Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis

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DNP Project Approval Form

This is to certify that Anna Rumi successfully defended their project entitled:

Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis

on November 26, 2019.

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# Table of Contents

Acknowledgements ........................................................................................................... 5
Abstract .............................................................................................................................. 6
Introduction ........................................................................................................................ 7
Background and Significance ............................................................................................ 7
Project Purpose, Aim, and Objectives .............................................................................. 9
Theoretical Framework ...................................................................................................... 10
Literature Review ............................................................................................................... 12
Design, Methods, and Data Collection .......................................................................... 16
Ethical Considerations ....................................................................................................... 18
Data Analysis .................................................................................................................... 19
Results ............................................................................................................................... 20
Discussion ......................................................................................................................... 23
Conclusion ......................................................................................................................... 28
Deliverables to Project Site ............................................................................................... 28
Contribution to Scholarship and Practice ........................................................................ 29
DNP Essentials .................................................................................................................. 30
Strengths and Limitations ................................................................................................. 31
Future Implications and Recommendations .................................................................... 32
References ......................................................................................................................... 34
Tables ................................................................................................................................. 39

  Table 1 ............................................................................................................................... 39
  Table 2 ............................................................................................................................... 40
Acknowledgements

I wish to express my tremendous gratitude to Dr. Christopher Barrick for all of his guidance in preparing this study protocol and statistical analysis. I thank Dr. Christian Marks also for his guidance in preparation of the study protocol and working through the IRB approval process. I must thank ECMC Reporting Consultant Carla Russo for her meticulous recovery of requested data for this review. I also wish to acknowledge the assistance of Jou-Fei Huang of the University at Buffalo Political Science department for her statistics consultation. Lastly, I extend my utmost gratitude to Dr. Cheryl Spulecki for her continued mentorship and encouragement in completing this project and Dr. Loralee Sessanna for her time and feedback in editing this paper and navigating the DNP Project.
Abstract

Obesity decreases oxygen reserve and increases sensitivity to opioids and risk for opioid-induced respiratory depression (OIRD). Dexmedetomidine, an alpha-2 agonist, presents a promising solution to prevent OIRD. Vulnerability to respiratory compromise among obese bariatric surgery patients warrants examining how an intraoperative dexmedetomidine infusion may decrease perioperative opioid requirements among adult patients undergoing laparoscopic sleeve gastrectomy. This study aimed to compare opioid requirements within 24 hours after the induction of anesthesia between patients who underwent laparoscopic sleeve gastrectomy in an urban hospital in Buffalo, NY in a one-year time period who received an intraoperative dexmedetomidine infusion as part of a bariatrics enhanced recovery after surgery protocol to patients who underwent the same procedure but had not received the infusion. Neuman’s Systems Model was used as a holistic nursing approach to guide practical application of research. A retrospective chart review was conducted and one-way between subjects ANOVA was performed to compare the effect of an intraoperative dexmedetomidine infusion on perioperative opioid consumption between those patients who received the infusion and those who did not. A total of 150 patient charts were included in this analysis. There was a significant effect of intraoperative dexmedetomidine on amount of opioids consumed intraoperatively at the p<.05 level \( F(1, 56) = 4.041, p = 0.049 \) but not on amount of opioids consumed postoperatively. These results suggest that intraoperative dexmedetomidine is associated with a significant reduction of intraoperative opioid requirements but not postoperative opioid requirements among adult obese patients undergoing laparoscopic sleeve gastrectomy.

Keywords: dexmedetomidine, bariatric surgery, opioid induced respiratory depression, sleeve gastrectomy, ERAS
Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis

As anesthesia providers become increasingly accountable for the outcomes and costs of their clinical care, standardization through evidence-based practice protocols such as those promoting Enhanced Recovery after Surgery (ERAS) will become more prevalent in shaping anesthesia practice (Moore, 2019). ERAS protocols optimize perioperative outcomes and care, with specific goals related to decreasing opioid requirements and thereby the risk of opioid-induced respiratory depression (OIRD) in such vulnerable populations as obese patients undergoing bariatric procedures (Blumenthal, 2019). The incidence of severe respiratory depression and associated death related to treatment for acute and perioperative pain is estimated at 0.5% (Dahan et al., 2018). Multimodal analgesia as an opioid minimization technique is a cornerstone of ERAS and presents a promising solution to address the life-threatening complication of OIRD through the use of non-opioid agents, specifically intraoperative infusion of alpha-2 agonist dexmedetomidine (Sultana, Torres, & Schumann, 2017). Successfully implementing and sustaining any component of ERAS relies on evaluation of its effectiveness (Blumenthal, 2019). Evaluation of the use of an intraoperative dexmedetomidine infusion as part of a current bariatric ERAS protocol at an urban hospital in Buffalo, NY is needed for that institution to determine if its intended outcome of decreasing perioperative opioid requirements among patients undergoing bariatric surgery is being achieved.

Background and Significance

Obesity decreases oxygen reserve, impairs the function of respiratory muscles, and increases susceptibility to atelectasis and sensitivity to opioids with an associated risk of OIRD (Sherif & Elsersy, 2017; Tonner, 2017). OIRD is caused specifically by activation of μ-opioid
receptors of respiratory centers in the brainstem leading to diminished, irregular, and eventually
cessation of breathing which could culminate in cardiopulmonary arrest and death (Dahan et al.,
2018). Gupta et al. (2018) noted the extreme variation in defining OIRD, with reported
incidences ranging from 0.04-0.5% when defined by associated naloxone administration, to 23-
41% when assessed by hypoxemia or hypopnea.

Obese patients are increasingly presenting for bariatric surgery, specifically laparoscopic
sleeve gastrectomy, with such respiratory problems as sleep apnea contributing to their
vulnerability to postoperative pulmonary complications including increased sensitivity to
opioids, low oxygenation and retained carbon dioxide (Barreca, Renzi, Tankel, Shalhoub, &
(2017) highlighted the goal of minimizing opioid use among obese surgical patients to prevent
respiratory depression, central muscle rigidity, pharyngeal muscle weakness, and obstructed
breathing. Among obese patients presenting for bariatric surgery, vulnerability to respiratory
compromise warrants attention to how a strategy of perioperative multimodal analgesia, as
presented in a bariatics ERAS protocol, may correlate with opioid requirements intra and
postoperatively.

Alpha-2 agonist dexmedetomidine has been a focus of multimodal analgesic strategies
for use intraoperatively as adjuvant to general anesthesia for its characteristic attenuation of the
stress response to surgery and provision of sedation while not contributing to significant
respiratory depression (Sherif & Elsersy, 2017). The analgesic effect of dexmedetomidine is
suggested to be attributed to common inhibitory G-protein pathways shared among alpha-2,
adenosine and µ-opioid receptors, where the spine is the principle site of alpha-2 agonist
mediated analgesia (Tonner, 2017). Although the ERAS Society in its guidelines for
Perioperative Care in Bariatric Surgery concluded that current evidence does not support routine use of dexmedetomidine as part of a multimodal analgesic strategy, the Society failed to suggest other specific anesthetic agents or techniques as well as a recommended standardized anesthetic protocol for bariatric surgery (Thorell et al., 2016). In light of the current lack of evidence, but with enough evidence supporting intraoperative use of a dexmedetomidine infusion for bariatric surgery, evaluation of the use of the infusion as part of the newly implemented Bariatrics Enhanced Recovery Protocol (Appendix A) at an urban hospital located in Buffalo, NY needs to be completed to determine whether its intended outcome of opioid minimization is being achieved.

**Project Purpose, Aim, and Objectives**

The purpose of this Doctor of Nursing Practice (DNP) project was to examine the effect of a dexmedetomidine infusion administered intraoperatively as part of an enhanced recovery protocol for bariatric surgery on opioid requirements within 24 hours after the induction of anesthesia among patients age 18 years and older undergoing laparoscopic sleeve gastrectomy at an urban hospital located in Buffalo, NY, compared to no infusion. The specific aim of this project was to contribute evidence in support of or against routine use of intraoperative dexmedetomidine infusion among adult obese patients presenting for laparoscopic sleeve gastrectomy as part of a multimodal analgesic strategy through protocol evaluation examining correlation to opioid requirements. Project objectives were to 1) conduct a retrospective chart review to compare opioid requirements administered at any point within 24 hours after the induction of anesthesia, as documented on the patient medical record, among patients who underwent laparoscopic sleeve gastrectomy prior to implementation of the enhanced recovery protocol and had not received an intraoperative dexmedetomidine infusion, to those patients who
underwent laparoscopic sleeve gastrectomy and had received the infusion as part of the protocol; and 2) contribute evidence to the hospital in support of or against routine use of intraoperative dexmedetomidine infusion among adult obese patients presenting for laparoscopic sleeve gastrectomy as part of a multimodal analgesic strategy. The results have been made available to the project site’s key stakeholders including anesthesia providers, bariatric surgeons, perioperative registered nurses, other allied health professionals, and patients.

