# EFFECTIVENESS OF CARDIAC ERAS MULTIMODAL ANALGESIA ON PERIOPERATIVE PAIN IN ADULT CARDIAC SURGERY PATIENTS

by

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# ABSTRACT

CHRISTINE SISK. Effectiveness of Cardiac ERAS Multimodal Analgesia on Perioperative Pain in Adult Cardiac Surgery Patients. (Under the direction of Dr. KATHLEEN JORDAN)

Cardiac surgeries often rely on opioid analgesics, which can lead to adverse effects. The implementation of the multimodal analgesic approach, as a part of the ERAS protocol, has the potential to optimize intra- and postoperative pain management, leading to reduced opioid-related complications and improved patient outcomes. The purpose of this study was to evaluate the efficacy of multimodal analgesia within a Cardiac Enhanced Recovery After Surgery (ERAS) program in reducing postoperative pain and opioid consumption in adult cardiac surgery patients. This study compared the effects of cardiac ERAS multimodal analgesia against traditional opioid-based analgesia on postoperative pain and opioid consumption during the operation and the initial 24 hours postoperative.

The study was conducted at a level-one trauma center that had recently implemented the ERAS protocol on all cardiac surgical patients. Data was collected retrospectively from patients undergoing cardiac surgeries before and after the protocol's implementation. The pre-ERAS group received traditional opioid-based analgesia, while the ERAS group received the ERAS multimodal analgesia protocol.

Data analysis revealed significantly lower intraoperative opioid consumption in the post-ERAS group compared to the pre-ERAS group ($U = 1496.00$, $p = .026$, $z = -2.30$). However, no statistically significant differences were observed in opioid consumption between the groups at 6 hours and 24 hours postoperatively. These findings suggest the ERAS protocol's effectiveness in reducing intraoperative opioid requirements but limited impact on postoperative opioid consumption within the first 24 hours.

The study demonstrates that cardiac ERAS multimodal analgesia can effectively reduce intraoperative opioid consumption, highlighting its potential as a valuable component of perioperative pain management in cardiac surgery. While the findings did not show a significant reduction in postoperative opioid use, implementing such protocols can still offer benefits for patient care. This includes reducing opioid-related adverse effects and potentially improving patients' overall recovery. Further research is needed to explore the longer-term impacts of multimodal analgesia on postoperative opioid consumption and patient outcomes in cardiac surgery.

# DEDICATION

I dedicate this DNP scholarly paper to my loving family whose unwavering support and encouragement have been the driving force behind my pursuit of knowledge and professional growth. Phillip, Ellison, and Mason, your patience and understanding during the late nights and weekends devoted to research have made this journey possible.

Additionally, I extend my heartfelt dedication to my project chair, Dr. Kathleen Jordan, whose guidance and support have been instrumental throughout the last two years. Your expertise and encouragement have shaped this scholarly endeavor, and I am truly grateful for your mentorship.

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# CHAPTER 1: INTRODUCTION

Enhanced recovery after surgery (ERAS) programs utilize evidence-based, patient-centered care pathways to expedite recovery and improve outcomes after surgery (Markham, 2018). An essential component of all ERAS protocols is the utilization of multimodal analgesia (MMA). Multimodal analgesia is defined as the use of more than one pharmacologic class of pain medication that acts upon different receptors along the pain pathway (Schwenk & Mariano, 2018). The use of multimodal analgesia has been shown to improve postoperative pain control while also reducing the use of narcotic analgesics and their related side effects during the perioperative period. ERAS protocols utilizing multimodal analgesia have been developed in almost every surgical specialty; however, the use of ERAS principles in cardiac surgery is still in the developing stages of implementation (Markham, 2018). To further evaluate Cardiac ERAS multimodal analgesia, an analysis of the efficacy of multimodal analgesia was conducted in adult cardiac surgery patients intraoperatively and in the first 24 hours postoperatively.

## 1.1 Background

Postoperative pain is an often-underestimated phenomenon and the presence of pain after surgery can lead to a myriad of postoperative complications (Bignami, 2018). Pain is associated with various physiological consequences including the systemic release of stress hormones and inflammatory mediators which increases the risk of postoperative mortality (Li, 2018). Opioid analgesics have been the cornerstone of pain management in surgery for decades. However, opioids are known to lead to adverse effects such as sedation, respiratory depression, nausea, vomiting, and ileus. Evidence shows multimodal opioid-sparing analgesia can provide significantly better pain control than traditional opiate-based plans through the additive or synergistic effects of different types of analgesics (Engelman et al., 2019). This allows for

decreased narcotic requirements intraoperatively and postoperatively in cardiac surgery patients avoiding the deleterious side effects of opioids (Rafiq, 2014).

The ERAS concept was initially applied to colorectal surgery, and in 2005, the first evidence-based colorectal ERAS protocol was developed (Gelman, 2018). Since its inception, multiple published studies have shown reduced postoperative complications, decreased length of stay, and improved outcomes when ERAS pathways are implemented. In 2019, the Cardiac ERAS Society, a subgroup of the ERAS Society, published guidelines for cardiac surgery ERAS which led to increased awareness of the safety and efficacy of ERAS in cardiac surgery (Engelman et al., 2019). Cardiac ERAS protocols are still developing and the implementation of multimodal analgesia in this patient population is rapidly evolving. Multimodal analgesia is a vital component of ERAS protocols and implementation in cardiac surgery has been shown to decrease opioid consumption and improve outcomes postoperatively (Subramaniam, 2021). However, additional research is needed to evaluate the effectiveness of these multimodal protocols.

## 1.2 Problem Statement

Pain after cardiac surgery is caused by several factors including sternotomy, sternal retraction, saphenous vein harvesting, surgical retraction, and chest tube insertion (Rafiq, 2014). Individualized anesthetic care plans are created for every cardiac surgery patient, including a robust pain management plan. Opioids have been the cornerstone of cardiac analgesia for decades; historically, pain management plans in cardiac anesthesia were solely narcotic-based. Recent concerns related to opioid side effects, hyperalgesia, addiction, and the opioid pandemic have led practitioners to explore techniques based on non-opioid and multimodal regimes (Thompson-Brazil, 2019). Research has proven that utilization of multimodal analgesia offers

significantly better pain control than traditional opiate-based plans in cardiac surgery patients (Rafiq, 2014).

Despite the proven efficacy of ERAS and multimodal analgesia, implementation in cardiac surgery has been slow to operationalize. Cardiac surgery patients are known to have a wide variety of comorbidities and complex pathologies leading to hesitation to implement ERAS principles in this area. Additionally, the use of cardiopulmonary bypass (CPB) and the complex nature of cardiac surgery itself have contributed to this hesitation (Gebauer et al., 2022). Unfortunately, there is a lack of evidence examining specific multimodal, opioid-sparing protocols and their effectiveness in cardiac surgery. Specific concerns related to cardiac surgery including systemic anticoagulation, and activation of the systemic inflammatory response with exposure to the cardiopulmonary bypass circuit are among a few concerns with applying existing multimodal analgesic protocols from other surgical specialties (Shaw, et al., 2022). Anesthetic management of these complex patients has relied heavily on opioids for decades. Additionally, most facilities use standardized anesthetic protocols in the cardiac surgery arena. These providers must show a willingness to change and break long-standing beliefs on the best ways to manage this patient population (Gebauer et al., 2022).

Many hospitals, including Atrium Health in Charlotte, North Carolina (NC), are beginning to implement cardiac ERAS programs since research supports the safety and efficacy in this patient population. Further research is needed to evaluate the effectiveness of these cardiac ERAS and multimodal analgesic plans.

