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# Implementation of a Beta Blocker Protocol

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# IMPLEMENTATION OF A BETA BLOCKER PROTOCOL

by

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Dedication

I would like to dedicate this paper to my loving husband, who facilitated my entire doctoral education with his unending love, support, and encouragement.

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## Abstract

Background: Beta blockers are recommended by the American College of Cardiology/American Heart Association Guidelines for high and intermediate-risk cardiac patients undergoing non-cardiac surgery. Beta blockers are a class of drugs that moderate the effects of increased catecholamine levels on the heart by selectively blocking beta receptors in the heart and blood vessels, resulting in a lower heart rate and blood pressure. Beta blocker use perioperatively has been shown to reduce the risk of ischemia and infarction.

Purpose: The purpose of this project is to address beta blocker use in a group of anesthesia providers who routinely attend to high-risk and intermediate-risk cardiac patients undergoing non-cardiac surgery in a medium-sized private hospital in suburban South Florida. There are barriers to the implementation of the published guidelines for beta blocker administration, including lack of awareness of the best current practice and a lack of a formal beta blocker protocol at the institutional level.

Methods: A simple and inexpensive beta blocker protocol was implemented and evaluated by various means. Beta blocker administration practices were examined and documented prior to and after protocol implementation. Beta blocker usage was examined prior to and after protocol implementation

Findings/Implications: It was hypothesized that increased anesthesia provider awareness would lead to increased administration of perioperative beta blockers to high-risk and intermediate-risk cardiac patients undergoing non-cardiac procedures. Although

there was a knowledge increase related to the new beta blocker protocol, no change in practice was observed.

Chapter 1: Introduction

**Problem Identification**

According to published estimates, 27 million non-cardiac surgeries are performed in the United States annually; four to six percent of patients with cardiac disease or cardiac risk factors undergoing non-cardiac surgery will have a myocardial infarction (MI), up to 1% will have a stroke, and 2-3% will die of cardiac and non-cardiac causes (White et al., 2010). The leading cause of postoperative morbidity and mortality is perioperative MI (Savio et al., 2011). There is a mortality rate of 15-25% in patients having an MI after non-cardiac surgery and a mortality rate of 65% in patients having a cardiac arrest after non-cardiac surgery (Devereaux et al., 2005). Perioperative complications can prolong hospital stays significantly, add to overall healthcare costs, and consume healthcare resources.

Beta blocker use perioperatively has been shown to reduce the risk of ischemia and infarction, and is recommended by the American Heart Association and the American College of Cardiology (Beckman et al., 2006) for patients already on beta blockers and high-risk patients having non-cardiac surgery. The recommendations are not as clear for intermediate and low-risk patients (White et al., 2010). Appropriate perioperative beta blockade in high-risk patients has been a national standard of care since 1996, although guidelines for implementation have been updated several times and continue to evolve (Wallace, Au, & Cason, 2010). Not all institutions and anesthesia

providers follow this standard of care or the ACC/AHA guidelines consistently (Lindenauer et al., 2005).

**Abbreviated Literature Review**

Numerous trials have looked at the benefits and risks of beta blocker therapy in various patient populations. A literature search was conducted using the search terms *perioperative beta blockers* and *perioperative beta blocker protocols*. PUBMED and CINAHL were queried. PUBMED returned 78 articles using the following limits: humans; clinical trials; meta-analyses; practice guidelines; English; MEDLINE; Adults 19+; 1995-2011. CINAHL returned 49 full text articles dated between 1995 and 2011.

Four random controlled trials (RCTs) evaluated the perioperative use of beta blockers in non-cardiac surgery; first, the Perioperative Ischemia Evaluation (POISE) looked at 8351 patients with a 30-day follow up; second, the Beta Blocker in Spinal Anesthesia (BBSA) looked at 219 patients with a 1-year follow-up; third, in the Atenolol Study, Mangano, Layug, Wallace, and Tateo (1996) looked at 200 patients with a 2-year follow-up; fourth, the Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography (DECREASE), looked at 112 patients with a 30-day follow-up. The Atenolol and DECREASE studies were influential in increasing perioperative beta blocker administration and this led to clinical practice guidelines, institutional benchmarking, and performance measures. Not everyone was convinced that aggressive beta blockade was safe and effective; the Atenolol and DECREASE trials were both criticized for their small sample size, lack of placebo control, and the chosen method of statistical analysis (London, 2008). White, et al. (2010) critiqued these four RCTs and

concluded that the use of beta blockers reduces the MI rate but increases the frequency of stroke, severe hypotension, and severe bradycardia. Wallace et al. (2010) showed a significant association between perioperative beta blockade and postoperative survival in patients with existing indications for beta blockade.

**Historical Development of Guidelines**

The 1996 Atenolol Study provided evidence that perioperative beta blockers reduced mortality. In 1998, Wallace et al. developed a protocol based on this evidence and called it the Perioperative Cardiac Risk Reduction Therapy (PCRRT); until its introduction, only patients in RCTs received perioperative beta blockers by study specific protocols. The PCRRT protocol is simple and easy to follow and has been adopted by a number of hospitals and hospital systems (Wallace et al., 2010).

In 2001, the Agency for Healthcare Research and Quality (AHRQ) recommended the use of beta blockers to reduce perioperative cardiac events and mortality in high-risk patients undergoing non-cardiac surgery. However, controversies remained in the literature regarding the use of beta blockers in patients of low or moderate risk having non-cardiac surgery (VanDenKerhof, Milne, & Parlow, 2003).

The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines issued a 2006 focused update on perioperative beta blocker therapy in response to this therapy becoming a quality measure for the Physicians Consortium for Performance Improvement and the Surgical Care Improvement Project (Beckman et al., 2006). The recommendations produced by the Task Force were intended for use in these national quality initiatives and contained three levels of evidence (A, B, and C), and three classes of recommendations (Class I; Class II, a and b;

and, Class III). The focused update recommendations were integrated into the revised ACC/AHA guidelines on perioperative cardiovascular evaluation for non-cardiac surgery in 2009. The 2009 ACC/AHA consensus guidelines state that there is a Class I recommendation to continue beta blockers in patients who are currently taking them and a Class IIa recommendation to start titrated beta blockers in patients with coronary artery disease or in intermediate to high-risk patients. There is also a Class IIb recommendation for beta blockers in intermediate to low-risk patients, although the usefulness is uncertain (Eldrup-Jorgensen, 2011).

**Clinical Practice**

Anesthesia providers usually practice autonomously and are relatively free to implement evidence-based practices and clinical guidelines in the operating room (OR), limited only by the drugs and equipment available. Limiting factors include available choice of beta blockers, lack of consensus in the literature regarding the best choice of beta blocker, and fear of possible iatrogenic complications (VanDenKerhof et al., 2003; Baxter & Kanji, 2007).

The integration of a simple and inexpensive beta blocker protocol into routine clinical practice can lead to improved outcomes in select cardiac patients undergoing non-cardiac surgery (Armanious, Wong, Etchells, Higgins, & Chung, 2003; Baxter & Kanji, 2007; Wallace et al., 2010). Successful protocol implementation requires clinician acceptance, participation, and evaluation (Baxter & Kanji, 2007). Numerous protocols have been published in the anesthesia literature and implemented with varying degrees of success. One such protocol implemented in the Ottawa Hospital, Ottawa, Canada, demonstrated that the standardization of a perioperative protocol to identify at-risk

patients coupled with heightened anesthesia provider awareness led to an increase in beta blocker use and a reduction in adverse cardiac events (Baxter & Kanji, 2007).

