INTRAOPERATIVE DOSING OF DEXAMETHASONE IN TYPE II DIABETICS UNDERGOING BARIATRIC SURGERY

by

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ABSTRACT

NATALIE DIANE GABHART. Intraoperative Dosing of Dexamethasone in Type II Diabetics Undergoing Bariatric Surgery. (Under the direction of DR. STEPHANIE WOODS)

Purpose: Identifying trends in the intraoperative dosing of dexamethasone in type II diabetic patients undergoing bariatric procedures at a community hospital to determine impact of the dose received on perioperative glycemic control.

Background: Dexamethasone is a corticosteroid and despite its many documented benefits when administered perioperatively to surgical patients, it is often withheld in the type II diabetic population out of concern for postoperative hyperglycemia.

Methods: Retrospective chart reviews of 36 type II diabetics receiving dexamethasone undergoing bariatric procedures were completed. Inclusion criteria: type II diabetics, procedures <4 hours, patients with a HbA1C reading 6.5-8.9%, patients who are non-pregnant, patients with an ASA classification of I, II, or III, and who are not taking chronic steroids.

Results: Of the 36 perioperative glycemic trends reviewed, there was a significant increase (t = 8.72, p<0.001) between the preoperative and immediate postoperative blood glucose readings for dexamethasone doses 4-10 mg (p <0.011). This increase was not associated with age, HbA1C, or surgery length. The dose level itself did not influence actual BG level changes (t = -.87, p = .390).

Conclusion: Dexamethasone increases postoperative BG significantly in DMII patients undergoing bariatric surgery in the immediate postoperative period. However, it should be noted that there was not a significant difference between preoperative BG and the 24-hour postoperative BG level. Two patients who did not receive dexamethasone also showed an increase in BG that approached significance (p = .060). These results suggest that further study on the effects of dexamethasone dosing and perioperative glycemic control is necessary.

Key words: Hemoglobin A1C (HbA1C), dexamethasone, diabetic II, type 2, bariatric, intraoperative

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DEDICATION

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
ASA	American Society of Anesthesiologists
BG	blood glucose
BMI	body mass index
DMII	Type II Diabetes
EMR	electronic medical record
ERAS	enhanced recovery after surgery
HbA1C	Hemoglobin A1C
HDL	high density lipoprotein
HPA	hypothalamic-pituitary-adrenal
IRB	International Review Board
IV	intravenous
M/Mdn	mean/median
mg or mg/dL	milligrams or milligrams per deciliter
OR	operating room
PACU	post-anesthesia care unit
PHI	patient health information
PICO	population, intervention, comparison, outcome
PONV	postoperative nausea and vomiting
QI	quality improvement
SD	standard deviation

CHAPTER 1: INTRODUCTION

1.1 Background

Dexamethasone is a powerful corticosteroid that has become a commonly used medication administered by anesthesia providers intraoperatively to patients undergoing a multitude of surgical types. Multimodal medication strategies are becoming increasingly popular for their use in enhanced recovery after surgery (ERAS) protocols. The protocols are aimed at structuring the perioperative process to help the patient achieve as fast and safe of a recovery as possible. These evidence-based protocols usually involve guidelines for anesthesia providers when developing their anesthetic plan to enable a faster wake up and return to functional status (Riley, 2022). Dexamethasone has many multimodal benefits for patients undergoing surgery, its most popular indication for anesthesia providers being to prevent postoperative nausea and vomiting (PONV). Its other benefits include enhanced analgesia and anti-inflammatory properties that aid in the body's ability to cope with the stress response to surgery (Bonilla et al., 2022). However, when it comes to diabetic patients (particularly type II), many anesthesia providers seem to be hesitant to administer a single dose of dexamethasone, even in low doses of 4 mg, due to its potential for hyperglycemia 6-12 hours postoperatively in type II diabetics (Nagelhout & Elisha, 2018).

1.2 Problem Statement

Dexamethasone has a unique ability to be utilized in several different clinical scenarios and has earned its position as a common medication administered in the operating room. According to Corcoran et al. (2021a), up to 50% of surgical patients may receive intraoperative dexamethasone, thus emphasizing its increased usage in the intraoperative area. A known side effect of dexamethasone is the potential for postoperative hyperglycemia. However, in the type II

diabetic population the true severity of this blood glucose increase that is related independently to dexamethasone and any subsequent adverse outcomes are topics that are only beginning to be studied. A lack of agreement on dosing with dexamethasone intraoperatively is made apparent in one of the most utilized textbooks for nurse anesthesia education: Nagelhout and Elisha (2018). These authors state, "a dose of 4 mg IV is recommended after anesthesia induction…some clinicians prefer a higher dose of 8 mg IV" (Nagelhout & Elisha, 2018, p. 195). Unfortunately, these authors do not document why some clinicians prefer this higher dose. When the diagnosis of diabetes is added, this topic becomes even more of a debate among anesthesia providers – evidenced by the current research being conducted to investigate the best practices. It is also important to recognize potential confounding variables and effects surgery can have physiologically on the body that increase serum blood glucose. These factors include other medications containing glucose-based solutions (i.e. dextrose), blood products, exogenous catecholamines, parenteral nutrition and the surgical sympathetic activation of the hypothalamo-pituitary-adrenocortical (HPA) axis. This HPA activation leads to an increase in the body's blood sugar level due to intrinsic cortisol release from the body's overall stress response to surgery (Nagelhout & Elisha, 2018)