### 1.3 Purpose

The project lead recognized the need to evaluate multimodal analgesic interventions' efficacy to decrease postoperative pain in cardiac surgery. This scholarly project evaluated the

efficacy of multimodal analgesia as part of a cardiac ERAS program in adult cardiac surgery patients during the first 24 hours postoperatively. The project lead wanted to show how the implementation of multimodal analgesia as part of cardiac ERAS can decrease narcotic consumption and improve outcomes postoperatively. An expected outcome of this project also included the improvement of anesthesia providers' knowledge of the implementation and efficacy of cardiac ERAS multimodal analgesia. It is also important to note the association between improved patient outcomes and decreased opioid use secondary to the multimodal approach to perioperative pain management. This includes decreased length of stay, postoperative complications, and patient-reported pain scores.

## 1.4 Clinical Question

The PICOT question used to address this clinical problem was: In adult cardiac surgery patients (P), how does cardiac ERAS multimodal analgesia (I), compared to traditional opioid-based analgesia (C), affect postoperative pain and narcotic requirements (O) during the first 24 hours postoperatively (T)?

## 1.5 Project Objectives

Blunting surgical stress response is the primary goal of any anesthetic care plan. Traditional pain management plans for cardiac surgery are based solely on opioid analgesics, which have many adverse effects. The goal of this DNP scholarly project was to provide needed evidence to support the greater use of multimodal analgesia as part of a cardiac ERAS protocol. Implementation of a cardiac ERAS multimodal analgesia pathway at Atrium Health was expected to lead to decreased postoperative pain and decreased narcotic requirements in cardiac surgery patients.

The primary measured outcome of this project was to demonstrate decreased opioid consumption intraoperatively and during the first 24 hours after surgery following the implementation of cardiac ERAS multimodal analgesia. A decrease in narcotic usage would indicate that multimodal analgesia decreased opioid use and postoperative pain in this patient population. This decrease in narcotic usage should lead to decreased adverse effects and complications related to opioid analgesics. Additionally, during the implementation of this project, anesthesia providers' knowledge of multimodal analgesia effectiveness as part of a cardiac ERAS protocol at Atrium Health was increased.

## 1.6 Conclusion

Opioids have played a fundamental role in cardiac anesthesia since its inception. The opioid epidemic and concerns related to opioid side effects have led practitioners to evaluate newer methods of pain control for all surgical procedures; multimodal analgesics are critical in surgical ERAS protocols. Cardiac ERAS protocols are still developing and the implementation of multimodal analgesics in the patient population is evolving. Current literature supports the use of multimodal analgesia in cardiac surgery patients, which has been proven to decrease opioid consumption and improve outcomes. However, additional research is needed to evaluate the effectiveness of these multimodal protocols. This scholarly DNP project shows how the implementation of multimodal analgesia as part of cardiac ERAS can decrease narcotic consumption perioperatively.

# CHAPTER 2: LITERATURE REVIEW

A comprehensive review of the literature was performed using CINAHL, PubMed, and Cochrane. The search was driven by the PICOT question and the key terms *cardiac surgery, multimodal analgesia (MMA)*, and *cardiac ERAS*. Search term combinations included *cardiac surgery* AND *multimodal analgesia*, and *cardiac ERAS* AND *multimodal analgesia*. The search was limited to journal articles with abstracts and published after 2017. Articles involving children or those solely discussing regional anesthesia were excluded. The initial search yielded 41 results. Fourteen were excluded after screening their abstracts. The remaining 27 articles were assessed, and 14 were eligible for final synthesis. One older study (Rafiq et.al., 2014) was included as it was the only randomized control study and is still referenced in current literature. There was consensus among the reviewed studies that multimodal analgesia lowered opioid consumption.

## 2.1 Retrospective studies

Of the fourteen articles reviewed (see Table 1), five retrospective studies were included (Aguerreche et al., 2021; Guinot et al., 2019; Loria et al., 2022; Markham et al., 2018; Ward et al., 2022). Four of the five retrospective studies showed decreased opioid use after the implementation of multimodal analgesia. Ward et al. (2022) was the only study reviewed that showed no significant decrease in opioid consumption after MMA implementation; however, MMA was only implemented postoperatively and only included two non-opioid adjunct analgesic drugs: Tylenol and Pregabalin. All other retrospective studies included the use of three or more multimodal non-opioid drugs. Most included Acetaminophen (Guinot et al., 2019; Loria et al., 2022; Markham et al., 2018; Williams et al., 2018) and Gabapenoids (Loria et al., 2022; Markham et al., 2018; Williams et al, 2018) along with either Dexmedetomidine (Aguerreche et

al., 2021; Markham et al., 2018), NSAIDS (Guinot et al., 2019; Loria et al., 2022) or Ketamine (Aguerreche et al., 2021; Guinot et al., 2019). One retrospective study included magnesium in their multimodal approach (Aguerreche et al., 2021).

### 2.2 Timing of Multimodal Analgesia

Comprehensive ERAS programs involve preoperative, intraoperative, and postoperative interventions to improve patients' outcomes after surgery. Most ERAS multimodal pain management plans include interventions during all phases of perioperative care, beginning with preemptive administration of non-opioid analgesics preoperatively and continuing with multimodal analgesic medication administration intraoperatively and postoperatively. All studies included the implementation of multimodal analgesic drugs preoperatively, intraoperatively, and postoperatively except one. Ward et al. (2022) implemented multimodal analgesia only after cardiac surgery and did not add any multimodal drugs during the preoperative or intraoperative time. This study also was the only one to show no decrease in postoperative opioid consumption, which suggests that implementing multimodal analgesia during the preoperative and intraoperative phases is crucial to the effectiveness of multimodal analgesia in the cardiac surgery patient. Bignami et al. (2018) and Thompson-Brazil (2019) discussed the importance of preoperative, preemptive analgesia in reducing opioid requirements after surgery.

### 2.3 Randomized Control Study

There was only one randomized control study in the selected literature. Rafiq et al. (2014) showed significantly lower pain scores after the implementation of multimodal analgesia consisting of acetaminophen, gabapentin, dexmedetomidine, and NSAIDs. This study also showed a statistically significant decrease in nausea and vomiting in the multimodal group. Williams et al. (2018) also showed statistically significant decreases in gastrointestinal

complications as well as an overall decreased length of stay. In total, three studies (Guinot et al., 2019; Markham et al., 2018; Williams et al., 2018) showed a decrease in hospital or ICU length of stay after the implementation of multimodal analgesia. While this DNP project did not monitor other outcome measures like length of stay or GI complications, the association between these improved outcomes and the multimodal approach to pain management is important to point out. Opioid analgesia is associated with multiple postoperative complications such as delirium, somnolence, nausea, and vomiting. Therefore, one can deduce that any reduction in opioid use would also decrease the side effects associated with opioids.

### 2.4 Literature Reviews

Five of the fourteen articles were literature reviews (Brown et al., 2018; Nazarnia et al., 2021; Noss et al., 2018; Shaw et al., 2022; Thompson-Brazil, 2019), and two systematic reviews were included (Bignami et al., 2018; Engelman et al., 2019). All of the literature reviews discussed the use of Acetaminophen, Gabapenoids, Ketamine, and NSAIDS as part of a multimodal pathway including their effectiveness in decreasing narcotic requirements after cardiac surgery. Only one literature review (Nazarnia et al., 2021) and one retrospective study (Aguerreche et al., 2021) discussed the use of magnesium in a multimodal analgesia pathway. Magnesium is one of the multimodal drugs in the pathway used in this DNP project along with Acetaminophen, Gabapentin, Ketamine, and NSAIDs.

