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Evaluating the Likelihood of Use of Bispectral Index Guided Anesthesia as a Strategy to Reduce Postoperative Delirium in Surgical Patients 65 Years of Age or Older

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EVALUATING THE LIKELIHOOD OF USE OF BISPECTRAL INDEX
GUIDED ANESTHESIA AS A STRATEGY TO REDUCE
POSTOPERATIVE DELIRIUM IN SURGICAL
PATIENTS 65 YEARS OF AGE OR OLDER

by

Simon Jack Gibson

A Capstone Project
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and the Department of Advanced Practice
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in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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ABSTRACT

EVALUATING THE LIKELIHOOD OF USE OF BISPECTRAL INDEX GUIDED ANESTHESIA AS A STRATEGY TO REDUCE POSTOPERATIVE DELIRIUM IN SURGICAL PATIENTS 65 YEARS OF AGE OR OLDER

by Simon Jack Gibson

December 2016

Postoperative delirium (POD) is the most common postoperative complication in the elderly, accounting for approximately \$164 billion in costs per year in the United States (Inouye, Westendorp, & Saczynski, 2014, p. 911). This complication occurs in as many as 50% of elderly patients, but can be prevented as much as 40% of the time (Inouye et al., 2014). The use of processed encephalographic monitoring, such as Bispectral Index (BIS) monitoring, to guide anesthetic dosage is the single intraoperative intervention with enough evidence to support it as a recommendation for use to reduce POD (American Geriatrics Society, 2015). There were two parts to this project. The goal of part 1 was to evaluate recent trends in BIS monitor use for patients 65 years of age or older through retrospective chart review. The goal of part 2 was to conduct a voluntary survey to assess anesthesia provider's knowledge of current recommendations, opinions, barriers to use, and if there are plans for practice change related to BIS monitor use. Data collected during part 1 demonstrated the odds ratio of BIS use in this sample overall 0.078, indicating that the likelihood of BIS being used in this sample was 12.8 times lower than BIS not being used ($n=281$, $p<0.001$) No patients over 80 years old or those who underwent neurological surgery in this sample received BIS monitoring. The use of

BIS monitoring in this sample correlated with surgical type rather than age. Survey data collected during part 2 indicated that 100% of survey respondents were unaware of the recommendations for BIS monitoring in patients over 65 years of age as a measure to reduce POD (n=10). Seventy percent of respondents indicated a willingness to change practice based on current evidence.

Keywords: Postoperative delirium, Bispectral Index (BIS) monitoring, processed encephalographic monitoring, elderly

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DEDICATION

I would like to thank my wife, Nicole, for her unwavering support at home while I completed this project.

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LIST OF ABBREVIATIONS

<i>AGS</i>	American Geriatric Society
<i>ASA</i>	Anesthesiologist Society of America
<i>BIS</i>	Bispectral Index
<i>CAM</i>	Confusion Assessment Method
<i>CMS</i>	Centers for Medicare and Medicaid Services
<i>DSM-IV</i>	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
<i>IBM</i>	International Business Machines
<i>ICU</i>	Intensive Care Unit
<i>MAC</i>	Minimum Alveolar Concentration
<i>MMSE</i>	Mini Mental Status Examination
<i>POD</i>	Postoperative Delirium
<i>SPSS</i>	Statistical Package for the Social Sciences

CHAPTER I - INTRODUCTION

Background

Delirium can be defined as an acute decline in cognitive function, as an acute change in consciousness and attention, or as acute brain failure (American Geriatrics Society, 2015, Inouye et al., 2014, Rudolph, 2015,). This is an all too frequent complication among elderly patients that was first described over 2500 years ago, yet modern medicine continues to struggle with the prevention and treatment of this costly problem (Inouye et al., 2014). The difficulty in preventing delirium is due to the multifactorial nature of the disease. Despite the fact that a single stressor can cause delirium in a patient, it is generally considered to be caused by a group of contributing factors that result in declining cognitive function (Inouye et al., 2014). For example, delirium may be precipitated by a single dose of sedative medication in a frail patient, while it would take a series of stressors to trigger delirium in a young and healthy patient (Inouye et al., 2014). When delirium does occur, disruption of large-scale networks of neurons leads to the interference of neurotransmission or cellular metabolism either directly or indirectly (Inouye et al., 2014). This disruption in neuronal networks is thought to cause the disorganized and delusional cognition associated with delirium.

Despite the serious implications for patients who develop postoperative delirium (POD), the current understanding of its pathogenesis remains poor (Rudolph, 2015). Investments in delirium research are underwhelming when compared to research on other major diseases, with only \$14 million invested by the National Institutes of Health in 2014 compared to almost 10 times that investment for Alzheimer disease research (Rudolph, 2015). The complexities of delirium and the relative lack of funding for

research make it less likely that causative factors of POD will be identified in the near future (Rudolph, 2015).

Significance

Postoperative delirium (POD) is the most common postoperative complication among geriatric patients after surgery, with a rate of occurrence as high as 50% (American Geriatrics Society, 2015). Delirium represents a serious complication possibly leading to longer hospital stays, loss of function or death. Estimated costs are over \$164 billion annually in the United States (Inouye et al., 2014, p. 911). The high cost in lives and money is significant, but perhaps the most compelling reason to pursue improvement in delirium prevention is that it can be avoided in up to 40% of patients (Inouye et al., 2014).

The effects of delirium often go beyond the monetary cost and mortality. The development of delirium comes with ripple effects that involve both the patient and family and friends of the affected patient. Partridge, Martin, Harari, and Dhesi (2013) conducted a literature review that synthesized qualitative and quantitative studies relating to the experience of delirium from the perspective of patients, their family, and medical staff. As many as 75% of patients who survive delirium in the intensive care unit (ICU) have memory of being confused or in a dream-like delusional state, while delirium recall in non-ICU populations vary from the majority having no recollection, to all patients having some recollection (Partridge et al., 2013). This is important because delusional recall is associated with development of post-traumatic stress disorder (PTSD) in 19% to 22% of ICU survivors (Partridge et al., 2013). Recall of delirium also leads to severe distress in 80% of affected patients (Partridge et al., 2013). Family members exposed to

distress during episodes of delirium experience negative emotions including guilt, anxiety, helplessness, and exhaustion (Partridge et al., 2013). The experience was described as being frustrating, scary, and stressful, but these emotions could have been dampened if family members knew that confusion was going to be likely (Partridge et al., 2013).

Understanding that a significant amount of POD is preventable drives the search for best practices to reduce the incidence. There are many risk factors for development of POD, including age greater than 65 years, cognitive impairment, inadequately controlled pain, alcohol use, sleep deprivation, hypoxia or hypercarbia, poor nutrition, dehydration, use of psychotropic medications, and severe illness (Chow, Rosenthal, Merkow, Ko, & Esnaola, 2012). This wide range of risk factors for developing POD makes it difficult to define a single intervention that anesthesia providers can use to decrease the risk. In addition, the relative lack of research limits the ability of anesthesia providers to provide evidence based practice changes that would have adequate support in the literature.

Awareness of risk factors and adjustment of the anesthetic plan could have a significant impact on delirium in the postoperative period (American Geriatrics Society, 2015). Patients with two or more risk factors and patients presenting for emergency surgery are considered at higher risk than other surgical patients (American Geriatrics Society, 2015). The use of BIS guided anesthetic dosing should be considered as part of an anesthetic plan to reduce risk of POD in those patients who have been identified at higher risk of the complication.

In 2015, the American Geriatrics Society (AGS) released their best practice statement for screening, diagnosis, and preventative measures of postoperative delirium

in older adults. This guideline summarizes and synthesizes current research into recommendations clinicians can use to ensure they are providing evidence based care. The AGS 2015 guidelines highlight use of processed electroencephalographic monitors as one intraoperative intervention with evidence to support its use to reduce POD. The Bispectral Index (BIS) monitor is a processed electroencephalographic monitor available to anesthesia providers at a local facility.

Problem Statement

Postoperative delirium is a common postoperative complication in the elderly surgical population. This complication can be costly for both the patient and the healthcare system. Research indicates the use of processed encephalographic monitors, such as the BIS monitor, reduce the risk of POD and associated costs of anesthetic delivery.

Needs Assessment

Surgical procedures performed on patients 65 years of age or older account for an estimated 1/3 of inpatient procedures (Hall, DeFrances, Williams, Golosinskiy, & Schwartzman, 2010). According to U.S News and World Report (2016), 6,563 inpatient surgeries were performed at a local hospital in southeast Mississippi last year. This equates to an estimated 2,165 inpatient surgical procedures performed on patients over 65 years of age in the last year (Hall et al., 2010, U.S. News & World Report, 2016). The U.S. Census Bureau reports approximately 40.3 million people residing in the U.S. who were 65 years or older as of 2010 (West, Cole, Goodkind, & He, 2014). This population is expected to steadily increase, with estimates of 47.8 million projected in 2015 and 56.4 million projected for 2020 (West et al., 2014). The portion of this population served by a

512 bed hospital in southeast Mississippi was approximately 43,928 according to 2010 U.S. census data (West et al., 2014). This growing elderly population will increase demand for healthcare services, including surgical services, for years to come.