In addition, dexamethasone is thought to work on inhibiting postoperative nausea and vomiting (PONV) via anti-inflammatory mechanisms. These anti-inflammatory effects are also believed to help mitigate the neurohumoral stressors that surgery places on the body by suppressing the release of neuropeptides after tissue injury, leading to effects such as decreases in postoperative pain and improved quality of recovery post-surgery (Myles and Corcoran, 2021). Regardless of the documented benefits that dexamethasone has to offer patients undergoing surgery, there is a wide variety in practice and a lack of clear guidance when it

comes to dosing dexamethasone in these patients. To create a true guideline and define evidence-based practice to anesthesia providers, the impact of dexamethasone on type II diabetic glycemic levels perioperatively must be better understood.

1.3 Purpose and Objectives

The primary purpose of this larger quality improvement (QI) project is to identify trends in the intraoperative dosing of dexamethasone and perioperative blood glucose levels in type II diabetic patients undergoing genitourinary, orthopedic, or bariatric procedures. This part of the QI project aims at assessing glycemic trends perioperatively in bariatric type II diabetic patients and comparing those trends to the dexamethasone dose received (or lack thereof). Secondly, this project strives to create a record of any potential effects of dexamethasone on patient glycemic trends postoperatively based on the dose received and compared to their level of glycemic control (as determined by preoperative HbA1C), age, surgical type, and overall length of surgery. The end goal is to contribute to a foundation for the development of a clinical practice guideline for anesthesia providers when choosing how to safely dose dexamethasone in type II diabetic patients to optimize patient outcomes.

1.4 Clinical Question - overall PICO

In type II diabetic patients, aged 35-75, undergoing orthopedic, bariatric, or genitourinary procedures lasting less than 4 hours at a full-service community hospital, does the intraoperative administration of IV dexamethasone have an effect on postoperative blood glucose levels compared to preoperative blood glucose levels? The main focus of this project (which is part of a larger quality improvement (QI) project) is documenting the dose of dexamethasone administered to bariatric patients and any alterations in blood glucose levels perioperatively.

CHAPTER 2: REVIEW OF LITERATURE

Literature Review: Methodology

This literature search was conducted using the databases PubMed, Web of Science, CINAHL, and ScienceDirect via the University of North Carolina Charlotte Library services. The literature search was conducted from January 15th, 2023, to February 10th, 2023, and a librarian specializing in Allied Health was consulted to assist with the search methodology. All searches were limited to a 10-year time frame in an organized effort to find more current practices and evidence.

Keywords were selected based off the PICO question "In type II diabetic patients, aged 35-75, undergoing bariatric procedures lasting less than 4 hours at a full-service community hospital, does the intraoperative administration of IV dexamethasone have an effect on postoperative blood glucose levels compared to preoperative blood glucose levels?" In each database, searches were completed utilizing a variety of different keywords to curtail the results. Keywords utilized included: dexamethasone, blood glucose, surgery, diabetes, type II diabetes mellitus, blood glucose concentrations, anesthesia, intraoperative, gastrointestinal, and bariatric. Advanced search techniques in PubMed consisted of added queries and the usage of AND/OR term identifiers. Advanced search techniques in Web of Science utilized citation references to obtain like sources and cited references from prominent articles.

2.1 Bariatric Procedures, Patient Population, and Importance

According to the World Health Organization, being overweight and obese is defined as "abnormal or excessive fat accumulation that presents a risk to health" (WHO, 2021). This risk to health is precisely the reason bariatric procedures are being performed globally as obesity rates have increased three-fold in the last 40 years (WHO, 2021). Bariatric surgery has the goal of enabling weight loss that could not be previously achieved with various failed medical

interventions and is performed with the goal of decreasing the severity (or eliminating) any associated comorbidities. The comorbidities and chronic medical conditions associated with obesity (BMI $\geq$ 30) are well documented in the literature. Examples include type II diabetes, chronic kidney disease, cardiovascular disease, hypertension, obstructive sleep apnea, nonalcoholic fatty liver disease, cancer, and metabolic syndrome (Mechanick et al., 2020). Metabolic syndrome is diagnosed in the obese patient when they have the presence of at least three of the following: central obesity (based on waist circumference), dyslipidemia (serum triglycerides $\geq$150 mg/dL or HDL $\leq$40 mg/dL in males/$\leq$50 mg/dL in females), hypertension (or being on antihypertensive medications), and hyperglycemia (fasting glucose >100 mg/dL or utilization of antihyperglycemic medications). The presence of at least three of these conditions increases the patient's risk five times for developing type II diabetes mellitus and are at double the risk of dying from myocardial infarction or stroke (Barash et al., 2017, p. 1283-1284).