### 2.5 Multimodal Drug Combinations

All reviewed articles discussed the use of various multimodal drugs and their effects on opioid consumption in cardiac surgery patients. However, many different combinations of drugs were used in each study. Engelman et al. (2019) included a clinical guideline for Cardiac ERAS and recognized that there is no single pathway for multimodal analgesia, but recommended a

combination of multiple non-opioid analgesics including Acetaminophen, Tramadol, Gabapenoids, and Dexmedetomidine along with various local anesthesia and regional anesthesia techniques.

## 2.6 Local Anesthesia

Despite eliminating articles focusing solely on the use of regional and local anesthesia as non-opioid adjuncts, seven of the fourteen articles discussed the evolving and important role of local anesthesia in cardiac ERAS and multimodal pain pathways (Bignami et al., 2018; Brown et al., 2018; Engelman et al., 2019; Guinot et al., 2019; Markham et al., 2018; Noss et al., 2018; Shaw et al., 2022). It is apparent that regional and local anesthesias play an important role in controlling pain in the cardiac surgery population and decreasing the use of opioids. Unfortunately, time, access, and competency issues are prevalent and ultimately inhibit the use of regional anesthesia at many hospitals.

The literature review supported the use of a multimodal pain pathway as part of a cardiac ERAS program to decrease narcotic use and associated complications. Various non-opioid, adjunct analgesics have been studied and shown to reduce opioid consumption postoperatively. Multimodal analgesia has been shown to significantly decrease opioid consumption in the perioperative period.

## 2.7 Theoretical Framework

Kurt Lewin's Change Management Model provides a simple, easily-applied conceptual framework for this project. According to Lewin (Lewin, 1947), the process of creating change first involves showing the need for a change followed by taking steps to move toward the new norm and, finally, integrating that new norm as part of practice. The three steps of unfreezing, moving, and refreezing can be easily applied to this project.

Opioids are associated with various undesirable side effects, hyperalgesia, and addiction. Additionally, the explosion of the opioid epidemic has led practitioners to discover analgesic techniques based on non-opioid and multimodal regimes (Thompson-Brazil, 2019). These concerns paired with the dramatic increase in ERAS protocols in other surgical arenas are driving the first step of this project. A change is needed, and according to Lewin's change model, recognition of this is the first step in creating change (Mitchell, 2013).

The second step, "moving," is when change is initiated (Mitchell, 2013). This step involved the implementation of the cardiac ERAS pathway at Atrium Health. Ensuring all key stakeholders understood the reasons for the project before implementation was the key to the success of this project. The moving phase of this project included the creation of databases to ensure compliance with multimodal analgesia and to monitor the effects of multimodal interventions on narcotic usage. Education of key stakeholders was also an integral part of the moving phase of this project.

Refreezing is the final stage of Lewin's change model and occurs when the change is established and desired outcomes have been obtained (Mitchell, 2013). This step will occur once the use of multimodal analgesia becomes part of the standard of care in cardiac surgery at Atrium Health. Continued education and continual monitoring for compliance with all aspects of Cardiac ERAS will ensure this project is sustainable. Providing data on the impact of decreased narcotic usage after the implementation of multimodal analgesia will help solidify cardiac ERAS as the best practice for cardiac surgery patients.

# CHAPTER 3: METHODS

Even though the implementation of ERAS in cardiac surgery is a new concept, ERAS is widely accepted throughout the perioperative space. The idea of cardiac ERAS is currently gaining popularity and Atrium Health was excited to pioneer this new concept. Buy-in from Atrium Health and members of the cardiac surgery team was a key strength of this project. Additionally, the cardiac ERAS pathway including the multimodal regimen is backed by strong, high-level evidence and has been developed by this project's key stakeholders in the cardiac operating rooms and ICU.

## 3.1 Project Design

This DNP quality improvement (QI) project was designed to provide evidence to support the reduction in opioid use after the implementation of multimodal analgesia in cardiac surgery. A comprehensive multimodal analgesia plan was developed utilizing the best evidence available. The ERAS multimodal plan included interventions during all phases of perioperative care including the preemptive administration of non-opioid analgesics preoperatively and continuing with multimodal, synergistic analgesics intraoperatively and postoperatively (see Table 1).

## 3.2 Sample

The sample included adult cardiac surgery patients at Atrium Health Carolinas Medical Center (CMC) in Charlotte, North Carolina. Cardiac ERAS was implemented on all adult cardiac surgical patients at Atrium Health including an evidence-based, comprehensive multimodal analgesia protocol. All patients undergoing cardiac surgery with cardiopulmonary bypass were included. Exclusion criteria were minimized to exclude only cardiac transplant and ventricular assist device (VAD) patients. Patients with a history of chronic pain requiring preoperative

opioids and those with substance abuse disorder were also excluded. Patients with prolonged mechanical ventilation postoperatively (greater than 8 hours) were also excluded.

### 3.3 Setting

The scholarly project was implemented at Atrium Health Carolinas Medical Center (CMC) in Charlotte, North Carolina, an 874-bed, level-one trauma center where over 500 cardiac surgery cases were performed in 2022. Cardiac ERAS is a relatively new concept at this facility. It was implemented on all cardiac surgical patients at Atrium Health in October of 2022. Successful implementation included active participation from all practitioners involved in the perioperative care of cardiac surgery patients both in the preoperative area, the operating room, and the Cardiac Intensive Care Unit.

### 3.4 Intervention

The Cardiac ERAS pathway at Atrium Health includes multiple interventions focused on various aspects of care including goal-directed fluid therapy, postoperative nausea and vomiting prophylaxis, infection control bundles, and multimodal analgesia (see Table 2). This scholarly project focused on whether the implementation of multimodal analgesia as part of the cardiac ERAS pathway would lead to decreased opioid use postoperatively. Sample data was gathered from electronic surgical and anesthetic records to create a database of adult cardiac surgery patients that met the sample criteria. A sample of patients who received cardiac surgery before Cardiac ERAS implementation in 2022 was utilized to create a control or pre-ERAS sample group. Records of patients were extracted after successful implementation in 2023 to create the post-ERAS intervention group. Manual chart reviews were conducted to ensure patients with prolonged ventilation, chronic pain, and substance abuse disorder were excluded and that all aspects of multimodal analgesia were followed.

### 3.5 Measurement tools

The cardiac ERAS protocol was developed at Atrium Health based on current evidence-based recommendations and a review of current literature. The multimodal pain management plan was developed and implemented in October 2022 (see Table 2). Education of the anesthesia and nursing staff was an important element in ensuring compliance and understanding of cardiac ERAS.

The measurement tool used for the data collection on opioid consumption is morphine milligram equivalents (MMEs) taken directly from the patient's electronic medical record (EMR). MME is a standard calculation that measures the equivalency of opioid dosages to morphine using a morphine conversion factor developed by the CDC (see Table 3). MME is used to measure the patient's total opioid dosage into a standard value based on morphine and its potency (cdc.gov, n.d.). Atrium Health's EMR has been updated to convert intraoperative and postoperative opioids to MMEs.

### 3.6 Data Collection Procedure

Sample data was gathered from electronic surgical and anesthetic records to create a database of adult cardiac surgery patients that meet the sample criteria. Patients who received cardiac surgery from May 1, 2022, through July 31, 2022, were identified to create a control or pre-ERAS sample group. The intervention group included patients who received cardiac surgery from May 1, 2023, through July 31, 2023, after cardiac ERAS implementation to create the post-ERAS group. Manual chart reviews were conducted to ensure patients with prolonged ventilation, chronic pain, and substance abuse disorders were excluded. Comprehensive chart reviews were completed on all patients in the study group to confirm all multimodal analgesic interventions were performed. Compliance with the multimodal analgesia regimes during the

entire perioperative course was evaluated with chart and MAR reviews. This included the preoperative administration of Tylenol and Gabapentin, the intra-operative administration of ketamine and magnesium, and the postoperative administration of Tylenol and lidocaine transdermal (see Table 1). The cardiac ERAS dashboard was built to include cardiac surgery patients that meet all inclusion criteria.