Purpose

The purpose of this project is twofold. Part 1 will objectively measure the current use of BIS guided anesthesia at a local hospital through retrospective chart review to determine if anesthesia providers are using BIS monitoring in elderly surgical patients in accordance with current guidelines. Part 2 will evaluate anesthesia provider's current knowledge of the 2015 AGS recommendations, attitudes and barriers to BIS use, and if there are plans to change practice. The results of this project are expected to have implications for anesthesia providers and their patients.

Clinical Practice Questions

The questions guiding part 1 and 2 of this project are: "In surgical patients 65 years of age or older, do anesthesia providers at a local facility include Bispectral Index monitor (BIS) intraoperatively to guide anesthetic depth as recommended in recent literature as a strategy to reduce the incidence of POD?" Also, "are anesthesia providers at this facility aware of current recommendations to use processed encephalographic monitoring in patients 65 years of age or older, what are the barriers to use of BIS monitoring, and are there plans to change practice based on current literature?"

Theoretical Framework

The theoretical foundation of this study is Neuman Systems Model. Betty Neuman introduced her theory in 1970, with multiple updates taking place since its introduction (Neuman & Fawcett, 2011). Her model focuses on changes in patients as a

response to external stressors and the use of prevention interventions that maintain wellness (Neuman & Fawcett, 2011). The values of this theory are based on wellness and the interaction of person, the environment, health, and nursing (Neuman & Fawcett, 2011). This interaction is a system of balance between the patient and their environment, where all variables involved in that system work together to shape a patient's health (Neuman & Fawcett, 2011). Neuman categorized her model as a wellness model, with achievement and maintenance of optimum health being the goal (Neuman & Fawcett, 2011). This model is applicable to prevention of POD by using BIS guided anesthesia due to its preventative stance. Use of BIS guided anesthesia in patients at risk of POD is an intervention that addresses the primary level of prevention. Avoiding deep levels of anesthesia in elderly surgical patients minimizes disruptions in their system that can lead to delirium.

The two major components of Neuman's model are stress and systematic feedback loops (Neuman & Fawcett, 2011). Patients represent an open system with constant input, process, output, and feedback loops that form a pattern of organization (Neuman & Fawcett, 2011). These patient systems allow the patient to be part of their own personal system as well as larger systems such as family or community (Neuman & Fawcett, 2011).

Neuman suggests that there are five variables to be aware of, including physiological, psychological, sociocultural, developmental, and spiritual (Neuman & Fawcett, 2011). These variables must be taken into account as they relate to the system as a whole. Neuman's model considers how the patient system interacts with their environment and these five variables affect that interaction as part of a patient defense

system (Neuman & Fawcett, 2011). This defense system is made up of a flexible line of defense, a normal line of defense, and lines of resistance (Neuman & Fawcett, 2011). The flexible line of defense protects the normal line of defense and can be altered in short periods of time (Neuman & Fawcett, 2011). The normal line of defense is the standard nurses can use to determine deviation from normal health, as it represents long term system stability (Neuman & Fawcett, 2011). The lines of resistance function to return the system to normal health if the other defenses fail (Neuman & Fawcett, 2011). This defense system protects against stressors that can disrupt the system (Neuman & Fawcett, 2011). Stressors are made up of external forces that cause system instability, with positive or negative effects depending on how the system handles the stress (Neuman & Fawcett, 2011). Treatment of patients can depend on how they have responded to these stressors.

Neuman's model includes the concepts of primary, secondary, and tertiary prevention (Neuman & Fawcett, 2011). Primary prevention bolsters the patient's defenses prior to any stress occurring and also reduces potential stressors (Neuman & Fawcett, 2011). Secondary prevention occurs after the initial reaction to stress, and its goal is to find the vulnerability and protect central structures in the patient system (Neuman & Fawcett, 2011). Tertiary prevention is a supportive phase where the system is recharged and recovered after treatment (Neuman & Fawcett, 2011). These stages of prevention work together to both prevent injury and help patient recovery if injury does occur.

DNP Essentials

DNP essential I: Scientific underpinnings for practice. This essential outlines the scientific foundations of nursing practice based on natural and social sciences (Chism,

2013). The science of nursing has grown to include the development of nursing theories to guide practice (Chism, 2013). Neuman's systems model describes a preventative form of intervention that protects existing levels of defense in a patient's system (Neuman & Fawcett, 2011). The use of BIS monitoring as a preventative measure is consistent with Neuman's model and DNP essential I.

DNP essential II: Organizational and systems leadership for quality improvement systems thinking. This essential focuses on the use of systems leadership to improve patient care outcomes (Chism, 2013). This project is focused on the evaluation of the use of an intervention that has been shown to reduce a costly postoperative complication. The use of BIS monitoring to guide anesthetic depth can reduce risk of POD in an at risk population.

DNP essential III: Clinical scholarship and analytical methods for evidence-based practice. This essential requires the evaluation of evidence, outcomes, and methodologies within healthcare practices (Chism, 2013). This project will implement a review of literature to evaluate methods to reduce the risk of POD in the elderly surgical population. With support from current research, an evaluation of current practice at a local hospital will be done to determine need for practice change.

DNP essential IV: Information systems/technology and patient care technology for the improvement and transformation of health care. This essential describes the use of information systems technology to gather and evaluate evidence in healthcare delivery (Chism, 2013). This project will involve the use of data extraction from patient electronic medical records (EMR) and the use of electronic databases for a review of literature.

DNP essential VI: Interprofessional collaboration for improving patient and population health outcomes. “This essential is specifically related to the IOM’s mandate to provide safe, timely, equitable, effective, efficient, and patient centered care” (Chism, 2013, p. 17). The use of evidence based practices in the care of patients at risk of developing POD will involve collaboration between anesthesia providers and other members of the care team who are involved in perioperative care. Education of other providers on preventative strategies will be an integral part of this project.

DNP essential VII: Clinical prevention and population health for improving the nation’s health. Illness prevention is part of the foundation of nursing practice (Chism, 2013). This project is focused on the prevention of a postoperative complication that can improve overall health in this community. Application of any intervention that is found to be effective in reducing POD in the elderly population would improve overall health of the population as a whole.

DNP essential VIII: Advanced nursing practice. As part of the role of an advanced practice nurse, we must be able to implement and evaluate therapeutic interventions based in science (Chism, 2013). This project is focused on the evaluation of the use of an intervention that can reduce POD. The basis of the intervention will be formed by a review of current literature that supports a change in practice. Once current use of BIS monitoring is determined, a broader implementation can be introduced in order to maximize the benefits for the population of interest.

Summary

This section discussed the general implications of POD on the elderly surgical population. Not only does this complication come with a high monetary cost, but the loss

of life associated with it is perhaps even more significant. Knowing that POD can be prevented in as many as 40% of the cases that are diagnosed encourages providers to implement practice changes that are supported by literature to reduce the incidence of POD.

One intraoperative intervention with enough supporting literature to support its use is BIS monitoring (American Geriatrics Society, 2015). The use of BIS guided anesthesia has the potential to reduce both the costs of anesthetic delivery and the incidence of POD in the elderly surgical population. This intervention is supported by the AGS in their 2015 best practice statement regarding POD in elderly patients. Objective evaluation of current practices related to the use of BIS monitoring as a strategy to reduce POD in accordance with current guidelines will guide future practice changes. Literature supporting the use of BIS guided anesthesia will be discussed in detail in the following chapter.

CHAPTER II – REVIEW OF LITERATURE

The following chapter contains a description of the methods used to conduct the review, a discussion of the findings, and a summary conclusion. This review of literature will cover the topics of cost of BIS monitoring, relationship between BIS guided anesthesia and POD, and the relationship between BIS guided anesthesia and postoperative mortality.