**Theoretical Framework**

Betty Neuman’s Systems Model was used as the theoretical framework for this project. Neuman’s Systems Model is an open, holistic perspective to addressing a variety of health issues and may be interpreted for wide use among different health care disciplines (Neuman, 2017). As a holistic nursing approach to guiding practical application of research, the model was used to gain new knowledge regarding the effect that a dexmedetomidine infusion has on opioid requirements among obese adult bariatric surgery patients. The model describes the individual as a system having a central core for basic survival protected by outer and inner layers of defense in response to given stressors from the environment (Ahmadi & Sadeghi, 2017; Neuman, 1982). Health may be seen as a continuum within the system between wellness and illness that is changing constantly, whereby wellness happens when total systems needs are met and illness happens when instability and energy depletion arise (Ahmadi & Sadeghi, 2017; Neuman, 1982). Neuman’s Systems Model views nursing as a means of addressing the whole person and all variables that affect one’s response to stress, with the aim of promoting stability through reducing stressors to maintain health of the individual’s system through nursing intervention (Ahmadi & Sadeghi, 2017; Neuman, 1982). Neuman identifies levels of intervention as primary, secondary and tertiary prevention of stressors, where primary prevention is in place to reduce the
possibility of encountering a stressor, secondary prevention is in place after an individual has a response to a stressor, and tertiary prevention is focused on readjustment toward stability (Ahmadi & Sadeghi, 2017; Neuman, 1982). This DNP project, with the purpose of investigating the effectiveness of an intraoperative dexmedetomidine infusion on reducing opioid requirements within 24 hours after the induction of anesthesia to thereby reduce the potential risk of OIRD among obese adult patients undergoing laparoscopic sleeve gastrectomy, may be framed in the context of these levels of intervention.

Intraoperative dexmedetomidine infusion as the intervention to be evaluated may be seen as a way of promoting stability through the stress of surgery. It is considered as a primary prevention measure in the sense of being administered to prevent the body’s stress response and pain of surgical stimulation, which is the essence of anesthesia. An extension of this context of primary preventive use of dexmedetomidine, as framed in this model, may be seen in its intended use of reducing perioperative opioid requirements to prevent respiratory complications among obese adult patients undergoing laparoscopic sleeve gastrectomy. Secondary prevention can be applied to evaluating the effectiveness of intraoperative infusion of dexmedetomidine in determining the patient’s stress response to surgical stimulation and pain that may not have been prevented by administering the infusion. Tertiary prevention, as readjustment toward patient stability, would be applied to determining how to effectively treat the stress response to surgery and pain that had not been otherwise prevented by the dexmedetomidine infusion to further evaluate the effectiveness of this intervention. Neuman’s System Model demonstrates its flexibility and evolving application to clinical inquiry in taking on a holistic and preventive focus to evaluating the intervention of an intraoperative dexmedetomidine infusion among bariatric surgery patients.
Literature Review

A review of the health-related literature was conducted to explore the risk of OIRD and use of dexmedetomidine among adult obese bariatric surgery patients using the following keywords both singularly and in multiple combinations: dexmedetomidine, bariatric surgery, sleeve gastrectomy, opioid induced respiratory depression, and ERAS. Databases searched, limited to the years 2014 to 2019 to ensure current evidence-based literature was reviewed for the purpose of this project, included PubMed, CINAHL, and the Cochrane Database of Systematic Reviews. Reference lists of each systematic review and meta-analysis were manually searched. Studies conducted with adults aged 18 years and older and published in English with full text available were included in the review. Case reports and editorial articles were excluded. Eleven studies in total were included in this review and a summary of the findings are presented below.

Risk of OIRD

The risk of OIRD among surgical patients has been investigated and reported in current literature providing evidence to be applied toward its prevention. In their systematic review and meta-analysis of risk factors for OIRD among surgical patients, Gupta et al. (2018) determined obstructive sleep apnea (OSA), cardiac, and pulmonary disease to be among factors increasing the risk for developing OIRD. Demographics including age, gender, body mass index, and American Society of Anesthesiologists (ASA) physical status were not significant predictors of OIRD, nor was type of surgical procedure performed (Gupta et al., 2018).

A retrospective chart review of opioid consumption among patients with OSA who had undergone laparoscopic bariatric surgery showed approximately 60% of patients presenting for these procedures suffered from moderate-to-severe OSA and an increased sensitivity to opioids
(Turan et al., 2015). This increase in opioid sensitivity was evidenced by patients with longer preexisting desaturations in polysomnography having had consumed significantly less opioids in the first 24 hours after surgery (Turan et al., 2015). A closed claims analysis of a search of the Anesthesia Closed Claims Project database done to investigate the likelihood of postoperative OIRD being involved in these sentinel events and to strategize toward preventing them further, revealed the majority of these incidents occur within 24 hours after surgery (Lee et al., 2015). There are numerous risk factors for OIRD that may not even be applicable to all patients who develop it (Lee et al., 2015).

**Effect of Dexmedetomidine on Opioid Consumption**

In their prospective, randomized trial among 150 morbidly obese patients undergoing laparoscopic sleeve gastrectomy, Sherif and Elsersy (2017) compared morphine consumption within 48 hours from the emergence of anesthesia to use of a dexmedetomidine infusion among one group of patients to a lidocaine infusion among another group to a control group given no infusion during the procedure. The authors found that the group administered the dexmedetomidine infusion during their procedure consumed the least morphine postoperatively, followed by the lidocaine infusion group and then control group, which consumed the most morphine postoperatively (Sherif & Elsersy, 2017). The use of dexmedetomidine or lidocaine infusion is recommended to decrease postoperative opioid use (Sherif & Elsersy, 2017). A single bolus of dexmedetomidine administered at the time of surgical closure to patients undergoing laparoscopic Roux-en-Y gastric bypass surgery, however, did not significantly reduce immediate or total consumption of hydromorphone postoperatively, as reported by the authors in their randomized control trial (Ranganathan et al., 2019).
A 2016 systematic review of the perioperative use of dexmedetomidine for acute pain among adults after abdominal surgery also found dexmedetomidine to have some sparing effect on postoperative opioid consumption (Lundorf, Nedergaard, & Moller, 2016). While the authors noted the low quality of evidence to support this claim due to poor study design among those included in their review, most studies comparing dexmedetomidine to no treatment found that dexmedetomidine decreased opioid consumption for pain within 24 hours after surgery (Lundorf et al., 2016). Authors in their systematic review investigating current evidence on perioperative outcomes among patients with OSA receiving acute opioid analgesia did find a significant reduction in opioid requirements in the first 24 hours among patients receiving intraoperative dexmedetomidine during uvulopalatopharyngoplasty (Cozowicz, Chung, Doufas, Nagappa, & Memtsoudis, 2018).

A meta-analysis and trial sequential analysis of the perioperative analgesic profile of dexmedetomidine infusions in morbidly obese patients undergoing bariatric surgery found patients having received dexmedetomidine infusions required significantly less morphine in the first 24 hours following surgery (Singh et al., 2017). The authors reported a statistically significant reduced consumption of postoperative morphine reported in the first 24 hours of surgery among obese patients receiving either intraoperative or both intra and postoperative dexmedetomidine infusions during their bariatric procedure (Singh et al., 2017).

Abu-Halaweh et al. (2016) found in their pilot study that additional morphine doses needed were not significantly different between one group of bariatric surgery patients given a dexmedetomidine infusion postoperatively to another group given a morphine infusion postoperatively. In one randomized controlled study, intraoperative dexmedetomidine infusion compared to placebo significantly decreased postoperative morphine consumption within the
first 24 hours among patients undergoing laparoscopic cholecystectomy (Bielka, Kuchyn, Babych, Martycshenko, & Inozemtsev, 2018). While the ERAS Society does suggest that among bariatric surgery patients opioid minimization techniques do appear to lessen complication rates and that non-opioid analgesics be used as part of a multimodal systemic analgesic strategy, it could not, however, based on current evidence, recommend the routine use of dexmedetomidine as part of this strategy (Thorell et al., 2016).