Bariatric surgery, and specifically, metabolic procedures, are aimed at ameliorating these chronic conditions. Metabolic procedures are a subtype of bariatric surgery that leads to an alteration in gastrointestinal physiology to decrease gastric size. Other physiologic changes include a limitation of hunger hormone secretion which helps decrease appetite and caloric intake, enhanced insulin sensitivity to improve glycemic control, and facilitate weight loss that was not previously sustainable through any previously tried medical means (Morey-Vargas et al., 2022). The three most common metabolic procedures include gastric banding, sleeve gastrectomy, and Roux-en-Y gastric bypass. Gastric banding involves the insertion of an adjustable gastric band around the proximal stomach to restrict gastric volume and subsequent caloric intake. It is a shorter procedure compared to other bariatric surgery options. Sleeve gastrectomy is a more permanent procedure that involves the actual removal of a portion of a

stomach to decrease its capacity and is performed laparoscopically in approximately 1-2 hours. Gastric bypass (also known as Roux-en-Y) is a much more complex metabolic procedure that requires the creation of a gastric pouch and a gastro-jejunal anastomosis. The stomach is divided in two and the larger, remaining portion of the stomach along with the duodenum and jejunum is completely bypassed yet retain their abilities to secrete digestive fluids to the bowel (Reeve & Kennedy, 2022). Over the years, studies have shown superior improvements in glycemic management for those affected by type two diabetes who undergo bariatric surgery when compared to previous attempts at medical and lifestyle management. Specifically: "metabolic surgery should be considered in patients with type II diabetes and obesity (BMI $\geq$ 35) when hyperglycemia is inadequately controlled with lifestyle and optimal medical therapy" (Mechanick et al., 2020, p. 179).

As bariatric surgery has become more widely used, strategies at enhanced recovery and improved perioperative management have been developed. This specific patient population is required to undergo rigorous medical optimization and clearance prior to having the procedure and make these patients perfect candidates for ERAS (enhanced recovery after surgery) protocols. These protocols involve providing counseling, education, physical optimization through weight loss/exercise, medical optimization of any current comorbidities, as well as nutrition and fluid management in the immediate preoperative period. Postoperative goals involve preventing PONV, utilizing opioid-sparing techniques, and avoiding tubes or drains if possible. These principles are utilized to promote early mobility and early oral intake postoperatively (Riley, 2022). With these ERAS strategies in mind, it can be understood why dexamethasone given prior to induction of anesthesia or shortly thereafter has been closely studied for its role in reducing postoperative nausea and vomiting, improving analgesia, and

facilitating a faster recovery from these procedures through a suppression of the body's stress response to the surgery itself (Morey-Vargas et al., 2022).

One of the documented indications for having bariatric surgery involves being a diagnosed type II diabetic in combination with obesity. Perioperative glucose management is a key part of ensuring these patients have a successful outcome from their procedure. They may even see a remission in their type II diabetes diagnosis or have a decrease in overall need for oral antihyperglycemic medications to manage their diabetes (Mechanick et al., 2020). Concerns for postoperative hyperglycemia from perioperative intravenous dexamethasone administration in doses ranging from 4-10 mg remain under investigation. Determining the significance of a hyperglycemic response postoperatively can often be confounding as it is nearly impossible to determine if the hyperglycemia was a result of surgical stress, other medications administered intraoperatively, or directly from the administered dexamethasone (regardless of the dose).

Additional Benefits to Dexamethasone in the Bariatric population

Although there are more studies to be performed on the benefits and risks of single dose dexamethasone use perioperatively, its utilization for other surgery types has been reassuring with the only negative side effect being the physiological rise in blood glucose levels as already mentioned. According to Stenberg et al. in their guideline for perioperative care in bariatric surgery: "In elective surgery for inflammatory bowel disease, a single dose of 8 mg dexamethasone upon induction of anesthesia reduced postoperative ileus, the intensity of postoperative pain, and length of stay" (2022, p. 735). With regards to ERAS protocols as mentioned previously, 8 mg dexamethasone is documented as an "independent intervention to mitigate the perioperative stress response and secondarily prevent PONV" (Schwartz & Gan, 2020, p. 694).

Potential Adverse Effects of Dexamethasone in Bariatric Surgery

As discussed previously, a side effect of dexamethasone related to its direct effects on the neurohumoral system to aid the body in mitigating the stress response to surgery is elevated serum blood glucose levels. Postoperative hyperglycemia is a well-documented risk factor for the development of surgical site infections. In patients undergoing bariatric surgery, this could affect their recovery and lead to subsequent readmissions or even more surgeries to treat the infection. Furthermore, general complications of unmanaged hyperglycemia include dehydration through volume depletion, electrolyte abnormalities, ketoacidosis, hyperosmolar states, and altered mental status which could contribute to postoperative delirium and increased falls. The treatment for this postoperative hyperglycemia is insulin therapy (Morey-Vargas et al., 2022). However, once a patient receives bariatric surgery, their control over their blood sugar may be more difficult to manage with the change in caloric intake and alterations to their digestive hormones depending on which procedure they had performed. Metabolic operations also lead to rapid reductions in insulin requirements, dietary changes, and alterations in medication requirements that may increase their risk for hypoglycemia postoperatively (Morey-Vargas et al., 2022).