**The Problem**

Evidence exists to support the use of beta blockers in high-risk and intermediate-risk cardiac patients undergoing certain non-cardiac procedures. The purpose of this project was to address the use of beta blockers in a group of anesthesia providers, both certified registered nurse anesthetists (CRNAs) and medical doctor anesthesiologists (MDAs) who routinely attend to high-risk and intermediate-risk cardiac patients undergoing non-cardiac surgery in a medium-sized, private suburban hospital in the Southeastern United States. The study was implemented and evaluated. Beta blocker administration practices were examined and documented prior to and after protocol implementation. It was hypothesized that increased anesthesia provider awareness of the ACC/AHA guidelines for beta blocker administration would lead to increased administration of beta blockers to high-risk and intermediate-risk cardiac patients undergoing non-cardiac procedures. The PICO question used to identify the evidence for the project was "In anesthesia providers caring for cardiac patients undergoing non-cardiac surgery how does an increase in awareness of ACC/AHA guidelines for perioperative beta blocker administration influence compliance and decrease major perioperative complications?"

**Definitions**

**Anesthesia Provider**

A certified registered nurse anesthetist (CRNA) is an advanced practice registered nurse (APRN) who has acquired graduate-level education and board certification in anesthesia. A medical doctor anesthesiologist (MDA) is a medical doctor who has successfully completed an accredited residency program in anesthesia. No board certification is necessary to practice.

**Risk**

The Revised Cardiac Risk Index (RCRI) is a clinical prediction rule for use during preoperative care for prediction major cardiac complications of non-cardiac surgery originally published in 1977; six equally weighted cardiovascular risk factors (high-risk surgery, history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, preoperative serum creatinine level >2.0 mg/dl) are scored one point each. Low-risk is one point or less, moderate-risk is two points, high-risk is three or more points.

**Protocol**

Protocol is a document that describes in detail the plan for conducting a clinical study. The study protocol explains the purpose and function of the study as well as how to carry it out. It describes the objectives, design, methodology, statistical considerations, and organization of the clinical trial.

**Clinical Practice Guidelines**

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (Institute of Medicine, 1990).

**Summary**

In summary, Chapter One introduced the challenges/problems with beta blocker use, the potential benefits of using beta blockers, an abbreviated literature review, and a brief description of the proposed project. Research questions used to search the literature and definitions were also provided.

# Chapter Two: Review of the Literature

In this chapter, a more thorough review of the literature is included. The role of beta blockers in preventing perioperative cardiac events is examined, methods of risk identification and reduction are identified, literature supporting the use of perioperative beta blockers is evaluated, and a critical appraisal of the literature is presented. A literature search was conducted using Medline, CINAHL, and PUBMED for high level evidence using the following key terms: *perioperative beta blockers and perioperative beta blocker protocols*. Articles dating back to 1995 that had the key terms were reviewed.

## Role of Beta Blockers

Beta blockers have been used clinically since the 1960s to treat hypertension, heart failure, and coronary artery disease. They exert their beneficial anti-arrhythmic, anti-inflammatory, and anti-renin-angiotensin effects by blocking beta 1 and 2 receptors found throughout the body. The major direct effects are heart rate reduction, which increases diastolic perfusion time; and reduced myocardial contractility, which reduces myocardial oxygen demand. Beta blockers decrease sympathetic tone, which indirectly reduces inflammation and shear stress leading to stabilization of coronary plaques. The physiological rationale for perioperative beta blockade is to reduce the stress state brought on by surgery with its associated fasting, anesthesia, intubation, extubation, pain, hypothermia, and bleeding (Devereaux et al., 2005). This stress state involves increased cortisol and catecholamine levels leading to increases in heart rate, blood pressure, coronary artery shear stress, insulin deficiency, and free fatty acids. These factors can all lead to increased oxygen demand and perioperative myocardial ischemia, which is

strongly associated with preioperative myocardial infarction (Devereaux et al., 2005). Beta blockers can attenuate both kinds of perioperative MIs; those caused by an asymptomatic coronary plaque rupturing in patients with multiple risk factors for MI but no critical stenosis, and those with a fixed coronary stenosis leading to a predisposition to mismatch myocardial oxygen supply and demand. Studies have shown that a significant proportion of fatal perioperative MIs are due to an increase in oxygen demand in the setting of fixed coronary stenosis (decreased supply) (Landesberg, 2003).

**Risk Identification**

The key to successful prevention of perioperative cardiac events in non-cardiac surgery lies with identifying patients at risk for these events and optimizing them before surgery. Patients with active cardiac conditions need to be identified, evaluated, and treated before surgery. Simple clinical markers can identify patients at increased risk for perioperative cardiac events. The Revised Cardiac Risk Index is a common preoperative risk stratification strategy that has been validated in prospective studies and is based on the Lee Index (Lee et al., 1999). Six equally weighted cardiovascular risk factors (high-risk surgery, history of ischemic heart disease, history of congestive heart failure, history of cerebrovascular disease, preoperative treatment with insulin, preoperative serum creatinine level >2.0 mg/dl) are scored one point each. Perioperative cardiac complications with no risk factors are 0.4%, one risk factor 0.9%, two risk factors 7%, and three or more risk factors 11%. The ACC/AHA algorithm for preoperative risk assessment can also be used to stratify cardiac patients undergoing non-cardiac surgery. It is limited in its validity as it was not derived from a prospective study and includes

judgments from committee members (expert opinions) (Devereaux et al., 2005). Once perioperative risk has been quantified, risk mitigation can be considered.

Prophylactic perioperative use of beta blockers in high-risk and intermediate-risk cardiac patients undergoing non-cardiac surgery may be protective and reduce the risk of perioperative cardiovascular complications. The first RCT addressing the issue of perioperative beta blockers was conducted by Mangano et al. in 1996 (Mangano et al., 1996). The authors concluded that the perioperative administration of atenolol decreased perioperative ischemia and caused an increased rate of event-free survival at six months in 200 high-risk cardiac patients undergoing non-cardiac surgery. As part of the Multicenter Study of Perioperative Ischemia Research Group, Dr. Wallace at UCSF-VA Medical Center developed a perioperative cardiac risk reduction therapy (PCRRT) using beta blockers and clonidine for those patients in whom beta blockers are contraindicated (BBAC). Perioperative myocardial ischemia is a risk factor that can actually be modified, unlike fixed risk factors such as age, hypertension, peripheral vascular disease, diabetes, coronary artery disease, and hyperlipidemia. Prophylactic beta blockers are one medical therapy that can modify and reduce the risk of perioperative cardiac morbidity and mortality by up to 90% (Wallace, 1998).

**Literature Review**

In appraising the literature, multiple levels of evidence were reviewed. Articles on perioperative use of beta blockers ranging from case studies to systematic reviews were all appraised. This paper reviews multiple levels of evidence; two randomized studies, and two combined meta-analysis and systematic reviews. Two large, longitudinal cohort studies are also examined, as well as two expert reviews.

