INTRAOPERATIVE DOSING OF DEXAMETHASONE IN TYPE II DIABETICS UNDERGOING GENITOURINARY PROCEDURES

by

Morgan Pullium

A doctoral scholarly project submitted to the faculty of The University of North Carolina at Charlotte in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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ABSTRACT

MORGAN PULLIUM. Intraoperative Dexamethasone Dosing in Type II Diabetics Undergoing Genitourinary Procedures. (Under the direction of DR. STEPHANIE WOODS, PH.D, RN)

The purpose of this quality improvement project was to identify trends in the intraoperative dosing of dexamethasone in type II diabetic patients undergoing genitourinary procedures at a full-service community hospital and to determine impact of dosage level on postoperative glycemic response compared to preoperative blood glucose levels. Dexamethasone is a corticosteroid that has many dose-dependent benefits when administered perioperatively to surgical patients. It is often withheld in the type II diabetic population out of concern for effects on postoperative glycemic control due to the side effect of hyperglycemia.

The method of this quality improvement project consisted of a retrospective chart review of patients with type II diabetes undergoing genitourinary procedures. Data inclusion criteria included patients who: are type II diabetics, had procedures that lasted less than four hours, had a documented preoperative hemoglobin A1C reading within the last twelve months ranging from 6.5-8.9%, are non-pregnant, are not taking oral steroidal medications, and had an ASA classification of I, II, or III.

Forty-nine charts were reviewed and overall there was no significant change in blood glucose in the postoperative period ($t = 0.92$, $p = 0.361$). The dose of dexamethasone (4, 8, or 10 mg) had no effect on the change in blood glucose levels ($t = -1.14$, $p = 0.263$). Additionally, changes in blood glucose were not found to be associated with age, HbA1C, or ASA status.

Dexamethasone administration for patients undergoing genitourinary procedures had no significant impact on blood glucose levels in the postoperative period. These findings may be a result of the shorter length of surgery, in that all 49 charts in this sample consisted of different

cystoscopy procedures and had an average surgery length of 66 minutes. Further study is needed to help facilitate anesthesia provider's decision-making for dexamethasone dosing in type II diabetics.

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DEDICATION

I am dedicating this project to those that have been with me through every step of my academic journey – your support has given me the strength to reach this milestone. To my mom - you have been my strongest ally throughout this journey and your enthusiasm, prayers, and daily words of wisdom truly helped guide me through school (and life). To my dad- your determination and drive has helped shape me in all aspects of my academic career, and without your support this would not have been possible. To April – you have always and will always be my role model and hero, thank you for showing me what hard work and dedication look like and giving me a guide to achieving my dreams. To my study group turned forever friends, Caitlin, Cameron, Mara, & Megan – I would not have made it through school without all of you and I will forever be grateful we got to go through this journey together. To the girls of 724 – there aren't enough words to describe how instrumental you each have been in shaping my life these past ten years, thanks to you I have stayed inspired to always follow my dreams. To the rest of my family and friends who have shown me persistent encouragement – I am incredibly appreciative of the love and support I have received and my sincerest thanks to you all.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
ASA	American Association of Anesthesiologists
BG	blood glucose
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRNA	Certified Registered Nurse Anesthetist
GU	genitourinary
HbA1C	hemoglobin A1C
HPA	hypothalamo-pituitary-adrenocortical
IRB	Institutional Review Board
IV	intravenous
MAC	monitored anesthesia care
MDA	Medical Doctor of Anesthesiology
mg	milligram
mg/dL	milligrams per deciliter
mg/kg	milligrams per kilogram
mmol	millimole
mmol/L	millimoles per liter
OR	operating room
PACU	post anesthesia care unit
PADDAG	Perioperative Administration of Dexamethasone and Glucose Trial
PADDI	Perioperative Administration of Dexamethasone and Infection Trial
PONV	postoperative nausea and vomiting

QI	quality improvement
SPO	Structure Process Outcome model
UTI	urinary tract infection

CHAPTER I: INTRODUCTION

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. Utilized for its multimodal benefits for patients under surgery, its most popular indication for anesthesia providers is 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).

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). When the diagnosis of diabetes is added, this topic becomes even more of a debate with 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.

Purpose

The purpose of this quality improvement project is to identify trends in the intraoperative dosing of dexamethasone in type II diabetic patients undergoing genitourinary surgery.

Specifically, this project, which is part of the larger QI project, strives to create a record of effects of dexamethasone on patient glycemic levels postoperatively based on the dose received and factors including HbA1C and preoperative blood glucose levels in patients undergoing genitourinary surgery. Overall, the goal is to develop a foundation for the creation of a clinical practice guideline for anesthesia providers when choosing how to safely dose dexamethasone in their type II diabetic patients to optimize patient outcomes.

Clinical Question - PICOT

In type II diabetic patients, aged 35-75, undergoing 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?

CHAPTER II: 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 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 in an attempt to curtail the results. Keywords utilized included: dexamethasone, blood glucose, surgery, diabetes, type II diabetes mellitus, blood glucose concentrations, anesthesia, intraoperative, renal, gynecologic, urologic, genitourinary, and urogynecologic. 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.

Genitourinary Procedures, Patient Population, and Importance

Genitourinary procedures include surgeries that are associated with any part of the urinary or reproductive system. Additional terminology of procedures that fall under the canopy of genitourinary include: urologic, gynecologic, and urogynecologic. This surgical population of

patients undergoing genitourinary procedures is important due to the fact that many patients with type II diabetes experience comorbidities involving the genitourinary system, often from issues related to diabetic nephropathy, diabetic autonomic neuropathy affecting the bladder, or obesity (Nagelhout & Elisha, 2018). Understanding the impact in the literature of dexamethasone dosing and blood glucose concentrations for this specific surgical population is crucial when considering the extent of patients undergoing genitourinary procedures that have type II diabetes.