Summary

This review of current health related literature revealed several studies supporting both the risk of OIRD among surgical patients (Gupta et al., 2018; Lee et al., 2015; Turan et al., 2015), and the potential reduction in perioperative opioid consumption dexmedetomidine stands to facilitate (Bielka et al., 2018; Cozowicz et al., 2018; Lundorf et al., 2016; Singh et al., 2017; Sherif & Elsersy, 2017). More evidence, however, is needed to translate to definitive practice guidelines specific to bariatric surgery. This is evident among the most relevant clinical recommendations by the ERAS Society as well as findings of the included systematic reviews (Cozowicz et al., 2018; Lundorf et al., 2016; Thorell et al., 2016).

Each study, systematic review, and meta-analysis included in this literature review varied on exact dexmedetomidine administration protocol, from intraoperative to postoperative infusion to one time dose given on surgical closure, as well as exact type of surgical procedure performed. One systematic review included all abdominal surgery, while another investigating risk of OIRD included all types of surgery, and another related to perioperative outcomes in patients with OSA receiving opioids for acute surgical pain was also not specific to bariatric surgery (Cozowicz et al., 2018; Gupta et al., 2018; Lundorf et al., 2016). Postoperative dexmedetomidine infusion was found to have a similar effect as a postoperative morphine infusion on supplemental morphine
dose requirements in the first 24 hours following laparoscopic gastric bypass, banding or sleeve gastrectomy among bariatric surgery patients (Abu-Halaweh, 2016). Implementing multimodal analgesia and non-opioid analgesics would decrease opioid consumption and thereby decrease the risk of OIRD (Gupta et al., 2018; Cozowicz et al., 2018).

**Design, Methods, and Data Collection**

The project design was a retrospective chart review of adult bariatric surgery patients undergoing laparoscopic sleeve gastrectomy at Erie County Medical Center (ECMC) in Buffalo, NY. Charts of those patients having received a dexmedetomidine infusion intraoperatively as part of the hospital’s Bariatrics Enhanced Recovery Protocol were reviewed to investigate the infusion’s association with perioperative opioid requirements and compared to charts of those patients undergoing laparoscopic sleeve gastrectomy not having received the infusion. The project employed quantitative methods to obtain data on the outcome measure of patients’ total amount of opioids received within 24 hours after the induction of anesthesia, as compared to whether or not a dexmedetomidine infusion was administered intraoperatively.

Upon approval of the study protocol by University at Buffalo’s (UBs) Institutional Review Board (IRB) (Appendix B), the principal investigator completed the project site’s Research Application through its Risk Management department. Upon approval of this application by the project site’s Associate Medical Director (Appendix D), the verified approval and study protocol were forwarded to the project site’s Healthcare Information Technology Management. Requested data per the study protocol and by email and phone communication with the principal investigator was then collected by the project site’s Information Technology Reporting Consultant, de-identified and uploaded as a Microsoft Excel file to a secure server called Watchdoxx. Access to the server was granted to the principal investigator. While it was
originally anticipated that the principal investigator would collect data directly from the medical record, due to the project site’s records keeping and release policy for research purposes to protect patient information, the Information Technology Reporting Consultant collected all data directly from the electronic record and provided it to the principal investigator via the secure server.

Data was collected by the Information Technology Reporting Consultant from those charts containing specific Current Procedural Terminology (CPT) code 43775 for laparoscopic sleeve gastrectomy performed between August 2018 and August 2019 for this review (Centers for Disease Control and Prevention (CDC), 2019). Adults aged 18 years and older undergoing laparoscopic sleeve gastrectomy at the project site between August 1, 2018 and August 1, 2019 were included for this chart review. Charts of patients under age 18 and above age 90, pregnant women and prisoners, or those undergoing any bariatric procedure other than laparoscopic sleeve gastrectomy, were excluded per the study protocol.

De-identified patient information collected included age, ethnicity, race, gender, weight, and ASA physical classification status. Primary study variables of whether or not the patient received a dexmedetomidine infusion intraoperatively per the Bariatrics Enhanced Recovery Protocol and the total amount of opioids consumed within 24 hours of the induction of anesthesia as documented on the hospital medication administration record were also collected among all medications documented as received in the immediate preoperative, intraoperative, and postoperative periods. Timing of each administration as the number of minutes within the procedure the medication was given was also included among collected data. Procedure dates, timing in exact start and finish times, as well as duration of each procedure in minutes were also included. All of these data were collected and organized into a Microsoft Excel file by the
Ethical Considerations

Although the targeted patient population for this chart review did not represent a particularly vulnerable population and approval for the study was granted by UB’s IRB and the project site’s Associate Medical Director, certain ethical considerations do apply. Protection of patient data by securing information on computers with specific passwords or locked physical storage was a fundamental ethical consideration of ensuring privacy of study participants (W.K. Kellogg Foundation, 2017). Transparency to stakeholders through their review of the process of data analysis and interpretation to ensure that conclusions were drawn directly from the evidence (National Center for Chronic Disease Prevention and Health Promotion, 2011) was also an important ethical consideration for this project. Lastly, it was imperative that study results be disseminated to stakeholders given the resources expended and information gained from the evaluation process (National Center for Chronic Disease Prevention and Health Promotion, 2011).

All clinical research approval at the project site flowed through its Risk Management department. Upon IRB, protocol and project site Research Application approval for this chart review, Risk Management requested the data be collected by the project site’s Information Technology Management, who de-identified the data and uploaded it to a secure server called WatchDoxx made available to the principal investigator. Only de-identified patient data is held by the principal investigator and research team. All these data will be stored for three years and then destroyed.
While private records were accessed to collect data for this study, this represented a minimal invasion of privacy because the principal investigator and research team gained access to these records through institutional gatekeepers who released only de-identified data. These gatekeepers were the Risk Management department and Information Technology Management at the project site who were not affiliated with the research project and gave permission to access patient data. The research team was authorized to access protected health information without consent for this records review by virtue of the HIPAA (Health Insurance Portability and Accountability Act) waiver and consent waiver which were verified by the project site’s Risk Management before the information was provided. Study results have been disseminated to project site stakeholders including anesthesia providers who will share these with allied health professionals and patients as is necessary or appropriate for further review to best inform clinical practice.

Data Analysis

Data analysis focused on the association of use of a dexmedetomidine infusion administered intraoperatively to total amount of opioids consumed within 24 hours of the induction of anesthesia as documented on the medication administration record. Data from the Microsoft Excel file provided by the project site’s Information Technology Reporting Consultant were all coded to numeric values for conversion to statistics software. Total amount of opioids administered in the perioperative period were reviewed and converted to morphine milligram equivalent doses as described in Table 1 (Apex Anesthesia Review, 2019; CDC, 2017; Open Anesthesia, 2019). IBM SPSS Statistics version 25 software was used for the analysis with expert consultation to verify appropriate analytic procedures were followed. Descriptive and
frequency analyses were used to formulate demographics information and amounts of morphine milligram equivalents administered by dexmedetomidine infusion versus no infusion groups.

The overarching research question was to determine the significance of group differences in perioperative opioid consumption between those patients having received the dexmedetomidine infusion intraoperatively and those not having received the infusion. Since the amount of total opioids consumed, as measured in morphine milligram equivalents, is the one dependent variable and a ratio measurement analyzed in relation to the intervention of a dexmedetomidine infusion versus no infusion as the independent variable and a nominal measurement, one-way between subjects analysis of variance (ANOVA) was conducted to compare the effect of an intraoperative dexmedetomidine infusion on total amounts of opioids consumed within 24 hours of the induction of anesthesia (Polit, 2010; Tabachnick & Fidell, 2019). Total amounts of opioids consumed were calculated each in the intraoperative and immediate post-operative periods in this 24 hour timeframe, and each interval total was compared to whether or not a dexmedetomidine infusion had been used intraoperatively per the Bariatrics Enhanced Recovery protocol.

Results

One-way between subjects ANOVA as seen in Table 5 was performed to compare the effect of an intraoperative dexmedetomidine infusion on intraoperative opioid requirements as measured by morphine milligram equivalents administered during the procedure between those patients who received the infusion and those who did not. There was a statistically significant effect of the intraoperative dexmedetomidine infusion on opioid requirements during the intraoperative time interval at the p<.05 level for each group [F(1, 56) = 4.041, p = 0.049]. One-way between subjects ANOVA as seen in Table 6 was also performed to compare the effect of
the intraoperative dexmedetomidine infusion on postoperative opioid consumption as measured by morphine milligram equivalents administered during the postoperative period up to 24 hours from the induction of anesthesia between those patients who received the infusion and those who did not. There was not a statistically significant effect of the intraoperative dexmedetomidine infusion on opioid requirements during the postoperative time interval at the p < .05 level for patients having received the intraoperative dexmedetomidine infusion and those not having received the infusion [F(1, 140) = 2.556, p = 0.112].