**Randomized Controlled Studies**

The Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography (DECREASE) study by Poldermans et al. (1999), examined 112 high-risk patients undergoing major vascular surgery in a randomized, multi-center study. High-risk patients were identified by clinical risk factors and positive results on dobutamine stress echocardiography. Patients were stratified to receive bisoprolol, a beta blocker (59 patients), or placebo (53 patients); the group randomized to bisoprolol had significant reductions in perioperative cardiac death and nonfatal MI. The overall rate of the combined endpoint of nonfatal myocardial infarction and death from cardiac causes was 34% (95% CI, 21 to 48%) in the placebo group, compared to 3.4% (95% CI, 0 to 8%) in the bisoprolol group. The estimated relative risk of death in the bisoprolol group compared to the placebo group was calculated to be 0.09 (95% CI, 0.02 to 0.37) ($P<0.001$). Statistical analysis methods were presented and were appropriate for the data. The high rate of serious perioperative events in the placebo group was considered consistent with other studies on similar high-risk patients. The authors concluded that bisoprolol reduced the perioperative incidence of death from cardiac causes and nonfatal MI in high-risk patients undergoing major vascular surgery. The limitations of this study included its lack of blinding, although no major differences were found by the authors in the major aspects of perioperative treatment across the eight institutions involved in the study; this lack of blinding may have contributed to reporting errors and bias on the part of the investigators. The importance of this study was the decrease in death and other serious perioperative complication in high-risk patients.

The Perioperative Ischemic Evaluation (POISE) trial by Devereaux et al. (2006) was designed to investigate the effects of perioperative beta blocker use. It was a large, random controlled trial that instituted a single large dose of oral, extended release metoprolol (a beta blocker) in 8,351 beta blocker naïve, at-risk patients in 190 hospitals in 23 countries (4,144 in the metoprolol group and 4,177 in the placebo group). Study treatment was started 2-4 hours before surgery and continued for 30 days. The prespecified primary outcome was a composite of cardiovascular death, nonfatal MI, and nonfatal cardiac arrest at 30 days after randomization. Analyses were by intention to treat. Statistical analysis methods were appropriate for the data and all 8,351 patients were included.

The authors found statistically significant reductions in the primary outcomes of cardiac death, nonfatal MI, and cardiac arrest (hazard ratio 0.84, 95% CI 0.70-0.99; P=0.0399); this beneficial effect resulted from fewer MIs in the metoprolol group. The beneficial effect was counterbalanced by an increase in stroke (hazard ratio 2.17, 95% CI 1.26-3.74; P=0.0053) and non-cardiac death (hazard ratio 1.33, 95% CI 1.03-1.74; P=0.0317) in the beta blocker group versus the controls. The authors concluded that the results of this trial provide evidence that perioperative beta blockers prevent nonfatal MIs but increase the risk of nonfatal stroke, and that the variable beneficial effects of beta blockers were correlated with risk assessment, as the incidence of perioperative complications was contingent upon the number of risk factors present (high-risk surgery, ischemic heart disease, congestive heart failure, cerebrovascular disease, insulin-dependent diabetes, and renal failure). Limitations to the study included the possible inappropriate (both the dosage and the timing of administration) acute administration of

high-dose beta blocker therapy to beta blocker naïve patients. This study points out the importance of risk stratification and the beneficial effects of beta blockers in at-risk patients undergoing non-cardiac surgery.

**Systematic Reviews and Meta-Analyses**

Devereaux et al. (2005) published a systematic review to determine the effectiveness of perioperative beta blocker treatment in patients having non-cardiac surgery. Using seven search strategies, they identified twenty-two trials that randomized a total of 2,437 patients. Eligibility criteria included perioperative outcomes within thirty days of surgery, total mortality, cardiovascular mortality, nonfatal MI, nonfatal stroke, nonfatal cardiac arrest, hypotension needing treatment, bradycardia needing treatment, and bronchospasm. Two researchers independently evaluated study eligibility (k=0.96) and abstracted data (k=0.69-1.0). Outcomes were defined as above plus the composite outcome of major perioperative cardiovascular events (cardiovascular death, nonfatal MI, nonfatal cardiac arrest). Perioperative beta blockade did not show any statistically significant beneficial effects on any of the individual outcomes, but did show a significant beneficial relative risk of 0.44 (95% CI 0.20-0.97) for the composite outcome of cardiovascular mortality, nonfatal MI, and nonfatal cardiac arrest.

The stated strengths of the review were the multiple search strategies used to identify RCTs, verification of the data with all trialists, and evaluation of the reliability and conclusiveness of the available evidence using formal interim monitoring boundaries. The stated weaknesses of the review were the focus on short-term (30 day) outcomes, as it is possible that perioperative beta blockers affect long term outcomes, and the heterogeneity of the included studies, which weakens the reliability of the findings. The

authors concluded that their review provides encouraging evidence that perioperative beta blockers may reduce the risk of major cardiovascular events during the perioperative period. However, the evidence seems too unreliable to draw definitive conclusions. This is an important review as it supports the use of beta blockers in high-risk patients undergoing non-cardiac surgery.

A more recent systematic review and meta-analysis was conducted by Savio et al. in 2011. The authors searched electronic databases for RCTs of the perioperative use of esmolol (a short-acting intravenous beta blocker) in non-cardiac surgery. Statistical heterogeneity was assessed primarily by meta-regression. Their search identified 67 trials of 3,766 patients undergoing non-cardiac surgery. Data was extracted from the selected trials by two reviewers and included patient characteristics, study quality, drug dosages, methods of administration, changes in vital signs, and incidence of unplanned hypotension, bradycardia, myocardial ischemia, MI, and death. The quality of the studies was limited by small sample size and poorly defined allocation concealment. In the seven trials reporting the effect of esmolol on the magnitude and frequency of myocardial ischemia, it was found to decrease the frequency of myocardial ischemia in comparison with placebo (OR 0.17, 95% CI 0.02-0.45 $p<0.001$). The effects of esmolol on the incidence of perioperative MI or stroke were not assessed because these events were too infrequent in the retrieved studies. In the 67 studies, there were 6 documented MIs and no reported strokes.

The stated strengths of the review were: scrutinizing the text of each study for all adverse effects; including all adverse effects in the primary analysis; contacting all selected authors for missing information, unpublished data, or clarification of the results.

The effect of study quality on the outcome was compared using trial size, allocation concealment, and blinded outcome adjudication. The stated weaknesses of the review were: the quality of the included studies was mixed; the sample sizes were generally small (the median size was 40 patients); 4 studies had no blinding protocol; allocation concealment was only reported in 5 studies; 10 studies did not conduct an intention-to-treat analysis. The authors concluded that esmolol has the potential to be both a safe and effective drug by providing protection against myocardial ischemia in patients undergoing non-cardiac surgery. This is an important conclusion as esmolol is readily available perioperatively, has a rapid onset and a short half-life, and can be titrated to the desired effect. The authors also recommended further studies of esmolol use in high-risk patients to establish a perioperative safety and efficacy profile for esmolol.

**Cohort Studies**

Lindenauer et al. (2005) conducted a retrospective cohort study of 782,969 patients, 18 years or older, who underwent major non-cardiac surgery in 329 hospitals throughout the United States between 2000 and 2001. The data was extracted from Premier's Perspective, a database developed for measuring the quality and use of healthcare. The authors used propensity-score matching to adjust for differences between those who received beta blockers and those who did not, and compared in-hospital mortality using multivariable logistic modeling. They concluded that the relationship between perioperative beta blocker treatment and the risk of death varied directly with cardiac risk. Among the 580,665 patients with a RCRI score of 0 or 1, treatment was associated with no benefit and possible harm. Among the patients with a RCRI score of 2, 3, or 4 or more, the adjusted odds ratio for death in the hospital for each was 0.88 (95%

CI, 0.80 to 0.98), 0.71(95% CI, 0.63 to 0.80), and 0.58(95% CI, 0.50 to 0.67), respectively. This study showed that beta blockers were clearly beneficial in moderate and high-risk patients (two or more risk factors) undergoing major non-cardiac surgery, and that there was no benefit and possible harm in low-risk patients (less than two risk factors). The authors concluded that ongoing national efforts to increase patient safety by increasing the perioperative use of beta blockers appear warranted as the use of beta blockers was associated with a reduced risk of death in the hospital among at-risk patients undergoing major non-cardiac surgery.