2.2 Synthesis of literature/Theoretical Framework

Many documented trials that have been conducted to compare blood glucose levels perioperatively among diabetic and non-diabetic patients who receive dexamethasone tend to use similar descriptors such as “significant” when describing a rise in blood sugar for patients who receive dexamethasone perioperatively. As noted in two randomized controlled trials: this “significant” rise varied with a range increase of 40-43 mg/dL, peaking at 6-10 hours yet had a maximum blood glucose concentration of 187 mg/dL for diabetic patients who received 8 mg of

dexamethasone (Purushothaman et al., 2018; Nazar et al., 2009). As previously stated, the ADA recommends a blood glucose range from 80-180 mg/dL in perioperative patients. The patients in these studies are therefore presenting on the upper limit for this suggested range (Nazar et al., 2009). Two trials that focused on bariatric (Roux-en-Y) and abdominal surgery specifically examined type II diabetics receiving 8-10 mg dexamethasone and found similar magnitudes of increase in blood sugar among diabetics of similar HbA1C levels prior to surgery (Hans et al., 2006; Nazar et al., 2009). Hans et al., (2006) however noted that these increases in glycemic response post dexamethasone administration were of "debatable clinical significance" but agreed that "poorly controlled diabetes and severe obesity can influence the development of hyperglycemia" (p. 164). The maximum blood glucose concentration noted by Hans et al. was 232.2 mg/dL. They labeled this as being "debatable clinical significance" (p. 167, 2006).

In summary, the clinical relevance of an increase in serum blood glucose levels postoperatively with dexamethasone administration is debatable. There is not a lot of data documenting any direct adverse outcomes in this specific patient population. (Riley, 2022, p. 127). There is clear documentation of a rise in blood glucose postoperatively from the administration of dexamethasone intraoperatively in type II diabetic patients however, it remains unclear if this transient rise in blood glucose is an independent contributor to adverse outcomes in this patient population. Thus, it is difficult to prove that the effects of a transient increase in blood glucose outweigh the multimodal benefits that dexamethasone administration is known to provide. Enhanced recovery protocols have certainly designated a place for dexamethasone as a drug not to be withheld in the bariatric patient population, regardless of type II diabetic diagnosis.

CHAPTER 3: METHODOLOGY

3.1 Project Design - Data Collection

The method of this quality improvement project consisted of a chart review conducted by a data collection champion in anesthesia leadership at the chosen hospital. Information and data were collected in an overall chart review of surgical patients with type II diabetes undergoing orthopedic, gastrointestinal, or genitourinary procedures at a full-service community hospital. This project specifically addressed patients undergoing bariatric surgeries. This project has a comparative design that includes patients' preoperative HbA1C results in addition to all serum glucose levels during or following their surgical procedure. A HbA1C reading enables the provider to determine how well that patient's blood glucose level has been controlled over the last three months and is utilized in diagnosing type II diabetes. According to Nagelhout & Elisha (2017), a HbA1C level less than 5.7% is normal, 5.7%-6.4% is high risk, and greater than 6.5% is considered a diabetic diagnosis. The chart review also included dexamethasone drug administration information including the dose and timing of administration (compared to induction and anesthesia stop times). This information was compared to other patients undergoing the same surgical procedure to assess the trend of glucose fluctuation in type II diabetics who received a dose of dexamethasone intraoperatively. To stratify the data and assess trends, several chart reviews included patients with type II diabetes who did not receive a dose of dexamethasone to assess blood glucose alterations. As a comparative design, the limitation of this quality improvement project will be the lack of control of confounding variables, but efforts have been made to be descriptive in the inclusion and exclusion criteria to minimize these variables.

3.2-3.3 Sample & Setting - Inclusion and Exclusion Criteria

This overarching quality improvement project includes type II diabetic surgical patients undergoing orthopedic, bariatric, and genitourinary procedures at the full-service community hospital site between the ages of 35-75. Other criteria include patients scheduled for procedures less than four hours, a documented preoperative HbA1C reading within the last twelve months ranging from 6.5-8.9%, patients who are non-pregnant, and patients with an ASA classification of I, II, or III. Patients are required to have postoperative blood glucose levels drawn on arrival to the postoperative anesthesia care unit (PACU) and further measurements taken if admitted for an overnight stay. All existing results have been examined in the chart review. To minimize confounding variables, exclusion criteria must also be defined. This project excluded patients with type I diabetes, patients on chronic steroid therapy, patients who take any prescribed antihyperglycemic medications the day of the procedure, and any patient with significant comorbidities that qualify them as an American Society of Anesthesiologists (ASA) IV or V status. An ASA IV status is defined as, “a patient with severe systemic disease that is a constant threat to life,” and a ASA V status is defined as, “A moribund patient who is not expected to survive without the operation” (ASA, 2020).

The anticipated number of charts to review was thirty-five random samples from each surgical population with the appropriate inclusion factors. To ensure the accuracy of data collection for type II diabetics receiving a surgical dose of dexamethasone, the same inclusion and exclusion factors were used to assess all appropriate patient samples from each surgical population. All data was coded and given appropriate markers once all the information was ready for dissemination to other parties to preserve patient confidentiality. A data collection sheet was compiled to give descriptions of each chart area necessary for review. This allowed for the charts

to be reviewed in an organized fashion in the most effective manner. This data collection also included specific operating room (OR) protocols specific to the full-service community hospital site that might initially prevent all needed data to be made available. As dexamethasone is a medication given for a few different uses intraoperatively, different doses are expected among the surgical procedures. Serum glucose levels were assessed from preoperative to the postoperative period of the acquired sample populations following dexamethasone dosing which was then analyzed and reported on with the developed mean changes, standard deviations, and ranges based on each surgical procedure. HbA1C levels were reported on as well to assess for any commonalities among patients who might have a larger hyperglycemic response to intraoperative doses of dexamethasone. Having this portion of data to review will offer the chance to report on the level of significance a single dose of dexamethasone has on a type II diabetic patient undergoing an orthopedic, gastrointestinal, or genitourinary procedure.