The mean morphine milligram equivalent requirements during the intraoperative time interval among patients not having received a dexmedetomidine infusion versus having received a dexmedetomidine infusion and are displayed in Table 3. Missing cases in each group are seen at the bottom of Table 3 indicating no record of opioid administration in the intraoperative time interval, which for the group having received the dexmedetomidine infusion was 38 out of 46 cases accounting for 82.6% of patients. For the group not having received a dexmedetomidine infusion, 54 out of 104 cases missing accounted for 51.9% of patients with no record of opioid administration during this time interval in this sample. Figure 1 provides graphic representation of the difference in morphine milligram equivalent requirements during this intraoperative time interval between those patients receiving no dexmedetomidine infusion and those receiving an infusion.

Postoperative morphine milligram equivalents by dexmedetomidine infusion versus no dexmedetomidine infusion are presented in Table 4. The mean morphine milligram equivalent requirements were higher for both no dexmedetomidine infusion and dexmedetomidine infusion groups in this postoperative time interval compared to requirements in each of the two groups during the intraoperative time interval. For this postoperative time interval, 5.8% of cases were
missing as 6 out of 104 patients with no record of opioid administration among those in the no
dexmedetomidine infusion group. This compares to 4.3% of missing cases as 2 out of 46
patients with no record of opioid administration among the dexmedetomidine infusion group
during this postoperative time interval. Figure 2 provides graphic representation of the
difference in morphine milligram equivalent requirements during this postoperative time interval
between those patients receiving no dexmedetomidine infusion and those receiving an infusion.

A total of 150 charts of patients undergoing laparoscopic sleeve gastrectomy at ECMC
within the specified timeframe meeting inclusion criteria were analyzed spanning the dates of
November 6, 2018 to August 1, 2019. Patient demographics and clinical characteristics
including age, gender, weight in kilograms, and ASA physical classification by those who
received a dexmedetomidine infusion versus no dexmedetomidine infusion are summarized in
Table 2. Primary procedure types requested for CPT code 43775 were reported with descriptions
as either laparoscopic gastric sleeve (87.3% of cases), repair of laparoscopic gastric sleeve
(4.6%), midline laparoscopic gastric sleeve (2.7%), laparoscopic gastric sleeve, possible open
(1.3%), and the remaining as laparoscopic gastric sleeve with either upper, and lysis of, or EGD
scope (4.2%) descriptions. Mean procedure time in this sample was 46 minutes, with a range of
28 to 115 minutes reported, while mean anesthesia time was 194 minutes, ranging from 64 to
477 minutes.

A total of 46 patients received an intraoperative dexmedetomidine infusion among this
sample. The range of patient weight for the entire sample was from 76 up to 277 kilograms.
Women accounted for 78% (n=117) of all cases included, while men represented 22% (n = 33).
The mean age at time of visit in this sample was 41 years, and patients ranged in age from 19 to
71 years old. Figure 3 provides a graphic summary of each group dexmedetomidine versus no
dexmedetomidine infusion by weight in kilograms, age, and gender. Demographic reporting of race in this sample found 77.3% of patients identified as white, 15.3% as black, 1.3% as American Indian/Alaska Native, 0.7% as multiracial, 4% as other, and the remaining 1.3% declined.

Discussion

Key Findings

These results suggest an intraoperative dexmedetomidine infusion has a statistically significant effect on intraoperative but not postoperative opioid requirements among patients undergoing laparoscopic sleeve gastrectomy in this sample. It is important to note the missing cases of morphine milligram equivalents for each intraoperative and postoperative time intervals as representing cases of patients not having received any type of opioid in each of these specified periods. There were several instances of missing opioid administrations throughout the sample included in this chart review, reflecting these instances of patients not having received opioids during the given perioperative period. As could have been predicted, most (82.6%) of patients receiving an intraoperative dexmedetomidine infusion did not receive any opioids during the intraoperative time interval. This is suggestive of the specifications of the project site’s Bariatrics Enhanced Recovery Protocol to administer a dexmedetomidine infusion intraoperatively and that no opioids be given without first consulting the surgeon during this time interval.

Far fewer opioid administrations were missing during the postoperative time interval, indicating greater opioid requirements during this period. This interval was of course a longer duration of time than the intraoperative time interval, but more importantly represents the period in which no dexmedetomidine infusion was being given. The administration procedure followed
of the project site’s protocol that is the focus of this evaluation was that a dexmedetomidine infusion be administered during the intraoperative time interval only and that it be stopped by the anesthesia provider upon exiting the operating room. While the elimination half-time of dexmedetomidine is two to three hours and could suggest a potentially prolonged therapeutic effect beyond when it is administered into the postoperative period, the context-sensitive half-time as four minutes after a ten minute infusion (Flood, Rathmell, & Shafer, 2015) which by definition increases as the duration of the infusion increases, more accurately informs us of the abbreviated duration of the infusion’s therapeutic effect beyond the time it is discontinued. Therefore, it may have been predicted that postoperative analgesic requirements would have increased in absence of the infusion. This point would also inform the project site of the need for determining best dexmedetomidine administration protocol in the potential revision of its current procedure to perhaps incorporate a bolus at some point.

The scope of this project did not include inquiry as to why certain patients did not receive the dexmedetomidine infusion even once the protocol was in place. The clinical indication for patients not having received the dexmedetomidine infusion intraoperatively once the protocol was in place was likely due to the potential for hypotension and bradycardia potentiated by its alpha-2 agonist mechanism of action. These hemodynamic effects of decreased heart rate and blood pressure could potentially be exaggerated in patients already on angiotensin converting enzyme inhibitors, beta-blockers, calcium channel blockers, or other anti-hypertensive medications.

This project did reveal a slightly larger sample size (n = 150) than anticipated in the study protocol, which was projected to be around 100-120 charts meeting inclusion criteria. Some variation was found in the description of the primary procedure performed relative to
laparoscopic sleeve gastrectomy as specified in the study protocol. Most procedures were described as laparoscopic gastric sleeve (87.3%), while 4.6% were reported as repair of laparoscopic gastric sleeve, and others described as either midline laparoscopic gastric sleeve (2.7%), laparoscopic gastric sleeve, possible open (1.3%), and the remaining as laparoscopic gastric sleeve with either upper, and lysis of, or EDG scope (4.2%) descriptors. This presents some deviation from the study protocol which specified laparoscopic sleeve gastrectomy would be the only procedure included. These, however, were the descriptions provided as inclusive for requested cases per the CPT code 43775 for laparoscopic sleeve gastrectomy as specified in the study protocol and provided by the project site’s records consultant. The primary procedure description of laparoscopic gastric sleeve did represent most cases included in this sample. The extent of variation of the other procedure descriptions that differed from the majority of cases described as laparoscopic gastric sleeve was deemed negligible and since the data provided was inclusive as described in the study protocol for those cases specific to CPT code 43775, all procedure descriptions provided in the sample were analyzed for the purposes of this project.

Assessment of the impact of preoperative medications as part of the project site’s Bariatrics Enhanced Recovery Protocol under review is beyond the scope of this study. Self-administration of preoperative pain medications listed as part of the protocol including celecoxib and acetaminophen elixir could not be confirmed. However, based on the infrequency of these medications indicated as administered in the immediate preoperative period that would be documented on the hospital’s medication administration record and provided as part of the data sample for this chart review, we may infer that patients had self-administered them before arriving to the hospital the day of surgery per specifications in the protocol.
With regard to preoperative pregabalin administration, most patients in the group receiving the dexmedetomidine infusion also had documented administration of pregabalin in the preoperative period as specified to be administered per the protocol. The scope of this study as a retrospective chart review could not control for all variables of the protocol otherwise included as part of its multimodal analgesic strategy. However, initiation of this review as an evaluation of one component of the protocol does give way to evaluation of its other components, as well as the potential for controlled study designs to be developed to further evaluate its impact to best inform clinical practice guidelines.

Mean procedure time reported of 46 minutes compared to mean anesthesia time of 194 minutes warrants attention to why there may be such a disparity in these time intervals. These procedure and anesthesia times, however, were not analyzed relative to whether a dexmedetomidine infusion was administered. They reflect the range of the entire sample, regardless of presence or absence of a dexmedetomidine infusion.

