamine 0.2 – 0.4 mg IM 90 minutes preoperatively. Further sedation was given in the operating room, as required, with midazolam 0.5-2.0mg. IV. Fluid loading with a crystalloid of choice IV was given via a large bore peripheral IV. Prior to induction, peripheral arterial access was established. After pre-oxygenation, anesthesia was induced with propofol (1-2mg/kg IV), rocuronium (0.6-1.0 mg/kg IV), sufentanil (3 – 5 mcg/kg IV), and ketamine (2 mg/kg IV). Blood pressure was maintained with small IV boluses of crystalloid and titrated boluses of ephedrine or phenylephrine IV. The patient was intubated in the usual fashion and an 8.5 French internal jugular line was inserted. Transesophageal echocardiography probes were routinely placed in the esophagus. The patient was maintained with isoflurane (minimum end-tidal concentration 0.6%) or desflurane (minimum end-tidal concentration 2%), or sevoflurane (minimum end-tidal concentration 1.5 – 2.0%).

Parasternal marcaine was administered by the surgeons. Post-procedure, a sternal dressing was applied and whenever possible, the patient was extubated in the operating room. Morphine or sufentanil IV was administered prior to extubation, titrated to respiratory rates in the range of 18-22 breaths per minute. If not contraindicated, prior to transfer to the SICU, the patient received rectal acetaminophen 650 mg. Patients were then admitted to the SICU for routine postoperative care and received IV morphine for pain. In the absence of contraindications, one dose of rectal naprosyn was administered in the SICU two to four hours post admission.

Data Analysis

Data analysis was provided by the University of Manitoba Biostatistical Consulting Unit, using the Statistical Analysis System version 9.0 (ASA institute Inc., Cary, NC). During the development of the research proposal, statistical research advice was obtained from this consulting unit. To provide a descriptive profile of the samples, descriptive statistics (percentages, means, and standard deviations) were applied to the demographic and outcome data. Demographic, intraoperative, and postoperative data were compared between the two groups, using paired t tests, Fisher's exact tests, and Kruskall-Wallis test. Multiple regression analyses exploring predictors of extubation time and LOS was applied to the sample. An alpha level of 0.05 was used for all statistical tests.

Ethical Considerations

The research proposal was submitted to the Education and Nursing Research Ethics Board (ENREB), University of Manitoba and the Research Review Board of SBGH prior to the initiation of the study procedures. On behalf of the researcher, the PHIA trustee, or research assistant approved by the PHIA trustee, initiated the contact for the request for participation to the potential participants. This removed any pressure that the potential participants may feel in negating consent to someone with whom they may come into future contact with as a healthcare provider. Informed consent was obtained from the subjects.

Questions from potential participants were welcomed both by providing written contact information and by follow-up telephone calls. Should participants have wished to contact the principal investigator, contact information was provided. The subjects were not contacted by the primary investigator. There was no deception or withholding of information to the participants.

Within six months after completion of the research, participants who indicated their preference on the consent form to receive a written summary will be mailed a brief summary of the study findings.

There were no anticipated risks to subjects or their healthcare providers. The retrospective chart data collection and chart review did not require direct patient input. Their care had been completed and the chart review did not alter their care. There were no immediately tangible benefits to those who had their charts reviewed. Future cardiac surgery patients may benefit from this research based evaluation of practice.

Confidentiality and anonymity were maintained by having each entry into the electronic spreadsheet numerically coded to protect the subject's identity. The paper data files were kept in a locked drawer in the researcher's office. Only the researcher and the research nurse had access to these files. Data will be destroyed after a period of ten years, in accordance with the policy and procedures for destruction of personal health information as outlined by SBGH (on site shredding).

There were no costs to the subjects involved in this study. Self addressed and stamped envelopes were provided. Study subjects were not compensated.

Summary

In summary, a retrospective, descriptive correlational design was utilized to describe and explore the cardiac surgery outcomes of TSA and to compare the outcomes with the "standard cardiac general anesthetic" (GA) technique. The literature review, in combination with the researcher and thesis committee's clinical expertise, established a foundation for a comprehensive data collection instrument. The pilot study nature of this research merited the inclusion of a large number of variables. Ethical guidelines were addressed. The findings of this study are presented in the subsequent chapter.

Chapter V: Results

This chapter presents the findings of the pilot study that was designed to describe and explore the cardiac surgery outcomes of TSA and to compare the outcomes with "standard cardiac anesthetics" (GA). The primary research hypothesis was that TSA improves patient outcomes The Human Response to Health and Illness Model (HRM) was used to address the following research questions:

1. What are the person factors of the study cohort?
2. Are the person factors predictors of surgical outcomes?
3. What are the perioperative pathophysiological surgical stress responses of TSA and standard GA in cardiac surgery patients?
4. What is the efficacy of TSA compared to standard GA alone for cardiac surgery?
5. If there is a difference in the pathophysiological surgical stress response outcomes between the TSA and standard GA, is the difference predictive of efficiency?

Statistical Analysis

Retrospective chart review data collection was completed over six months for the time period from July, 2003 to May, 2005. All data were coded and entered into a computer Microsoft Excel spreadsheet. Data analyses were provided by the University of Manitoba Biostatistical Consulting Unit, using the Statistical Analysis System version 9.0 (ASA institute Inc., Cary, NC).

This chapter includes the results of the data analyses, beginning with the baseline demographic person factors of the sample population. To provide a descriptive profile of the samples, descriptive statistics (percentages, means, and standard deviations) were applied to the demographic and the outcome data. Depending on the type of data, chi-square analysis was used to compare group proportions, t-tests or analyses of variance (ANOVA) compared means, while Kruskall-Wallis or signed rank tests, and Spearman correlation coefficients compared skewed, and/or ordinal data.

More specifically, the Chi-square test is a frequency test applied to ordinal-level data or nominal data. Chi-square analysis tests the hypotheses about the proportion of cases that fall into different categories. When the total sample size is small or when cells have 0 frequencies, the Fisher's exact test is more appropriately used. Parametric ANOVA was used to test the differences between means, to compare variation between groups, and contrast means to variation within groups. The Kruskall-Wallis test is a nonparametric analog to ANOVA for use with ordinal-level data or when a markedly non-normal distribution does not meet the assumptions for ANOVA.

Spearman's correlational coefficient was used to determine to what extent the two variables are related to each other. Spearman's correlation coefficient was applied to the data because the data did not meet the normality assumption for the Pearson's correlation coefficient. Demographic, intraoperative, and postoperative data were compared using either the matched samples or the entire sample population, as appropriate. Significance was set at 0.05. The results will be presented within the context of the research questions.

The Sample

The study sample consisted of 70 SBGH cardiac surgery patients for the time period of January 2003 to May 2005. Of the 49 patients who had their cardiac surgery done with TSA during this time period, 35 provided signed consent to partake in the study. These 35 patients were then matched for surgeon (100%), procedure, gender, and age (within 10 years). Table 6 presents the matched person characteristics for gender and procedure. The matched person factor of age is included in Table 7. The Fisher's exact test was used to make inferences about sample differences in the nominal data when expected frequencies were less than 5. For the larger group cell sizes in the number of grafts comparisons, chi-square analysis was applied. Thus, the final study sample consisted of 35 TSA patients who were matched with 35 GA patients. The goal of the matching was to achieve homogenous samples and thus, strengthen the comparisons of the study outcomes.

Table 6.

Matched Person Factor Baseline Categorical Descriptors of Sample (N=70)

Characteristic	TSA		GA		Probability	
(%)	n	(%)	n	(%)	p-value	Sig.
Males	31	(88.6)	30	(85.7)	.72	N/S
Females	4	(11.4)	5	(14.3)	.73	N/S
No. grafts					.53*	N/S
≤ 2	12	(34.3)	12	(34.3)		
3	14	(40.0)	11	(31.4)		
4	9	(25.7)	8	(22.8)		
≥5	0	(0.0)	4	(11.4)		
Radial artery harvest	4	(11.4)	5	(14.7)	.73	N/S
Aortic valve replace	4	(11.4)	4	(11.4)	1.00	N/S
Mitral valve replace	3	(8.6)	3	(8.6)	1.00	N/S
Mitral annuloplasy	1	(2.9)	1	(2.9)	1.00	N/S
Redo surgery	1	(2.9)	1	(2.9)	.50	N/S

Note. Fisher's Exact Test
*Chi-Square value for group= 4.419 df= 0.22

Due to the relatively small number of surgeries from the ORSOS database that could be matched on all of these characteristics, surgeon was a priority match, then procedure, age, gender, and date of surgery. Five surgeons performed all procedures and were matched 100% of the time. Only 3 matched pairs had an age difference of ≥ 10 years. Due to the relatively small volume of cardiac surgery cases done at SBGH, controlling for the variables of surgeon, procedure, gender, age, and approximate date of surgery, was difficult. If, for example, the best match of the TSA with 4 CABGs, was similar in all variables except that the GA patient had had 3 CABGs, that patient would have been recruited. To eliminate researcher bias, the number of grafts was selected to advantage the GA group. For example, the TSA patient would have had 4 grafts, and the matched pair GA patient would have had 3 grafts. Both CABG and valve repair/replacement patients were included in the study. The GA group was selected to match the TSA group as closely as possible, using the type of procedure, specifically CABG and type of valve replacement or repair. Eight valve surgeries were included in the study; four were combined valve replacements and CABG. One redo operation was performed in the TSA group and specifically matched. Due to the small number of women who had valve surgery, one less female was included in the TSA group than the GA group. Although priority was given to matching for surgeon, procedure, gender, and age, only 4 matched pairs had surgery dates that were greater than 3 months apart.

Analysis of Research Questions

Question One

What are the person factors of the study cohort?