### 3.7 Data Analysis

Once all charts for the pre-ERAS and post-ERAS groups were reviewed and all inclusion and exclusion criteria were applied, a comparison was conducted between groups. This comparison intended to explore if the implementation of multimodal analgesia as part of a cardiac ERAS program would lead to decreased pain, as evidenced by decreased morphine consumption. Morphine consumption was assessed in three periods: Intraoperative, 6 Hours Postoperative, and 24 Hours Postoperative. The dependent variable for the project was the Treatment Group (pre-ERAS and post-ERAS).

The initial plan involved using the independent samples t-test to compare the differences in the levels of morphine consumption between the two groups during each specific period. The test was deemed appropriate for comparing two groups whose dependent variable is measured at a continuous scale (Field, 2017). Before running the analysis, the data was tested for the assumptions of normality of distribution and the presence of outliers. The normality of distribution was assessed using the Saphiro-Wilk test, and outliers were assessed through boxplot inspection. When these assumptions were not met, the analysis plan was revised to employ the Mann-Whitney U test. This non-parametric test was selected as it is appropriate for data that do not follow a normal distribution (Field, 2017).

Noncompliance with all aspects of the multimodal pathway by practitioners would threaten the success of this scholarly project. Comprehensive chart reviews were completed on all patients in the study group to confirm that all multimodal analgesic interventions were performed.

### 3.8 Ethical Considerations

Institutional review board (IRB) approval was obtained on May 16, 2023, from the UNC-Charlotte IRB committee. IRB approval was also obtained from the Atrium Health/Wake Forest IRB committee on July 10, 2023. Confidentiality was addressed in this DNP scholarly project by ensuring all patient identifiers were blinded in the report before the dissemination of results. Manual chart reviews required the project lead to review patient charts and medications given during the perioperative time. However, the pre-ERAS and post-ERAS data used for comparison in this project did not include any patient identifiers.

# CHAPTER 4: PROJECT RESULTS

An analysis was conducted to evaluate the efficacy of multimodal analgesia in adult cardiac surgery patients. The PICOT question that guided this project was: In adult cardiac surgery patients (P), how does cardiac ERAS multimodal analgesia (I), compared to traditional opioid-based analgesia (C), affect postoperative pain and narcotic requirements (O) during the first 24 hours postoperatively (T)? This chapter begins with a description of the study sample, followed by the results of the statistical analyses from the study.

## 4.1 Sample Demographic Information

The sample for the scholarly project comprised adult cardiac surgery patients at Atrium Health Carolinas Medical Center (CMC) in Charlotte, North Carolina. The data for the project was categorized into two groups: pre-enhanced recovery after surgery (pre-ERAS) and post-enhanced recovery after surgery (post-ERAS). For the pre-ERAS group, data from 92 patients who underwent cardiac surgery between May and July 2022 were reviewed. Of these, 33 were excluded due to intubation times exceeding eight hours. Additionally, two were excluded based on chronic pain or substance abuse issues. The final sample size for the pre-ERAS group was 57. In the post-ERAS group, data from 103 patients who underwent cardiac surgery between May and July 2023 were reviewed. Out of these, 34 were excluded due to prolonged intubation times. Furthermore, four were excluded due to chronic pain or substance abuse issues. Consequently, the final sample size for the post-ERAS group was 65.

The average age of patients in the pre-ERAS group was 63.12 years, with a standard deviation of 12.42 years (Table 1). The results indicated a wider range of ages around the mean in this group. The age range for this group was between 31 and 83 years. On the other hand, the post-ERAS group had a higher average age of 66.26 years and a smaller standard deviation of

8.43 years. The results suggested a more concentrated distribution of ages around the mean. The age range for the post-ERAS group was from 46 to 78 years.

Table 1

*Age Characteristics of Patients in Pre-ERAS and Post-ERAS Groups*

| | Pre-ERAS (n = 57) | | Post-ERAS (n = 65) | |
|---|---|---|---|---|
| | $\bar{x}$ | *S* | $\bar{x}$ | *S* |
| Age | 63.12 | 12.42 | 66.26 | 8.43 |

Regarding gender distribution, there were a total of 9 females (15.79%) and 48 males (84.21%) in the pre-ERAS group, as shown in Table 2. In comparison, there were 18 females (27.69%) and 47 males (72.31%) in the post-ERAS group. The variety of cardiac surgery procedures between the two groups is shown in Table 3. Patients in the pre-ERAS group predominantly underwent Coronary Artery Bypass Grafting (CABG), with 31 cases (54.39%). Valve-only procedures were the second most common (26.32%), followed by combined CABG/valve surgeries (7.02%), aortic aneurysm repairs (10.53%), and other procedures (1.75%). CABG was also the most frequent procedure in the post-ERAS group, with 36 cases (55.38%). The other cases showed a similar pattern of prevalence across the procedure types, demonstrating a consistent approach in surgical treatment between the two groups.

Table 2

*Gender Distribution Among Pre-ERAS and Post-ERAS Cardiac Surgery Patients*

| | Pre-ERAS (n = 57) | | Post-ERAS (n = 65) | |
|---|---|---|---|---|
| | n | % | n | % |
| Gender | | | | |
| Female | 9 | 15.79 | 18 | 27.69 |
| Male | 48 | 84.21 | 47 | 72.31 |

Table 3

*Cardiac Surgery Procedure Distribution Among Pre-ERAS and Post-ERAS Cardiac Surgery Patients*

| | Pre-ERAS (n = 57) | | Post-ERAS (n = 65) | |
|---|---|---|---|---|
| | n | % | n | % |
| Cardiac Surgery Procedure | | | | |
| CABG | 31 | 54.39 | 36 | 55.38 |
| Valve-only | 15 | 26.32 | 14 | 21.54 |
| CABG/Valve | 4 | 7.02 | 3 | 4.62 |
| Aortic Aneurysm | 6 | 10.53 | 9 | 13.85 |
| Other | 1 | 1.75 | 3 | 4.62 |

4.2 ERAS Multimodal Analgesia Results

The present study evaluated the effect of ERAS multimodal analgesia on postoperative pain as measured with opioid consumption in morphine milligram equivalents (MME). MME was assessed in three periods: intraoperative, 6 hours postoperative, and 24 hours postoperative. The dependent variable was the treatment (pre-ERAS and post-ERAS). Table 4 shows the average and standard deviation for each group.

Table 4

*Comparison of Intraoperative and Postoperative Morphine Milligram Equivalents (MME) Between Pre-ERAS and Post-ERAS Groups*

| | Pre-ERAS (n = 57) | | Post-ERAS (n = 65) | |
|---|---|---|---|---|
| | $\bar{x}$ | *S* | $\bar{x}$ | *S* |
| Intraoperative MME (mg) | 166.77 | 48.33 | 146.69 | 28.64 |
| 6 Hours Postoperative (mg) | 26.95 | 16.44 | 26.92 | 18.53 |
| 24 Hours Postoperative (mg) | 96.57 | 88.99 | 83.57 | 44.04 |

*4.2.1 Intraoperative MME*

Intraoperative MME levels between the pre-ERAS and post-ERAS groups were compared using the Mann-Whitney U test. The test was selected because the data for both groups did not meet the assumption of a normal distribution, as assessed by the Shapiro-Wilk test, $p < .05$. Boxplots also showed multiple extreme outliers in both groups (Figure 1). However, since these were genuine data points, they were retained for analysis. The Mann-Whitney U test is appropriate for this situation, where the data are not normally distributed (non-parametric) and multiple outliers exist. The Mann-Whitney U test revealed that opioid usage in post-ERAS patients was statistically significantly lower than that in pre-ERAS patients, $U = 1496.00$, $p = .026$, $z = -2.30$. The findings suggest that the ERAS multimodal analgesia protocol reduced intraoperative opioid consumption in cardiac surgery patients.