Wallace et al. (2010) conducted an epidemiological analysis of 38,799 operations performed at the San Francisco VA Medical Center between 1996 and 2008. Four patterns of beta blocker use were identified: none, addition, withdrawal, and continuous. Logistic regression, survival analysis, and propensity analysis were performed. The perioperative addition of a beta blocker to the medical management of patients with 2 or more risk factors was associated with improved 30 day (OR 0.52, 95% CI 0.33-0.83, p=0.0006) and 1 year survival (OR 0.64, 95% CI 0.51-0.79, p=0.0001), as was the continuous use of beta blockers (30 day OR 0.68, 95% CI 0.47-0.98, p=0.04) (1 year OR 0.82,95% CI 0.67-1.0, p=0.05) in patients already on them, during the perioperative period compared to patients receiving none. Withdrawal of beta blockers during the perioperative period resulted in increased risk for 30 day (OR 3.93, 95% CI 2.57-6.01, p=0.0001) and 1 year (OR 1.96, 95% CI 1.49-2.58, p=0.0001) mortality. The authors found that undertreatment with beta blockers is still common, and that prospective risk assessment and treatment with beta blockers could potentially reduce perioperative mortality further still. The authors also found that the association between the risk of

death and perioperative beta blocker treatment varied with cardiac risk; patients without identifiable cardiac risk had no benefit and possible harm from perioperative beta blockers.

**Expert Reviews**

An expert review by Flu et al. (2009) provided an extended overview of leading observational studies, meta-analyses, RCTs, and guidelines assessing perioperative beta blocker therapy. The authors summarized the studies, guidelines, and meta-analyses to allow readers to place their strengths and weaknesses into perspective. They identified the key issues: patients undergoing major non-cardiac surgery are at high risk for cardiovascular morbidity and mortality; the majority of cardiac events in patients undergoing major vascular surgery are asymptomatic; the high frequency of perioperative cardiac complications reflects the high incidence of underlying coronary artery disease. Treatment recommendations based on the current literature and the experience of the authors were provided. They proposed that all intermediate and high-risk patients undergoing high-risk vascular procedures be treated with low-dose beta blockers, ideally started 30 days before surgery. The goal of the beta blocker therapy should be to achieve a heart rate of between 65-70 beats per minute. Withdrawal of beta blocker therapy shortly before surgery or in the immediate postoperative period was strongly discouraged, as it may lead to adverse myocardial effects. They concluded that adequate heart rate control by beta blockers exerts a beneficial effect towards postoperative morbidity and mortality.

A second expert review was published in 2010 by White et al. to describe the benefits and risks associated with the use of beta blockers in non-cardiac surgery. It was

aimed at pharmacists to provide brief advice on how to handle specific drug therapy problems as part of a clinical consultation series. The stated purpose of the article was to critique key RCTs and meta-analyses evaluating the perioperative use of beta blockers in non-cardiac surgery. According to the authors, the choice of articles to critique was based on a systematic review of the literature and included the POISE and the DECREASE trials described above. The authors concluded that the use of perioperative beta blockers in non-cardiac surgery can protect against postoperative MI but may increase the risk of hypotension, bradycardia, and stroke.

**Conclusion**

Based on the findings of this literature review, the existing consensus is that beta blockers should be used perioperatively in high and intermediate-risk cardiac patients undergoing major non-cardiac surgery.

# Chapter Three: Methodology

The purpose of this evidenced-based project was to evaluate the effectiveness of a short training program for anesthesia providers to increase their use of beta blockers in high and intermediate-risk cardiac patients undergoing non-cardiac surgery. The project design is an interventional one-group pre-test, post-test study. The research questions were as follows:

1. Was there a change in the percentage of anesthesia providers using beta blockers before and after the PowerPoint intervention?
2. Was there a change in the perception of anesthesia providers regarding the use of perioperative beta blockers before and after the PowerPoint intervention?
3. Was there a change in the amount of beta blockers used perioperatively before and after the PowerPoint intervention?

## Sample

A convenience sample of anesthesiologists and certified registered nurse anesthetists at a medium-sized hospital in suburban south Florida were asked to participate.

## Methods

This interventional, one-group pre-test post-test study design consisted of the following:

1. The primary investigator conducted a retrospective review of the pharmacy

records to quantify beta blocker usage during the perioperative period. The time frame for the review was the 3-month period immediately preceding the pre-test and planned intervention.

2. All Health Insurance Portability and Accountability Act information was honored. Data on individual patients was used in aggregate form only.
3. All eligible anesthesia providers completed a pre-test, a post-test, and viewed a PowerPoint presentation on patient selection for beta blocker administration.
4. Pharmacy records for the 3-month period of time following the intervention were assessed for the quantity of beta blockers administered to patients in the perioperative period. The outcome of interest was the increase in use of beta blockers in perioperative patients after the intervention. This outcome was evaluated 3 months after the participants viewed the PowerPoint presentation.

**Setting**

The study took place at a large suburban hospital in South Florida. This hospital is a private, 450 bed full-service facility that has been providing a range of healthcare services to residents of Fort Lauderdale, Florida for over 50 years. It is fully accredited by the Joint Commission and specializes in comprehensive adult medical care, orthopedic surgery, bariatric surgery, a complete range of cardiovascular services, and maternal and newborn care.

**Data Collection and Evaluation**

Once Institutional Review Board (IRB) approvals and written consents were obtained, participants were asked to complete an anonymous one-page pre-intervention questionnaire on their knowledge and practice regarding perioperative use of beta

blockers. When all questionnaires were completed, a 25-slide PowerPoint was emailed to all eligible anesthesia providers outlining the use of beta blockers in cardiac patients undergoing non-cardiac surgery. This evidence-based intervention was designed to give the anesthesia providers the best information about perioperative beta blocker use. The intended outcome of this intervention was to increase the use of beta blockers at this facility thereby improving patient outcomes. This project took place over 3 consecutive months. Final data collection was completion of the same anonymous questionnaire 3 months following the pre-intervention questionnaire. The data collected on beta blocker usage during the 3-month study period was compared to beta blocker usage for the 3 months immediately preceding the pre-intervention questionnaire.

**Feasibility and Resources**

The resources needed to ensure project completion include the facility keeping beta blockers stocked in the operating rooms, the pre-anesthesia area, and the post-anesthesia care unit. Medications were charged to the patient so that there were usually no budgetary considerations. As beta blockers cost much less that the cost of treating a perioperative MI, this financial plan justified the need, feasibility, and sustainability of the proposed project.

**Institutional Review Board**

Institutional Review Board (IRB) approval was obtained from both the University of North Florida (UNF), and the participating clinical site through Western Institutional Review Board (WIRB). Once both IRBs formally approved, data collection began. All data was collected anonymously and handled in an aggregate manner. There was no need to connect participant responses from pre-test to post-test, so there was no master list or

any identifying information. Prior to starting the project, signed consent was obtained, scanned into UNF's secure server, then shredded and discarded. There was no link between consent and participant responses. The raw data will be kept for three years.