Person factors were operationalized as the preoperative and intraoperative factors that may influence the postoperative outcomes (See Tables 3 and 4). Person factors were retrieved from the charts in the patient history and physical examination, which are completed prior to cardiac surgery. Non-modifiable person factors included basic demographic data such as gender and age. Smoking is an example of a modifiable person factor (Mitchell et al., 1991). Person factors that were controlled during the matching process included; surgeon, procedure, gender, and age and approximate date of surgery (within 3 months).

Baseline characteristics of the 2 groups were analyzed and compared using parametric, paired ANOVA. Variation between groups was contrasted to variation within groups. The F-test takes this pairing into account and is equivalent to the paired t-test. A summary of the mean values (□), standard deviations (SD), and ANOVAs of the continuous data are presented in Table 7. There were no significant differences between the groups that could affect the interpretation of results with respect to age, height, weight, body mass index (BMI), cross clamp minutes (x clamp min.) or CPB minutes.

Table 7.

Comparison of Person Factor Baseline Continuous Variables of the Two Groups (N=70)

Characteristic	**TSA(□)**	**SD**	**GA(□)**	**SD**	**f-value**	**df**	**p value**
Age (years)	64.4	10.8	64.4	10.3	0.0	34	.947
Weight (kg)	85.5	13.9	87.3	14.6	0.28	34	.601
Height (cm)	167.5	19.3	171.1	7.3	1.21	34	.279
BMI	33.3	2.3	29.8	4.9	0.77	34	.387
X clamp min.	78.7	40.1	79.0	33.9	0.0	34	.966
CPB min.	114.9	50.6	118.9	44.9	0.27	34	.069

Note. ANOVA

Specific baseline categorical person factor results are provided in Table 8. For the nominal and ordinal data with expected frequencies less than 5, the non-parametric, Fisher's exact test was used to make inferences about sample differences. For the larger group cell sizes in the number of grafts comparisons, chi-square analysis was applied. There were no significant differences between the groups in the preoperative person factors of smoking, hypertension, diabetes, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), preoperative myocardial infarction (MI), class four angina, ejection fraction, or chronic atrial fibrillation. Descriptors of medication use, including β-blocking agents, lipid lowering agents, angiotensin converting enzymes (ACE) inhibitors and diuretics were also non-significant.

Table 8.

*Comparison of Person Factor Baseline Categorical Variables of the 2 Groups (N=70)**

Characteristic (%)	TSA n	TSA (%)	GA n	GA (%)	p-value	Sig.
Smoker					[1] .69*	N/S
Never	15	(42.8)	11	(33.3)		
Previous	16	(45.7)	18	(54.5)		
Current	4	(11.4)	3	(9.0)		
Hypertension	24	(68.5)	25	(71.4)	1.00	N/S
Diabetes	11	(31.4)	7	(20.0)	0.41	N/S
Asthma	1	(2.9)	0	(0.0)	1.00	N/S
PVD	4	(11.8)	2	(5.7)	.42	N/S
COPD	3	(8.6)	3	(8.6)	1.00	N/S
Other lung disease	2	(5.7)	0	(0.0)	.49	N/S
CVA/TIA	0	(0.0)	3	(8.6)	.23	N/S
Renal disease	8	(22.9)	7	(20.0)	1.00	N/S
CHF history	8	(22.9)	7	(20.0)	1.00	N/S
CHF current	3	(8.5)	2	(5.7)	.64	N/S
Preop MI					[2] .34*	N/S
≤3 months	10	(28.6)	12	(34.3)		
3-6 months	0	(0.0)	3	(8.6)		
6-12 months	2	(5.7)	1	(2.9)		
Class IV angina	7	(20.0)	8	(27.6)	1.00	N/S
Ejection fraction					[3] .53*	N/S
>60%	17	(48.6)	18	(51.4)		
40-60%	10	(28.6)	13	(37.1)		
21-39%	7	(20.0)	4	(11.4)		
<20%	1	(2.9)	0	(0.0)		
Chronic atrial fib.	3	(8.6)	3	(8.6)	1.00	N/S
β Blocker	26	(74.3)	23	(67.6)	.60	N/S
Digoxin	2	(5.7)	0	(0.0)	.49	N/S
Ca Channel blocker	7	(20.0)	7	(20.0)	1.00	N/S
Lipid lowering agents	20	(57.1)	24	(68.6)	.45	N/S
Oral Hypoglycemic	9	(25.7)	4	(11.4)	.22	N/S
Insulin	1	(2.9)	0	(0.0)	1.00	N/S
ACE inhibitors	18	(51.4)	20	(57.1)	.81	N/S
Angiotensin II	2	(5.7)	2	(5.7)	1.00	N/S
Diuretics	13	(37.1)	11	(31.4)	.17	N/S

Note. Fisher's Exact Test * Chi-square value for group [1]Smoker, df=2, Chi-square= .743, [2]Pre op MI, df=3, Chi-square= 3.896, [3]Ejection fraction, df= 3, Chi-square= 2.238

In summary, the typical patient in the study cohort was a male, in his 6^{th} or 7^{th} decade of life, with hypertension, a history of a previous MI with relatively preserved LVEF, undergoing 2-3 CABG surgery. The majority of patients had co- morbidities of hypertension, moderate obesity, and smoking. Common medical therapy included: β Blockers, lipid lowering agents, and ACE inhibitors. Because there were no significant statistical differences between the two groups, we did not expect these variables to confound the analyses of the primary research questions.

Question Two

Are the person factors predictors of surgical outcomes?

Surgical outcomes for this study included evidence of the pathophysiological response to surgical stress. Although, due to the small sample size, there was insufficient power to address this question using multivariate analysis, correlational analyses were applied to the data to identify the univariate strength of the relationships between the person factors and surgical outcomes. The type of analysis was determined by the type of data measurement. Fischer's exact test was used for nominal data comparison; Kruskall-Wallis (KW) test was used to compare ordinal data ranks between the groups, Spearman's correlational coefficients were used to compare skewed data (see Table 9).

Table 9.

Person Factor Correlates of Surgical Outcomes*

Person Factor	*Outcome*	*Test*	*Statistic*	*df*	*p-value*
↑ Cross Clamp Time	↑ Time to Extubation	Spearman	0.300		.012
	↑ Postoperative LOS	Spearman	0.289		.020
↑ CPB Time	↑ Time to Extubation	Spearman	0.306		.014
	↑ Postoperative LOS	Spearman	0.352		.003
↑Number of Grafts	↑ Vasopressor Duration	KW	16.598	3	.001
	↑Creatinine ≥ 50% preop	KW	15.079	3	.002
Valve Replacement	↑ Vasopressor Duration	KW	14.303	3	.002
	↑Creatinine ≥ 50% preop	KW	16.656	3	.002
Female Gender	↑ Time to up in Chair	KW	6.558	1	.010
	↑ LOS SICU	KW	.029	1	.029
↑ Age	↑ LOS SICU	Spearman	.265		.030
	↑ postoperative LOS	Spearman	.547		<.0001
	↑ Vasopressor Duration	Spearman	.446		<.0001
	↑ Time to up in Chair	Spearman	.241		.048
↑ BMI	↑ Time to Extubation	Spearman	.249		.038
	↑ Time to O_2 per n/p	Spearman	.285		.175
Diabetes	↑ incidence vasopressor	Fisher's			.008
	↑Creatinine ≥ 50% preop	KW	5.984		.014
COPD	↑Creatinine ≥ 50% preop	Fischer's			.019

Lower Ejection Fraction	↑Creatinine ≥ 50% preop	KW	11.062	3	.014
Pre op MI	↑Creatinine ≥ 50% preop	KW	8.657	3	.034
Class IV Angina Class	↑Time to O_2 5l/NP	KW	10.946	1	.001
	↑ Duration of Inotropes	KW	7.567	1	.006
	↑ Number on Inotropes	Fischer's			.008
	↑ Time to Extubation	KW	3.909	1	.048
CHF History	↑ Duration of Inotropes	KW	5.033	1	.025
CHF Current	↑ Duration of Inotropes	KW	22.096	1	<.0001

Note. KW=Kruskall-Wallis test (H/X^2 statistic), Fischer's= Fisher's Exact test, Spearman= Spearman's Rank Correlational Coefficient (r value statistic)

Question Three

What are the perioperative pathophysiological surgical stress responses of TSA and standard (GA) in cardiac surgery patients?

Because of the small cell sizes and the nature of the data, Fisher's exact tests were utilized to determine if there were significant differences in the complication rates between the two groups. A comparison of complications for the TSA and GA groups is presented in Table 10.

Table 10.

Comparison of Complications (N=70)

	TSA (n)	%	GA (n)	%	p-value
Postoperative MI	0	(0.0)	1	(2.8)	1.0
New onset atrial fibrillation	11	(31.4)	13	(37.1)	.801
Re-operation for bleeding	1	(2.8)	6	(17.1)	.055
Required blood product transfusion	11	(31.4)	8	(22.8)	.592
Vasopressor support SICU	17	(48.6)	23	(65.7)	.227
Inotrope support SICU	3	(8.6)	7	(20.0)	.306
Sternal dehiscence	0	(0.0)	0	(0.0)	1.0
Renal failure requiring dialysis	1	(2.8)	0	(0.0)	1.0
↑ Serum creatinine $\geq$ 50% preop value	2	(5.7)	6	(17.1)	.151
Respiratory failure requiring reintubation	1	(2.8)	2	(5.7)	1.0
Significant pleural effusion	5	(14.3)	5	(14.3)	1.0
Paralytic ileus	0	(0.0)	0	(0.0)	1.0
Cerebral vascular accident/ TIA	0	(0.0)	0	(0.0)	1.0
Postoperative confusion	2	(5.7)	3	(8.6)	1.0
Incisional leg infection	0	(0.0)	1	(2.8)	1.0
In hospital death	0	(0.0)	1	(2.8)	1.0
Neuraxial hematoma	0	(0.0)	0	(0.0)	1.0

Note. Fisher's exact test

In summary, new onset atrial fibrillation requiring treatment, blood loss requiring transfusion, hemodynamic instability requiring postoperative vasopressor requirement, and significant pleural effusions noted as hindering respiratory function were the most common complications that occurred in the study cohort overall. There were no statistically significant complication rate differences between groups. However, the re-operation for bleeding was approaching significance. No patient was suspected of or diagnosed with a neuraxial hematoma.