3.4 Method and timeline of Data Collection

As part of the chart review, charts were flagged of patients undergoing the surgical procedures at the full-service community hospital that were scheduled for a surgery lasting less than four hours. Lab results included any serum glucose readings perioperatively as well as any HbA1C levels. Opportunity to review home medications allowed for proper review of the data collected to assess trends and rule out patients on chronic steroid therapy as well as identify oral antihyperglycemic agents that may have been taken on the day of surgery. Dexamethasone dosing intraoperatively was imperative for review to examine the trends of dosing among anesthesia providers and assess any dose changes among different surgical procedures. The chart review of the dexamethasone dosing provided an abundance of information on any hyperglycemic changes that may result with dexamethasone dosing among type II diabetic

surgical patients. Serum glucose levels review allowed a review of the trends in possible hyperglycemic results in the hours following dexamethasone dosing.

The first step in the timeline for data collection consisted of successfully defending the project proposal on April 18th, 2023. After a successful proposal defense, the process for filling out Institutional Review Board (IRB) applications for the institution (Atrium health/Wake Forest Baptist) and University of North Carolina at Charlotte began. IRB approval from the institution was granted on July 11th, 2023. IRB approval from UNC-Charlotte was granted on August 4th, 2023 (Appendices B & C). With the IRB approval secured for both Wake Forest and UNC-Charlotte, the data collection process and chart review commenced with an allotted 6-week timeframe for data collection. After a minor delay, the chart review process took place from September 15th-18th, 2023.

3.5 Measurement Tools

The tools utilized to organize and assess all data were Microsoft Excel and the report review tool in EPIC electronic medical record system.

3.6 Data Collection procedures

With IRB approval and the assistance of anesthesia department leadership, the chart review commenced with the report review system in Epic EMR. Leadership developed a report in the search system narrowed down to the search identifiers: hospital name, surgeries occurring between January 1st, 2023, through August 31st, 2023, ASA status I-III, age 35-75, diabetes diagnosis, procedure length 0-240 minutes, and HbA1C value 6.5-8.9%. The primary search yielded 8,567 patients. A subsequent filter for general surgery was applied that yielded 88 potential patients. A manual search was then conducted for bariatric patients as there was no specific filter for bariatric surgery. Charts of patients who underwent Roux-en-Y gastric bypass,

gastric sleeve procedures, or a combination of interventions were reviewed. This manual audit revealed 26 eligible patients out of the 88 identified charts. To ensure a minimum total of 35 patients were identified, the chart review was extended back from January 1st, 2023 - August 31st, 2023, to September 1st, 2022 - August 31st, 2023. All other filters remained unchanged. This extended search led to 126 potential patient charts. Another manual sorting process for bariatric surgeries identified 13 more patients for a total of 39 bariatric patients potentially meeting criteria. Out of those 39 patients, three had to be excluded as two did not have a recorded pre-operative blood glucose documented, and one was removed due to documented postoperative complications that required a return to the OR within 24 hours of the primary procedure. A total of 36 patients were utilized for the final analysis. After the chart review process was completed, the de-identified codebook (Appendix A) was sent to Dr. Job Chen for statistical analysis at the University of North Carolina at Charlotte on September 19th, 2023. The evaluated results were received on October 6th, 2023.

3.7 Data Analysis

After the data collection period of this project and chart review concluded, data was organized utilizing Excel software and statistically analyzed. Part of the statistical data analysis was completed with the assistance of Dr. Job Chen, an Associate Professor within the UNC-Charlotte School of Nursing who has a background in mathematics and applied quantitative methods. Dr. Chen served as a valuable resource and assisted in obtaining statistical values from the data collection provided via the chart review. Probability level of .05 was the criteria established for statistical significance in this project. When patients were identified per the chart review and were missing inclusion criteria they were excluded from the final analysis (i.e. preoperative blood glucose readings, missing postoperative blood glucose readings, etc.). The

comparison between pre and postoperative blood glucose levels were based on paired t-tests. ANOVA was used to examine differences across surgery type. Linear regression was utilized to evaluate associations of blood glucose with other continuous variables such as baseline HbA1c, length of surgery, and age.

3.8 Ethical Considerations - Confidentiality

This project was approved by the institutional review board at Wake Forest School of Medicine and the University of North Carolina at Charlotte (Appendices B & C). The chart review of the sample population included data analyses of electronic medical records at the full-service community hospital site. The data was reviewed by the Director of Anesthesia Clinical Quality and Practice and the appropriate confidential patient markers were assigned to protect patient health information (PHI). As the electronic medical records supply several personal details, the only materials reviewed for this quality improvement project were the markers for the sample size. These markers included patient age, surgical procedure and listed duration, medical history and diagnoses, ASA status, patient home medication regimen, lab results from their hospital stay, lab results from previous primary care providers (HbA1C), and the intraoperative anesthetic record. Further efforts to maintain anonymity included identifying patients by initials rather than names, preventing any distribution of medical records beyond group members, securely storing data on password protected laptops that are secured and pre-approved by the hospital facility to access patient health information, and identifying data by surgical group when disseminating information. Once all data was secured and logged, all other patient identifiers were terminated to maintain anonymity. All other data was coded using a secure algorithm only accessible to the immediate team members.