Search Methods

A comprehensive search of the literature was conducted to locate relevant articles related to the use of any preoperative medication or intervention and the risk of POD in elderly patients undergoing general anesthesia for surgery of any kind. Multiple databases were used including CINAHL with Full Text, Academic Search Premier, MEDLINE/PubMed, PRIMO, PsycArticles, and Psychology and Behavior Sciences Collection. Results were initially limited to full text articles published in English and in peer-reviewed journals between 2010 and 2016, and expanded to include older articles which were repeatedly cited. The initial search term was *postoperative delirium* which resulted in 2,686 articles. The search was further narrowed by adding the term *anesthesia* which resulted in 212 articles returned. The search was further limited by adding *cost*, AND *mortality*, AND *elderly*, AND *Bispectral Index* which resulted in 18 articles for review. Inclusion for this review was determined by review of abstracts of potential articles for relevance to the topic. Articles were included if the study involved the association of Bispectral Index monitoring with POD in elderly surgical patients. Articles were excluded if they were duplicate results, if their title or abstract demonstrated they did not include the correct population, or they did not examine the chosen topic. This

refinement resulted in 4 articles chosen for inclusion in this review. The search was then expanded to reference lists of included articles for relevant studies. An additional 6 articles were chosen for inclusion, making the total of 10 articles that were chosen for inclusion in this review. Themes included in the review included cost, sedation depth and mortality, and BIS use and reduction of POD.

Cost

Punjasawadwong, Phongchiewboon, and Bunchungmongkol (2014) conducted a systematic review of 36 randomized control trials to determine if the use of BIS can reduce the risk of intraoperative awareness, consumption of anesthetic agents, the cost of the anesthetic, or recovery times in patients having a procedure under general anesthesia. The authors found that there was a significant reduction in the risk of intraoperative awareness during anesthesia, total anesthetic agent used was reduced, and shorter recovery times (Punjasawadwong et al., 2014). The authors did not see a significant difference in the time to discharge home due to a combination of systems and surgical factors that prolonged discharge times (Punjasawadwong et al., 2014). The cost of anesthesia was reduced in BIS guided anesthesia as well, with a cost of 0.70 EUR (\$15.63 USD) vs 0.98 EUR (\$1.09 USD)/min/70kg patient (Punjasawadwong et al., 2014). The cost of monitoring per patient is approximately \$15 USD (Punjasawadwong et al., 2014). This correlates with a potential cost savings of \$0.31 USD per minute of anesthesia in a 70Kg patient using Sevoflurane (Punjasawadwong et al., 2014).

This study was consistent with a study by Ellerkmann et al., published a systematic review in 2006 to examine the link between BIS values and total dose of anesthetic drug administration. This article was outside the date ranges initially set in the

review, but was included due to recurring citations in other literature. They included 14 randomized control trials in their analysis (Ellerkmann et al., 2006). There was a significant correlation between mean BIS values during a procedure and the dose of hypnotic drug used, with a 2% reduction in drug use for every BIS point (Ellerkmann et al., 2006). This overall reduction in dose of anesthetic agents lowers costs associated with anesthetic delivery on a per-patient basis.

The impact of BIS guided anesthesia on other postoperative outcomes such as nausea and vomiting, cognitive dysfunction, or mortality was not evaluated in either of these studies. The results from these studies served as an important aspect of this project due to evaluation of the costs of BIS monitoring and the impact that BIS guided anesthesia can have on total costs of delivering anesthesia. In addition, these studies demonstrated that total anesthetic dose was consistently reduced with use of BIS monitoring (Punjasawadwong et al., 2014).

Bispectral Index and Reduction of Postoperative Delirium

Sieber et al. (2010) investigated the effect of light sedation depth during spinal anesthesia for hip fracture repair in patients 65 years old or older on prevalence of POD. They divided 114 elderly patients into light (BIS of 80) or deep (BIS of 50) propofol sedation groups for the procedure (Sieber et al., 2010). They used the CAM or MMSE to assess the patients from postoperative day 2 until discharge to detect delirium incidence (Sieber et al., 2010). They found that there was a decrease in prevalence of delirium by 50% in the light sedation group as compared to the deep sedation group (Sieber et al., 2010). The prevalence of POD was 19% in the light sedation group compared to 40% in the deep sedation group (n=114; $p=0.02$) (Sieber et al., 2010).

Further support of BIS monitoring was demonstrated by Radtke et al. (2013), who conducted a randomized control trial to determine if guiding anesthetic depth with the use of BIS monitors would reduce the incidence of POD. Their study included data from 1,155 patients aged 60 years or older (Radtke et al., 2013). The researchers performed preoperative evaluations of cognitive function as a baseline, then assessed delirium twice daily from postoperative day 1 through 7 using criteria from the DSM-IV (Radtke et al., 2013). They found that the use of BIS guided anesthesia in this population was associated with lower incidence of POD, with a prevalence of 16.7% in the BIS group and 21.4% in the control group ($p=0.06$) (Radtke et al., 2013). To further investigate this association, the researchers used multivariate analysis and found that BIS values of less than 20 were independently associated with POD risk ($p=0.006$, OR=1.027) (Radtke et al., 2013).

Use of BIS guided anesthesia was also shown to be beneficial by Chan, Cheng, Lee, Gin, and CODA Trial Group (2013), who conducted a randomized control trial to determine the impact of BIS monitoring on POD and cognitive decline. The study included 921 elderly patients who were having major non-cardiac surgery (Chan et al., 2013). After baseline cognitive function tests, these patients were randomized to receive either BIS guided anesthesia or routine anesthetic care (Chan et al., 2013). Anesthetic depth in the BIS group was titrated to BIS values of 40-60 intraoperatively (Chan et al., 2013). Bispectral Index values were measured in the non-BIS guided group, but the anesthesia providers were blinded to the measurements (Chan et al., 2013). Postoperatively, the researchers administered neurological testing at one week and at three months after surgery (Chan et al., 2013). The results indicated that 15.6% of patients in the BIS guided group developed delirium, compared to 24.1% of the patients

in the standard care group ($p=0.01$) (Chan et al., 2013). Patients in the standard care group had BIS values that were significantly lower than in the BIS guided group, 36 compared to 53 respectively ($p<0.001$) (Chan et al., 2013). Cognitive function in each group was similar at 1 week postoperatively, however, the rate of cognitive dysfunction in the BIS group was 10.2% at the 3 month follow up, compared to 14.7% in the control group (odds ratio 0.67; $p= 0.025$) (Chan et al., 2013).

Further support for BIS guided anesthesia was reported by Whitlock et al. (2014), who published results of a cohort study done to ascertain the incidence of delirium in patients enrolled as part of a larger clinical trial. This sub-study group included 310 patients who were enrolled in the BAG-RECALL clinical trial for risk of developing intraoperative awareness (Whitlock et al., 2014). The patients were randomized into a BIS guided anesthetic group or end tidal anesthetic agent concentration guided group (Whitlock et al., 2014). The goal of the BIS guided group was maintenance of BIS score between 40-60 (Whitlock et al., 2014). Delirium was assessed twice daily until either postoperative day 10 or discharge from ICU, whichever occurred first (Whitlock et al., 2014). Assessment of delirium was done using the CAM by a trained ICU nurse who was blinded to group assignments (Whitlock et al., 2014). The results were that 18.8% of patient in the BIS group developed POD, compared to 28% of patients in the end tidal anesthetic agent guided group (odds ratio 0.6; $p=0.058$) (Whitlock et al., 2014).

Finally, Santarpino et al. (2011) conducted a retrospective cohort study to measure the association between BIS use and postoperative neurological outcomes and delirium in aortic surgical patients. This study included retrospective review of records of 292 patients undergoing aortic surgery necessitating circulatory arrest (Santarpino et al.,

2011). Anesthetic technique was standardized for all patients in this study, with BIS readings recorded prior to induction and every 15 minutes during the procedure (Santarpino et al., 2011). The researchers calculated a ratio between baseline BIS values and the minimum recorded BIS value intraoperatively for each patient and classified them into 1 of 5 groups based on the ratio for comparison (Santarpino et al., 2011). A total of 53 patients in this study developed POD (Santarpino et al., 2011). One-way ANOVA and post-hoc analysis indicated that a reduction in BIS of 25-30% from baseline was found to be a significant risk for development of POD ($p < 0.001$) (Santarpino et al., 2011).

Sedation Depth and Mortality

Brown, Azman, Gottschalk, Mears, and Seiber (2014) conducted a randomized control trial to evaluate the effect of low BIS scores on postoperative mortality in elderly patients. The study included 114 patients over 65 years of age who had been admitted for hip fracture repair who received spinal anesthesia combined with intravenous sedation. They found that there was a lower one-year mortality in patients with serious comorbidities who were given light sedation (BIS > 80) for the procedure as compared to those who received deeper sedation (Brown et al., 2014). Light sedation in this sample resulted in one-year mortality of 22.2% as compared to 43.6% in the deep sedation group (95% confidence interval; $p = 0.04$) (Brown et al., 2014).

The multifactorial nature of postoperative complications can add conflicting results. Lindholm et al. (2009) conducted a controlled trial to determine the validity of previous studies who found that deep anesthesia was a risk factor for death within 1-2 years postoperatively. They included 4,087 patients admitted for surgery using general

anesthesia (Lindholm et al., 2009). They reported that BIS values of less than 45 were found to be an independent predictor of mortality, along with preexisting malignancy, ASA score of 4, and age over 80 years (Lindholm et al., 2009). BIS scores, however, were no longer significant if malignancy was added as a covariate in the analysis (Lindholm et al., 2009).