Question Four

What is the efficacy of TSA compared to standard GA alone for cardiac surgery?

Efficacy describes the ability of a technique to do more good than harm; it describes the therapeutic potential of a technique (Tugwell et al., 1986). This question was addressed by comparing the differences in the group pathophysiological variables and the analgesia used to provide patient comfort.

There were no significant differences between the groups with respect to the amount of chest tube losses over the first 6 hour period. The TSA group had a mean chest tube loss of 565 milliliters (mls) with a SD of $\pm$ 355 mls. The GA group had a mean chest tube loss of 502.9mls with a SD of $\pm$ 386 mls. Chi- square analysis compared groups for blood product usage, and found no significant differences between the groups. However, there was a trend for more TSA patients (11 versus 8) to require a blood transfusion. One TSA patient required postoperative dialysis for renal failure.

Although multivariate analysis was not feasible due to the small sample size, the overall trend was that TSA patients experienced fewer complications (see table 10). The re-operation for bleeding rate was approaching statistical significance. After adjusting for sample size, further statistical analysis and odds ratio calculation, determined that the GA group was 7.3 times more likely to have a re-operation than the TSA group. TSA patients had a minor trend toward fewer complications in 11 out of 18 categories including: postoperative MI, new onset atrial fibrillation, re-operation for bleeding, vasopressor support in SICU, inotrope support in SICU, postoperative requirement for intraaortic balloon pump, serum creatinine increase to twice preoperative level, respiratory failure requiring reintubation, postoperative confusion, incisional leg infection, and in hospital death. TSA and GA patients had the same complication rates in regards to sternal dehiscence, paralytic ileus, significant pleural effusion, CVA, and neuraxial hematoma.

The efficacy of TSA was further operationalized to include the ability of TSA to provide more optimal patient comfort than GA. It was postulated that TSA could reduce the effects of operative pain stimuli and subsequent postoperative analgesia requirements. Table 11 presents a comparison of the interval mean amounts of morphine administered to the 2 groups.

Table 11.

Comparison of IV Morphine Usage in Total Milligrams per Time Period of the Two Groups (N=60)*

Time (hours postop)	**TSA(□)**	SD	**GA(□)**	SD	F value	df	P value
0-6	3.10	3.94	10.91	4.70	55.65	29	<.0001
6-12	.83	1.68	5.21	3.90	30.68	29	<.0001
12-18	1.60	2.59	3.70	2.05	12.76	29	.001
18-24	1.16	1.83	2.90	3.36	8.22	29	.008
24-30	1.43	2.13	2.36	2.39	2.37	29	.134
30-36	.96	1.51	1.33	2.12	.57	29	.458
36-42	.41	.85	1.13	1.79	3.64	29	.066
42-48	.40	1.00	1.16	1.66	4.76	29	.037
Total	9.91	9.31	28.73	11.32	50.74	29	<.0001

Note. *ANOVA

Over the first 24 hour postoperative period, morphine usage was significantly different between the two groups, with the TSA group receiving less than the GA group. The TSA group total morphine usage was significantly less than the GA group overall ($p<.0001$). Four people in the GA group were given Fentanyl instead of morphine. Because the opioid that was compared was morphine, it was decided to exclude the patients who received fentanyl from the analysis. Matched pair analysis necessitated the exclusion of these matched pairs. The pair in which an early postoperative death occurred was also excluded from the analysis. There were no significant differences between the groups in total Tylenol suppositories, Tylenol#3, plain Tylenol, or Percocet usage. Mean Tylenol #3 tablet usage in the TSA group and the GA group were essentially the same (□ =13 ±7).

In summary, there appeared to be a minor trend toward reduced complication rates in the TSA group. The low complication rates of both groups and the small sample size prohibited multiple regression analysis. There was no evidence of any harm elicited by the TSA procedure. There was significantly less postoperative intravenous morphine use in the TSA group.

Question Five

If there is a difference in the pathophysiological surgical stress response outcomes between the two samples, is the difference predictive of efficiency?

Efficiency describes the cost benefit in terms of measurable outcomes such as LOS (Halpin et al., 2003). Outcome variables that were operationalized to describe efficiency included length of endotracheal intubation, LOS in the SICU, and the hospital. Due to early postoperative death of one patient in the GA group, this matched pair was excluded from the subsequent analysis.

The duration of postoperative endotracheal intubation was significantly shorter in the TSA group compared to the GA group ($p<.0008$). On average, the TSA group was extubated 4.9 hours earlier than the GA group. The median difference between the two groups was 1.5 hours, indicating that, on average, the TSA group was extubated 1.5 hours prior to their matched pair. Chi-square analysis was used to make inferences about differences in group proportions of this nominally measured data. TSA patients were significantly more likely to be extubated in the operating room than the GA group. Table 12 reports the time to extubation by postoperative time periods.

Table 12.

Comparison of Time to Extubation (N=68)*

	TSA		*GA*		X^2	df	p-value
	n=	%	*n=*	%			
Extubated in OR	28	(82.4)	10	(29.4)	18.65	2	<.0001
< 4 hours	30	(88.2)	19	(55.9)	9.24	1	.0098
4-12 hours	3	(8.8)	8	(23.5)			
> 12 hours	1	(2.9)	7	(20.6)			

*Note.** Chi-square analyses

Length of stay in the SICU was not statistically different (ANOVA: F = .66, df = 33, h p= .422). The mean SICU LOS for the TSA group was 22.4 hours with a SD of 6.3 hours. The GA group had a mean LOS of 21.3 hours with a SD of 5.2 hours.

The hospital LOS was not statistically different between the two groups. However there was a trend toward a reduced mean LOS for the TSA group as outlined in Table 13. In the TSA group, the mean total number of hospital days until discharge was 3 days less than that of the GA group. 17 out of 34 or 50% of the TSA sample was discharged ≤ 5 days postoperatively compared to 11 out of 34 or 35% of the GA group (p=.33). The TSA median LOS was 5.5 days compared to 6.0 days in the GA group.

Table 13.

Postoperative Hospital Length of Stay (N=68)

	Mean LOS (days)	SD (days)	f-value	df	p value
			1.67	33	.205

TSA	7.5	4.0
GA	10.4	11.9

Note. ANOVA

In summary, efficiency, as measured by reduced length of endotracheal intubation has been substantiated. The TSA group demonstrated a trend toward reduced hospital LOS. As operationalized in this study, TSA demonstrated the ability to enhance cost efficiency.

Summary

This chapter presented the findings of the research questions, which were developed to describe, explore, and compare the cardiac surgery outcomes of TSA and the "standard cardiac anesthetics" (GA). Various statistical approaches including, descriptive statistics (percentages, means, and standard deviations) were applied to the demographic and outcome data. Demographic, intraoperative, and postoperative data were compared between the two groups, using paired t tests, Chi-square tests, Fisher's exact test, Kruskall-Wallis test, ANOVA, and Spearman correlation coefficients. Significance was set at $p \leq 0.05$.

Person factors, which described the two samples, were presented. Person factors that may serve as significant predictors of surgical outcome were also noted. There were no statistical differences in person factors between the matched groups. Thus, it is unlikely that these factors confounded the primary research comparison questions. Matched pair analysis was applied to a number of the variables including time to extubation, SICU LOS, and postoperative hospital LOS. Pathophysiological surgical stress responses that mirror surgical risk and morbidity were provided. There were no statistically significant differences between the complication rates of the two groups.

Data were presented to describe the efficacy and the efficiency of TSA. Efficacy of TSA, as operationalized by analgesic use, was substantiated. Significantly shorter extubation times and a trend toward reduced mean postoperative hospital LOS in the TSA group provided evidence to support the efficiency of TSA.

Chapter VI: Discussion of Findings

The discussion of the study findings presented in chapter five will be discussed in the context of relevant literature and will focus on the application of the conceptual model, and the five primary research questions. These questions addressed the primary research hypotheses that were used to direct the exploration of the TSA cardiac surgery outcomes, with comparisons to the standard anesthetic (GA) cardiac surgery outcomes. An overview of the appropriateness of the Human Response to Health and Illness Model (HRM) as the conceptual framework for this study is provided. With the goal of encouraging further exploration of the ability of novel anesthetic adjuncts to improve surgical outcomes, this pilot study's limitations and implications in respect to nursing education, nursing implications for practice, and future research will be discussed in the subsequent sections.

Discussion of Research Questions

Question One

What are the person factors of the study cohort?

This research question was developed to describe the overall sample, as well as to compare the person factors in the 2 groups. This pilot research study consisted of a relatively small proportion of the total number of cardiac surgery cases that are performed at one hospital. Therefore, it was important to determine if the sample was representative of the cardiac surgery population, not only at SBGH, but also in the broader context. Approximately 746 cardiac surgeries were performed at SBGH in 2005. Of that number, 24.4% were females and 75.6% were males. The majority of procedures were CABG, with 20% of surgeries being valve replacements. Radial artery bypass grafts were used in 82 patients. The mean age of the patient population was 64 years (ORSOS Data Bank, SBGH).

Overall, the percentage of females included in this study was lower than that of the general cardiac surgery population at SBGH (12.8% versus 24.4%). Although this may have occurred randomly, it is also possible that the presentation and treatment of women excluded them from becoming TSA candidates. For example, one may speculate that presenting women were anticoagulated or had other exclusion criteria for TSA.