**Data Analysis**

Raw data was entered into Vovici at UNF, and checked for errors. Analysis was performed using SPSS statistical software (version 16.0, 2005, Chicago, IL) with statistical significance determined at $p<0.05$. Descriptive statistics were also used. The Wilcoxon Signed-Rank Test was performed in order to examine between group differences in the use of beta blockers from pre-test to post-test. This evidence-based practice project looked to see if there was a change in overall anesthesia practice with regard to beta blocker administration. In the event that participants dropped from the study, it did not impact the project since only overall change was measured. This change in practice was quantified by comparing beta blocker usage for the 3 months preceding the intervention with usage for the 3 months after the intervention by examination of pharmacy records.

# Chapter Four: Results

This chapter describes the study population using mean scores and frequency of the variables. Analyses were executed using SPSS statistical software (version 16.0, 2007, Chicago, IL) with statistical significance determined at $p \leq 0.05$. Data were analyzed using descriptive statistics and the Wilcoxon Signed-Rank Test to determine group differences between pre-test to post-test assessments.

A total of 19 anesthesia providers participated in this evidence-based practice project; 16 were male (78.9%) and 3 were female (21.1%). No provider was under age 30, three (15.8%) were 30-39, seven (36.8%) were 40-49, six (31.6%) were 50-59, and three (15.8%) were over 60. Three providers had been in practice for 5 years or less (15.8%), two providers had been in practice 5-10 years (10.5%), two providers had been in practice 10-15 years (10.5%), seven providers had been in practice 15-20 years (36.8%), and five providers had been in practice over 20 years (26.3%).

## Pre-Intervention Results

At the beginning of the study period all of the anesthesia providers were aware of studies in the literature related to prophylactic perioperative beta blocker use in cardiac surgical patients undergoing non-cardiac surgery who are at risk for cardiac complications (100%). Only five providers (26.3%) were aware of the anesthesia department protocol for prophylactic beta blocker blockade in patients scheduled for non-cardiac surgery who are at risk for cardiac complications. Eight providers (42.1%) were not aware, and six providers (31.6%) were not sure if there was a department protocol. A risk assessment tool was used by three providers (15.8%) all the time, six providers (31.6%) frequently, six providers (31.6%) occasionally, and four providers (21.1%) never

used a risk assessment tool. Opinions on the prophylactic administration of beta blockers to patients with known coronary artery disease and patients with two or more risk factors for coronary artery disease differed: fourteen providers (73.7%) strongly agreed, and five providers (26.3%) mildly agreed that prophylactic beta blockers have an effect on postoperative outcomes; eleven providers (57.9%) strongly agreed, five providers (26.3%) mildly agreed, and three providers (15.8%) neither agreed nor disagreed that prophylactic beta blockers have an effect on postoperative outcomes in patients that have two or more risk factors for coronary artery disease.

**Post-Intervention Results**

Seventeen of the original nineteen participants filled out the post-test questionnaire. Two anesthesia providers resigned and relocated elsewhere during the study period. At the end of the study period, five providers (29.4%) were aware of the department protocol for perioperative beta blocker administration, eight providers (47.1%) were not aware, and four providers (23.5%) were not sure. A risk assessment tool was used by three providers (17.6%) all of the time, six providers (35.3%) frequently, four providers (23.5%) occasionally, and four providers (23.5%) never. Opinions on the prophylactic administration of beta blockers to patients with known coronary artery disease and patients with two or more risk factors for coronary artery disease differed: fourteen providers (82.4%) strongly agreed, and three providers (17.6%) mildly agreed that prophylactic beta blockers have an effect on postoperative outcomes; twelve providers (70.6%) strongly agreed, three providers (17.6%) mildly agreed, and two providers (11.8%) neither agreed nor disagreed that prophylactic beta blockers have

an effect on postoperative outcomes in patients that have two or more risk factors for coronary artery disease.

**Beta Blocker Inventory**

A total of 211 doses of beta blockers (esmolol and metoprolol) were dispensed in the perioperative setting (not including the cardiac operating rooms) between March 21, 2012 and June 21, 2012, comparable to 220 doses dispensed during the study period of June 22, 2012 through September 21, 2012. The perioperative setting is comprised of the OR Holding area, where all surgical patients are prepared for surgery; the 16 non-cardiac operating rooms in the Main OR; and the PACU (post anesthesia care unit), where all surgical patients, except post-open heart patients, are recovered. The increase of nine doses of beta blockers is not statistically significant ($p>0.05$), nor is it clinically significant.

**Conclusion**

The results indicate that all of the anesthesia providers were aware of studies in the literature related to prophylactic perioperative beta blocker use in cardiac surgical patients undergoing non-cardiac surgery who are at risk for cardiac complications. This knowledge and the 25-slide PowerPoint intervention were unsuccessful in changing provider practice as there was no increase in the number of beta blockers used or in the use of a risk assessment tool. There was also no increase in provider awareness about the beta blocker protocol that was implemented.

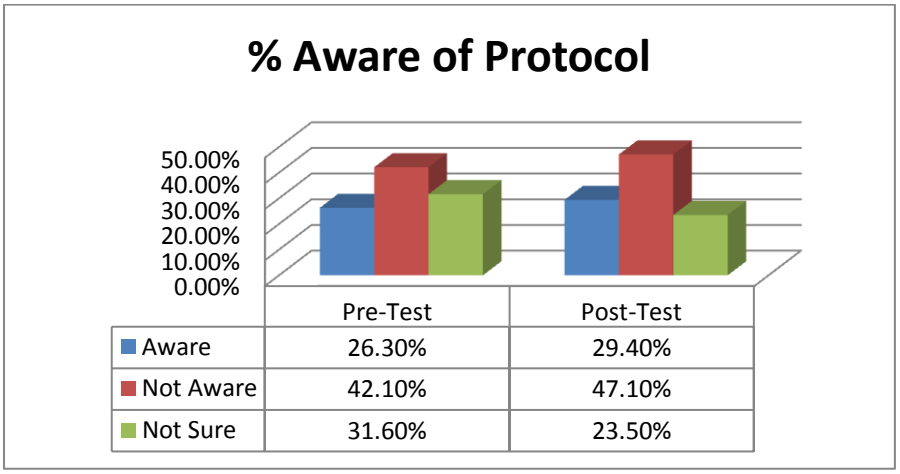


*Figure 4.1.* Protocol Awareness.