An additional conflicting study was published by Kertai et al., who performed a study in 2011 to determine if BIS values of less than 45, total anesthetic dose, comorbidities, or intraoperative events would be independently associated with postoperative death. They included 1,473 patients who were admitted for non-cardiac surgery, and assigned them to a BIS guided anesthesia protocol or an anesthetic agent concentration protocol group (Kertai et al., 2011). The goals of either protocol was to keep BIS values between 40-60, or end-tidal anesthetic agent concentration between 0.7-1.3 MAC values respectively (Kertai et al., 2011). The results showed no significant association between postoperative delirium and decreased survival in this group of patients (Kertai et al., 2011). They found that survival was associated with age, ASA score, and ICU stay duration postoperatively (Kertai et al., 2011).

Conclusion

This review outlined the methods used to locate relevant research and included a summary and discussion of the findings. The overarching theme of the majority of available research is that use of BIS guided anesthesia reduces the risk of POD, though there are other factors involved that can contribute significant risk (Chan et al., 2013, Radtke et al., 2013, Santarpino et al., 2011, Sieber et al., 2010, Whitlock et al., 2014). Research has also demonstrated that use of BIS guided anesthesia reduces overall

anesthetic dose and therefore costs of delivering an anesthetic (Punjasawadwong et al., 2014). This reduction in anesthetic dose is consistent with Neuman's model in that it minimizes disruptions in a patient's defensive system, helping to maintain optimal wellness. In regards to mortality, Brown et al. (2014) indicated that light anesthetic depth can reduce mortality. However, Lindholm et al. (2009) and Kertai et al. (2011) found that anesthetic depth alone was not necessarily a significant factor in postoperative mortality when other variables were included in the analysis. In conclusion, implementing the use of BIS guided anesthesia into routine practice to reduce the risk of POD is supported in the literature. This intervention has the potential to reduce overall costs of anesthesia delivery while improving outcomes in a vulnerable population.

CHAPTER III - METHODOLOGY

The methodology for this study addresses two clinical questions: “Do anesthesia providers include Bispectral Index monitoring (BIS) intraoperatively to guide anesthetic depth as a strategy to reduce the incidence of POD?” Also, “are anesthesia providers at this facility aware of current recommendations to use processed encephalographic monitoring in patients 65 years of age or older, what are the barriers to use of BIS monitoring, and are there plans to change practice based on current literature?” The purpose of this chapter is to describe the methods used to gather and interpret data to answer the project questions. The sample, setting, design, data collection procedures, and analysis methods are described in the sections that follow.

The American Geriatrics Society (2015) published a best practice statement based on their recent review of literature. Despite the general lack of research focused on specific interventions to prevent POD, there has been sufficient research that supports the use of processed encephalographic monitoring intraoperatively to reduce incidence of postoperative delirium (American Geriatrics Society, 2015). Using this recommendation, anesthesia providers can implement a clinical practice change to reflect current evidence related to the care of patients at risk of POD. Evaluating compliance with this recommendation in practice will determine the level of need for practice change aimed at decreasing the risk of POD in at-risk patients, which could reduce costs in terms of money and lives. Additional information regarding attitudes, barriers, and practice change potential with current anesthesia providers will identify areas that need improvement and guide development of strategies to implement evidence based practice.

Results of this project will be applicable to anesthesia providers serving patients 65 years of age or older in a local 512 bed level 2 trauma center in Southeast Mississippi.

Design

This project uses both an odds ratio to describe current practice and survey data to anticipate practice changes. Part 1 is an analysis using data that will be collected by retrospective chart review of elderly inpatients who had general anesthesia for surgery between February 1, 2015 and December 31, 2015. Part 2 is a qualitative study using a voluntary survey of anesthesia provider's current practices, attitudes, and plans for practice change after receiving information from a voluntary fact sheet presentation and verbal discussion.

Part 1 of this project involved the review of anesthesia records for documented BIS monitor use. After reviewing records, the likelihood of use of BIS guided anesthesia in the elderly surgical population at the facility was calculated. For the purpose of this project, likelihood is defined as the odds ratio of a patient receiving BIS guided anesthesia versus not receiving BIS guided anesthesia, as calculated in statistical analysis.

Part 2 of this project included presentation of current literature related to use of BIS guided anesthesia to anesthesia providers at a local facility, which was accomplished through fact sheet presentation and discussion on site. Attendance was voluntary, and there was no compensation for participation. The second part of this project included a voluntary five question paper survey that was completed by anesthesia providers to determine their current practices, attitudes, and beliefs related to BIS monitor use.

Setting

This descriptive study included a retrospective chart review conducted at a 512 bed hospital in Southeast Mississippi. The facility is a level II trauma center that has 17 operating rooms. There are multiple types of surgeries performed at this facility, including: general, thoracic, obstetric, gynecological, orthopedic, cardiac, vascular, neurological, ophthalmological, oral, and intra-abdominal. Surgical services are offered for pediatric and adult populations (Forrest Health, 2016). There are approximately 6,500 inpatient procedures at a local facility every year, with one third (2100) of those involving patients who are 65 years of age or older (Hall et al., 2010, West et al., 2014).

Population

Part 1: The patient population of interest included surgical patients aged 65 years or older, who presented for any surgery requiring general anesthesia between February 1, 2015 and December 31, 2015. Power analysis, using an online power analysis calculator for logistic regression, indicates the need for 310 patients total to achieve an alpha of 0.05 and power of 80% (<http://clincalc.com/stats/samplesize.aspx>). Inclusion criteria for the study included inpatients aged 65 years or older, regardless of gender, comorbidities, ASA physical status class, or surgery type requiring general anesthesia. Exclusion criteria includes age less than 65 years, or surgical procedures not requiring general anesthesia.

Part 2: The provider population of interest is the group of anesthesia providers who serve the surgical population at the same facility included in part 1 of this project. There are 30 anesthesia providers who routinely staff this facility.

Procedure

Data Collection

Approval for this project was obtained through the Institutional Review Board (IRB) of The University of Southern Mississippi and the facility where the study was conducted prior to starting data collection.

Part 1: Patient charts were reviewed through use of an electronic medical record query of an Epic based charting system. Variables included in the query are patient age of 65 years or greater, use of general anesthesia, and BIS monitor use. Data from the query was de-identified on receipt. Information was transferred to an electronic data collection form created for this project. Patient population data was related to BIS use in the surgical patient aged 65 years or older. Data collection was accomplished by electronic chart reviews of elderly patients who have undergone surgery requiring general anesthesia in the participating facility between February 1, 2015 and December 31, 2015.

Part 2: Anesthesia provider population data was gathered through voluntary paper surveys to be completed after reviewing a fact sheet and verbal discussion. The survey consisted of 5 open-ended questions relating to current practice, planned practice changes, and barriers to BIS guided anesthesia use. There are 30 providers who routinely staff at this facility. Survey responses are presented in the results.

All gathered data will be stored for 6 months after all graduate school requirements have been met. Data will be stored in a password protected file on a personally owned computer. All project data will be deleted 6 months after all graduate school requirements have been met. Ethical guidelines for the treatment of human subjects in research was followed at all times.

Data Analysis

Part 1: Analysis of data collected was done with the aid of the International Business Machines (IBM) program Statistical Package for the Social Sciences (SPSS) version 24. The use of BIS monitoring in elderly surgical patients was evaluated with logistic regression analysis to calculate the odds ratio of BIS guided anesthesia being utilized at this facility.

Part 2: Collection and summarization of survey responses was done by hand. All responses were anonymous, and were grouped together by question and answers for description. Results expressed current anesthesia provider practices and opinions related to current recommendations for the care of patients 65 years of age or older.

Summary

Postoperative delirium in elderly surgical patients can be a costly problem. Evaluating BIS monitoring practices at a local facility for compliance with current recommendations from the AGS (2015) determined there is need for improvement in the future. This section outlined the sample, setting, design, data collection procedures, and analysis methods that were used in this project.

CHAPTER IV – ANALYSIS OF DATA

This section contains the results of data collection from part 1 and 2 of this project. All data and results from analysis will be presented. Limitations of the project will be discussed, with implications for practice to follow.