CHAPTER 4: PROJECT FINDINGS/RESULTS

There are several factors that were pulled from the chart review to gain a better understanding of the effect of dexamethasone dosing in type II diabetic patients. Table 1 outlines the demographics reviewed and Table 2 identifies the difference in blood glucose values between the preoperative and immediate postoperative period based on dexamethasone dosing. To analyze these differences, paired *t*-test statistical analysis was completed to determine differences between pre- and post-blood glucose levels with varying levels of dexamethasone dosing. This was a major area of interest identified during the review of literature regarding the implications of different dosing of dexamethasone (for example 4 mg vs 8 mg). Additional data analysis was performed to determine if there are any statistically significant differences in blood glucose concentrations roughly 24 hours postoperatively based on the dosage of dexamethasone individuals received intraoperatively.

The 36 patients that met criteria to participate in this study were all labeled as ASA III status. The American Society of Anesthesiologists classify ASA III patients as "a patient with severe systemic disease" (ASA, 2020). Poorly controlled type II diabetes mellitus is classified as one of the systemic diseases that qualifies a surgical patient for ASA III status. The average age of the sample was 49.75 (sd = 9.46) with a range from 35 to 68 years old. The shortest surgery length was 38 minutes and the longest was 205 minutes, with an average length of surgery about 2 hours (M = 121.97, sd = 36.03). The different surgical procedures included 72.2% Roux-en-Y gastric bypass, 22.2% gastric sleeve, and 5.6% were "other" or a combination of these procedures. An example of a combination procedure was a patient that had a conversion of a gastric sleeve to a Roux-en-Y type bypass. Of the 36 patients included, only 2 patients (5.6%) did not receive dexamethasone, 4 patients received 4 mg (11.1%), 11 received 8 mg (30.6%), 18

received 10 mg (50%), and 1 (2.8%) received 12 mg. The average dose received of dexamethasone was 8.22 mg (*sd* = 2.82, *Mdn* = 10).

Table 1. *Demographics of type II diabetics undergoing bariatric surgery*

	Sample size (*n*)	Range	Mean	Standard Deviation
Age (years)	36	35-68	49.75	9.46
ASA status				
III	36	100%		
Length of surgery (minutes)	36	38-205	121.97	36.03
Dexamethasone Dose (mg)	36	0-12	8.22 (*Mdn*=10)	2.82
0	2 (5.6%)			
4	4 (11.1%)			
8	11 (30.6%)			
10	18 (50%)			
12	1 (2.8%)			
Surgery Type				
Roux-en-Y	26 (72%)			
Gastric Sleeve	8 (22%)			
Combo/other	2 (5%)			
A1C	36	6.1-9.3%	7.43%	0.80

When comparing the preoperative blood glucose (BG) to the immediate postoperative blood glucose (BG) overall there was a significant increase ($t = 8.72$, $p<0.001$) (see Table 2). Immediate postoperative BG was defined as the first blood glucose taken upon arrival to the post anesthesia care unit (PACU) or on arrival to the inpatient unit (whichever came first). The change in BG was not associated with age ($t = -1.60$, $p = .297$), HbA1C ($t = -0.23$, $p = .817$), or surgery length ($t = 1.05$, $p = .301$). The dose of dexamethasone that was received was not associated with the different bariatric surgery types ($F = 1.65$, $p = .207$).

There was a significant increase in blood glucose in the immediate postoperative period with dexamethasone doses of 4-10 mg (*ps* <0.011), but not in the two patients who did not receive dexamethasone ($p = 0.060$). While there was a significant increase in blood glucose with administration of dexamethasone, the dose level itself did not influence the actual change of blood glucose levels in the immediate postoperative period ($t = -.87$, $p = .390$). The type of surgery also did not influence BG change in the immediate postoperative phase ($F = 0.63$, $p = .537$). Table 2 summarizes the pre- and post- BG levels for each group in this immediate postoperative phase as defined above.

Table 2. *Pre-operative, immediate post-operative, and change in blood glucose across different groups.*

	Pre BG	Post BG	BG Change	*p*-value
Overall	133.1 (51.5)	179.6 (53.4)	46.5 (32.0)	< .001
Dexamethasone dose (mg)				
0	129.5 (29.0)	182.5 (21.9)	53.0 (7.1)	.060
4	132.0 (26.3)	189.5 (46.1)	57.5 (20.6)	.011
8	130.2 (45.2)	182.1 (48.6)	51.9 (43.1)	.003
10	129.4 (58.1)	168.2 (53.6)	38.7 (28.0)	< .001
12	242.0 (NA)	312.0 (NA)	70.0 (NA)	NA
Surgery Type				
Gastric sleeve	113.9 (30.0)	149.6 (29.2)	35.8 (29.0)	.010
Roux-en-Y	141.2 (56.6)	190.2 (57.6)	49.0 (33.8)	< .001
Combo/other	104.5 (12.0)	162.0 (7.1)	57.5 (4.9)	.039

Note: p-value tested the difference between pre and post BG and were based on paired t-tests.