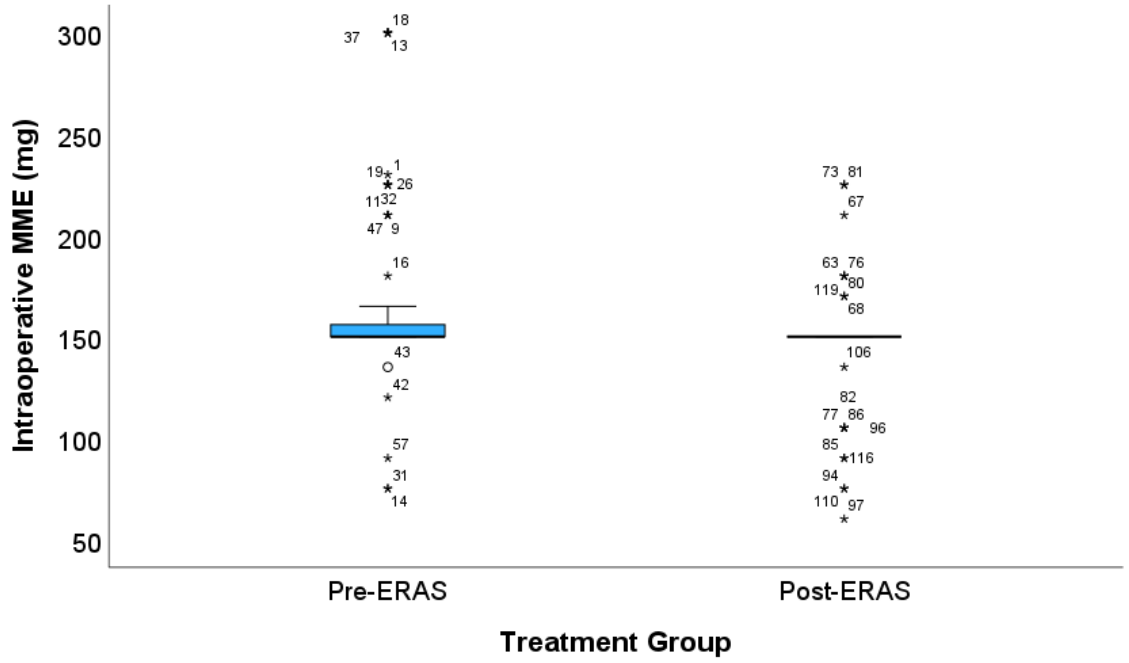


Figure 1. *Boxplot of Intraoperative MME for Pre-ERAS and Post-ERAS Groups*

*4.2.2 Six Hours Postoperative*

The differences in MME levels between the pre-ERAS and post-ERAS groups 6 hours postoperatively were also evaluated using the Mann-Whitney U test. The Shapiro-Wilk test indicated that the data for the post-ERAS group did not meet the assumption of a normal distribution, $p < .05$. A mild outlier was noted in the post-ERAS group, as shown by the boxplots (Figure 2). The Mann-Whitney U test revealed no statistically significant difference in opioid consumption between the post-ERAS and pre-ERAS groups, $U = 1813.00$, $p = .839$, $z = -.20$. The findings suggest that implementation of ERAS protocols did not significantly affect opioid consumption in the six-hour postoperative period.

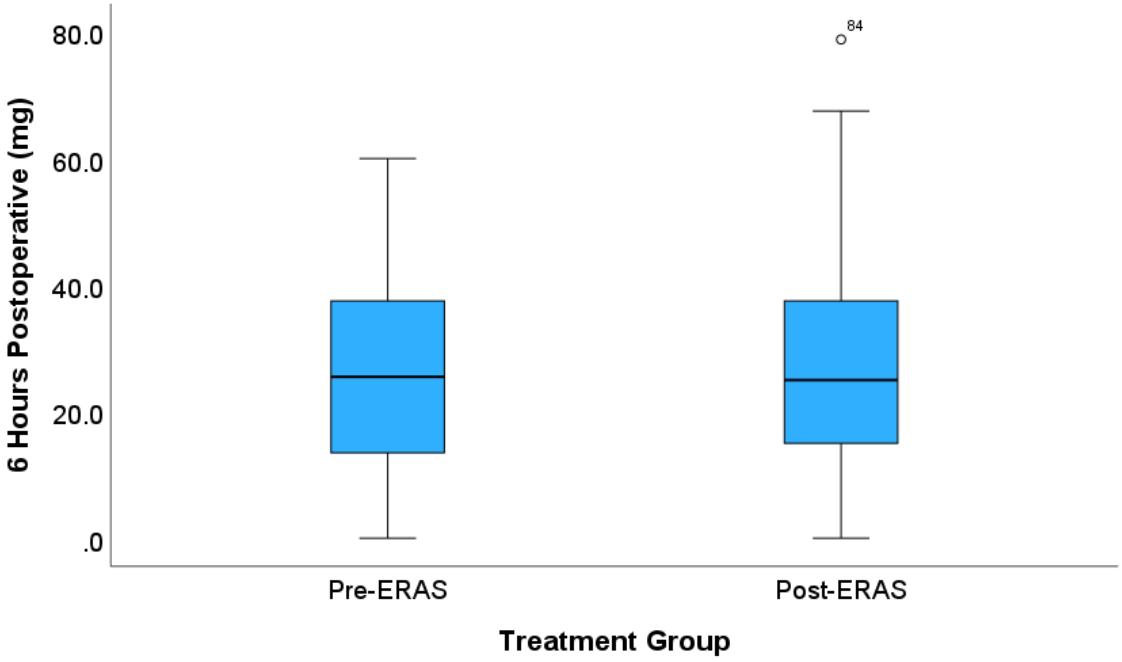


Figure 2. *Boxplot of 6 Hours Postoperative MME for Pre-ERAS and Post-ERAS Groups*

*4.2.3 Twenty-Four Hours Postoperative*

The Mann-Whitney U test was used to compare MME levels between the pre-ERAS and post-ERAS groups 24 hours postoperatively. This test was chosen because the Shapiro-Wilk test

confirmed that the pre-ERAS group's data violated the assumption of normal distribution, $p < .05$. Furthermore, the boxplots identified several extreme outliers in the pre-ERAS group (Figure 3). These data were retained for analysis since they were genuine data points. The Mann-Whitney U test indicated no statistically significant difference in opioid consumption between the post-ERAS and pre-ERAS groups, $U = 1859.00$, $p = .973$, $z = .033$. The results suggest that ERAS multimodal analgesia did not significantly impact longer-term opioid use.