Discussion

Part 1

This project included a retrospective chart review of patient records in the year 2015, starting December 31, 2015 and working backwards in time until 312 patient records had been reviewed. Data was presented after database query coordinated through information technology staff at the facility. Only patient charts who met inclusion criteria were presented for review. Data was de-identified upon receipt, with only the variables of interest of age category, surgery category, and BIS monitor data transferred to the data collection tool. No personally identifiable health information was recorded. Data from any point preceding February 2015 was not available to query with the current system in place at the facility, therefore the data collection planned for records in 2014 was not accomplished. A sample size of 310 was desired based on results of an online sample size calculator for logistic regression ($p=0.05$, $CI=80\%$), and an expected population of 1600 patients who meet inclusion criteria (www.raosoft.com/samplesize.html). The sample size was calculated using the most recent report of approximately 6,000 inpatient surgical procedures at a local facility in the last year, with approximately one-third of those being elderly patients (Hall et al., 2010, U.S. News & World Report, 2016). Due to data from the entire year being unavailable to query, the expected sample of 2000 was reduced to 1600 patients.

Records were reviewed starting with those who had surgery December 31, 2015 and proceeding backward in time until a total of 312 records were reviewed. Data was analyzed with IBM's Statistical Package for the Social Sciences (SPSS). Binary logistic regression was employed to determine which independent variables (age category or surgical category) were predictors of BIS monitor use during a surgical procedure.

For this analysis, patients were divided into various categories based on age and surgical type. Patients were grouped into 3 age groups based on existing categories: 65-69 (young old), 70-79 (middle old), and 80+ (very old). Six surgical categories were created to broadly encompass all types of surgical procedures in this sample of patients: vascular, general, neurological, cardiac, thoracic, and orthopedic. The cardiac and thoracic categories were combined, creating a cardio-thoracic category, due to only 3 patients having undergone thoracic surgery in this sample.

Initial sample size was 312 (n=312). Twenty-one outliers were eliminated through data screening with Mahalanobis distance and Chi square critical value comparisons, with remaining sample of 291 (n=291). The final SPSS model only included subgroups with $p < 0.05$.

Binary logistic regression was conducted to determine which independent variables (age or surgical category) are predictors of BIS monitor use (yes or no). Data screening led to the elimination of several outliers. Regression results indicated that the overall model fit of three variables was marginal (-2 Log likelihood = 131.198) but was statistically reliable in determining use of BIS monitoring [$\chi^2(1) = 19.658, p < 0.001$]. The model correctly classified 92.8% of cases. Regression coefficients are presented in table 1.

Table 1

Regression Coefficients for Model Variables

	B	Wald	df	Sig.	Exp(B)
Vascular 70-79 yrs	-1.464	4.156	1	0.041	0.231
Cardio-Thoracic 65-69 yrs	-1.575	4.755	1	0.029	0.207
Cardio-Thoracic 70-79 yrs	-2.547	19.139	1	0.000	0.078
Constant	2.277	3.442	1	0.064	9.744

Variables were entered using forward likelihood ratio entry. SPSS output indicated that OR for BIS monitor use in this sample was 0.078. This indicates that for every patient 65 years of age or older, the likelihood of receiving BIS monitoring during a general anesthetic is 12.8 times lower than not receiving BIS monitoring. Further analysis was done to explore descriptive properties of this sample. Below is a table summarizing the number of cases in each age category by surgical type, separated by use of BIS or no use of BIS.

Table 2

Surgical Category, Age, and BIS Use

		Vascular	General	Neurological	Cardio-Thoracic	Orthopedic
65-69	BIS(N)	10	39	4	17	28
	BIS(Y)	1	1	0	3	2
70-79	BIS(N)	19	43	7	15	41
	BIS(Y)	3	1	0	7	3
80+	BIS(N)	2	25	5	3	33
	BIS(Y)	0	0	0	0	0

In addition, odds were calculated for each age and surgical subgroup. Below are the results of those calculations. In some categories there were no recorded cases that included BIS monitoring, which is denoted by "--".

Table 3

Odds of BIS Use (Y) By Surgical and Age Group

	65-69	70-79	80+
Vascular	0.1	0.157	--
General	0.026	0.024	--
Neurological	--	--	--
Cardio-Thoracic	0.176	0.466	--
Orthopedic	0.072	0.073	--

Table 4

Odds of BIS Use (N) By Surgery and Age Group

	65-69	70-79	80+
Vascular	9.99	6.35	--
General	39	42.48	--
Neurological	--	--	--
Cardio-Thoracic	5.67	2.14	--
Orthopedic	13.93	13.71	--

The data show that no-one in the age category of 80+, representing the very old group, received BIS monitoring during their surgery. Also, no recorded neurological cases in this sample received BIS monitoring. The category with the highest odds of receiving BIS monitoring was the cardio-thoracic patient who was 70-79 years of age

(0.466), though the correlation to that specific surgical procedure may be related to practices to reduce intraoperative awareness rather than POD.

Part 2

The second part of this project included a voluntary paper survey of anesthesia providers at a local 512 bed level 2 trauma facility in southeast Mississippi. Providers were presented with a fact sheet summary and discussion of current research and recommendations for care of patients 65 years of age or older to reduce the risk of POD. Opportunities for participation were offered on multiple occasions in an effort to include as many providers as possible. The facility was visited in person on 5 separate days, with one hour each day devoted to speaking with providers and offering the survey. Survey packets included a fact sheet, cover letter, paper survey, and a pre-addressed stamped envelope for return of the survey by mail if desired. Discussion of literature and the opportunity to complete the survey was provided to 16 anesthesia providers. Response rate was 62.5%, with a total of 9 surveys were returned in person, and 1 returned by mail.

Question 1: All (10) survey respondents indicated they were unaware of the 2015 AGS recommendation to use processed encephalographic monitoring in patients 65 years of age or older. One provider indicated awareness of other literature related to the impact of BIS monitoring in reducing POD, but not the AGS recommendation specifically.

Question 2: All (10) survey respondents indicated they do not use BIS monitoring routinely in patients 65 years of age or older.

Question 3: Six respondents (60%) indicated there was no barrier to using BIS in their practice. Four respondents (40%) described barriers that included BIS monitoring

being unnecessary, difficulty locating supplies and/or a working monitor, and too much variability in BIS readings obtained from the monitors.

Question 4: Three respondents (30%) indicated no plans to change current practice, 2 (20%) indicated they would “possibly” change their practice, and 5 (50%) indicated they did plan to change practice based on current evidence.

Question 5: One respondent (10%) indicated there are no situations where they would consider use of a BIS monitor. Nine respondents (90%) indicated varying types of cases where a BIS monitor use would be considered, to include the following: emergency cases, “bring back” heart cases, total intravenous anesthesia (TIVA), high acuity patients who would not tolerate moderate levels of anesthesia, carotid surgery, patient history of malignant hyperthermia, history of intraoperative recall, extreme anxiety, cardiac or neurosurgery, and geriatric patients.

Limitations

Limitations for part 1 include limits to date ranges available for the chart review restricted the available data to only a portion of one year planned for inclusion. This prohibited this project from exploring whether or not a difference in use of BIS monitoring in the patient population of interest was present after the 2015 AGS recommendation. This limit was offset slightly by the inclusion of a question of awareness of the recommendation on the paper survey in part 2 of this project, however no quantitative data could be compared to confirm the survey results. In addition, generalizability to populations outside of this facility may not be feasible due to variations in practices of different anesthesia personnel staffing other facilities. This was a small scale study with a population limited to one facility who had surgery requiring

general anesthesia during the study period. This limited population and location may introduce unique variables that are not applicable in other locations or cohorts of patients.

Limitations of part 2 of this project are related to availability and willingness of anesthesia providers to participate in a voluntary survey. Access to providers for in person discussion and presentation of a fact sheet related to current literature is dependent on surgical and staff scheduling. Also, providers may be unwilling to share honest opinions related to current practices. These limitations were minimized by multiple site visits to present evidence, and by making the survey anonymous to encourage free and honest comments and opinions.

The limitation of data analysis was that one researcher entered and analyzed data, increasing the risk for researcher bias and errors of data entry. There is also the possibility of data being unavailable if anesthesia providers did not document BIS monitor readings in the electronic record.

Summary

The questions guiding part 1 and 2 of this project were: “Do anesthesia providers include Bispectral Index monitoring (BIS) intraoperatively to guide anesthetic depth as a strategy to reduce the incidence of POD?” Also, “are anesthesia providers at this facility aware of current recommendations to use processed encephalographic monitoring in patients 65 years of age or older, what are the barriers to use of BIS monitoring, and are there plans to change practice based on current literature?” The discussion below summarizes the findings of part 1 and 2 of this project which relate to answering both research questions.

Part 1 of this project included a retrospective chart review of patients 65 years of age or older who underwent general anesthesia at a local 512 bed level 2 trauma center in southeast Mississippi. The review revealed that the use of BIS monitoring in patients 65 years of age or older occurred in only 7.2% of cases included in this sample. The odds ratio of BIS monitor use in this sample is 0.078, indicating patients in this sample were 12.8 times less likely to receive BIS monitoring than to receive it. No patients 80 years of age or older received BIS monitoring, regardless of surgical category.