This difference in the extended anesthesia time compared to procedure time could potentially be explained by a prolonged time needed to emerge and extubate patients safely. Physiologic factors of obesity such as a baseline decrease in oxygen reserve and increased potential for atelectasis after being in the supine position for the surgical procedure each contribute to respiratory compromise in the immediate postoperative period. Factors such as these could account for the increased time as reflected in prolonged anesthesia time to achieve optimized respiratory function meeting criteria for safe extubation of the trachea. Opioid administration could of course further contribute to this respiratory compromise in potentially correlating with increased time needed for emergence from anesthesia as seen in the extended anesthesia times relative to procedure times reported in this sample. While beyond the scope of
the analysis for the purposes of this project, inquiry into the effect an intraoperative
dexmedetomidine infusion may have on anesthesia time may be another pertinent point of
review of the potential benefits of its use in decreasing time for emergence from anesthesia.

Neuman's Systems Model as the theoretical framework in guiding and implementing this
project proved appropriate in its intended use. Use of the model for this project was framed in
the context of the model's levels of prevention as primary, secondary and tertiary prevention. As
an intervention to promote stability through the stress of surgery, intraoperative
dexmedetomidine infusion as a primary prevention measure was examined for its use of
preventing the stress response and pain of surgical stimulation otherwise treated by opioid
administration. Results do suggest use of the intraoperative dexmedetomidine infusion has a
significant effect on decreasing opioid requirements during surgery, and therefore may be
deemed effective in preventing the stress response and pain of surgical stimulation that would
otherwise have required treatment with opioids. The decreased use of intraoperative opioids
associated with use of the intraoperative dexmedetomidine infusion further implies primary
prevention of the respiratory compromise otherwise associated with opioid administration in the
context of this framework.

Framing the intraoperative infusion of dexmedetomidine as an intervention to promote
stability through the stress of surgery at the secondary level of prevention to determine the stress
response to surgical stimulation and pain that may not have been prevented appropriately relates
to this project as seen in the results of the percentage of patients receiving a dexmedetomidine
infusion intraoperatively but having still required intraoperative opioid administration. This is
evident among the 17.4% or 8 out of 38 patients who received an intraoperative
dexmedetomidine infusion and still required opioid administration in the intraoperative period.
These data also relate to the context of Neuman’s Systems Model of tertiary prevention in determining how to effectively treat the stress response to surgery and pain not otherwise prevented by the administration of an intraoperative dexmedetomidine infusion, as evidently was achieved by use of opioids in this sample.

Conclusion

Intraoperative dexmedetomidine infusion is associated with a significant reduction of intraoperative opioid requirements but not postoperative opioid requirements among patients undergoing laparoscopic sleeve gastrectomy in this sample. Missing cases of morphine milligram equivalents indicate no opioids were received during the intraoperative time interval among 82.6% of patients also receiving a dexmedetomidine infusion during that period. This finding is consistent with the project site’s Bariatrics Enhanced Recovery Protocol specifying a dexmedetomidine infusion be administered and no opioids be used intraoperatively. Obese patients are increasingly presenting for bariatric surgery with the potential for respiratory compromise and associated risk of OIRD. These facts warrant attention to opioid minimization techniques in this population given their vulnerability to respiratory complications. Clinical inquiry as how best to achieve this must continually be developed. Standardization through use of practice protocols incorporating multimodal analgesic strategy among this patient population must lead clinicians to establishing guidelines for the anesthesia care of bariatric surgery patients.

Deliverables to Project Site

This study provided the project site with an evaluation of a component of its newly implemented Bariatrics Enhanced Recovery Protocol for the aforementioned stakeholders. The project yielded data on the impact of an intraoperative dexmedetomidine infusion component of
the protocol on perioperative opioid requirements among bariatric surgery patients undergoing laparoscopic sleeve gastrectomy in this sample. The project also initiated evaluation of the Bariatrics Enhanced Recovery Protocol in potentially determining how to best evaluate the protocol’s other components. Data from this study could also potentially be used toward developing strategies for the project site to analyze the cost effectiveness, financial sustainability, and effect on anesthesia times of the use of an intraoperative dexmedetomidine infusion during laparoscopic sleeve gastrectomy.

This retrospective chart review compared opioid requirements within 24 hours after the induction of anesthesia between patients who received a dexmedetomidine infusion to those not having received a dexmedetomidine infusion undergoing laparoscopic sleeve gastrectomy at ECMC. The study results following one-way ANOVA suggest an intraoperative dexmedetomidine infusion has a statistically significant effect on intraoperative but not postoperative opioid requirements among patients in this sample. There was a difference in intraoperative opioid requirements as measured in morphine milligram equivalents detected between those patients who received an intraoperative dexmedetomidine infusion and those who did not receive a dexmedetomidine infusion. This may have been predicted since the protocol calls for no opioid administration intraoperatively with the dexmedetomidine infusion. These findings, however, still contribute evidence in support of the need for further practice inquiry to establish more definitive guidelines for perioperative care during bariatric surgery.

Contribution to Scholarship & Practice

This project contributed to scholarship and clinical practice toward development of the body of knowledge on multimodal analgesia in ERAS protocol for bariatric surgery. This project promoted synthesis and translation of practice on how intraoperative dexmedetomidine is
associated to decreasing perioperative opioid requirements. This project contributed to fulfilling the need for practice inquiry toward generating evidence to improve patient outcomes, specifically in evaluating an intervention to achieve opioid minimization to decrease the risk of OIRD among obese surgical patients (Moran, Burson, & Conrad, 2020). This evidence has been disseminated to the identified stakeholders to be further evaluated and inform clinical practice to achieve optimum patient outcomes among those undergoing laparoscopic sleeve gastrectomy at the project site (Moran et al., 2020).

**DNP Essentials**

The DNP Essentials addressed by this project included Scientific Underpinnings for Practice (I), Clinical Scholarship and Analytical Methods for Evidence-Based Practice (III), Interprofessional Collaboration for Improving Patient and Population Health Outcomes (VI), Clinical Prevention and Population Health for Improving the Nation’s Health (VII), and Advanced Nursing Practice (VIII). Scientific Underpinnings for Practice (I) was addressed through examining the mechanism of action of dexmedetomidine and how it was used to reduce perioperative opioid requirements. Clinical Scholarship and Analytical Methods for Evidence-Based Practice (III) was addressed in this project through practice inquiry of a component of an ERAS protocol for bariatric surgery. This project employed statistical analysis to determine group differences associated with opioid requirements between those patients receiving an intraoperative dexmedetomidine infusion and those not receiving an infusion. Interprofessional Collaboration for Improving Patient and Population Health Outcomes (VI) was addressed in this project through collaboration on data collection and analysis methods with faculty outside the discipline of nursing and the project site’s information technology reporting consultant and through engagement with project site chief physician anesthesiologist as a stakeholder in this
practice inquiry and as a project facilitator. Clinical Prevention and Population Health for Improving the Nation’s Health (VII) was addressed in this project through evaluation of an intervention to prevent OIRD among obese surgical patients. Lastly, Advanced Nursing Practice (VIII) was addressed in this project through hospital protocol evaluation by the DNP project student that lead to evidence-based translation of patient outcomes to clinical practice decision making. The role of the advanced practice nurse in addressing clinical issues as discovered through this project must be that of an updated consumer of research as well as possessing an ability to critically evaluate current practice, synthesize and translate evidence in health literature and research into informed clinical practice.

**Strengths and Limitations**

This study presented the first inquiry into evaluation of the Bariatrics Enhanced Recovery Protocol at the project site and may serve as a starting point to evaluating its other components and overall impact. This analysis yielded a slightly larger sample size of 150 patients than anticipated of the approximately 100-120 subject projected. The topic of this project of investigating intraoperative use of dexmedetomidine is relevant and applicable to anesthesia practice in providing actual evidence to inform clinical practice.

There are several limitations to this project. Time allotted for analysis completion and the absence of funding or time to apply to receive funding for this study are among the major limitations. The level of evidence as a retrospective chart review also limits the rigor of this clinical inquiry. Based on these time and budget limitations, interpretation had to come from the data available for analysis. Further investigation beyond these constraints to implement prospective, controlled studies are needed to determine a causal relationship between dexmedetomidine and perioperative opioid requirements. This study was also limited to a
retrospective chart review of one type of bariatric procedure performed at one institution. Data was also not directly collected from the medical records by the principal investigator given the project site’s records release policy for the purposes of research.

**Future Implications and Recommendations**

More evidence from prospective, randomized controlled studies is needed to translate to definitive practice guidelines in the perioperative pain management of bariatric surgery patients. This project does contribute to the development of the body of knowledge on multimodal analgesia in ERAS protocol for bariatric surgery in fulfilling the need for practice inquiry toward generating evidence to improve patient outcomes. Clinical inquiry should continually be employed to expand on a given body of knowledge. Buy-in from stakeholders, leadership, resources and logistical execution are all needed to facilitate this inquiry.