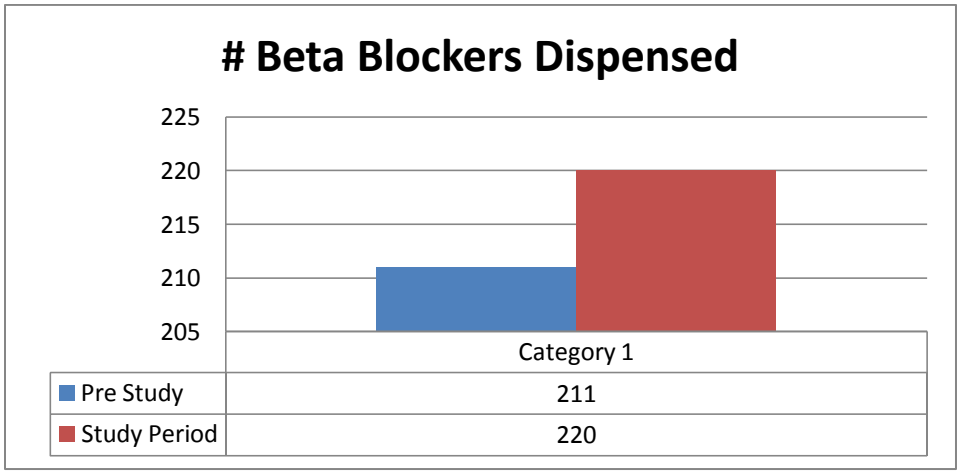


*Figure 4.2.* Beta Blockers Dispensed

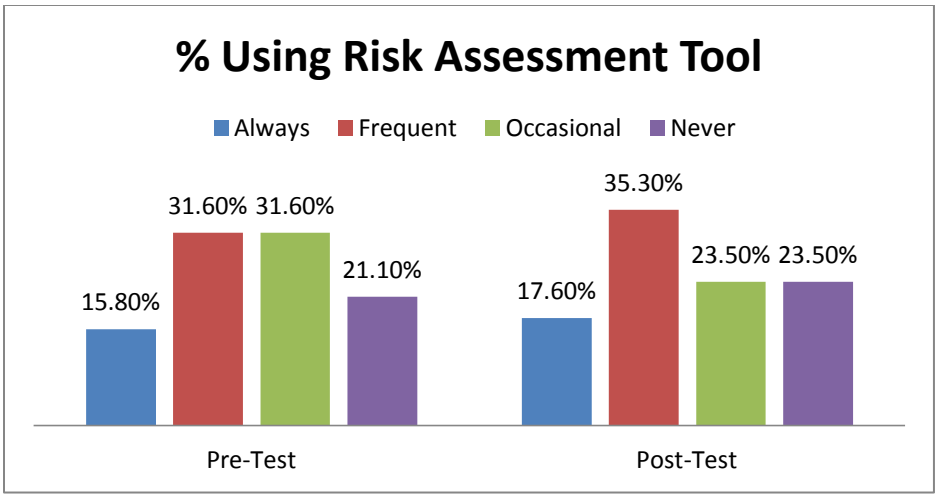


*Figure 4.3* Risk Assessment Tool Use.

# Chapter Five: Discussion

This chapter provides a discussion of the anesthesia providers' use of perioperative beta blockers, interventions to promote beta blocker usage, and lessons learned in the process. Implications for evidence-based practice and future research are also presented.

## Discussion of Use of Beta Blockers

This evidence-based project did not produce the results that this investigator expected; there was no change in the percentage of anesthesia providers using beta blockers before and after the PowerPoint intervention. This conclusion was supported by the absence of any increase in beta blockers dispensed during the study period and by the comparison of pre-test usage to post-test usage (figure 4.2).

There was no change in the perception of anesthesia providers regarding the use of perioperative beta blockers before and after the PowerPoint intervention. There was no change in awareness of a departmental beta blocker protocol noted in the post-test compared to the pre-test despite the introduction of a written beta blocker order set and risk assessment tool (figure 4.3) as part of the anesthesia preoperative orders. There was no change in provider perception about the use of beta blockers in high and intermediate-risk patients noted in the post-test compared to the pre-test (figure 4.1).

There was no statistically significant change in the amount of beta blockers dispensed perioperatively during the study period compared to the previous 90 days. The

PowerPoint presentation seemed to have no effect in increasing the use of beta blockers in the perioperative period.

**Interventions**

The study intervention consisted of a 25-slide PowerPoint presentation outlining the rationale for beta blocker use in high and intermediate risk cardiac surgical patients undergoing high and intermediate risk non-cardiac surgery. This presentation was supplemented by a new pre-printed preoperative order set that included a risk assessment tool and an easy check-box beta blocker order set. This order set was introduced at the beginning of the study period and has become the default preoperative order set (pre-anesthesia orders before the study period and during the study period).

The implementation of the protocol was facilitated by the Chief of Anesthesia on the day my project began. At the Department of Anesthesia bi-weekly meeting he passed out the new pre-anesthesia order set that I created, which incorporates a risk assessment tool along with easy to use checkboxes to facilitate beta blocker orders preoperatively. The new and old order sets are in the Appendix. Because of the dynamics of the work environment, it was felt that the introduction was best handled by him as a Departmental initiative.

**Lessons Learned**

More than a 25-slide PowerPoint is needed to change anesthesia providers' awareness of beta blocker usage in cardiac patients undergoing high and medium-risk non-cardiac surgery. Facilitating this awareness with an easy-to-use preprinted order set was not sufficient to change practice. Reinforcement by including a risk assessment tool on the preprinted order set was also not sufficient to change provider practice.

A more positive result may have been obtained with stronger buy-in from the Department of Anesthesia leadership. Other strategies to improve increases in beta blocker usage in appropriate patients could include a presentation at a Department meeting followed by a group discussion about proper patient selection. Reinforcement could also include a checkbox on the anesthesia record concerning beta blocker status.

**Strengths and Weaknesses**

The strength of this project is the application of evidence-based knowledge of perioperative beta blocker usage in cardiac surgical patients undergoing non-cardiac surgery to improve postoperative outcomes and decrease morbidity and mortality. The major weakness of the project was the small number of participants (19), the short 90-day duration of the study period, and the distinct possibility that the participants did not view the 25-slide PowerPoint that outlined the evidence supporting perioperative beta blocker usage in cardiac patients undergoing high and medium-risk non-cardiac surgery.

**Clinical Practice Implications**

Results indicate that heightened awareness of anesthesia providers did not occur and did not lead to increased beta blocker use perioperatively. Controversy about patient selection criteria for perioperative beta blockade remains. The evidence and the ACC/AHA guidelines are clear for high-risk and low-risk patients. Even with risk-assessment tools, it is not always clear which medium-risk patients will benefit from beta blockers. The ACC/AHA guidelines for medium-risk patients are nonspecific and leave it up to the individual provider to determine if the benefit of beta blocker administration outweighs the risk of adverse outcomes such as hypotension, bradycardia and stroke.

Further clarification of the guidelines for medium-risk patients could promote increased utilization of beta blockers in this patient population.

The participants in this study were all aware (100%) of the published literature on the benefits of beta blocker therapy, but not all have incorporated this knowledge into their practice. This may be due to individual reluctance to interpret national guidelines and apply them clinically. It may also be due to their desire to not harm patients that may not benefit from the administration of beta blockers.

**Future Directions for Research**

This investigator will seek to continue and expand this evidence-based project by participating in the creation of a hospital-wide beta blocker order set as part of a new computer physician order entry (CPOE). Another reinforcement strategy will be the introduction of a patient's beta blocker status into the verbal time-out that is routinely performed right before any procedure starts. This confirmation of beta blocker status is already a part of the verbal time out for all cardiac procedures and could be extended to include all cardiac patients undergoing non-cardiac procedures.

More studies are needed to provide better evidence about the benefits of beta blockers in high and intermediate risk cardiac patients undergoing high and intermediate risk non-cardiac surgery. As evidence accumulates indicating better patient outcomes when beta blockers are used appropriately, anesthesia providers may be more willing to change their practice by incorporating this evidence. These studies should be large, multi-center prospective random controlled trials to validate the use of beta blockers in high and intermediate-risk cardiac patients undergoing noncardiac surgery. It would be especially important for these studies to focus on the kinds of beta blockers, doses,

routes, and timing of administration that would optimize positive patient outcomes in this particular patient population.

**Conclusion**

This evidence-based project has shown that no change in practice occurred after dissemination of the best and most recent clinical evidence on perioperative beta blocker administration to cardiac patients undergoing non-cardiac surgery. Other strategies will need to be developed to increase anesthesia provider awareness, as well as to facilitate beta blocker use in appropriate patients with the goals of improving clinical outcomes and decreasing morbidity and mortality in this patient population.