The number of patients with valve replacements who were included in the study was similar to the total percentage of valve replacements performed (20%) at SBGH. The number of radial artery harvest grafts was also representative of the SBGH cardiac surgery population. The mean age of the study sample was similar to that of the general cardiac surgery population (64 years). Thus, the sample of this pilot study appeared to be fairly representative of the cardiac surgery population at SBGH.

In the broader context, other cardiac research studies report similar person factors. Kowalewski et al. (1994) reported a mean age of 62 years with 16 % being female. Scott et al. (2001) reported a mean age of 59 with a 13 % female inclusion. Lee et al. (2003) reported a mean age of 61 years with an 11% female content. However, these cited studies did not include valvular heart surgeries; therefore these percentages are not directly comparable.

Although, surgeon, procedure, age, gender, and approximate surgical date were the only variables used in the matching, the two samples were also well matched on numerous additional person factors (see Tables 6 and 7). It is likely that controlling for these variables facilitated the goal of homogeneity of the 2 groups in terms of the co-morbidities described as person factors. The data analysis identified that there were no statistically significant person factor differences between the two groups. Thus, it would appear that these 4 person factors were central to achieving the goal of homogeneity in the 2 groups. The similarity of the person factors between the groups added strength to the ability to compare the two groups; as well, the similarities of the 2 groups to the general cardiac surgery population contributes to the generalizability of the study findings to the broader population of cardiac surgery patients

Question Two.

Are the person factors predictors of surgical outcomes?

Surgical outcomes for this study included the measurement of outcomes that could provide evidence of the pathophysiological response to surgical stress.
This research question was developed to identify the significant predictors of surgical outcomes, independent of type of anesthetic intervention. For the purposes of this pilot study, a broad range of person factor variables were collected. Guided by the HRM, operationalization of the variables determined the specific data collected. Because there were no statistical differences in person factors between the two groups, we did not expect these factors to confound the primary research questions.

Due to the small sample size and the large number of person factor variables, there was insufficient power to address this question using multivariate analysis. However, Kruskall-Wallis, Chi-square, Fisher's exact test, and Spearman correlational coefficients were applied to the data to identify univariate relationships between the person factors and surgical outcomes. The results of this univariate analysis did, however, provide food for thought.

The results of the analysis did lend support to the decision to control for the variables of surgeon (100%), procedure, gender, and age (within 10 years). The matched control of these variables served to strengthen the rigor of the group comparisons. For example, the skill of the surgeon can affect the duration of cross clamp time and CPB time, which were predictors of postoperative length of stay and duration of endotracheal intubation. Previous research by Wen, et al. (2006) concluded that the skill and experience of the individual surgeons is a more critical factor for patient outcome than either hospital equipment or surgical teams.

The decision to match for procedure is supported by the results that indicated a significant correlation between the number of grafts as well as the valve repair procedure to longer vasopressor duration and increases in serum creatinine to 50% or greater levels above the preoperative baseline. The duration of vasopressor usage and the rise in serum creatinine are indicators of pathophysiological decompensation. The type of procedure was matched to attempt to control for severity of disease, duration of CPB and general surgical risk. It is well known that cardiac valve replacements and combined valve replacements plus CABG procedures are higher risk than elective CABG (Aggarwal et al., 2006).

Female gender correlated significantly with the length of time until the patient was up in chair and the duration of LOS in SICU. That is, females were not ambulated as quickly as males and tended to stay in SICU longer than their male counterparts. Both of these correlates could be reflective of postoperative stability and recovery. It is possible that other correlations with gender were not statistically significant partly due to the small number of women in the sample. However, previous research has indicated that women experience postoperative complications such as: myocardial infarctions, low cardiac output syndromes, and respiratory dysfunction more frequently than men (Miller, 1998). Miller and Grindel (1999) identified differences in symptom presentation, gender bias in referral for treatment, and altered preoperative profile, which included more co-morbidities, as factors that negatively affect female gender cardiac surgery outcomes.

Age was correlated with LOS in SICU, postoperative LOS, vasopressor duration, and length of time until first up in chair. This is consistent with findings from previous studies. For example, octogenarians were found to have higher co-morbidities and mortality even after controlling for 16 potential confounding variables (Johnson, et al., 2005).

Although several of these research findings lend support for the decision to match samples, it is important to note that univariate analysis is not capable of independently predicting outcomes. Each subject could have numerous confounding variables. Strong correlation does not indicate a causal relationship between two variables. However, keeping in mind the purpose of the question, had the samples been significantly different in characteristics, the data from this question may have directed analysis with control for specific variables. The significant relationships highlighted in these analyses can provide insight for follow-up in future studies.

Question Three

What are the perioperative pathophysiological surgical stress responses of TSA and standard GA in cardiac surgery patients?

This research question addressed the purely descriptive component of the outcome evaluation of TSA and the "standard cardiac anesthetic" (GA) technique. The five overall most common postoperative complications that occurred in the study cohort were: new onset atrial fibrillation requiring treatment, blood loss requiring transfusion, hemodynamic instability requiring postoperative vasopressor requirement, and significant pleural effusions noted as hindering respiratory function.

The TSA study sample was relatively small and it was compared to a matched control GA group. The complication rates do not necessarily represent that of the entire population of SBGH cardiac surgery patients. However, as previously discussed, the study sample was relatively similar to that of the 2005 SBGH cardiac surgery patient population. Post cardiac surgery complications in the study cohort were also similar to those reported in the literature (Kowalewski et al., 1994; Scott et al., 2001).

In summary, the purpose of this question was simply to report the perioperative, pathophysiological surgical stress responses that occurred in each group. Further discussion, integrating possible links with the physiology and pathophysiological perspective, and comparing these findings between groups, as well as with previous research are included in the discussion of the subsequent two questions.

Question Four

What is the efficacy of TSA compared to standard GA alone for cardiac surgery at SBGH?

This research question was developed to describe the therapeutic potential of TSA. Identifying factors that impact on morbidity is important because the overall number or patients who require cardiac surgery continues to increase and cardiac programs consume a large proportion of health resources, most notably via the need for critical care and hospital beds. Thus, any techniques that facilitate a reduction in the overall incidence of complications will ameliorate postoperative recovery and benefit both individual patient's well being and the viability of the healthcare system overall (Scott et al., 2001). The relationship between efficacy and efficiency is close and interrelated. Reduced morbidity benefits both the patient and the cost to the healthcare system. For the purposes of this question, analysis of efficacy focused on the individual patient.

While there were no statistically significant differences in complication rates between the two groups, there were a number of possible clinically significant trends. The inability to reach statistical significance may have been influenced by the small sample size. Although not statistically significant, even a small trend in the reduction of complication rates can have clinical significance. As well, differences in the re-operation for bleeding variable did approach significance at p=.0548. Adjusting for sample size, the GA group was 7.3 times more likely to have a re-operation for postoperative bleeding than the TSA group. Scott et al. (2001) found a similar trend in their research. The mechanism for this is unclear; however, a decreased surgical stress response and subsequent more stable hemodynamic status would put less stress on new surgical sites.

Postoperative MI, new onset atrial fibrillation, re-operation for bleeding, vasopressor support in SICU, inotrope support in SICU, and postoperative requirement for intraaortic balloon pump are indicators of hemodynamic instability. The greater use of vasopressors in the GA group is a specific example of the effects of the ability of the surgical stress response to cause decompensation. The sustained surgical stress response, which burdens the cardiovascular system by increasing HR, myocardial contractility, and systemic vascular resistance, may result in hypertension, tachycardia, and dysrhythmias and may lead to myocardial ischemia in susceptible patients (Lubenow et al., 2001).

Based upon the assumption that TSA effectively attenuates the surgical stress response, the findings of this study support the results of previous research that examined surgical stress and interventions designed to attenuate it. For example, Hoar et al. (1980) found that the surgical stress response correlated significantly with deterioration of the circulatory status, as measured by elevated preload pressures and cardiac index depression. The study concluded that sympatho-adrenal activation is reflective of the stress response and is a potential cause of ischemic injury.

Previous studies have also reported support for the hypothesis that anesthetic procedures similar to TSA can reduce the negative hemodynamic effects of early activation of the surgical stress response. Liem et al. (1992 a) reported findings that supported the ability of high thoracic epidural with bupivicaine and sufentanil combined with general anesthesia to provide improved hemodynamic stability. Their study reported increased stroke volume, fewer inotrope and vasopressor requirement, and less myocardial ischemia requiring nitroglycerine treatment. The authors suggested that this hemodynamic stability with TEA during CABG may be due to the blockade of the cardiac accelerator fibers (T1-T5) and the sensory blockade, which prevented hemodynamic response to noxious stimuli. They also contended that lower than baseline heart rates combined with vasodilatory effects of TEA on stenosed arteries may explain why none of the TEA patients developed ischemic ECG changes during the pre CPB period.

Kowalewski et al. (1994) used an anesthetic technique that used supplemental subarachnoid bupivicaine and morphine. They reported a minimal hyperdynamic response to surgery and achievement of cardiac sympathectomy with their technique. They state that this controlled hemodynamic response may be an advantage of this novel anaesthetic technique

Lee et al. (2003), in a randomized, double blinded, controlled study of cardiac surgery patients (N=38), compared an IT bupivicaine (ITB) group to a control placebo group. Results further supported the ability of anesthetic procedures similar to TSA to attenuate the early surgical stress response. The ITB group had significantly less β receptor dysfunction. Results also revealed that serum markers of the stress response were significantly lower in the ITB group. A significant finding was that the ITB group had improved regional wall motion in the post intubation and the pre-CPB periods. There was a trend for improved left ventricular wall motion in the post-CPB period. The authors discuss the significance of this finding as being in keeping with previous work that reports the physiological benefits of cardiac sympathectomy, which include: relieved angina, improved ST segment depression, improved oxygen supply and demand ratio in ischemic myocardium, increased diameter of stenotic epicardial coronary arteries, and improved left ventricular function (Blomberg, Emanueslsson, & Ricksten, 1989; Blomberg et al., 1990; Klassen, et al., 1980; Kock, et al., 1990). These physiological benefits are likely to reduce the pathophysiological decompensation which would be manifested by hemodynamic instability indicators as operationalized in the current study.