The project serves to the shed light on the future standardization of anesthesia care based on these procedure-specific protocols and how ERAS will shape this culture of care. Project results have been disseminated to the identified stakeholders to inform clinical practice toward achieving optimum patient outcomes among those patients undergoing laparoscopic sleeve gastrectomy at the project site (Moran et al., 2020). This highlights the importance of clinicians needing to be informed consumers of research and evaluating evidence both in literature and from the evaluation of their own practice to take ownership of developing these protocols and setting the care standards.

Lastly, further investigation into this project topic to evaluate this protocol may determine potential cost effectiveness and financial sustainability of use of intraoperative dexmedetomidine infusion during bariatric surgery as well as best administration procedures. Inquiry into the effect an intraoperative dexmedetomidine infusion may have on anesthesia time
may be another pertinent point of review of the potential benefits of its use in decreasing time for emergence from anesthesia and the implications of operating room workflow. Evaluation into the other components of the protocol as well as its overall impact are also points of further investigation stemming from this project.
References


### Tables

**Table 1**

*Morphine Milligram Equivalent Doses*

<table>
<thead>
<tr>
<th>Type of Parenteral Opioid</th>
<th>Morphine Milligram Equivalents (MMEs)/Parenteral Equianalgesic Dose</th>
<th>MME Conversion Factor</th>
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</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>10 milligrams (mg)</td>
<td>1</td>
</tr>
<tr>
<td>Meperidine</td>
<td>100 mg</td>
<td>0.1</td>
</tr>
<tr>
<td>hydromorphone</td>
<td>1.4 mg</td>
<td>7</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>100 micrograms (0.1 mg)</td>
<td>100</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Type of Oral Opioid</th>
<th>Oral Morphine Milligram Equivalent</th>
<th>MME Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td>30 mg</td>
<td>1</td>
</tr>
<tr>
<td>hydrocodone</td>
<td>30 mg</td>
<td>1</td>
</tr>
<tr>
<td>Tramadol</td>
<td>300 mg</td>
<td>0.1</td>
</tr>
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</table>

(Apex Anesthesia Review, 2019; CDC, 2017; Open Anesthesia, 2019)
Table 2

*Patient Demographics and Clinical Characteristics by Dexmedetomidine Infusion*

<table>
<thead>
<tr>
<th>No Dexmedetomidine Infusion (n = 104)</th>
<th>Dexmedetomidine Infusion ( n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>42 ± 12</td>
</tr>
<tr>
<td></td>
<td>39 ± 10</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Female = 78</td>
</tr>
<tr>
<td></td>
<td>Male = 26</td>
</tr>
<tr>
<td></td>
<td>Female = 39</td>
</tr>
<tr>
<td></td>
<td>Male = 7</td>
</tr>
<tr>
<td><strong>Weight (kilograms)</strong></td>
<td>132 ± 34</td>
</tr>
<tr>
<td></td>
<td>130 ± 31</td>
</tr>
<tr>
<td><strong>ASA Physical Classification:</strong></td>
<td>II = 3</td>
</tr>
<tr>
<td></td>
<td>III = 95</td>
</tr>
<tr>
<td></td>
<td>IV = 6</td>
</tr>
<tr>
<td><strong>II Moderate</strong></td>
<td>II = 1</td>
</tr>
<tr>
<td><strong>Systemic Disease</strong></td>
<td>III = 44</td>
</tr>
<tr>
<td><strong>III Severe Disease</strong></td>
<td>IV = 1</td>
</tr>
<tr>
<td><strong>IV Life Threatening Disorder</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> ASA = American Society of Anesthesiologists Physical Classification</td>
<td></td>
</tr>
<tr>
<td>° Values are expressed as mean ±SD</td>
<td></td>
</tr>
</tbody>
</table>
Table 3

*Intraoperative Morphine Milligram Equivalents by Dexmedetomidine Infusion*

<table>
<thead>
<tr>
<th>MMEs</th>
<th>No Dexmedetomidine Infusion (n = 104)</th>
<th>Dexmedetomidine Infusion (n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>13.56</td>
<td>9.63</td>
</tr>
<tr>
<td>Minimum</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Maximum</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td>Missing</td>
<td>54</td>
<td>38</td>
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</tbody>
</table>
Table 4

Postoperative Morphine Milligram Equivalents by Dexmedetomidine Infusion

<table>
<thead>
<tr>
<th>MMEs</th>
<th>No Dexmedetomidine Infusion (n = 104)</th>
<th>Dexmedetomidine Infusion (n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>24.31</td>
<td>19.86</td>
</tr>
<tr>
<td>Minimum</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Maximum</td>
<td>64</td>
<td>57</td>
</tr>
<tr>
<td>Missing</td>
<td>6</td>
<td>2</td>
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Table 5

**ANOVA of Dexmedetomidine Groups by Intraoperative Morphine Milligram Equivalents**

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>106.788</td>
<td>1</td>
<td>106.788</td>
<td>4.041</td>
<td>.049</td>
</tr>
<tr>
<td>Within Groups</td>
<td>1479.695</td>
<td>56</td>
<td>26.423</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1586.483</td>
<td>57</td>
<td></td>
<td></td>
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</table>
Table 6

ANOVA of Dexmedetomidine Groups by Postoperative Morphine Milligram Equivalents

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>599.298</td>
<td>1</td>
<td>599.298</td>
<td>2.556</td>
<td>.112</td>
</tr>
<tr>
<td>Within Groups</td>
<td>32829.498</td>
<td>140</td>
<td>234.496</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>33428.796</td>
<td>141</td>
<td></td>
<td></td>
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</table>
Figure 1. Intraoperative Morphine Milligram Equivalents by Dexmedetomidine Infusion

Figure 1. Morphine milligram equivalents (MMEs) required during intraoperative time interval between those patients receiving no dexmedetomidine infusion (0) and those receiving a dexmedetomidine infusion (1) intraoperatively.
Figure 2. Postoperative Morphine Milligram Equivalents by Dexmedetomidine Infusion

*Figure 2.* Morphine milligram equivalents (MMEs) required during postoperative time interval between those patients receiving no dexmedetomidine infusion (0) and those receiving a dexmedetomidine infusion (1) intraoperatively.
Figure 3. Weight, Age and Gender by Dexmedetomidine Infusion

Figure 3. Top left is graphic representation of weight distribution, and lower left is graphic representation of age distribution of the sample between those patients who received no dexmedetomidine infusion (0) and those who received an infusion (1). Bar chart at right side is representation of gender distribution of the sample between those patients who received no dexmedetomidine infusion (0) in blue and those who received an infusion (1) in red.
### Appendix A

**ECMC Bariatrics Enhanced Recovery Protocol**

**Key Points:**
- **Multi-modal pain management**
- **Avoid narcotics to prevent paralytic ileus and minimize n/v**
- **Standardized IV fluid management to minimize bowel edema and anastomotic leaks**

<table>
<thead>
<tr>
<th>Pre-OP</th>
<th>Induction</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Lansoprazole (Prevacid) 15 mg qd 7 days prior to surgery (not to be taken morning of surgery)</td>
<td>- Propofol, Versed</td>
</tr>
<tr>
<td>- Carb 4 hrs prior to scheduled arrival time</td>
<td>- Ketamine to be reserved for use in chronic pain patients</td>
</tr>
<tr>
<td>- Carb 4 hrs prior to scheduled arrival time</td>
<td>- Dexamethasone 10 mg IV for all patients</td>
</tr>
<tr>
<td>- Carb 4 hrs prior to scheduled arrival time</td>
<td>- Lidocaine bolus 1 mg/kg, max dose 100 mg</td>
</tr>
<tr>
<td>- Carb 4 hrs prior to scheduled arrival time</td>
<td>- If HTN during induction, consider labetalol or esmolol as opposed to fentanyl</td>
</tr>
<tr>
<td>- Carb 4 hrs prior to scheduled arrival time</td>
<td>- No esophageal temp probe</td>
</tr>
<tr>
<td>- Take at home morning of surgery with carb drinks:</td>
<td></td>
</tr>
<tr>
<td>- Lansoprazole (Prevacid) 15 mg PO to be given upon arrival by anesthesia</td>
<td>- Muscle relaxant &amp; volatile anesthetic</td>
</tr>
<tr>
<td>- If diabetic:</td>
<td>- Dexamethasone 0.7 mcg/kg/hr (actual wt) to begin immediately post-induction</td>
</tr>
<tr>
<td>- FSBG on arrival</td>
<td>- Goal is to avoid all IV narcotics. If anesthesia team feels that narcotic is necessary should consult with surgeon before administering</td>
</tr>
<tr>
<td>- Low dose sliding scale coverage</td>
<td>- After leak test is completed anesthesia team to:</td>
</tr>
<tr>
<td>- Hover Mat on OR table</td>
<td>- o Give Zofran 4 mg IV</td>
</tr>
<tr>
<td>- Lovenox 40 mg SQ to be given by RN</td>
<td>- o Decrease Precedex to 0.3 mcg/kg/hr</td>
</tr>
<tr>
<td>- SCDs sleeves to BLEs</td>
<td>- D/C Precedex prior to leaving OR</td>
</tr>
<tr>
<td>- Protonix 40 mg IV to be given by RN</td>
<td></td>
</tr>
<tr>
<td>- Antibiotics as ordered on pre-op order form</td>
<td>- Fluids:</td>
</tr>
<tr>
<td>- If first case of the day void 30 minutes prior to schedule start time, following cases void immediately after seen by surgeon</td>
<td>- 1:1 liter LR (including preop)</td>
</tr>
<tr>
<td>- First line antiemetic is Zofran, followed by Benadryl as second line</td>
<td>- IV bolus fluids as needed</td>
</tr>
<tr>
<td>- First line pain management medication is Dilaudid</td>
<td></td>
</tr>
<tr>
<td>- expedite d/c from PACU</td>
<td></td>
</tr>
</tbody>
</table>
# Appendix B
University at Buffalo Institutional Review Board Approval Letter