This data indicates that the likelihood of receiving BIS monitoring at this facility, as defined by calculated odds ratios, is low. Bispectral Index monitor use in patients in this sample correlated with surgical type more than age category, with cardio-thoracic surgical patients having the highest odds of receiving BIS monitoring compared with other types of surgery. However, it is important to note that the use of BIS in cardiothoracic surgery may be related to practices to prevent intraoperative awareness, rather than POD. Neurological surgical patients, and patients 80 years of age or older in this sample did not receive BIS monitoring. This analysis establishes a baseline of BIS monitor use to measure against in the future, and represents an opportunity for changes in local anesthetic practices to better reflect evidence in the care of this patient population.

Part 2 of this project included a presentation of a fact sheet and in person discussion of current literature related to BIS use and POD in patients 65 years of age or older. Survey responses indicated an overwhelming lack of awareness of a recommendation released in early 2015. This lack of awareness demonstrates a need for improved dissemination of current literature to providers who are actively involved in the population of interest. However, even with presentation of current literature to support

use of BIS monitoring, 30% of providers indicated no plans to change their current practices, with 1 provider who indicated they would never consider use of a BIS in any circumstance. This unwillingness to change may be related to prior experiences with faulty equipment, circumstances where BIS monitor data was inaccurate, or concerns over costs of using the monitor. Seventy percent of providers who responded indicated willingness to change their practice as it relates to BIS use, with mentions of various surgical procedures or patient populations where they will consider using BIS monitoring. Willingness to change practice when presented with current evidence supporting change highlights the need to continuously be exposed to current literature related to patient populations served.

DNP Essentials

DNP essential I: Scientific underpinnings for practice. Current literature provides evidence that supports the use of BIS monitoring in patients 65 years of age or older to reduce risk of developing POD. Evaluation and education of current practices at a local facility represents science based support for anesthesia practice.

DNP essential II: Organizational and systems leadership for quality improvement systems thinking. This project focused on use of an intraoperative monitor that reduces risk of POD in patients 65 years of age or older. Education of anesthesia providers at this facility regarding current literature that supports BIS monitor use provides quality improvement in the care of a vulnerable patient population.

DNP essential III: Clinical scholarship and analytical methods for evidence-based practice. This project included an in depth review of literature that supports use of BIS monitoring in patients 65 years of age or older. Also, an analysis of data gathered from a

chart review provided insight into current practice and a reference point for future improvements.

DNP essential IV: Information systems/technology and patient care technology for the improvement and transformation of health care. This project utilized literature databases for a comprehensive literature review. Also, an electronic patient record database was utilized for a retrospective chart review.

DNP essential VI: Interprofessional collaboration for improving patient and population health outcomes. Implementation of evidence based practices in the care of patients at risk of developing POD involves collaboration between anesthesia providers and members of the care team involved in perioperative care. Education of other providers on preventative strategies that reduce POD risk was an integral part of this project.

DNP essential VII: Clinical prevention and population health for improving the nation's health. This project was based on a preventative measure. The use of BIS monitoring in patients 65 years of age or older reduces risk of a common and costly complication. Reducing prevalence of POD improves overall health of a vulnerable population, thereby improving overall health of the nation.

DNP essential VIII: Advanced nursing practice. This project focused on evaluation of an intervention that is supported by evidence to reduce POD. Evaluation of current anesthetic practice in comparison to recommendations in the literature, and identification of attitudes and opinions of anesthesia providers related to BIS use provides a foundation for practice changes moving forward.

Implications and Recommendations to Clinical Practice

This project highlights a discordance between current recommendations in the literature with actual practice at this facility. The survey results demonstrate the need for more effective dissemination of current research among anesthesia providers at this facility. While all survey respondents were unaware of the current recommendation by the AGS to use BIS monitoring in patients 65 years of age or older, 70% of them indicated a willingness to change practice when presented with current literature to support it.

An opportunity for improvement in study design were noted during this project. Future studies with this population of anesthesia providers would benefit from electronic surveys in place of paper surveys. There was difficulty in reaching every provider due to staff and surgical scheduling. An electronic survey would be more effective in providing a convenient way to complete a survey, and it would have reached more providers at this facility.

Currently, there is no assessment tool in place at this facility to assess patients for delirium. In the future, implementation of a tool, such as the Confusion Assessment Method (CAM), to detect POD in patients at this facility would allow comparison of POD prevalence with or without BIS use. Also, integration of the BIS monitoring equipment into the electronic charting system at this facility would allow more consistent data to be recorded and eliminate the need to manually enter data obtained from the BIS monitor, thereby removing a potential barrier for recording BIS data.

Future projects focusing on POD should include assessment of risk factors for delirium as additional data points in a larger sample size, possibly using data from

resources such as Centers for Medicare & Medicaid Services (CMS). Additional data combined with assessments of the impact of BIS use on outcomes related to POD, including cost effectiveness, would be a logical next step.

Information gained from parts 1 and 2 of this project can be used to guide future improvements in education and information dissemination among providers at this 512 bed level 2 trauma center. Data from part 1 of this study provides a baseline assessment of BIS use among patients 65 years of age or older undergoing general anesthesia. Part 2 of this study described current provider knowledge of recent literature related to BIS monitor use, barriers to use, and plans for practice change. Future interventions to improve BIS use at this facility can be compared to this data as a measure of practice change.

APPENDIX A – Institutional Review Board Approval Letter



INSTITUTIONAL REVIEW BOARD
118 College Drive #5147 | Hattiesburg, MS 39406-0001
Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16080503
PROJECT TITLE: Evaluating the Likelihood of Use of Bi-spectral Index Guided Anesthesia as a Strategy to Reduce Post-Operative Delirium in Surgical Patients 65 Years of Age or Older
PROJECT TYPE: New Project
RESEARCHER(S): Simon Gibson
COLLEGE/DIVISION: College of Nursing
DEPARTMENT: Nurse Anesthesia Program
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Exempt Review Approval
PERIOD OF APPROVAL: 08/18/2016 to 08/17/2017
Lawrence A. Hosman, Ph.D.
Institutional Review Board

APPENDIX B – Facility Institutional Review Board Approval Letter



DATE: August 3, 2016

TO: Simon Gibson, BSN

FROM: [REDACTED] Hospital Institutional Review Board

STUDY TITLE: [930616-1] EVALUATING THE LIKELIHOOD OF USE OF BISPECTRAL INDEX GUIDED ANESTHESIA AS A STRATEGY TO REDUCE POSTOPERATIVE DELIRIUM IN SURGICAL PATIENTS 65 YEARS OF AGE OR OLDER

SUBMISSION TYPE: HIPAA IRB Waiver of Authorization

ACTION: APPROVED

APPROVAL DATE: July 20, 2016

EXPIRATION DATE: July 19, 2017

REVIEW TYPE: Full Committee Review

The [REDACTED] Hospital Institutional Review Board (H IRB) has reviewed and approved the Waiver of Authorization for use of protected health information (PHI) for this research study as outlined in the approved research protocol.

In approving this Waiver of Authorization, the [REDACTED] H IRB has determined the following criteria has been met:

The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

- An adequate plan to protect the identifiers from improper use and disclosure
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to and use of the requested information

In making this determination the FGHI IRB has followed the requirements of the Common Rule using Full Board Review procedures.

APPENDIX C -Facility Institutional Review Board Exemption Letter



DATE: August 3, 2016

TO: Simon Gibson, BSN

FROM: [REDACTED] Hospital Institutional Review Board

STUDY TITLE: [930616-1] EVALUATING THE LIKELIHOOD OF USE OF BISPECTRAL INDEX GUIDED ANESTHESIA AS A STRATEGY TO REDUCE POSTOPERATIVE DELIRIUM IN SURGICAL PATIENTS 65 YEARS OF AGE OR OLDER

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS

DECISION DATE: July 20, 2016

REVIEW CATEGORY: Exemption category # B4

Thank you for your submission of New Project materials for this research study. [REDACTED] Institutional Review Board (IRB) has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

Even though your project is exempt from IRB review, the research must be conducted according to the proposal submitted to the IRB. If changes to the approved protocol occur, a revised protocol must be reviewed and approved by the IRB before implementation. Please be aware that changes to the research protocol may prevent the research from qualifying for exempt review and require submission of a new IRB application or other materials to the IRB.

If an unexpected situation or adverse event happens during your investigation, please notify the FGHI IRB as soon as possible. If notified, we will ask for a complete explanation of the event and your response. Other actions also may be required depending on the nature of the event.

If you have any questions, please contact Michele Stanley at 601-281-2424 or mstanley@forestgeneral.com. Please include your study title and reference number in all correspondence with this office.