Appendix A: Consent to Participate

Dear Participant,

My name is Jody Heriot and I am a graduate student at the University of North Florida. I am conducting research regarding the perioperative use of beta blockers. This study will attempt to determine the perceptions of anesthesia providers regarding the use of a perioperative beta blocker protocol before and after a PPT presentation designed to provide information regarding the use of beta blockers in cardiac patients undergoing non-cardiac surgery.

If you take part in my project, you will be asked to complete a survey, view a short PPT presentation and complete a second survey. I will also be reviewing aggregate pharmacy records to evaluate any changes in beta blocker usage during the study period. . This project has been fully approved by the Institutional Review Boards of both the University of North Florida and Holy Cross Hospital.

Participation in this study will take less than 30 minutes of your time over a 3 month period. Your responses will be anonymous. No one other than Jody Heriot will see your responses and your responses cannot be tied back to you. Although there are no direct benefits to you or compensation for taking part in this study, others may benefit from the information I find from the results of this study. Additionally, there are no foreseeable risks for taking part in this project. Participation is voluntary with no penalties for not responding to the questionnaire or ceasing participation. If you choose not to take part or to withdraw from this study, there will be no penalty or loss of benefits to which you would otherwise receive.

If you have any questions or concerns about this project, please contact me or my professor. If you have questions about your rights as a participant, you may contact the University of North Florida's Institutional Review Board Chairperson, Dr. Katherine Kasten, at 904-620-2498.

Thank you for your consideration.

Sincerely,

Jody Heriot, CRNA
Phone: 954-849-5808
mothermuffet@aol.com

Gerard Hogan, CRNA (Project Committee Chair)
Phone (904) 252-0937
gerard.hogan@unf.edu

_____ (print name) attest that I am at least 18 years of age and agree to take part in this study. A copy of this form was given to me.

Signature: _____ Date: _____

Appendix B: Beta Blockers and Surgical Outcomes Questionnaire

Please circle the most appropriate letter for each question.

1. Are you aware of studies in the literature related to prophylactic perioperative beta blocker use in patients undergoing non-cardiac surgery who are at risk for cardiac complications?
a) YES
b) NO

2. In your opinion does prophylactic perioperative administration of beta blockers in patients with known coronary artery disease, who are not already on regular beta blockers, have an effect on postoperative outcomes?
a) STRONGLY AGREE
b) MILDLY AGREE
c) NEITHER AGREE NOR DISAGREE
d) MILDLY DISAGREE
e) STRONGLY DISAGREE

3. In your opinion does prophylactic perioperative administration of beta blockers in patients with 2 or more risk factors for coronary artery disease, who are not on regular beta blockers, have an effect on postoperative outcomes?
a) STRONGLY AGREE
b) MILDLY AGREE
c) NEITHER AGREE NOR DISAGREE
d) MILDLY DISAGREE
e) STRONGLY DISAGREE

4. Does your department have a protocol for prophylactic perioperative beta blockade in patients scheduled for non-cardiac surgery who are at risk for cardiac complications?
a) YES
b) NO
c) DON'T KNOW

5. How often do you use prophylactic beta blockers, as a routine part of perioperative care, in at-risk patients with known coronary artery disease or 2 or more risk factors for CAD?
a) ALWAYS
b) USUALLY
c) SOMETIMES
d) SELDOM
e) NEVER

6. Approximately how many times in an average week would you administer prophylactic beta blockers?
a) 0
b) 1–2 TIMES
c) 3–5 TIMES
d) 5–10 TIMES
e) >10 TIMES

7. When do you generally start prophylactic beta blocker therapy?

a) BEGIN SEVERAL DAYS AHEAD OF SURGERY IN OUTPATIENT CLINIC
b) MULTIPLE DOSES PREOP FOR INPATIENTS
c) SINGLE PREOP DOSE
d) POSTOPERATIVELY

8. How long do you generally continue prophylactic beta blocker therapy?
a) PREOPERATIVELY ONLY
b) EARLY POSTOPERATIVELY
c) DURATION OF HOSPITAL STAY
d) LONGER

9. In what type of surgery do you consider prescribing prophylactic beta blockers? (Choose any that apply)
a) HIGH RISK (e.g. vascular, thoracic)
b) MODERATE RISK (e.g., major orthopedic, abdominal)
c) LOW RISK (e.g., cataract, peripheral)

10. Does type of anesthesia influence your decision to use prophylactic beta blockers (i.e., general, regional, local)?
a) YES
b) NO

11. When you use prophylactic beta blockers, what is your preferred drug?
a) METOPROLOL
b) ATENOLOL
c) ESMOLOL
d) OTHER

12. Do you use perioperative a2 agonists (e.g., clonidine) in patients with risk factors or known cardio-vascular disease when beta blockers may be contraindicated?
a) ALWAYS
b) SOMETIMES
c) NEVER

13. Do you use a risk assessment tool to determine patient suitability for perioperative beta blocker therapy?
a) ALWAYS
b) FREQUENTLY
c) OCCASIONALLY
d) NEVER

14. How long have you been practicing anesthesia?
a) 5 YEARS OR LESS
b) 5–10 YEARS
c) 10–15 YEARS
d) 15–20 YEARS
e)> 20 YEARS

15. What is your present age?
a) Under 30
b) 30–39

c) 40–49
d) 50–59
e) >60

16. What is your gender?
a) MALE
b) FEMALE

Appendix C: Post-intervention Order Set

**ORDERS:** ANOTHER BRAND OF GENERICALLY EQUIVALENT PRODUCT IDENTICAL IN DOSAGE FORM AND CONTENT OF ACTIVE INGREDIENT MAY BE ADMINISTERED UNLESS OTHERWISE SPECIFIED. *ORDER WITH CHECKED BOX (☑) IS THE *DEFAULT* ORDER AND IS AUTOMATICALLY ORDERED UNLESS OTHERWISE SPECIFIED. CHECK BOX TO ACTIVATE ORDER OTHER THAN THE DEFAULT. IF DEFAULT NOT DESIRED, STRIKE THROUGH DEFAULT ORDER.

**1. Emergency:** *Call Anesthesiologist STAT for the following:*

- *Symptomatic Bradycardia less than 40/minute: Atropine 0.5mg IVP. Repeat every 5 minutes PRN up to 1.5mg*
- *For Ventricular Tachycardia or PVC's above 6/minute: Lidocaine 1mg/kg IVP*
- *For Respiratory Rate below 10/minute: Naloxone (Narcan) 0.1mg IV every 1 minute x 4 PRN*
- *PRN Benzodiazepine Reversal: Romazicon (Flumazenil) 0.1mg IV x 1*

**2. Pre-Operative Medications:**

- ❑ Sodium Citrate 3gm/Citric Acid 2gm (Bicitra) 30ml PO x 1 dose
- ❑ Dexamethasone (Decadron) 4mg or 8mg IV x 1 dose
- ❑ Glycopyrrolate (Robinul) 0.2mg IV x 1 dose
- ❑ Midazolam (Versed) _____ mg IV x 1 dose. May repeat x 1 PRN anxiety.
- ❑ Fentanyl (Sublimaze) _____ mcg IV x 1 dose
- ❑ OFIRMEV 1000mg IVPB in 15 minutes x 1 dose

**3. PLEASE SELECT ONE OR INDICATE PRIORITY ORDER WITH NUMBERS:**

- ❑ _____ Granisetron (Kytril) 0.1mg IVP x 1 dose
- ❑ _____ Metoclopramide (Reglan) 10mg IVP x 1 dose
- ❑ _____ Ondansetron (Zofran) 4mg IVP x 1 dose
- ❑ _____ Famotidine (Pepcid) 20mg IVP slowly x 1 dose