The current research study demonstrated a trend for TSA to reduce the occurrence of postoperative peak increases of serum creatinine to levels that were greater than 50%

elevated above the preoperative values. In a previous prospective, randomized study of the potential benefits of TEA and analgesia in patients undergoing CABG, Scott and associates (2001) had a similar significant reduction in renal failure, as defined by a twofold increase in serum creatinine in the TEA group. Using a reduced significance in measurement criteria, the results of this pilot study demonstrated a similar trend. The exact mechanism in which TSA was able to achieve this remains unclear. However, a variety of underlying causes of ARF post cardiac surgery have been identified including: low cardiac output, acute tubular necrosis, multiple blood transfusions, renovascular emboli, preoperative contrast agents, nephrotoxic drugs, and prolonged CPB, (Bahar et al., 2005; Finkelmeier, 1995). It is possible that TSA has the ability to reduce the release of intrarenal angiotensin II, which causes afferent arteriolar constriction. This effect may improve renal blood flow and be of benefit to renal preservation. It is also possible that the stable hemodynamic course of TSA is protective and provides improved blood flow to organs including the kidneys. The pathophysiological mechanism of ARF is often one component of multi-organ failure and may be a part of low cardiac output syndrome and sepsis (Bahar et al, 2005).

The importance of the trend toward a decreased TSA group occurrence toward respiratory failure requiring reintubation, postoperative confusion, incisional leg infection, and in hospital death is more difficult to explain. The overall number of occurrences was exceedingly low and therefore, is difficult to interpret. The one in-hospital death in the GA group was a patient who had a history of a previous cardiac surgery. The cause of death was thought to be the extension of a recent preoperative MI. Future larger clinical trials of TSA may be able to demonstrate reduced MI rates as a reflection of the hypothesized benefits of TSA to improve oxygen supply and demand ratio in ischemic myocardium, increased diameter of stenotic epicardial coronary arteries, and improved left ventricular function.

There was no evidence that TSA incurred any harm to patients. In particular, no patients in this study were specifically investigated for, or diagnosed with, the complication of a neuraxial hematoma. This is an important finding as it lends support for the safety of the TSA technique. Previous research has identified the risk of neuraxial hematoma as being one of the barriers to epidural or intrathecal injection for cardiac surgery patient anesthesia and analgesia (Kowalewski et al; Lee et al., 2003; Scott et al., 2001). However, the literature also reflects questionable clinical judgments may have contributed to the only reported occurrence of this risk in the cardiac surgery population. Rosen et al. (2004) reported the occurrence of a postoperative epidural hematoma related to epidural anesthesia in a cardiac surgery patient. Multiple clinical risk factors, such as heparin infusion and thrombolytic alteplase injection were ignored. Postoperative thrombocytopenia further contributed to the derangement of the patient's coagulation system. The removal of the epidural catheter in the presence of impaired hemostasis may have contributed to further increase the bleeding.

Vandermeulen et al. (1994) concluded that knowledge of the pharmacological properties of the different anticoagulants in combination with strict patient selection, and awareness of the risks should enable enhanced safety of anesthetic practice without withholding anesthetic techniques from patients who would benefit from them.

The overall minor trend toward reduced complication rates in the TSA group is an optimistic finding that encourages future research to assess the efficacy of TSA. This contention is supported by research evidence. Ho et al. (2000) mathematically estimated the risk of a rare adverse event of neuraxial induced hematoma with a 95% confidence to be from 1:220,000 to 1:3,600 for spinal blockade. They stated that the acceptance of any technique into routine practice ultimately depends on the evidence that its associated risks can be justified in improved outcome measurements. They concluded that in the case of neuraxial hematoma due to regional blockade for cardiac surgery, there may be a sufficiently acceptable risk/benefit ratio to justify a large scale study on selected patients.

Efficacy can be further evaluated by measuring other potential benefits for the patient, such as patient comfort. The adequacy of pain control for cardiac surgery patients is paramount to both their physical and emotional recovery. Interventions that improve pain management are of benefit to the patient. According to the HRM, pathophysiological responses that move the patient toward decompensation should be the target responses for nursing interventions (Mitchell et al., 1991). It has been said that morbidity and mortality after major surgery occur in direct proportion to the level of physiologic response to surgical stress (Kehlet, 1993). It is possible that the trend in reduced complication rates is related to the ability of TSA to reduce the onset, intensity, and duration of the surgical stress response. The surgical physiological stress response occurs as a protective and adaptive mechanism, with the goal to achieve homeostatic balance. If the intensity and duration of the stimuli for the surgical stress response are reduced, the patient is more likely to be able to adapt to the surgical stress without pathophysiological decompensation.

Over the first 24 hour period, the TSA group total morphine usage was significantly less than the GA group ($p<.0001$). A significantly higher number of TSA patients were extubated in the operating room and the TSA group had a significantly reduced overall duration of endotracheal intubation compared to the GA group. There was one less patient in the TSA group that required reintubation for postoperative respiratory failure. These collective objective findings imply that TSA has the ability to enhance postoperative respiratory function. For example, postoperative respiratory recovery can be enhanced by the ability of the patient to deep breathe, clear secretions, circulate and produce surfactant, ventilate collaterally through the pores of Kohn, and adequately exchange oxygen and carbon dioxide. Recent research by Jacobsohn et al.(2005) supports the hypothesis that IT morphine (which is a component of TSA) can provide pain management and deep breathing benefits to cardiac surgery patients.

Because this was a retrospective study, it is impossible to assess pain scores. However, analgesic administration and pain assessment provided by the same group of nurses, in the same SICU, to both groups is a relatively objective data measurement that suggests that nurses subjectively and objectively assessed that the TSA patients were in need of less analgesia than the GA group.The HRM encourages inclusion of the "lived experience" of the patient in the assessment of outcomes. Because the pain experience is multifactoral and an individual experience for each patient, it is difficult to compare the "lived pain experience" of the two patient groups. Other studies have attempted to measure patient comfort by using patient satisfaction measurement scales. However, both Boulanger et al. (2002) and Jacobsohn et al. (2005) were unable to report any significant differences in patient satisfaction between analgesia groups. Both research groups reported overall high analgesic satisfaction scores and overall hospital satisfaction scores without significant differences between the groups. There remains a need for future research to better capture the "lived experience" of patients and to derive methods and tools that enable group experience comparisons.

In summary, this pilot study identified several trends in complication rates that lend support for the efficacy of TSA for cardiac surgery patients. To the individual patient who does not develop a life-threatening complication, the clinical significance of enhanced recovery is very real. An integrated review of the literature supports the findings of this research. Physiological and pathophysiological knowledge has been utilized to link the effects of the surgical stress response to outcomes. Specifically, the potential hemodynamic benefits of TSA have been presented in context of this study's findings and the findings of similar research. It is possible that the reduced surgical stress response is responsible for the stable hemodynamic course of TSA patients and consequent reduced trends in renal decompensation and the need for re-operation for postoperative bleeding. The results related to complications rates did not provide any evidence that TSA for cardiac surgery patients is harmful. Research both contending and supporting the likelihood of harm were summarized. Postoperative morphine administration was significantly less for the TSA group, which suggests that nurses assessed that their pain levels were lower than the GA group. Although this research cannot definitively conclude that TSA is efficacious, the findings do lend support to the efficacy of TSA in the cardiac surgery population.

Question Five

If there is a difference in the pathophysiological surgical stress response outcomes between the two samples, is the difference predictive of efficiency?

This research question was developed to assess the potential efficiency, or cost benefits of TSA. For the purpose of this question, cost referred to the amount of resource utilization/money spent by the facility and healthcare system, and not to negative, individual patient outcomes. The financial burden of cardiac surgery procedures are influenced by complexity of care, severity of illness, and length of hospitalization (Parsonnet, Bernstein, & Gera, 1996). A review article by Lee and Jacobsohn (2000) concludes that there is no indication for routine postoperative cardiac surgery mechanical ventilation. Early extubation has been associated with significant financial savings. In a random controlled trial of CABG patients (N=100), Cheng, Karski, Peniston, Raveendran, et al. (1996) concluded that early extubation reduced ICU costs by 53% and total costs per CABG patient by 25%. Furthermore, elective surgery cancellations were significantly reduced. Therefore, for the purposes of this study, variables that were operationalized to describe efficiency included length of endotracheal intubation, LOS in the surgical ICU, and hospital.

In the current or this study, the length of endotracheal intubation time postoperatively was significantly shorter in the TSA group compared to the GA group. A significantly greater number of patients in the TSA group were extubated in the operating room as compared to the GA group. Thus, clearly TSA did not prolong extubation. On average, the TSA group was extubated 1.5 hours prior to their matched pair.

These findings are consistent with previous research studies. For example, Liem et al. (1992 b) compared TEA to GA (N=54) and reported earlier awakening, earlier resumption of spontaneous breathing, and earlier extubation times. The results of a meta-analysis by Liu et al. (2004) indicated that TEA significantly reduced the risk of pulmonary complications as well as decreased the duration of endotracheal intubation. This is further substantiated by Jacobsohn et al. (2005) who examined the efficacy of low-dose IT morphine on extubation times and pain control after cardiac surgery. They concluded that low dose IT morphine did not delay early extubation.

The need or perceived need for mechanical ventilation necessitates the requirement for SICU stay, mechanical and manpower resources including physician coverage, a critical care nurse, and respiratory therapist. With the current fiscal challenges that cardiac surgery and postoperative recovery places on the healthcare system, any intervention that can reduce the burden without diminishing the quality of healthcare is of great value. Although in this study, the actual financial cost saving to the facility and healthcare system was not calculated, the significantly reduced number of TSA patients who required postoperative SICU ventilation, did serve to provide savings in the comprehensive costs of ventilation.