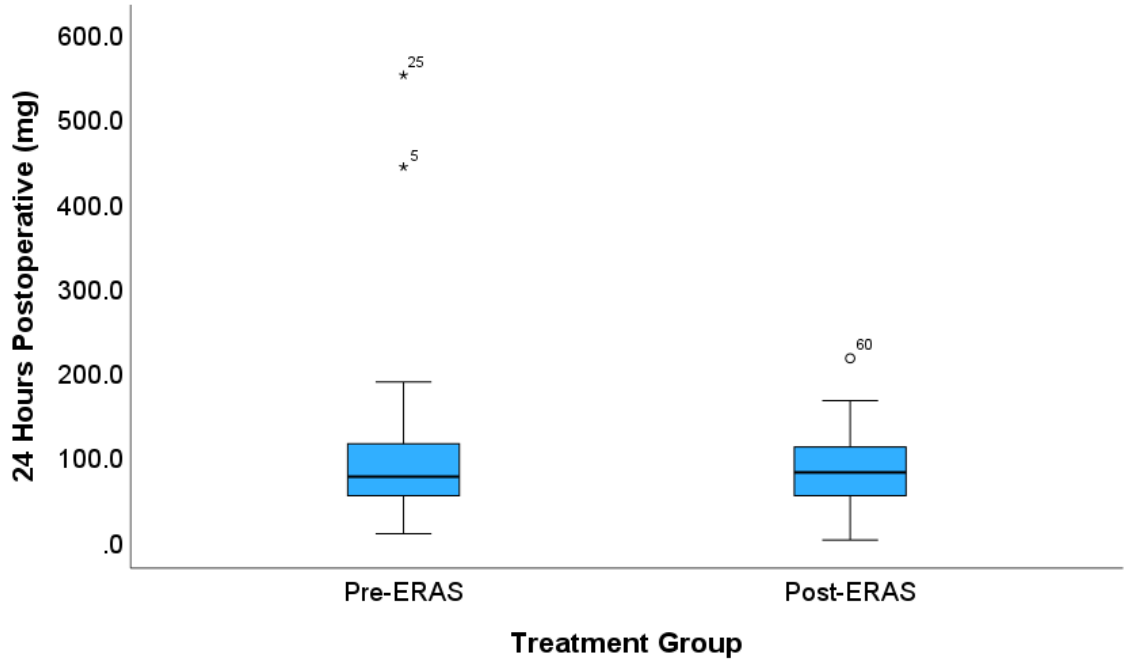


Figure 3**.** *Boxplot of 24 Hours Postoperative MME for Pre-ERAS and Post-ERAS Groups*

# CHAPTER 5: CLINICAL SIGNIFICANCE AND IMPLICATIONS

The Purpose of this DNP scholarly project was to study the effectiveness of Cardiac ERAS multimodal analgesia on perioperative pain. MME data was gathered from the electronic health record and analyzed to determine if implementation of MMA as part of a Cardiac ERAS program decreased pain and opioid use in the perioperative period. Data was analyzed intraoperatively and at 6 and 24 hours postoperatively. The use of opioids decreased perioperatively after MMA implementation, but the decrease was only statistically significant during the intraoperative period.

## 5.1 Discussion and Interpretation of Results

The findings from the scholarly project showed a statistically significant reduction in intraoperative mean Morphine Milligram Equivalents (MME) in the post-ERAS group. This finding aligns with those reported by Aguerreche et al. (2021), Guinot et al. (2019), Loria et al. (2022), and Markham et al. (2018), which showed a decrease in opioid use after implementing multimodal analgesia. The study results from this DNP scholarly project demonstrate that the ERAS multimodal analgesia protocol effectively decreases opioid use by anesthesia providers intraoperatively in the cardiac operating room.

However, comparisons of post-operative data between the Pre-ERAS and Post-ERAS mean MME presented a more nuanced view of the impact of ERAS multimodal analgesia. Postoperative data was obtained at 6 and 24 hours after surgery. Data from the study indicated that during the postoperative period, opioid use was relatively low during the first 6 hours after surgery in both the Pre-ERAS ($\overline{x}$ = 26.95) and Post-ERAS groups ($\overline{x}$ = 26.92). Post-cardiac surgery patients typically remain intubated and sedated for 4-6 hours after surgery. The data

suggests multimodal analgesia did not alter opioid use during this immediate post-operative period and opioid use is relatively low during the first 6 hours after surgery in this population.

Although the 24-hour postoperative MME data was not statistically significant, there was a decrease of 13.5% in MME means from 96.57 mg in Pre-ERAS to 83.57 mg Post-ERAS. Furthermore, the wide standard deviation, particularly in the Pre-ERAS group, indicates a wide range of opioid consumption before MMA implementation. This high variability makes detecting statistically significant differences between Pre- and Post-ERAS mean MME difficult. This high variability could be due to patient differences, such as pain tolerance, surgical complexity, or other perioperative pain management practices.

Consistent with previous studies, the findings from this scholarly project underscore the variability in multimodal analgesia, suggesting the personalized nature of pain management. This project demonstrates that combinations of multimodal analgesia may effectively reduce opioid consumption, particularly intraoperatively. However, the effectiveness of the multimodal drug combination is contingent upon individual patient characteristics, surgical procedures, and the timing of administration.

As a certified registered nurse anesthetist (CRNA) working in the operating room, much of the project lead’s education was focused on the implementation of intraoperative multimodal analgesia. Education on the multimodal analgesia pathway was provided on several occasions to CRNAs and anesthesiologists at Atrium Health to gain anesthesia providers’ buy-in for changing their practice. Many providers have used opioids as the primary anesthetic in cardiac surgery; changing this practice was a challenge. The statistically significant decrease in intraoperative opioid use is undoubtedly related to the improvement of anesthesia providers' knowledge of the implementation and efficacy of cardiac ERAS multimodal analgesia. Postoperative data was not

statistically significant and further education on multimodal analgesia in the cardiac ICU is necessary to ensure long-term success with opioid-sparing analgesia post-cardiac surgery.

## 5.2 Limitations

Several limitations to this scholarly project need to be acknowledged. The study used a quasi-experimental design without randomizing the Pre- and Post-ERAS group participants. This condition may potentially introduce selection bias. Despite efforts to select sample patients with certain criteria, the patients in the Pre-ERAS group could have differed from those in the Post-ERAS group regarding patient demographics, surgical techniques, or other clinical practice differences. The lack of randomization limits the ability to attribute the observed differences in MME directly to the ERAS implementation.

Furthermore, the sample for this scholarly project was limited to adult cardiac surgery patients at a single institution, Atrium Health CMC. The institution's services, accommodations, and other characteristics may not reflect those of other hospitals or cardiac surgery programs. Such conditions may limit the generalizability of the findings from this project. Future research across multiple centers would provide more comprehensive information in assessing the ERAS protocol's effectiveness in diverse clinical settings.

Lastly, the current electronic health record used at Atrium Health does not provide MME data after 24 hours postoperatively. MME data was only available intraoperatively and at 6 and 24 hours postoperatively. Further research could be conducted to analyze MMA effects on postoperative days 2 and 3 in cardiac surgery patients.

## 5.3 Recommendations

Several recommendations can be made based on the findings from this project. Nurses play a vital role in the implementation of ERAS protocols. Comprehensive education and

training programs are imperative to the success of ERAS and MMA implementation. These programs should detail the components of the multimodal analgesia plan, including the rationale for each intervention, the appropriate timing and dosage for medications, and their side effects. Such training will ensure that nursing staff are well-prepared to support the implementation of ERAS and MMA protocols.

Additionally, the findings of this project regarding the variability in post-operative MME underscore the importance of patient education and personalized pain management plans. Providers must educate patients about the goals and benefits of multimodal analgesia and emphasize the role of non-opioid medications in managing pain and facilitating recovery. Tailoring this education to address patients' concerns and expectations about pain and recovery may improve adherence to multimodal analgesia protocols and enhance patient satisfaction.

### 5.4 Future Projects or Research

A randomized controlled trial (RCT) would address the limitations related to the quasi-experimental design of this project. Randomization of the interventions would reduce subject selection bias and yield more definitive evidence regarding the efficacy of ERAS protocols in reducing opioid use and improving pain management.