## October 14, 2019

**Dear Anna Rumi,**

On 10/14/2019, the University at Buffalo IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Initial Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study</td>
<td>Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis</td>
</tr>
<tr>
<td>Investigator</td>
<td>Anna Rumi</td>
</tr>
<tr>
<td>IRB ID</td>
<td>STUDY00003715</td>
</tr>
<tr>
<td>Funding</td>
<td>None</td>
</tr>
<tr>
<td>Grant ID</td>
<td>None</td>
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<tr>
<td>IND, IDE, or HDE</td>
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</tbody>
</table>
| Documents Reviewed | * Excel Sheet for Data Collection, Category: Other;*  
* Scientific review form.pdf, Category: Other;*  
* Cert of De-Identification, Category: Other;* |

The University at Buffalo Institutional Review Board has considered the submission for the project referenced above on 10/14/2019 and determined it to be Exempt.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the Click system.

UBIRB exemption is given with the understanding that the most recently approved procedures will be followed and the most recently approved consenting documents will be used. If modifications are needed that may change the exemption determination, please contact the UBIRB Office. Also, see the Worksheet: Exempt Determination (HRP-312) for information on exemption criteria and categories.

As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:

1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the UBIRB is notified of:
   - All Reportable Information in accordance with the Reportable New Information Smart Form.

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**Page 2 of 2**

- Project closure/completion by submitting a Continuing Review/Modification/Study Closure Smart Form in Click.

3. Ensuring that the protocol is followed as approved by UBIRB unless minor changes that do not impact the exempt determination are made.
4. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.
5. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.
6. Bearing responsibility for securing any other required approvals before research begins.

If you have any questions, please contact the UBIRB at 716-888-4888 or ub-irb@buffalo.edu.
Appendix C
University at Buffalo Human Research Protections Program: Certification of De-Identification of Health Information for Research Purposes

Please check off each of the categories below to verify that these classes of identifiers pertaining to the research subject, their relatives, employers, or household members, can not be linked with the research subject’s health information generated or acquired as part of this protocol. These elements must be removed from health information, and the below affirmation provided, in order to consider health information de-identified per CFR 164.514(b)(2):

A. Names;
B. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalents provided, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
C. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
D. Telephone numbers;
E. Fax numbers;
F. Electronic mail addresses;
G. Social security numbers;
H. Medical record numbers;
I. Health plan beneficiary numbers;
J. Account numbers;
K. Certificate/license numbers;
L. Vehicle identifiers and serial numbers, including license plate numbers;
M. Device identifiers and serial numbers;
N. Web Universal Resource Locators (URLs);
O. Internet Protocol (IP) address numbers;
P. Biometric identifiers, including fingerprint and voice prints;
Q. Full face photographic images and any comparable images;
R. Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section.

PRINCIPAL INVESTIGATOR: I affirm that this research protocol will not collect any of the personal identifiers listed above and that, to the best of my knowledge, no information generated or collected as part of this research protocol can be used alone or in combination with other information in our possession to identify an individual who is the subject of the information.

The IRBNet Package containing this document must be signed in IRBNet Signature Requirement: Principal Investigator.

164.514(2)(b): A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by that covered entity, provided that: (1) Dermination. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being manipulated so as to identify the individual; and (2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.
October 23, 2019

Anna Rumi
2917 Main Street Apt 218
Buffalo, New York 14214

Re: "Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis"

Dear Ms. Rumi,

I wish to thank you for submitting an application to perform the above-named clinical research project at Erie County Medical Center Corporation. I have reviewed the application and am pleased to report that I am granting you permission to proceed with the project.

In approving this research project ECMCC expects that none of its patients will be approached by a researcher until their permission has been obtained by an ECMCC employee involved in their care. ECMCC also expects that patients will not be billed directly for any services (physician, laboratory, or pharmaceutical) for which the study provides reimbursement to the investigator. Also, please be sure to review ECMCC's Clinical Research Policy and Procedure posted on the intranet.

I note that that the UBIRB has determined that the research is Exempt. Data will be collected by ECMCC Information Technology Management, de-identified and uploaded to Watchdoxx. Access to Watchdoxx will be granted to you.

In approving this research project ECMCC grants you permission to use the data collected at ECMCC and expects that the data collected for use in this systematic review remain anonymous.

Please notify the Risk Management department at ECMCC upon completion or termination of the study.

Good luck with your research!

Sincerely,

Samuel Cloud, D.O.
Associate Medical Director

CC Bob Vail, Director of IT Security
Laura Fleming, HIPAA Compliance Officer
Amy Flaherty, Director of Risk Management

ERIE COUNTY MEDICAL CENTER CORPORATION
Project Purpose, Aims, & Objectives

- To determine the effect of an intravenous dexmedetomidine infusion on opioid requirements within 24 hours after the induction of anesthesia among patients age 18 years and older undergoing laparoscopic sleeve gastrectomy at ECMC, compared to no infusion
- To compare opioid requirements as those documented on the medical record administered at any point within 24 hours after the induction of anesthesia
- To initiate evaluation of the aspect of ECMC's Bariatrics Enhanced Recovery Protocol and determine its correlation to opioid requirements among obese patients presenting for laparoscopic sleeve gastrectomy
- To provide evidence in support of or against the use of dexmedetomidine as part of a multimodal analgesic strategy.
Background and Significance

Obesity decreases oxygen reserves, impairs function of respiratory muscles, increases susceptibility to atelectasis and ventilatory instability, with the associated risk of opioid-induced respiratory depression (OIRD) (Bennett et al., 2017; Tommer, 2017).

OIRD is caused specifically by activation of opioid receptors of respiratory centers in the hypothalamus leading to diminished, irregular breathing and eventually cessation of breathing, which could culminate in cardiopulmonary arrest and death (Gatlin et al., 2018).

There is much variation in defining OIRD, with its reported incidence ranging from 0.54-6.8%, when defined by established national guidelines, to 20-47%, when assessed by hypotension or hypoxemia (Dagal et al., 2016).