Sincerely,

Lewis E. Hatten, M.D.
Chairman, Institutional Review Board

APPENDIX D -Letter of Support



To: IRB Chair and Committee

This letter is in reference to Simon Gibson, SRNA who is conducting research for his capstone project at [REDACTED] Hospital in Hattiesburg, MS. The title of his proposed clinical scholarship and practice inquiry is *Evaluating the Likelihood of Use of Bispectral Index Guided Anesthesia as a Strategy to Reduce Postoperative Delirium in Surgical Patients 65 Years of Age or Older*. As Chief Anesthesiologist at FGH, I fully support this academic endeavor, and look forward to his findings and implications for clinical practice change for this population.

If there is any other information you should need, please do not hesitate to contact me.

Sincerely,

Joe H. Campbell, MD

PO
6051
602-2[REDACTED] 000 • [REDACTED]@general.com

APPENDIX E -Provider Survey and Cover Letter



THE UNIVERSITY OF
SOUTHERN MISSISSIPPI

COLLEGE OF NURSING
118 College Drive #5095 Hattiesburg, MS 39406
Phone: 601.266.5445 | Fax: 601.266.5927 | anising@usm.edu | www.usm.edu/nursing

Cover Letter and Survey

Evaluating the Likelihood of Use of Bispectral Index Guided Anesthesia as a Strategy to Reduce Postoperative Delirium in Surgical Patients 65 Years of Age or Older

Dear Survey Participant,

Hello, my name is Simon Gibson and I am a SRNA student at the University of Southern Mississippi. I am in the USM College of Nursing Nurse Anesthesia Program working on my clinical project. The purpose of this research study is to evaluate the likelihood of Bispectral Index monitor use intraoperatively in the surgical population 65 years of age or older, and to determine anesthesia provider awareness of BIS monitor use recommendations, attitudes and barriers related to BIS monitor use, and if there are plans for practice change. I am requesting for you to complete this 5 question survey, Bispectral Index Monitor Use Survey. This anonymous survey will take about 10 minutes. Your participation is voluntary. You must be 18 years of age to participate and by participating you are verifying that you are 18 years old or older. Completing this survey indicates an agreement to participate in this study.

There are no incentives or compensation for participation. There are also no risks to you with your participation. If you are unable to take this survey today but would like to complete it at a later time, take a copy of the survey and return it by 9/30/2016. This survey may be returned to me by mail in the supplied pre-addressed stamped envelope. Your responses to this survey will be kept confidential. In any reports written about this study will not reveal information that would allow anyone to identify who took part. Once submitted, survey answers cannot be withdrawn.

The student researcher in charge of this study is Simon Gibson, and he can be contacted at simon.gibson@eagles.usm.edu. My chair is Dr. Cathy K. Hughes at The University of Southern Mississippi College of Nursing Department on the Hattiesburg Campus. If you have any questions, my chair can be contacted at cathy.hughes@usm.edu. If you would like

any follow-up information or results from this survey, you can contact me at the email provided above.

This project has been reviewed by the University of Southern Mississippi Institutional Review Board (IRB) (Human Subjects Protection Review Committee which ensures that research projects involving human subjects follow federal regulations. Any questions or concerns about rights as a research subject should be directed to the chair of the Institutional Review Board, The University of Southern Mississippi, 118 College Drive #5147, Hattiesburg, MS 39406. (601) 266-6820.

Bispectral Index Monitor Use Survey

- 1.) Were you aware of the published recommendation from the American Geriatrics Society titled *Clinical Practice Guideline for Postoperative Delirium in Older Adults*, which recommended the use of processed encephalographic monitoring in patients 65 years of age or older as a way to reduce the incidence of postoperative delirium?
(Article reference DOI: 10.1111/jgs.13281)

- 2.) Do you currently use a Bispectral Index monitor routinely in patients 65 years of age or older?

- 3.) What barriers are there for use of Bispectral Index monitor use in your practice?

- 4.) Do you plan to change your practice based on available evidence?

- 5.) In what situations would you consider use of Bispectral Index monitoring in your practice?

APPENDIX F – Postoperative Delirium and Bispectral Index Monitor Fact Sheet

Evaluating the Likelihood of Use of Bispectral Index Guided Anesthesia as a Strategy to Reduce Postoperative Delirium in Surgical Patients 65 Years of Age or Older

A capstone project by Simon Gibson

Postoperative Delirium and Bispectral Index Monitoring Fact Sheet

- Postoperative delirium (POD) is the most common postoperative complication in patients 65 years of age or older, accounting for approximately \$164 billion in costs per year in the United States (Inouye, Westendorp, & Saczynski, 2014, p. 911).
- POD occurs in as many as 50% of patients 65 years of age or older, but can be prevented as much as 40% of the time (Inouye et al., 2014).
- In 2015, the American Geriatrics Society released recommendations aimed at prevention of POD, finding that the use of processed encephalographic monitoring intraoperatively to guide anesthetic dosage is the single intraoperative intervention with enough literature to support it as a recommendation for use to reduce POD (American Geriatrics Society, 2015).
- Recent literature suggests that there is an overall average reduction of POD prevalence of approximately 10% when comparing groups of patients who receive BIS guided anesthesia to those who receive routine anesthesia care (Chan et al., 2013; Sieber et al., 2010; Radtke et al., 2013; Whitlock et al., 2014; Santarpino et al., 2011).
- BIS values of 40-60 were associated with reduced incidence of delirium. Values of less than 20 were found to be independently associated with POD risk (Radtke et al., 2013).

APPENDIX G – Literature Review Table

Citation	Purpose	Design	Sample	Data Collection and Measurements	Level of Evidence	Results	Strengths and Weaknesses
Punjasawadwong, Y., Phongchiewboon, A., & Bunchungmongkol, N. (2014). Bispectral index for improving anaesthetic delivery and postoperative recovery.	To determine if the use of bispectral index can reduce the risk of intraoperative awareness, consumption of anesthetic agents, cost of anesthetic, and recovery time in patients undergoing general anesthesia.	Systematic Review of Randomized Controlled Trials	Thirty-six trials were included.	The authors searched the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and reference lists of articles for relevant studies.	Level 1 - Systematic review of RCT's	BIS guided anesthesia shows a statistically significant reduction in risk of awareness under anesthesia, reduced anesthetic agent consumption, and reduced recovery times and PACU stays. It did not reduce the time to readiness to be discharged home.	Strengths: Systematic review of RCT's. Weaknesses: Inability to blind providers in the studies increased risk of bias. High risk of selection bias in some included studies.

<p>Inouye, S. K., Westendorp, R. G., & Saczynski, J. S. (2014, March 8). Delirium in elderly people.</p>	<p>To complete a review of articles in order to highlight important topics and guide clinical practice.</p>	<p>Review</p>	<p>Thirty-five studies were selected for inclusion in the review.</p>	<p>Search of Medline, PubMed, and reference lists from articles using the key terms: Delirium, acute confusion, organic brain syndrome, etiology, pathophysiology, physiopathology, or pathogenesis. Review of work published Jan 1, 2004 and December 31, 2012 to provide overview of epidemiology. Review of articles published January 1, 1990 to December 31, 2012 for information on non-pharmalogical studies and validated risk prediction models.</p>	<p>Level 2- Systematic review of RCT's, quasi-experimental and non-experimental studies without meta-analysis</p>	<p>Recommendations include: Assess for delirium in all patients 65 years or older; use less psychoactive drugs; use non-pharmalogical interventions when possible; encourage family involvement in care; avoid bedrest when possible; maximize sensory perception; maximize patient involvement in care.</p>	<p>Strengths: Systematic review with rigorous inclusion criteria. Weaknesses: No meta-analysis</p>
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Brown, C. H., Azman, A. S., Gottschalk, A., Mears, S. C., & Seiber, F. E. (2014)	To determine effect of low BIS scores on postoperative mortality in elderly patients.	Randomized Controlled Trial	One-hundred fourteen patients over 65 years old admitted to hip fracture service at Johns Hopkins Bayview Hospital.	This study was based on a randomized trial done from 2005-2008. The authors examined long term mortality in patients who received light vs deep sedation in the original trial.	Level 2- Randomized Controlled Trial	In patients with serious comorbidities or Charlson score >6, light sedation (BIS >80) was associated with lower 1-year mortality.	Strengths: Based on results from a RCT. Weaknesses: Included only patients receiving spinal anesthesia.
Bellelli, G., Mazzola, P., Morandi, A., Bruni, A., Carnevali, L., Corsi, M., ... Annoni, G. (2014)	To examine the link between number of days with delirium and 6-month mortality.	Prospective, observational, cohort study	One-hundred ninety-nine patients admitted to an orthogeriatric unit at San Gerardo University Hospital.	Delirium was assessed using the confusion assessment method (CAM). The association between POD and 6-month mortality was determined using Multivariate Cox regression models.	Level 4 - Cohort study.	Fifty-seven participants developed POD. In the 6-month period after surgery, 35 participants died: 16 of 57 with POD and 19 of 142 with no POD.	Strengths: Daily assessment of delirium using screening (CAM) and diagnostic (DSM-IV-TR) tools. Weaknesses: Single site, small sample study so results may not be widely applicable. Lack of assessment of drugs that may influence delirium. Data regarding admission, or duration of delirium after discharge times were not assessed.