Length of stay in the SICU was not statistically different between the two groups. It has been postulated that developments in postoperative care of surgical patients has not kept pace with intraoperative developments that may enhance physiological stability soon after bypass (Lee & Jacobsohn, 2000). It is possible that the reason why stable cardiac patients were not transferred out of the SICU earlier is simply that it is not the current hospital unit practice. Delayed transfer to the ward may have been confounded by factors that are not related to the patient's readiness for transfer. An example of factors hindering transfer include: a shortage of beds to transfer into, caused by various factors such as nursing staff shortages and delays in housekeeping and room preparation.

In the TSA group, the mean postoperative hospital LOS was 3 days less than that of the GA group. Perhaps due to the LOS variability and small sample size, this difference was not statistically different. This trend may also have been buffered by the current routine practices of the unit, such as postoperative monitoring in the step-down unit for 24 hours or more. Based on these findings, a power analysis was completed; the findings indicated that a sample size of 161 pairs would be required to establish a statistically significant difference of 2.8 days. Therefore, future research should aim for a sample of at least 322 participants.

Previous research by Boulanger et al. (2002) of sixty-two elective cardiac surgery patients in a prospective, randomized, partly-blinded study designed to evaluate the use of IT morphine followed by patient controlled analgesia was similarly underpowered and unable to report a significant reduction trend in hospital LOS. It is possible that with increased experience in caring for TSA cardiac surgery patients, combined with evidence-based outcome research, healthcare providers will become more adept at maximizing the potential efficiency of TSA.

In summary, efficiency of TSA was supported by statistical significantly shorter length of endotracheal intubation time and a trend toward a decreased hospital LOS. The trends toward decreased rates of postoperative complications as discussed in question 4 are an important precursor to the potential ability of TSA to provide efficiency. Postoperative complications are known to increase SICU and postoperative hospital LOS.

This study's trends toward reduced postoperative complication rates further supports the hypothesis that larger trials combined with system supports, such as available postoperative ward beds, would have the potential to establish significantly decreased SICU and postoperative hospital LOS, and overall improvement in patient outcomes.

Summary

Five research questions have been addressed. The questions related to person factors served to describe the sample characteristics of both groups. Matching for surgeon, procedure, age, and gender, and approximate surgical date (3months) was an effective strategy to establish a relatively homogeneous sample. There were no significant differences in person factors between the groups, therefore, it is unlikely that these factors confounded the ability to achieve the primary goal to describe, explore, and compare the cardiac surgery outcomes of TSA with the "standard cardiac anesthetic" GA technique.

The perioperative pathophysiological surgical stress responses of each group were reported. This pilot study identified several trends in complication rates reduction that lent support for the efficacy of TSA for cardiac surgery patients. Postoperative morphine administration was significantly less for the TSA group, which suggests that their pain scores may have been lower, and which, in turn, supports the contention that the patient benefits with this procedure. As well, the results related to complications rates did not provide any evidence that TSA for cardiac surgery patients is harmful. Analysis that was related to healthcare system efficiency was significant, as reflected in the finding that TSA appears to reduce postoperative endotracheal intubation time. There was also a trend toward a reduction of hospital LOS in the TSA group.

In summary, this pilot study demonstrates that TSA has the potential to positively enhance patient recovery from cardiac surgery. This research identifies: a trend in reduction of complication rates; a significant reduction in postoperative narcotic analgesic requirement, and earlier extubation as positive outcomes of TSA. I believe that TSA shows the potential to be proven to be efficacious and efficient for cardiac surgery patients.

The Conceptual Framework Revisited

The use of nursing theory enhances the articulation and determination of the focus of nursing research and enables specific goals and outcomes to be measured (McEwan, 2002). The Human Response to Health and Illness Model was used to guide the entire research process of this study, from the conceptualization of variables to data analysis, and the discussion. As outlined in Chapter 2, the HRM is a biopsychosocial model that includes the physiologic, pathophysiologic, behavioral, and experiential perspectives (Mitchell, Gallucci, & Fought, 1991). For the purposes of this research, the HRM model was adapted to include the specific clinical therapeutic of TSA and the surgical stress response (See Figure 4). The revised HRM was a good fit with this thesis research.

For this research, the stress stimulus was the surgical procedure and the response to the surgical procedure was the surgical stress response. This research essentially evaluated the impact of a clinical therapeutic intervention, namely TSA, on the outcomes of the surgical stress response. The hypothesis was that decreasing or attenuating the surgical stress response may decrease the severity and duration of the stressor and facilitate adaptation, thus preventing the progression to the stage three, exhaustion phase. Because outcome evaluation of an intervention, such as TSA, can have broad outcome implications, the revised HRM served to provide organizational structure to the nursing science application in this research. Each step of the research process was guided by the constructs of the HRM, including the literature review and the operationalization of variables.

Thus, the overall performance of the modified model was satisfactory in guiding the research process. The HRM facilitated the review and investigation of the physiologic and pathophysiological responses, and provided a foundation for understanding the concepts to be studied. Assessment of patient characteristics was gleaned from the outline of person factor concept in the HRM. Identification of modifiable and non-modifiable person factors directed the researcher to control for variables that would strengthen the comparisons of the research groups.

Environmental factors were assessed by including the availability of human resources of the anesthesiologist who provides TSA. The environmental factor of surgeon selection or availability was also controlled. The premise of the model is that failure of the physiological regulatory system's ability to maintain homeostasis results in the pathophysiological responses, which are manifested as decompensation and illness. Accordingly, the interrelationships between each component of the model guided the researcher in multiple interacting facets of inquiry

One drawback of the model is that its terminology may make reading the study more difficult. To enable the reader to comprehend the concept terminology of the model, it was deemed necessary to repeatedly define these terms throughout this written document.

Because the research had a retrospective design, it was not possible to include the patient's experiential perspective. However, the utilization of the HRM facilitated the outcome analysis of numerous variables that will establish the foundation for future research, including the exploration of the experiential perspective. This was reflected in the findings related to postoperative narcotic usage, which substantiated the need for qualitative research, which would provide more explicit information related to the pain experience in this population.

Overall, this researcher found that the HRM guided the development and implementation of all facets of this research, from theoretical questions through design, operationalization of variables, data collection, analysis, and interpretation of results. The researcher would not hesitate to use this conceptual framework in subsequent research.

Limitations of the Study

In this pilot study, a retrospective, descriptive correlational design was employed to describe and explore the outcomes of the TSA technique and to compare these outcomes to a matched control sample who received GA. Although the study had numerous strengths, there were also limitations. The major limitations of this study included: its retrospective design, person factor data collection, small sample size, presence of unaccounted for intraoperative variables, and the ease of use of the data collection tool.

The retrospective design did not permit the investigation of experiential factors or the lived experience of the patients. The research relied on data that was previously recorded and was subject to incomplete data sets and recording error. For example, inconsistencies in drug recording dosages and durations, such as those of vasopressors, necessitated the use of drug duration and ordinal data, rather than more specific total dosages in microgram per kilogram per minute. Missing data contributed to the study's limitations. For example, because of the inconsistency in Troponin T lab work requests and subsequent sporadic reporting of levels, data analysis of this variable was not feasible.

Although a prospective cohort would be the ideal, delaying research outcome evaluation through attempts to recruit participants and conducting the research over a prolonged period of time prospectively, would impede progress or changes that could be made in the current TSA protocol. Furthermore, an advantage of this retrospective design was that the provision of care had been completed on these subjects and there was no possibility of this research biasing or altering the standard care.

The sample size was small and therefore there was insufficient power for more sophisticated, multivariate analysis of the data. In an already small TSA sample, the requirement to obtain consent for the retrospective data analysis was a deterrent to patient recruitment and study participation. The reasons for excluded participants were not fully explored, but did include reasons such as: changes of address, deterioration of medical condition, and personal choice.

In an effort to offset the disadvantage of the small sample size, the matching strategy was utilized. No other similar published studies have utilized matched control subjects. The matching of the two the samples strengthened the ability to compare the two groups.

Because of the small sample size, it was not possible to match cohorts on the basis of the individual anesthesiologist who provided the anesthesia to the GA group. The TSA procedure cases received their anesthetic from a single practitioner. The GA group received their anesthetic by more than one practitioner. It is likely that there was variation in the "standard cardiac general anesthetic" provided between different cardiac anesthesiologists. Future, randomly, controlled studies should control for anesthesiologist practitioner and further standardize the general anesthetic provided to the GA group.

The excel data collection tool that was utilized in this project was designed specifically for this study and therefore was not previously tested. Improvements in the spreadsheet would facilitate data collection and analysis. The main advantages of this would be in cost reduction for subsequent studies.

In summary, although this study did have limitations, the comprehensive data collection and strategies such as matching served to maximize the rigor of this research.

Implications & Recommendations

This pilot study has implications for future directions in nursing education, practice, and research, each of which will be discussed in turn.

Nursing Education

Ongoing learning is paramount to improving critical care patient management. Critical care nurses can play a key role in optimizing patient outcomes through the prevention, early detection, and management of the surgical stress response. To successfully manage clinical situations with the critically ill , and to be able to skillfully negotiate and collaborate with patients, families, and the multi-disciplinary team, nurses must have a comprehensive understanding of the physiology, pathophysiology, behavioral, and experiential responses to illness (Mitchell et al.,1991; Stannard et al., 1996). The HRM served to guide this multidimensional inquiry to describe and explore the cardiac surgery outcomes of TSA and to compare the outcomes with GA.

Information gained from this thesis project offers insight into the pathophysiological responses that cardiac surgery patients can manifest in response to surgical stress. Research indicates that there is a need for more education regarding the pain sequelae for student nurses, as well as for practicing nursing populations (Erkes et al., 2001). Page and Ben-Eliyahu (1997) strongly suggest that the implications for nursing practice are that adequate pain relief may not only be a primary concern for patient comfort, but may also be a matter of physiological necessity. The review of the physiology and pathopysiology of the surgical stress response supports this contention.