Of note, there was no significant difference between preoperative BG ($M = 133.1$, $sd = 51.5$) and the 24-hour postoperative BG levels ($M = 147.9$, $sd = 55.4$, $t = 1.90$, $p = .065$.). The 24-hour postoperative BG level was taken either just prior to discharge on postoperative day 2, or whichever documented blood glucose reading was closest to the 24-hour postoperative mark

while the patient was admitted intraoperative. Finally, the two patients who did not receive any intravenous dexamethasone intraoperatively also experienced a change in BG level postoperatively. Although this group is small, the increase in BG approached a level of significance ($p = 0.60$) and is worth noting for this project.

CHAPTER 5: SIGNIFICANCE AND IMPLICATIONS

5.1 Discussion of Results

The clinical question asked prior to undertaking this project was if the administration of IV dexamethasone influences postoperative blood glucose levels compared to preoperative blood glucose levels. Based on the data received, it has become clear that dexamethasone (regardless of the dose administered in this population) does have a significant effect on perioperative glycemic levels. Exactly half of the patients included in this sample size (n=18) received 10 mg IV dexamethasone post-induction. This is more than the traditional dosing of 4-8 mg dexamethasone given IV for PONV prophylaxis as noted by Nagelhout and Elisha (2018). As discussed previously, many anesthesia providers often avoid administering dexamethasone in the type II diabetic patient population out of concern for this rise in blood glucose postoperatively.

This project's results showed clear statistical significance in the immediate postoperative glycemic jump, yet the question remains if this jump in blood glucose contains any clinical significance as well. The subsequent analysis comparing the patient's preoperative blood glucose to their 24-hour postoperative blood glucose showed no statistically significant increase, meaning that these patients very quickly returned to their baseline level of glycemic control regardless of the dose received. This raises further questions such as if there is any true clinical significance or consequences from administering high dose (8-12 mg) perioperatively in the type II diabetic population. It is also worth exploring further how much a DMII patient's blood glucose increases postoperatively when they do not receive any dexamethasone at all. Based on the two patients who did not receive any dexamethasone, they also developed immediate postoperative blood glucose levels that approached a level of statistical significance (p=.06). These two patients experienced an average increase of 53 mg/dL in their blood glucose levels

between the preoperative and immediate postoperative phase. This was above the average increase among all patients (including those who received varying doses of dexamethasone) which was 46.5 mg/dL.

With the clinical concern for postoperative hyperglycemia often discussed among anesthesia providers, it is crucial to note that the patient with one of the highest blood glucose levels preoperatively (242 mg/dL) received the highest dose of dexamethasone perioperatively (12 mg IV). This patient experienced the highest increase in postoperative blood glucose by 70 mg/dL to a peak of 312 mg/dL immediately postoperatively. Unfortunately, it is difficult to discern from a chart review why this patient with such high blood glucose levels received such a high level of dexamethasone. This patient's HbA1C level was 8.5% prior to surgery and their 24-hour blood glucose level remained high at 347 mg/dL.

The bariatric patient population showed a statistically significant increase in blood glucose regardless of the dose of dexamethasone received. Meanwhile, another part of this overarching QI project involved DMII patients undergoing orthopedic surgery. This patient population did show a difference in blood glucose jump in patients who received 10 mg compared to patients who received a lower dose (Walker, 2023). Walker's results also noted that a longer surgery led to a larger change in BG, meanwhile this was not the case for bariatric patients (2023). The third branch of this QI project assessed type II diabetic patients undergoing genitourinary surgery. None of the patients who received dexamethasone experienced a statistically significant jump in their postoperative glycemic levels. (Pullium, 2023).

5.2 Limitations

This project was mostly limited by the small number of patients included and the lack of ability to have true control for determining if dexamethasone is the only factor contributing to a

postoperative increase in postoperative blood glucose levels. As discussed previously, there are many factors that can contribute to a patient's increase in postoperative blood glucose levels such as the body's natural stress response to surgery, medications that contain dextrose, or variations in the patient's comorbidities and HbA1C level. Another limitation in this population of type II diabetic patients undergoing bariatric surgery involves a skewed number of patients who received only high dose dexamethasone. Over half of these patients received 8 mg or more of IV dexamethasone. There is a limited amount of data in patients who received only 4 mg or none to compare. This is most likely due to ERAS guidelines influencing the amount of dexamethasone that these patients receive. A retrospective chart review also does not offer the entire picture of the patient's surgery when it comes to provider rationale for increasing, decreasing, or withholding altogether the dose of dexamethasone.

5.3 Implications for Nursing Practice

This small quality improvement project has affirmed that more investigation is warranted to determine if dexamethasone independently is responsible for postoperative hyperglycemia that has clinically significant consequences. As a provider, it is also crucial to understand that there are a multitude of factors that contribute to an increase in blood sugar perioperatively and that withholding dexamethasone intraoperatively may be intruding on the patient's ability to have an early recovery postoperatively.