Radtke, F. M., Franck, M., Lendner, J., Kruger, S., Wernecke, K. D., & Spies, C. D. (2013)	To determine if depth of anesthesia monitoring reduces incidence of POD.	Randomized Controlled Trial	The data of 1,155 patients over 60 years old or older was analyzed.	Cognitive function was evaluated prior to, 1 week, and 3 months postoperatively. Delirium was assessed two times a day through the first to the seventh postoperative day using criteria from the DSM IV.	Level 2 - Single randomized control trial.	Use of BIS guided anesthesia was associated with lower incidence of POD. Delirium in the BIS group was 16.7% and 21.4% in the control group.	Strengths: Assessment of delirium was performed by trained providers and the study was blinded. Weaknesses: One-hundred forty one patients were unblinded.
Gusmao-Flores, D., Salluh, J. I., Chalhub, R. A., & Quarantini, L. C. (2012)	To evaluate the effectiveness of the CAM-ICU and ICDSC for diagnosis of delirium in critically ill patients.	Systematic Review with Meta Analysis	Review of nine studies that evaluated 969 total patients using CAM-ICU, and 4 studies that evaluated 391 patients total using ICDSC.	Database search using MEDLINE, SciELO, CINAHL, and EMBASE.	Level 1 - Systematic review of RCT's	When compared to DSM-IV criteria, CAM-ICU had a specificity of 95.5% and sensitivity of 80% while ICDSC had a specificity of 81.9% and sensitivity of 74%.	Strengths: Systematic review that included the summary receiver operating characteristic (SROC) curve for evaluation. Weaknesses: No patient ages were included in the analysis.

Kertai, M. D., Palanca, B. J., Pal, N., Burnside, B. A., Zhang, L., Sadiq, F., ... B-Unaware Study Group (2011)	To determine if BIS values lower than 45, total anesthetic dose, comorbidities, or intraoperative events were independently associated with postoperative death.	Randomized Controlled Trial	The study included 1,473 patients who had noncardiac surgery.	Patients were assigned to either a BIS guided anesthesia protocol or anesthetic agent concentration protocol group. BIS scores of 40-60, or end-tidal anesthetic concentration of 0.7-1.3 MAC were maintained for each group.	Level 2 - Single randomized control trial.	The patients in the BIS guided group did not have lower mortality rates than the MAC guided group. Cumulative duration of BIS less than 45 was not associated with higher mortality.	Strengths: Study design. Large sample size. Weaknesses: Determining effect of anesthetic dose on mortality was limited by the multiple medications used in each patient. Study was not limited to elderly patients.
Sieber, F. E., Zakriya, K. J., Gottschalk, A., Blute, M., Lee, H. B., Rosenberg, P. B., & Mears, S. C. (2010)	To determine if limited sedation depth during spinal anesthesia for hip fracture repair in patients 65 years old or older would result in lower POD prevalence.	Randomized Controlled Trial	One hundred fourteen elderly patients randomized into light (BIS of 80) or deep (BIS of 50) propofol sedation groups.	Use of the CAM or the MMSE by a trained research nurse at approximately 10 AM on postoperative day 2, and using the CAM at approximately 10 AM from postoperative day 3 until discharge.	Level 2 - Single randomized control trial.	A decrease in the prevalence of delirium by 50% was observed in the light sedation group as compared to the deep sedation group. Actual dose of propofol was not independently associated.	Strengths: Study design. Weaknesses: Assessment of delirium only one time per day. Exclusion of patients with MMSE scores of less than 15 limits the generalizability to patients with moderate dementia.

Lindholm, M., Traff, S., Granath, F., Greenwald, S. D., Ekbohm, A., Lennmarken, C., & Sandin, R. H. (2009)	To determine validity of previous studies who found that deep anesthesia with BIS of <45 is a risk factor for death within 1-2 years after surgery and to determine the impact of malignancy on mortality in that period.	Controlled trial without randomization	Four thousand eighty-seven patients were included in the study.	Survivors BIS values were compared to non-survivors, then the association between BIS scores <45 and 2 year mortality, then the first step was repeated including preexisting malignancy as a covariate.	Level 3 - Controlled trial without randomization	BIS values of <45 were found to be an independent predictor of mortality, along with preexisting malignancy, ASA physical score of 4, age over 80 years. When malignancy was added as a covariate, BIS scores were no longer significant.	Strengths: Large sample size. Weaknesses: Not randomized.
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Ellerkmann, R. K., Kreuer, S., Wilhelm, W., Ropcke, H., Hoefl, A., & Bruhn, J. (2006)	To examine the link between lowered anesthetic drug administration and average BIS values.	Systematic review	There were 14 RCT studies included in this review.	A search of the MEDLINE database and the Cochrane Central Register of Controlled Trials between 1980-2006 was used. Reference lists of analysed articles were also searched for relevant articles.	Level 1 - Systematic review of RCT's	There was a significant correlation in mean BIS values and use of hypnotic drugs. Every BIS point correlated with a 2% reduction in hypnotic drug use.	Strengths: Study design. Weaknesses: Translation of these findings to other EEG parameters is not possible, which limits the clinical usefulness of these findings in some settings.
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Chan, M. T., Cheng, B. C., Lee, T. M., Gin, T., & CODA Trial Group (2013)	To test the impact of BIS monitoring on postoperative cognitive dysfunction.	Randomized Controlled Trial	There were 921 elderly patients having major non-cardiac surgery included in this study.	Patients were randomized to receive BIS guided anesthesia or routine anesthesia care. Anesthetic depth in the BIS guided group was titrated to BIS values between 40-60 intraoperatively. BIS values were measured in the routine group but not shown to the anesthesia provider. Neurological testing was done prior to, 1 week, and 3 months after surgery. Delirium was assessed using the CAM.	Level 2 - Single randomized control trial.	Patients in the standard care group had mean BIS values recorded significantly lower than the BIS guided group. There were 15.6% of patients in the BIS guided group who developed delirium, compared with 24.1% of patients in the control group. Cognitive function in both groups was similar at 1 week postoperative, but the POCD was lower in the BIS group at 3 months.	Strengths: Study design. Large sample size. Weaknesses: Unable to compare scores of neurological testing with other studies due to use of different tests.
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Whitlock, E. L., Torres, B. A., Lin, N., Helsten, D. L., Nadelson, M. R., Mashour, G. A., & Avidan, M. S. (2014)	To evaluate the incidence of delirium in patients randomized into BIS guided vs end tidal anesthetic concentration guided anesthesia protocols.	Cohort Study	There were 310 patients included in this study. This was a single-site substudy of the BAG-RECALL clinical trial. Patients enrolled in that trial were at risk of intraoperative awareness. Patients were randomized into a BIS guided group or age adjusted MAC groups. The goal in the BIS group was a BIS score between 40-60.	Delirium was assessed twice daily through the first of either postoperative day 10 or discharge from ICU. Assessment was done by a trained ICU nurse who was blinded to group assignments.	Level 4 - Cohort study.	Postoperative delirium occurred in 18.8% of the BIS group vs 28% of the end-tidal anesthetic group. Low average anesthetic gas dose, blood transfusion during surgery, ASA PS scores, and high EuroSCORE were found to be independent risk factors for delirium.	Strengths: Use of a trained nurse using CAM to assess delirium. Weaknesses: Relatively low sample size. No baseline assessments for pre-existing cognitive dysfunction. Single center cohort study so results may not be generalizable.
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Santarpino, G., Fasol, R., Sirch, J., Ackermann, B., Pfeiffer, S., & Fischlein, T. (2011)	To evaluate the use of BIS and its association with postoperative neurological outcome and delirium in surgical patients having aortic surgery.	Retrospective Cohort Study	There were 292 patients included in this study	Retrospective review of records of patients having aortic surgery with circulatory arrest. Anesthetic technique was standardized for all patients. BIS measurements were taken prior to induction and every 15 minutes after. A ratio between baseline and minimum BIS values was calculated.	Level 3 - retrospective cohort study	A total of 53 patients in this study developed POD. There was a significant risk increase with BIS value reduction of 25-30% from baseline.	Strengths: Comparison of baseline BIS values to intraoperative values. Standardization of anesthetic technique. Weaknesses: Small sample size. Arbitrary creation of groups based on BIS reduction, and the 15 minute time interval for BIS reduction. Lack of inclusion of other factors that contribute to POD in the statistical analysis.
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