Because little was previously known about the outcomes of TSA, critical care nurses did not have evidence-based research on which to base their practice. The availability of these research findings should enable the development and testing of care plans specific to the TSA patient population. Information related to TSA and the findings from this research need to be integrated into the current intensive care nursing program and staff education sessions. Enhanced nursing knowledge of the potential negative outcomes associated with the surgical stress response will encourage critical care nurses to focus attention on proactive care, such as pain prevention strategies, early detection of physiological consequences of pain, and improved holistic pain management that includes measures to alleviate the psychological, social, and physical components of pain.

Implications for Nursing Practice

In this time of increased demand for healthcare and the limited availability of resources, anesthetic techniques that optimize outcomes and increase efficiency are of particular interest to clinicians. TSA is one intervention that may serve to diminish the surgical stress response. Cardiac surgery is a potent physiological stressor, which challenges the ability of the patient to adapt to the stressor. Nurses should strive to proactively minimize the effects of the surgical stress response. Decreasing or attenuating the surgical stress response may decrease the severity and duration of the stressor and facilitate adaptation, thus preventing the progression to the stage three, exhaustion phase. Comprehensive knowledge of the surgical stress response and the potential associated negative patient outcomes will empower critical care nurses to act proactively to implement strategies to reduce the pathophysiological surgical stress response. In the context of Selye's work, early recognition of the alarm phase of the GAS will enable critical care nurses to prevent exhaustion of patient resources.

Results of this study provide evidence that can be used by the bedside nurse to plan nursing care for the TSA patient. Although it is important to acknowledge that each patient has a unique blend of person factors that will affect their level of acuity and ability to physiologically adapt to the stress of cardiac surgery, SICU nurses can anticipate that TSA patients will be at least as stable hemodynamically as GA patients. They may also require less vasopressor and inotropic support. It is reasonable for nurses to anticipate that the majority of TSA patients will be extubated prior to coming out of the operating room and that a large proportion will be extubated shortly after SICU admission. Nurses can also anticipate that TSA patients will generally not have more complications than GA patients.

Although, in this study significantly less postoperative narcotic analgesic given to the TSA group over the first postoperative 24 hours, it is still important to assess pain on an individual basis. Pain is a multidimensional experience that can be influenced by numerous influencing factors as outlined by the HRM. It would be erroneous to simply provide a reduced amount of analgesia to a TSA patient without comprehensive pain assessment and evaluation of analgesia interventions. The complex nature of pain requires that critical care nurses must be aware of the stimulus and the response components of pain, the factors that influence the cyclic nature of pain, as well as the drastic impact on the physiologic stress response. The fact that TSA group received less postoperative IV morphine for analgesia than the GA group indicates that critical care nurses are assessing their patients' pain and are individualizing their care plans to meet the needs of their patients.

A deficiency in outcome evaluation of new and innovative intraoperative procedures has hindered the development of evidence-based postoperative care. To fulfill their role as advocates for their patients, within the context of a holistic healthcare continuum of the patient and family, nurses must be active in the process of outcome measurement and evaluation. This pilot study has provided a starting point from which standardization of care, through the use of clinical pathways and evidence-based practice guidelines specific to TSA patients can be developed, implemented, and evaluated.

From a broader system perspective, when new technologies or procedures are implemented into patient care, there is a need for evidence-based evaluation. Nurses are capable of working collaboratively to evaluate the changes that occur around them. Nurses need to become leaders in the evaluation of technologies that affect them and their ability to affect patient outcomes. Nurse-managers need to become more involved in striving to provide the resource changes that could maximize the financial benefits of TSA. The lack of available ward beds needs to be addressed. It is comprehensive evidence-based evaluation, dissemination of findings, and incorporation of these findings into individual patient care and into the broader healthcare facility structure that can serve to move healthcare forward into the future.

Future Research

The findings from this pilot study suggest that there may be benefits of TSA for cardiac surgery patients. Prior to this study, no outcome evaluation of TSA had been reported. Future research should focus on how integration of the knowledge gained from this project can be utilized for TSA outcome evaluation. This study did not evaluate the knowledge of nurses related to TSA, nor did it evaluate their experiences in caring for patients who had TSA for their cardiac surgery. Research focusing on nursing education and care plan development and evaluation would be beneficial. It is important for nurses to continue to be involved in TSA research that focuses on the optimization of patient outcomes, efficacy, and efficiency.

The primary focus of this pilot study was on the physiological and pathophyisological human response to TSA as compared to GA for cardiac surgery patients. This retrospective research controlled for the variables of surgeon, procedure, age, gender and date of surgery. Future prospective research designed studies should more specifically control for anesthesiologist, preoperative medications, and general anesthetic. The HRM guided the collection of a broad range of person factors and operationalized variable data for this pilot study. The comprehensive data collected provided an accurate description of the study sample and patient postoperative recovery period. The inclusion of a data collection tool similar to this study would be recommended to future researchers. The HRM also provides direction for subsequent research related to the experiential or "lived" experience of the patients who had TSA for their cardiac surgery. Specifically, assessment of pain and patient satisfaction needs to be addressed. Innovative methods of measuring or describing the different experiences in regards to patient comfort and experience need to be developed. The first step in this quest would be adding a qualitative research component to future research. The findings from this study substantiate research strategies, including the development of a questionnaire that focuses on the potential benefits of TSA.

Further research designed to implement and evaluate appropriate and effective evidence-based clinical TSA patient care plans, is required. It is also possible, that by maximizing the TSA benefits for the patients, the positive outcomes will translate into more efficient use of hospital resources, such as ICU bed hours and reduced overall LOS. As a pilot study, this project establishes the foundation for subsequent research in this area.

Larger, prospective, randomized clinical trials would enhance the ability to evaluate predictors of complications and complication rates of cardiac surgery TSA with more rigorous statistical analysis procedures. The significant correlations of person factor predictors and outcomes highlighted in the analysis of this pilot study serve to provide insight for future studies. Although this study included a wide range of person factors, others that should be considered for inclusion are: marital status, social support, income, and education.

TSA is a recent development in cardiac anesthesiology. Unfortunately, it is unlikely that large sample sizes will be available in the near future. Therefore, it is particularly important to strengthen the rigor of future research studies. Prospective, randomized, controlled studies that encompass an evaluation of how TSA enhances outcomes, through the holistic perspective of the HRM model, are required. Prospective research would also enhance the rigor of the data collected; for example, the more accurate evaluation of serum markers, such as Troponin 1 at specific time intervals.

Creative strategies are needed to establish the efficacy and efficiency of TSA. Research to establish evidence of efficacy needs to go beyond the quantitative, physiological realm to include qualitative research that could provides insight into the "lived experience" of the TSA patient. Researchers should look at the possibility of modifying or developing measurement tools to evaluate the recovery of TSA patients. The Canadian health care system does not lend itself well to measures of efficiency as operationalized by financial cost. Future research that would include financial aspects of health care would be beneficial.

Conclusion

The primary purpose of this thesis research project was to describe, explore, and compare the cardiac surgery outcomes of TSA with "standard cardiac anesthetics" (GA). The research findings provided substantive evidence to achieve this goal. The primary research hypothesis that TSA improves patient outcomes was supported by the findings of a trend toward reduced complication rates, as well as significantly earlier extubation rates, statistically significant less IV morphine usage for the first postoperative 24 hours, and a trend toward earlier hospital discharge in the TSA group. Moreover, there was no evidence to suggest that the TSA procedure causes harm.

The overall objective of this study was to establish evidence-based knowledge that would enhance the ability of nurses to anticipate patient outcomes and to plan appropriate and effective research based, patient focused, nursing care. Nurses involved in caring for TSA patients will be able to incorporate the findings of this research into their practice. It is anticipated that this research based evidence will be disseminated and included in future healthcare education and practice to help to achieve the collaborative goal of maximizing the positive outcomes of TSA for cardiac surgery patients. As a pilot study, it is anticipated that this project will establish the foundation for subsequent research in this area.

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UNIVERSITY OF MANITOBA

APPENDIX A

Winnipeg Regional Health Authority Office régional de la santé de Winnipeg
Caring for Health À l'écoute de notre santé

A.H. MENKIS, MD, FRCS(C)

Medical Director, Cardiac Sciences Program
Professor & Chair of Cardiac Surgery

February 11, 2005

Susan Mertin
Pre-operative Assessment Nurse Clinician
Room A4012 – St. Boniface General Hospital
409 Tache Avenue
Winnipeg, MB

Dear Ms. Mertin:

RE: Research Project: Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Opioid and General Anesthesia versus General Anesthesia for Cardiac Surgery

Thank you for meeting with me and outlining your research proposal. This is a retrospective chart based review of cardiac surgery patients who had surgery between September 2003 and April 2005 at St. Boniface Hospital. I concur that this is a useful project and potentially would yield useful information. In my experience in the past, retrospect the chart of this kind, is best done by the PI or the PI's designate with medical and research background.

I support your research proposal in its present form and would welcome seeing the results as it will likely have a bearing on clinical practice.

Once again, thank you for meeting with me today.

Yours sincerely,

A.H. Menkis, MD, FRCS(C)
Medical Director, Cardiac Sciences Program
Professor and Chair of Cardiac Surgery
St. Boniface General Hospital
University of Manitoba

AHM/smg

APPENDIX B

Hôpital général St-Boniface General Hospital

Letter of Support

March 1, 2005

Dr. Diane Biehl, MD., FRCPC
Department Head of Anesthesia and Perioperative Medicine
Saint Boniface General Hospital
Professor, Faculty of Medicine
Department of Anesthesia, University of Manitoba
Business Tel: 204-237-2580

To whom it may concern:

I, Dr. Biehl, Head of the Department of Anesthesia and Perioperative Medicine for Saint Boniface General Hospital, have read and fully support the research proposal as submitted to ENREB entitled *Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia versus General Anesthesia for Cardiac Surgery.* I think that this is an extremely interesting research project and represents potential improvement for patient care.