Future studies involving multiple institutions could improve the generalizability of the findings. Including hospitals from different settings, including community hospitals, private hospitals, and academic medical centers would result in a large, diverse sample size. Results from these studies would provide a deeper understanding of how various institutional characteristics influence the implementation and effectiveness of ERAS protocols.

Furthermore, a project could be done to assess data beyond 24 hours post-operatively. Longitudinal studies could shed light on the impact of the longer-term effects of ERAS protocols

and opioid reduction including chronic pain incidence, opioid dependence, length of stay, or postoperative complications. Such research could show more comprehensive impacts of the cardiac ERAS and MMA protocols.

## 5.5 Summary

This DNP scholarly project was designed to evaluate the effectiveness of cardiac ERAS MMA on adult cardiac surgery patients at Atrium Health CMC. Implementation of a comprehensive cardiac ERAS protocol was instituted in October 2022 (Table 2) which included a robust multimodal pain management plan (Table 1). The goals of MMA are to decrease perioperative dependence on opioids as the primary analgesic for surgical pain while also providing better pain control than traditional opioid-based plans (Engelman et al., 2019). Literature has shown the effectiveness of MMA in other surgical specialties, but the complexity of cardiac surgery patients and the surgical procedure itself has led practitioners to be wary of accepting MMA as part of their pain management regime for this population.

The opioid pandemic has led anesthesia providers to redefine their pain management plans to include a more multimodal approach to decrease patients' exposure to opioids in the operating room. Opioids are associated with various perioperative complications. Literature suggests the risk of chronic opioid abuse in opioid naïve patients after exposure to opioids during surgery is increased (Schwenk & Mariano, 2018). This DNP scholarly project concluded that the implementation of an opioid-sparing MMA protocol led to statistically significant decreases in intraoperative opioid use in cardiac surgery patients. This proved that a reduction in opioid administration was achievable intraoperatively with a cardiac ERAS MMA protocol. Moreover, the statistics of this study highlighted that the postoperative period needs further evaluation and analysis after education and implementation of MMA and opioid-sparing analgesia.

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# APPENDIX A: CARDAIC ERAS AND MMA PATHWAYS

Table 1

*Atrium Health Adult Cardiac Surgery Cardiac ERAS Multimodal Analgesia Pathway*

| Preoperative | Intraoperative | Postoperative |
|---|---|---|
| • Acetaminophen 1000 mg PO given on arrival to Preop holding<br>• Gabapentin 300mg PO given on arrival to Preop holding | • Ketamine bolus 50mg and Magnesium 2-4gm bolus upon induction<br>• Propofol and/or Precedex drip | • Acetaminophen 650mg suppository upon arrival to ICU<br>• Gabapentin<br>  ○ Age <65 300mg PO Q8<br>  ○ Age >65 or CRCL<50 then 100mg PO Q8<br>  ○ If pre-surgical home dose of gabapentin >900mg/day, then continue home dosing<br>• Acetaminophen 1000mg PO Q6hrs<br>• Lidocaine transdermal film applied to chest |

Table 2

*Atrium Health Adult Cardiac Surgery ERAS Pathway*

| Perioperative |
|---|
| **Prehabilitation/Frailty**<br>• **Sternotomies including valve & CABG with clinical frailty scale of 5 or more referred to Cardiac Rehab prior to surgery** |
| **Medical optimization**<br>• **Renal**<br>• **Pulmonary**<br>• **Cardiac**<br>• **Endocrine** |
| **Nutrition screening**<br>• **CMP- Biomarker Albumin <3.5** |
| **Education Session**<br>• **Journey Book**<br>• **Remote Patient Monitoring Program**<br>• **Medications to Hold**<br>• **ERAS Bundle** |
| **Tobacco and Alcohol Cessation**<br>• **Advise 4weeks of alcohol cessation for patients that consume at least 5 alcohol equivalents per day, 2weeks otherwise**<br>• **Smoking cessation for at least 4 weeks** |
| **Fasting and Carbohydrate Treatment**<br>• **NPO for solids 8 hours before surgery except an oral carbohydrate drink given 4 hours prior to surgery** |
| **Home CHG Bathing**<br>• **Hibiclens soap solution the night before and morning of surgery** |
| **Multimodal Analgesia**<br>• **Acetaminophen 1000mg PO given on arrival to preop holding**<br>• **Gabapentin 300mg PO given on arrival to preop holding** |

| Intraoperative |
|---|
| **Infection Prevention Bundle**<br>• **CHG Bathing**<br>• **Hair Removal with electric clippers**<br>• **Antibiotic Prophylaxis within 1 hour before incision and additional dose if procedure >4 hours**<br>  • **DC within 48 hours after surgery** |
| **Multimodal Analgesia**<br>• **Ketamine bolus 50mg and Magnesium 2-4gm bolus upon induction**<br>• **Propofol and/or Precedex gtt** |
| **Postop Nausea Vomiting**<br>• **Preoperative screening for additional medications**<br>• **OG placed post TEE prior to leaving OR** |
| **Goal-Directed Therapy**<br>• **CI >2.2**<br>• **SvO2 >60**<br>• **UOP >0.5ml/kg/hour (ideal body wt.)**<br>• **Temp >36 degrees Celsius**<br>• **Glycemic Control**<br>  • **NON-DM >150mg/dl**<br>  • **DM >130mg/dl**<br>  • **Goal Range 90-120mg/dl**<br>• **Blood Management/Perfusion Bundle** |

- **Hgb>7g/dl or HCT>24**
- **Temperature >=36.5 degrees Celsius end of CPB**
- **Pressure MAPs 65-75mmhg**
- **Flow CI >= 2.2L/min/m2**
- **DO2's>=275ml/min**
- **Venous Sat's >=60%**

**Thermoregulation**

- **OR Room temp 70 degrees**
- **Under body bair hugger set at 43 degrees-high**

| Critical Care |
|---|
| **Communication**<br>• **Handoff Tools and Daily Goal Sheets**<br>  • **Transfer report for phases of care**<br>  • **Admission goal sheet**<br>  • **Daily ICU goal sheet** |
| **Multimodal Analgesia**<br>• **Acetaminophen 650 mg suppository on arrival**<br>• **Gabapentin**<br>  • **Age <65 300mg PO Q8**<br>  • **Age >65 or CRCL <50 then 100mg PO Q8**<br>  • **Excluded patients on HD**<br>  • **For all extubated patients hold dose for RASS -2, -3, -4,-5**<br>  • **Consider dose adjustment with renal insufficiency**<br>  • **If pre-surgical home dose of gabapentin >900 mg/day, then continue home dosing**<br>• **Acetaminophen 1000mg PO Q6 hours**<br>• **Oxycodone 5-10 mg PO every 4 hours PRN moderate pain 4-7**<br>• **Hydromorphone 0.5-1.0 mg Q 2hours PRN severe pain 8-10**<br>• **Lidocaine topical film apply 1 film transdermal daily to affected area PRN**<br>• **Bowel Protocol**<br>  • **Docusate 100mg PO bid to begin night of surgery**<br>  • **Senna 8.6 PO bid**<br>  • **PPI**<br>  • **Encourage gum chewing** |
| **Postop Nausea Vomiting**<br>• **OG placed post TEE prior to leaving OR**<br>• **Zofran prior to SBT and PRN** |
| **Nutritional Screening**<br>• **Dietician consult**<br>• **RN advances diet**<br>• **Oral Nutritional supplement**<br>  • **Ensure High Protein BID**<br>• **Mediterranean Diet** |
| **Goal-Directed Therapy**<br>• **CI >2.2 SvO2 >60**<br>• **UOP >0.5ml/kg/hour (ideal body wt.)**<br>• **Temp >36 degrees Celsius**<br>• **Glycemic Control**<br>  • **NON-DM >150mg/dl DM >130mg/dl**<br>  • **Goal Range 90-120mg/dl** |
| **Early Extubation**<br>• **Ventilator Protocol**<br>• **Decrease sedation on arrival and off at 1 hour mark**<br>• **Wake and Wiggle**<br>• **SBT (Zofran prior)**<br>• **Hour 3 and 5 RN/RT huddle**<br>• **If >6 hours, TN to organize RT/provider huddle at 12- and 18-hour mark** |
| **Infection Prevention Bundle**<br>• **CHG Bathing**<br>• **CLASBI** |