5.4 Recommendations

This project acts as a baseline for future investigation on the effects of different doses of dexamethasone on type II diabetic glycemic control perioperatively. Future projects should include provider questionnaires on what factors influence the way they choose to dose dexamethasone in this patient population. There should also be an increase in the number of

patients included in the chart review. Another suggestion to improve the quality of future study is the creation of a controlled study protocol for assessing total patient glycemic recovery to baseline postoperatively when receiving different doses of dexamethasone. Further investigation into the independent effects of dexamethasone dosing on perioperative glycemic control in type II diabetic surgical patients.

5.5 Summary

In summary, this quality improvement project has shown that type II diabetic patients undergoing bariatric surgery who receive dexamethasone (regardless of dose) experience a statistically significant increase in blood glucose levels in the immediate postoperative period. However, it should be noted that there was not a statistically significant difference between preoperative BG and the 24-hour postoperative BG level suggesting that this increase is transient. Two patients who did not receive dexamethasone also exhibited an increase in BG that approached significance ($p = .06$) which may indicate that type II diabetic patients experience an increase in blood glucose regardless of dexamethasone administration. These results suggest that further study on the effects of dexamethasone dosing and perioperative glycemic control is necessary to develop future guidelines and establish if this transient rise in blood glucose has true clinical significance in this patient population.

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APPENDIX A: CODE BOOK

Pt #	Received Dexa-methasone?	Bariatric Surgery type	Dose of Dexa-methasone (mg)	Pre-Operative Blood Glucose	Post-Operative Blood Glucose	BG Change	Pre-Op HgBA1C (%)	Age (yrs)	Length of surgery (min)	ASA Status	Prior To Discharge 24 hr BG
200	1	1	10	116	117	1	8.1	62	81	3	119
201	1	1	10	87	187	100	7.4	36	205	3	113
202	1	2	8	169	296	127	6.8	49	139	3	257
203	1	3	4	113	167	54	8.5	54	124	3	112
204	1	1	8	103	130	27	6.9	62	79	3	151
205	1	1	10	105	134	29	8.4	49	38	3	110
206	1	2	8	181	207	26	7.7	51	165	3	260
207	1	2	4	162	242	80	7.9	43	133	3	166
208	1	2	4	146	211	65	7.1	45	93	3	127
209	1	2	8	126	175	49	6.9	43	129	3	124
210	1	1	10	110	150	40	6.5	42	60	3	139
211	0	2	0	150	198	48	7.8	35	114	3	131
212	1	2	12	242	312	70	8.5	47	138	3	347
213	1	2	8	149	185	36	8.7	38	150	3	151
214	1	2	10	134	159	25	7.6	46	94	3	163
215	1	2	10	172	173	1	6.6	66	143	3	121
216	1	1	10	98	138	40	6.5	58	90	3	105
217	1	2	8	218	182	-36	7.7	45	156	3	126
218	1	2	8	84	138	54	6.6	44	101	3	127
219	1	2	10	336	362	26	8.7	53	128	3	208
220	1	2	4	107	138	31	6.8	39	149	3	114
221	1	2	8	93	132	39	7.1	46	145	3	79
222	1	2	10	126	116	-10	6.5	36	154	3	108
223	1	3	10	96	157	61	6.6	52	162	3	103
224	1	2	10	98	159	61	6.9	38	198	3	89
225	1	2	10	118	169	51	6.9	53	109	3	125
226	1	1	10	107	140	33	9.3	68	72	3	129
227	1	2	8	132	229	97	8.2	50	111	3	160
228	1	2	10	94	143	49	7.2	43	138	3	114
229	1	2	8	104	168	64	8.7	40	125	3	153
230	1	2	8	73	161	88	6.7	53	142	3	133
231	0	2	0	109	167	58	7.2	60	93	3	201
232	1	1	10	185	201	16	7.4	68	78	3	194
233	1	2	10	95	164	69	6.6	61	114	3	99
234	1	2	10	110	183	73	7.7	55	117	3	139
235	1	2	10	143	175	32	7.3	61	124	3	230
Key:	1=yes,0=no	*									

**1=Gastric sleeve, 2=Roux-en-Y, 3=Other/combo*

APPENDIX B: UNC-CHARLOTTE IRB APPROVAL LETTER

To:	Natalie Gabhart University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Approval Date:	04-Aug-2023
RE:	Notice of Determination of Exemption
Exemption Category:	4
Study #:	IRB-24-0031
Study Title:	Intraoperative Dosing of Dexamethasone in Type II Diabetic 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@charlotte.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.
8. Complete the Closure eform via Niner Research once the study is complete.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

APPENDIX C: WAKE FOREST SCHOOL OF MEDICINE IRB APPROVAL LETTER

Office of Research

INSTITUTIONAL REVIEW BOARD

WAKE FOREST UNIVERSITY HEALTH SCIENCES

MEMORANDUM

To: Danielle Brown
Atrium/Carolinas Healthcare System

From: Jeannie Sekits, Senior Protocol Analyst
Institutional Review Board

Date: 7/11/2023

Subject: Exempt Protocol: IRB00098449
Intraoperative Dosing of Dexamethasone in Type II Diabetic 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.

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our IRB registration numbers are

IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.
WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480