Dr. Trevor W. R. Lee is an anesthesiologist colleague, who I am confident has the necessary skills to participate in this research. I have full confidence in the research abilities of Dr. Lee and Susan Mertin.

Please feel free to contact me if you require any further assistance.

Yours truly,

Dr. Diane Biehl

APPENDIX C

Hôpital général St-Boniface General Hospital

Memorandum

To: **Cardiovascular Surgeons and Cardiovascular Anesthesiologists**

From: **Susan Mertin R.N., B.N., and Graduate Student**

Re: **Research Project**

Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia versus General Anesthesia for Cardiac Surgery

A research project is being undertaken to describe and explore the cardiac surgery outcomes of total spinal anesthesia with intrathecal morphine and general anesthesia (TSA) and to compare the outcomes with the "standard general anesthesia" technique. To achieve these goals, a retrospective, descriptive, correlational designed project is proposed utilizing chart reviews of cardiac surgery patients who had their surgery between September, 2003 and April 1st, 2005 at Saint Boniface General Hospital. This pilot project has received ethical approval from the Education and Nursing Research Ethics Board (ENREB), University of Manitoba. As well, the Department of Anesthesia and Perioperative Medicine has approved the project (see attached letter of support).

Please see the attached summary of the project, as submitted to NREB. If you have any questions about the project, please contact me directly. If you do not want your patients' charts to be utilized in this study, please contact me by (date to be determined – 2 weeks following mail out).

Contact Information:

APPENDIX D
Letter of Invitation to Participate

Date (insert)

Hôpital général St-Boniface General Hospital

Dear Sir/Madam:

As a previous cardiac surgery patient at Saint Boniface General Hospital (SBGH), you are being asked to participate in a research study. This research is supported by both the Department of Anesthesia and Perioperative Medicine and the Cardiac Sciences Program of Manitoba.

Under the supervision of my thesis committee, I, Susan Mertin, am conducting this research as part of the requirements for my master's degree in nursing at the University of Manitoba. I am also a nurse clinician in the Pre Assessment Clinic that you attended prior to having your surgery at Saint Boniface General Hospital. The title of the research study is: **Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia versus General Anesthesia for Cardiac Surgery.**

The purpose of this research study is to compare two different types of anesthesia, in terms of patient recovery or outcomes. The information needed for this study is in the charts of patients who have had cardiac surgery at SBGH between September 1, 2003 and April 1, 2005. Approximately 80 former patients are being recruited to participate. This study will involve the review of SBGH health records, specific to the cardiac surgery admission, and would include the retrieval of data such as your health history, (e.g. your age, whether or not you had a medical history of diabetes or hypertension), as well as technical data related to your surgery and recovery (e.g. how long your surgery lasted; what anesthetic you received, how long the breathing tube was in after your surgery, how long you had to stay in the intensive care unit and when you were discharged). It is anticipated that the results of this study may benefit the care of cardiac surgery patients in the future.

In accordance with the Personal Health Information Act of Manitoba, I am hereby requesting your permission to access your chart information for the purposes of this study. You will not be required to participate in person, to complete questionnaires or to attend meetings. Your personal data will be treated with the utmost respect; only I and/or my research nurse will be accessing your chart data. This information will be kept strictly confidential. Data that is collected and used in this research and potential presentations or publications will not be identifiable to you or anyone else. Your participation in this study is voluntary; your future health care at Saint Boniface General Hospital will not be affected in any way, if you choose not to participate in this study.

A consent form is included with this mailing. If you are interested in participating in the study, please use the addressed, stamped envelope provided. A follow-up telephone call will be made by the study staff to confirm that you have received this package and to answer any questions that you may have. Should you wish to contact me directly, I can be contacted by phone at...

Thank-you for your consideration,
Sincerely,
Susan Mertin, R.N., B.N., Graduate Student
Saint Boniface General Hospital/University of Manitoba

409 Taché, Winnipeg, Manitoba, Canada R2H 2A6
Tel (204) 233-8563 Website: www.sbgh.mb.ca

APPENDIX E

Hôpital général St-Boniface General Hospital

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title of Study: Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia versus General Anesthesia

Investigator: Susan Mertin R.N., B.N., Masters of Nursing Student
St. Boniface General Hospital
409 Tache Avenue
Winnipeg, Manitoba R2H 2A6

You are being asked to participate in a research study. Please take your time to review this Information and Consent Form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your regular doctor, friends and family. This consent form may contain words that you do not understand. Please feel free to contact the number provided to ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study

The purpose of the study is to describe and compare the outcomes of one type of anesthetic (drugs that made you comfortable/sleep during your surgery) to another type of anesthetic. The study will involve about 80 patients who had their cardiac surgery done at St. Boniface General Hospital between September 1, 2003 and April 1, 2005.

Study procedures

If you agree to take part in this study, you will need to initial each page and sign the last page of this form and return it in the self- addressed, stamped envelope provided. Please keep the enclosed second copy of this document for your records.

We would like your permission to review your medical chart at St. Boniface General Hospital to obtain information about your recovery after your cardiac surgery. The data collected will include basic health history information (e.g. age, whether or not you have a history of high blood pressure or diabetes), as well as measures related to your surgery/ recovery (e.g. the type of anesthetic; medications you received; how long the breathing tube was kept in after your surgery, how long you had to stay in the intensive care unit and when you were discharged).

There is no active participation required from you. However, we need to get your consent to access your medical records before we can gather this personal health information.

Risks and Discomforts

There are no anticipated risks to you for participating in this study. Other than signing consent to participate, no additional requests will be made to you related to this study.

Benefits

You may not benefit from participation in this research; however, the study should contribute to a better understanding of the effects anesthetic has on cardiac surgery recovery, and thus would benefit cardiac surgery patients in the future.

Costs

There will be no costs for you to participate. A self- addressed stamped envelope is enclosed for your response.

Payment for participation

You will not be paid for your participation in this study.

Alternatives

You do not have to participate in this study.

Confidentiality

Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. The Education and Health Research Ethics Boards at the University of Manitoba and St. Boniface General Hospital may also review your research-related records for quality assurance purposes. The findings of this study may be published in journals, presented at meetings and/or used for educational purposes. In any event, the information gathered from this project will be presented in aggregate from and your name will not be used. Personal information such as your name, address, telephone number will be kept in a separate file from your personal health information, to ensure anonymity. Only members of the research team will have access to the data. All the data will be kept in a locked file in the office of Ms. Mertin at St. Boniface General Hospital. After a period of 10 years, the study data will be destroyed and treated as confidential waste. By signing the attached Informed Consent Form you consent to direct access to your specific medical records related to your cardiac surgery admission at St. Boniface general Hospital.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You do not have to take part in this study. Your decision to not participate or to withdraw from the study will not affect your future medical care at this site.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research subject.

Investigator: Susan Mertin Tel No. [redacted]

Initials of Subject: ______

Research Nurse	Gayle Darroch	Tel No.	[redacted]
Research Nurse	Krystal Coldwell	Tel No.	

Do not sign this consent form unless you have a chance to ask questions and have received satisfactory answers to all of your questions.

This research has been approved by the Education/Nursing Research Ethics Board at the University of Manitoba. If you have any concerns or questions about your rights as a research subject, you may contact any of the above mentioned persons or the Human Ethics Secretariat at 474-7122, or e-mail Margaret_bowman@umanitoba.ca. A copy of this consent form has been given to you for your records and reference.

Feedback If you are interested, a summary of the research report may be mailed to you in approximately one year. Please indicate your preference below and include a mailing address to which the study summary should be sent.

Consent

1. I have read and understood this Information and Consent Form.
2. I understand that I will be given a copy of the signed and dated Information and Consent Form. My questions were answered to my satisfaction.
3. By signing and dating this document, I am aware that none of my legal rights are being waived.

Signature:______________________________ Date/Time: ______________

Printed name of above:____

Please indicate if you would like to receive a summary of the results of this study by circling your choice:

I would like to receive a mailed research report-- YES NO

If YES, please provide a mailing address to which the summary should be sent:

Name ______________________

Address______________________

____

 Initials of Subject: ______

"Blocked out due to FIPPA"

APPENDIX G

Hôpital général St-Boniface General Hospital

Room N1004 - 409 Tache Ave.
Winnipeg, Manitoba
Canada R2H 2A6
Tel: (204) 235-3623
Fax: (204) 237-9860

Research Review Committee
Approval Form

Principal Investigator: **Ms. Susan Mertin**

RRC Reference Number: **RRC/2005/0652**

Date: **April 25, 2005**

Protocol Title: **Perioperative Outcome Evaluation of Total Spinal Anesthesia Combined with Intrathecal Morphine and General Anesthesia Versus General Anesthesia for Cardiac Surgery**

The following is/are approved for use:
- **Protocol (undated) submitted to April 25, 2005 meeting**
- **Research Subject Information and Consent Form dated March 4, 2005**

The above was approved by Dr. B. Light, Chairperson, Research Review Committee, St. Boniface General Hospital, on behalf of the Committee. As the recommendations by the Research Review Committee have been met, final approval is now granted.

Sincerely yours,

Dr. B. Light
Chairperson, Research Review Committee
St. Boniface General Hospital

Please quote the above reference number on all correspondence.
Inquiries should be directed to the RRC Secretary
Telephone: (204) 235-3623 **Fax:** (204) 237-9860

cc: Ms. K. Neufeld, Director - Chief Nursing Officer
Dr. P. Hall, President of the Medical Staff
Mr. D. Mestdagh, Pharmacy Department
Ms. D. Halhead, Financial Services
Ms. S. Guinn, Health Records