| |
|---|
| • **CAUTI** |
| **Mobilization**<br>• **Progressive Mobility Protocol**<br>• **PT order for EVAL POD 1**<br>• **POD 1 OOB to chair with the target to ambulate BID**<br>• **Move in the Tube Patient Education**<br>• **Exclusion Criteria**<br>  • **Failed Safety Screen**<br>  • **Unstable hemodynamics (SBP<90>160, HR <40 >140, CI <2.2 and SvO2 <50)**<br>  • **Unstable arrhythmia**<br>  • **100% Epicardial paced**<br>  • **New cardiac ischemia on EKG**<br>  • **Exception with MD order for ambulation** |

| **Telemetry** |
|---|
| **Multimodal Analgesia**<br>• **Acetaminophen PO q8hrs and Gabapentin PO q8hrs**<br>• **Hydromorphone 0.25-0.5mg IV q6hrs PRN for severe pain and/or chest tubes Rarely ordered with exception of severe pain and CT's**<br>• **Oxycodone 5-10mg PO q6hrs PRN**<br>• **Lidocaine topical film apply transdermal QD PRN**<br>• **Bowel Regimen**<br>  • **Docusate 100mg PO bid**<br>  • **Senna 6.6 PO bid**<br>  • **PPI**<br>  • **Polyethylene glycol 1 packet POD 1**<br>  • **Bisacodyl 10 mg PO POD2 in am if no BM than PR on POD 3**<br>  • **Gum Chewing if tolerated TID** |
| **Infection Prevention Bundle**<br>• **CHG Baths**<br>• **CLASBI**<br>• **CAUTI** |
| **Mobilization**<br>• **"Move in the Tube" Sternal Precaution Education**<br>• **Up to chair for meals 3xday**<br>• **Ambulate in hallway 3xday with assistance**<br>• **PT consult based on initial PT assessment** |
| **Nutritional Screening**<br>• **Oral Nutritional supplement**<br>  • **Ensure High Protein BID**<br>• **Mediterranean Diet** |
| **Priority Discharge**<br>• **Set target discharge date**<br>• **Schedule all necessary follow-up appointments**<br>  • **High risk 1 week CT Surgery APP**<br>  • **MI 1 week with ACARD APP**<br>  • **PCP**<br>  • **ACARD**<br>  • **4-week CT Surgery APP**<br>• **Cardiac Rehab Referral**<br>• **Case Manager**<br>  • **Arrange for HH agency**<br>  • **Home resources to support**<br>  • **Potential physical, financial, and social barriers**<br>  • **Verify prescription coverage** |
| **Education**<br>• **Involve patient and family**<br>• **Written instructions**<br>  • **When to call the CT Surgery office** |

| |
|---|
| • 24/7 access to on call CT Surgery care team<br>• ED for only true emergencies<br>• Incision care<br>• Pain medications<br>• Symptoms of infection<br>• Mobilization "Move in the Tube" Sternal Precaution Education<br>• Daily weight, BP, and Temp<br>• Respiratory and Incentive Spirometry |

| Post Discharge |
|---|
| **Discharge Phone Calls**<br>• 24-48 hours post discharge<br>• Confirm follow up appts are scheduled<br>• Medication Reconciliation<br>• Review post discharge instructions and education<br>• When to call the CT Surgery office<br>• 24/7 access to on call CT Surgery care team<br>• ED for only true emergencies<br>• Incision care<br>• Pain medications<br>• Symptoms of infection<br>• Daily weight, BP, and Temp<br>• "Move in the Tube" Precautions<br>• Respiratory and Incentive Spirometry |
| **Remote Patient Monitoring**<br>• 48-hour post discharge video visit<br>• Weekly post discharge video visit for 30 days post DC<br>• Incisional image<br>• Daily biometric readings (wt., BP, HR, steps, sleep)<br>• Psychological Education Session |
| **Cardiac Rehab**<br>• Orientation 3-4 weeks post discharge<br>• Surgeon clearance at 4 weeks |

Table 3

*Morphine Milligram Equivalent (MME) Conversion factors*

| Opioid | Conversion Factor |
|---|---|
| Codeine | 0.15 |
| Fentanyl Transdermal (in mcg/hr) | 2.4 |
| Fentanyl IV (mcg) | 0.1 |
| Hydrocodone | 1.0 |
| Hydromorphine | 5.0 |
| Morphine | 1.0 |
| Oxycodone | 1.5 |
| Tramadol | 0.2 |

# APPENDIX B: IRB APPROVAL

CHARLOTTE
DIVISION OF RESEARCH

| | |
|---|---|
| **To:** | Christine Sisk<br>University of North Carolina at Charlotte |
| **From:** | Office of Research Protections and Integrity |
| **Approval Date:** | 16-May-2023 |
| **RE:** | Notice of Determination of Exemption |
| **Exemption Category:** | 4 |
| **Study #:** | IRB-23-0946 |
| **Study Title:** | Effectiveness of Cardiac ERAS Multimodal Analgesia on Postoperative Pain in Adult Cardiac Surgery Patients. |

This submission has been reviewed by the Office of Research Protections and Integrity (ORPI) and was determined to meet the Exempt category cited above under 45 CFR 46.104(d). This determination has no expiration or end date and is not subject to an annual continuing review. However, you are required to obtain approval for all changes to any aspect of this study before they can be implemented and to comply with the Investigator Responsibilities detailed below.

Your approved consent forms (if applicable) and other documents are available online at Submission Page.

**Investigator's Responsibilities:**

1. Amendments **must** be submitted for review and the amendment approved before implementing the amendment. This includes changes to study procedures, study materials, personnel, etc.
2. Researchers must adhere to all site-specific requirements mandated by the study site (e.g., face mask, access requirements and/or restrictions, etc.).
3. Data security procedures must follow procedures as described in the protocol and in accordance with OneIT Guidelines for Data Handling.
4. Promptly notify the IRB office (uncc-irb@uncc.edu) of any adverse events or unanticipated risks to participants or others.
5. Five years (5) following this approval/determination, you must complete the Admin-Check In form via Niner Research to provide a study status update.
6. Be aware that this study is included in the Office of Research Protections and Integrity (ORPI) Post-Approval Monitoring program and may be selected for post-review monitoring at some point in the future.
7. Reply to the ORPI post-review monitoring and administrative check-ins that will be conducted periodically to update ORPI as to the status of the study.

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

# MEMORANDUM

To: Exie Earnhardt
Atrium/Carolinas Healthcare System

From: Brian Moore, Chair
Institutional Review Board

Date: 7/10/2023

Subject: Exempt Protocol: IRB00097506
Effectiveness of Cardiac ERAS Multimodal Analgesia on Postoperative Pain in Adult Cardiac Surgery Patients

No protected health information will be used or disclosed in this research proposal; therefore the requirement for individual Authorization does not apply.

This research meets the criteria for a waiver of HIPAA authorization according to 45 CFR 164.512.

Exemption Category 4 - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. null (Category null).

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study is exempt. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. Each project requires a separate review and approval or exemption. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to meet the requirements for exemption.