Theoretical Framework: Neuman’s Systems Model

- **Open, holistic perspective to addressing a variety of health issues**
- **Individual is a system with a central core for basic survival processes supported by outer and inner layers of defenses in response to given stressors from the environment**
- **Health is a continuum within the system between wellness and illness**
- **Wellness happens when total system needs are met**
- **Illness happens when instability and energy depletion arise**

(Ahmadi & Sadeghi, 2017; Neuman, 2017; Neuman, 1982)
Neuman’s Systems Model (continued)

- Nursing as a means of addressing the whole person and all variables that affect care’s responses to stress → aim to promote stability through reducing stressors
- Levels of intervention as primary, secondary, and tertiary prevention of illnesses
- Project learned in the context of these levels of intervention

(Adcock & Bednarki, 2017; Neuman, 2017; Neuman, 1982)

Neuman’s Systems Model: Levels of Prevention

- Interpreting dexamethasone infusions as an intervention to provide stability through the stress of surgery:

  - Primary prevention:
    - Administered to prevent stress responses and pain of surgical stimulation
    - Prevention of surgical complications
  - Secondary prevention:
    - Diminishing acute stress responses to surgical stimulation and pain that may not have been prevented
  - Tertiary prevention:
    - Prevention of how to effectively treat stress responses to surgery and pain not otherwise prevented

Literature Review

- Review of health literature to investigate risk of DRO and use of dexamethasone among bariatric surgery patients
- Keywords: “dexamethasone,” “bariatric surgery,” “surgical anesthesia,” “opioid induced respiratory depression,” “SEAS”
- Databases searched included in 2014-2019: PubMed, CINAHL, and Cochrane Database of Systematic Reviews
- Reference lists of each systematic review and meta-analysis were manually examined
- Only studies among adult human subjects aged 18 years and older published in English with full text available were included
- Case reports and editorials were excluded
- Eleven studies in total were included in this review

Conclusions Drawn from Literature Review

- Evidence in support of the risk of DRO among surgical patients (Kaysa et al., 2016; Lee et al., 2018; Tunc et al., 2018)
- Evidence in support of a reduction in postoperative opioid consumption with use of dexamethasone (Nia et al., 2019; Coscuna et al., 2016; Lundorf et al., 2010; Bhat et al., 2011; Bhat et al., 2013)
- More evidence needed to translate to definitive practice guidelines specific to bariatric surgery → evident among most recent clinical recommendations by the BESG Society and findings of the included systematic reviews (Coscuna et al., 2016; Lundorf et al., 2010)
- Each study, systematically review, and meta-analysis included verbal on exact dexamethasone administration protocol, as well as exact type of surgical procedure performed
Conclusions Drawn from Literature Review (continued)

- Postoperative dexmedetomidine infusion was similar to postoperative remifentanil infusion in terms of supplemental narcotic dose requirements in the first 24 hours following laparoscopic gastric bypass, feeding or sleeve gastrectomy among bariatric surgery patients (Ahnoh, 2014).

- Implementing multimodal analgesia and non-opioid analgesia would decrease opioid consumption and thereby decrease the risk of OIH (Dupa et al., 2018; Cawern et al., 2018).

Design, Methods and Data Collection (continued)

- Retrospective chart review of adult bariatric patients undergoing laparoscopic sleeve gastrectomy at ECMC.

- Comparison between patients undergoing laparoscopic sleeve gastrectomy having received the dexmedetomidine infusion prospectively as part of the hospital’s Bariatric Enhanced Recovery Protocol to patients not having received the infusion to investigate the infusion’s association to postoperative opioid requirements.

- Qualitative methods to elicit data on outcome measures of patients’ initial amount of opioids received within 24 hours after the induction of anaesthesia, as compared to whether or not a dexmedetomidine infusion was administered prospectively.

- Ethical Considerations:

  - Transparency in stakeholders’ review process of data analysis and interpretation (National Center for Chronic Disease Prevention and Health Promotion, 2015).
  - Dissemination: study results to stakeholders (National Center for Chronic Disease Prevention and Health Promotion, 2015).
  - IRB Management at ECMC: Data accession plan for review uploaded to a secure server called Washburn made available to the principal investigator.
  - Only de-identified data is held by the principal investigator and research team.
  - Minimal invasion of privacy in accessing private records because access to records was gained through institutional gatekeepers and IRB Management: Healthcare Information Security Officers at ECMC not affiliated with research team.
  - Study results have been disseminated to project site stakeholders.
Data Analysis

- Association between use of dexmedetomidine infusion administered intravenously to total amount of opioids consumed as long as the intervention administered more within 36 hours of the induction of anesthesia.
- Total amount of opioids were converted to morphine equivalent doses since different
  opioid classes were administered.
- SPSS statistical software used for analysis.

Detected significant differences in postoperative opioid consumption between those patients having received the dexmedetomidine infusion and those not
having received the infusion. (ANOVA; p-value of 0.05).

Morphine Milligram Equivalent (MME) Conversions

<table>
<thead>
<tr>
<th>Drug of Reference</th>
<th>Morphine Milligram Equivalent (MME)</th>
<th>MME Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>1 mg/mg</td>
<td>1</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>10 mg/mg</td>
<td>5</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>10 mg/mg</td>
<td>2</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>100 mg/mg</td>
<td>100</td>
</tr>
</tbody>
</table>

Patient Demographics and Clinical Characteristics by Dexmedetomidine Infusion

- Results: 100 patients received dexmedetomidine infusion.
- Patient weight range 70 to 177 kilograms.
- Mean age of 49 years (range 21-72).
- 75.0% identified as female, 25.0% as male, 67.9% American Indian (tribe), 27.0% non-Indian, 1.0% other, 3.0% deferred.
- Mean preoperative time = 15 minutes (range 10-30 minutes).
- Mean anesthesia time = 56 minutes (range 46-97 minutes).
- Female 60.0% vs 69.0%.
- Male 40.0% vs 31.0%.
Conclusion

- Intraoperative dexmedetomidine infusion is associated with a significant reduction of intraoperative opioid requirements but not postoperative opioid requirements among patients undergoing laparoscopic sleeve gastrectomy in this sample.
- Missing cases of morphine milligram equivalents to opioids received among 22.2% of patients receiving the intraoperative dexmedetomidine infusion during the intraoperative time interval.
- The project's liver Bariatric Enhanced Recovery Protocol specified a dexmedetomidine infusion to be administered and no opioids to be used intraoperatively.

Strengths and Limitations of the Project

- First inquiry to evaluate this protocol
- Adequate sample size
- Practically applicable
- Limited to retrospective chart review of one type of bariatric procedure at one institution
- Data collection was not directly derived from the record by the principal investigator, relied on reporting consultant to project site
- Time constraints
- Lack of budget
Future Implications and Recommendations

- Evidence is needed from prospective, randomized, controlled studies.
- Exploration of the body of knowledge on multimodal pain management in bariatric surgery.
- Developing protocols for optimal pain management in bariatric surgery.
- Implementing evidence-based pain management protocols.
- Training healthcare providers in pain management.
- Patient education and support.
- Cost-effectiveness of pain management strategies.
- Ethical considerations in pain management.

Future research should include:
- Multimodal analgesia protocols.
- Evidence-based pain management in bariatric surgery.
- Patient satisfaction and outcomes.

References (Continued)


Effect of a Dexmedetomidine Infusion on Perioperative Opioid Requirements among Bariatric Surgery Patients: A Retrospective Analysis → Executive Summary to Erie County Medical Center, Buffalo, NY

Project Deliverable: Executive Summary

**Project Question**

Among patients aged 18 years and older undergoing laparoscopic sleeve gastrectomy at Erie County Medical Center, does an intraoperative dexmedetomidine infusion reduce their opioid requirements within 24 hours after the induction of anesthesia, compared to no infusion?

**Background and Significance**

- Enhanced Recovery After Surgery (ERAS) protocols are becoming increasingly popular in surgical practice, with evidence supporting their effectiveness.
- Specific aspects of ERAS that decrease opioid requirements, such as the use of α-2 agnostics, are being studied for their potential benefits.
- Dexmedetomidine, an α-2 agonist, has shown promise in reducing opioid consumption and improving patient outcomes when used intraoperatively.
- Postoperative care, including the use of an opioid infusion, is often necessary, with dexmedetomidine being considered a potentially effective alternative.
- The study aims to determine if the intended outcome of reducing opioid exposure and improving patient recovery can be achieved by using dexmedetomidine intraoperatively.

**Methods and Data Collection**

- **Reources and Methods**
  - Retrospective chart review of patients undergoing laparoscopic sleeve gastrectomy at ECMC
  - Inclusion criteria: Patients aged 18 or older, undergoing laparoscopic sleeve gastrectomy
  - Exclusion criteria: Pregnant patients, patients with comorbidities contraindicating the use of dexmedetomidine, and patients receiving non-opioid analgesics solely.
  - **Data Collection**
    - Demographic information
    - Surgical procedure
    - Duration of anesthesia
    - Opioid requirements intraoperatively and postoperatively

**Design, Methods, and Data Collection**

- **Data Analysis**
  - Association between use of dexmedetomidine in the induction phase and lower opioid requirements
  - Comparison of opioid requirements between groups
  - Statistical analysis using ANOVA

**Results**

- **Association between use of dexmedetomidine and lower opioid requirements**
  - Reduction in opioid requirements in patients receiving dexmedetomidine
  - Significant reduction in opioid consumption
  - **Conclusion & Implications**
  - Dexmedetomidine infusion during the induction phase may reduce opioid requirements postoperatively.
  - Further research is needed to confirm these findings and explore the potential benefits of this approach.

**References**

- [Title](#)
- [Author](#)
- [Publication](#)