**4.** ❑ STAT/Read portable CXR in Holding Area

**5.** ❑ O2 therapy per protocol

**6.** ❑ SpO2 monitoring

**7.** ❑ Obtain anesthesia consent

**8.** ❑ Additional Orders: _____

**9. CARDIAC RISK ASSESSMENT**

**A.** Patient already on Beta-blockers

- ❑ AM Dose Given
- ❑ HR > 60, Systolic BP > 100

**B.** Patient a Candidate for Beta-blockers (Check 2 or more)

- ❑ High Risk Procedure ❑ CVA / TIA ❑ CHF
- ❑ Ischemic Heart Disease ❑ DM (Insulin Dependent) ❑ CRI (Serum Creatinine > 2.0)

**C.** Beta-blocker Orders

- ❑ HR > 60, Systolic BP > 100
- ❑ Metoprolol 25mg PO with Sip of H2O
- ❑ Metoprolol 5mg IV Slow
- ❑ Patient not a Candidate for Beta-blockers

❑ **Contact Holding Area RN for issues/concerns/clarifications – extension 6300/5686.**

**The undersigned physician certifies that the laboratory tests ordered on this form are medically necessary for the diagnosis and treatment of this patient and the medical necessity of each test is accurately reflected in the patient's medical record.**

**DATE** _____ **TIME** _____ **PHYSICIAN SIGNATURE** _____

Holy Cross Hospital

**FORM #200-061**
04/25/2012 Page 1 of 1

**Drug Allergies:** _____
❑ No Known Allergies **Height:** _____
**Weight:** _____

☐ **STAT ORDER**

PATIENT LABEL

***PRE-OP HOLDING STANDING ORDERS***

Appendix D: IRB Certificate

UNF
UNIVERSITY of NORTH FLORIDA.
Office of Research and Sponsored Programs
1 UNF Drive
Jacksonville, FL 32224-2665
904-620-2455 FAX 904-620-2457
Equal Opportunity/Equal Access/Affirmative Action Institution

**MEMORANDUM**

UNF IRB Number: 315836-3
Approval Date: 6-12-2012
Expiration Date: Exempt - None
Processed on behalf of UNF's IRB KLC

**DATE**: June 12, 2012

**TO**: Dr. Gerard Hogan
NAP

**FROM**: Dr. Katherine Kasten, Chairperson
On behalf of the UNF Institutional Review Board

**RE**: Review of New Submission by the UNF Institutional Review Board IRB#315836-3:
"Implementation of a Beta Blocker Protocol"

---

This is to advise you that your project, "Implementation of a Beta Blocker Protocol" was reviewed on behalf of the UNF Institutional Review Board and has been declared Exempt, Categories 2 & 4." Therefore, this project requires no further IRB oversight unless substantive changes are made.

This approval applies to your project in the form and content as submitted to the IRB for review. Any variations or modifications to the approved protocol and/or informed consent forms that might increase risk to human participants must be submitted to the IRB prior to implementing the changes. Please see the UNF Standard Operating Procedures for additional information about what types of changes might elevate risk to human participants. Any unanticipated problems involving risk and any occurrence of serious harm to subjects and others shall be reported promptly to the IRB within 3 business days.

**Your study has been approved as of 6/12/2012**. Because your project was approved as exempt, no further IRB oversight is required for this project unless you intend to make a change that might elevate risk to participants. As an exempt study, continuing review will be unnecessary. When you are ready to close your project, please complete a Closing Report Form which can also be found in the documents library called "Forms and Templates" in IRBNet.

As you may know, **CITI Course Completion Reports are valid for 3 years**. Your completion report is valid through 10/19/2012 and Ms. Heriot's completion report is valid through 7/18/2014. If your completion report expires within the next 60 days or has expired, please take CITI's refresher course and contact us to let us know you have completed that training. If you have not yet completed your CITI training or if you need to complete the refresher course, please do so by following this link: http://www.citiprogram.org/. Should you have questions regarding your project or any other IRB issues, please contact the research integrity unit of the Office of Research and Sponsored Programs by emailing IRB@unf.edu or calling (904) 620-2455.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within UNF's records. A copy of this approval may also be sent to the dean and/or chair of your department.

Appendix D: Pre-intervention Order Set

**ORDERS:** ANOTHER BRAND OF GENERICALLY EQUIVALENT PRODUCT IDENTICAL IN DOSAGE FORM AND CONTENT OF ACTIVE INGREDIENT MAY BE ADMINISTERED UNLESS OTHERWISE SPECIFIED. *ORDER WITH CHECKED BOX (☑) IS THE *DEFAULT* ORDER AND IS AUTOMATICALLY ORDERED UNLESS OTHERWISE SPECIFIED. CHECK BOX TO ACTIVATE ORDER OTHER THAN THE DEFAULT. IF DEFAULT NOT DESIRED, STRIKE THROUGH DEFAULT ORDER.

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- *For Ventricular Tachycardia or PVC's above 6/minute: Lidocaine 1mg/kg IVP*
- *For Respiratory Rate below 10/minute: Naloxone (Narcan) 0.1mg IV every 1 minute x 4 PRN*
- *PRN Benzodiazepine Reversal: Romazicon (Flumazenil) 0.1mg IV x 1*

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- ❑ Dexamethasone (Decadron) 4mg or 8mg IV x 1 dose
- ❑ Glycopyrrolate (Robinul) 0.2mg IV x 1 dose
- ❑ Midazolam (Versed) _____ mg IV x 1 dose. May repeat x 1 PRN anxiety.
- ❑ Fentanyl (Sublimaze) _____ mcg IV x 1 dose
- ❑ OFIRMEV 1000mg IVPB in 15 minutes x 1 dose

**3. PLEASE SELECT ONE OR INDICATE PRIORITY ORDER WITH NUMBERS:**

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- ❑ _____ Metoclopramide (Reglan) 10mg IVP x 1 dose
- ❑ _____ Ondansetron (Zofran) 4mg IVP x 1 dose
- ❑ _____ Famotidine (Pepcid) 20mg IVP slowly x 1 dose

**4.** ❑ STAT/Read portable CXR in Holding Area

**5.** ❑ O2 therapy per protocol

**6.** ❑ SpO2 monitoring

**7.** ❑ Obtain anesthesia consent

**8.** ❑ Additional Orders:

❑ **Contact Holding Area RN for issues/concerns/clarifications – extension 6300/5686.**

**The undersigned physician certifies that the laboratory tests ordered on this form are medically necessary for the diagnosis and treatment of this patient and the medical necessity of each test is accurately reflected in the patient's medical record.**

**DATE** _____ **TIME** _____ **PHYSICIAN SIGNATURE** _____

Holy Cross Hospital

**FORM #200-061**
11/17/2011 Page 1 of 1

**Drug Allergies:** _____
❑ No Known Allergies
**Height:** _____
**Weight:** _____

☐ **STAT ORDER**

PATIENT LABEL

***PRE-OP HOLDING STANDING ORDERS***

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# Vita

Jody Heriot was born in Canada and moved to the USA as a teenager. She graduated from Northern Virginia Community College in Annandale, Virginia, with an AS in Nursing, and from George Mason University in Fairfax, Virginia, with a BS in Biology. Her nurse anesthesia training was at the Fairfax Hospital, now Inova Fairfax, in Fairfax, Virginia. She received her MSN from Samuel Merritt University in Oakland, California. She has been practicing anesthesia for over thirty five years, mostly in South Florida. Her area of specialty is Cardiothoracic Anesthesia, which she has practiced almost exclusively for the last twelve years.