In the United States, there is an increasing rate and prevalence of patients with type II diabetes, and it is estimated that 25% of diabetic patients will require surgery, with mortality rates estimated to be up to 5 times greater than those in nondiabetic patients (Loh-Trivedi, 2021). Common procedures that undergo general anesthesia include a myriad of cystoscopy cases to treat renal and urologic pathologies along with high incidence of gynecologic procedures being performed.

Synthesis of Results

Overall Effects of Dosing

Current controversy exists regarding impact of dexamethasone dosing on blood glucose levels; providers can pick from a wide range of doses including the mostly utilized 4 mg, 8 mg, or 10 mg. Multiple research studies have sought to understand the effects of different dexamethasone dosing on blood glucose levels of both diabetic and nondiabetic patients. The Perioperative Administration of Dexamethasone and Glucose trial (PADDAG trial) was a stratified, randomized clinical trial which administered either placebo, 4 mg, or 8 mg of dexamethasone after induction of anesthesia to both diabetic and nondiabetic patients (Corcoran et al, 2021b). Both 4 mg and 8 mg doses did not induce excessive hyperglycemia in patients with well-controlled diabetes and only the 8 mg dose in patients with a high baseline HbA1c caused a

significant increase in blood glucose. Murphy et al. (2014) conducted a similar randomized clinical trial to assess blood glucose concentrations of 4 mg dexamethasone versus 8 mg dexamethasone versus placebo in gynecologic surgical patients, and obtained comparable results to that of the PADDAG trial. Results concluded that blood glucose concentrations increased significantly in all groups – both the control, 4 mg dexamethasone, and 8 mg dexamethasone; however, there was no statistical difference between the increase in blood glucose between the groups who received dexamethasone and those who did not. Another randomized clinical trial conducted by Abdelmalak et al. (2013) sought to understand the response in blood glucose to dexamethasone in diabetic and nondiabetic patients along with the hyperglycemic response to surgery alone. This trial found similar results, in that dexamethasone did not produce significantly higher blood glucose levels and notably there was actually a greater increase in blood glucose concentrations in nondiabetic patients with a mean increase of 29 mg/dL more than that of diabetic patients.

In contrast, there were a number of studies which found dexamethasone dosing did have a significant impact on blood glucose levels. A retrospective database analysis found that a dose of 8-10 mg of dexamethasone was associated with significantly greater increase in blood glucose when compared to a dose of 4 mg (Low et al., 2015). In this analysis and study, the increase in postoperative blood glucose level was 25 mg/dL higher over 24 hours with 8 mg of dexamethasone than with 4 mg of dexamethasone – whereas the prior listed studies had not found significant increases in blood glucose levels with differing doses of dexamethasone. Fifty-four percent of patients in the 4 mg group experienced maximum blood glucose concentrations > 180 mg/dL compared to that of 74% of patients in the 8-10 mg group (Low et al., 2015). In a randomized controlled study conducted by Tien et al. (2016), statistical analysis confirmed that

dexamethasone administration was a significant predictor of maximum postoperative blood glucose increase, with the increase in 24 hours postoperative blood glucose being 1.9 mmol higher in patients who had dexamethasone as compared to those with ondansetron. It is important to note that while this study compared non diabetic to diabetic patients, the comparisons were made between 4 mg of ondansetron (a serotonin-antagonist used for prevention of PONV) administration versus 8 mg of dexamethasone administration, and lacked a control group, differing in the study design of both the Corcoran and Murphy trials. While Tien et al. (2016) did not look at differing doses of dexamethasone, their study found that dexamethasone increased blood glucose levels in both diabetics and nondiabetic patient groups.

In another comparative study of dexamethasone and ondansetron, the effects of dosing of dexamethasone were compared to the use of ondansetron in a comparable design to that of Tien, however the outcomes included the incidence of PONV and not blood glucose levels (D'souza et al., 2011). Interestingly, this study found that dexamethasone 4 mg was more effective for the prevention of PONV than that of 4 mg ondansetron or 8 mg of dexamethasone – unfortunately no blood glucose levels were obtained to allow for a comparative analysis of this study in regards to blood glucose concentrations (D'souza et al., 2011). In a systematic review, Apfel et al. (2012) found that female gender is the strongest patient-specific predictor of PONV and additionally that laparoscopic and gynecological surgery had statistical significance as independent predictors of PONV. These risk factors of female, laparoscopic, and gynecologic procedures are important to note when looking at impacts on the genitourinary procedure population.

Importantly, regarding the blood glucose levels and concentration results from the differing aforementioned studies- several of these trials took place outside of the United States, namely in the United Kingdom and Australia. When comparing study results, it was noted that

measurement of blood glucose labs were different based on the country of study. The United States utilizes blood glucose concentrations in mg/dL, while the international standard of measurement for blood glucose levels is mmol/L. The conversion of these measurements can be interpreted as follows: 10 mmol/L is the equivalent to 180 mg/dL when measuring blood glucose and denotes the standard for defining hyperglycemia (Joslin Diabetes Center, 2021). According to the American Diabetes Association (ADA), recommended perioperative blood glucose levels should be between 80 and 180 mg/dL (Morey-Vargas et al., 2022).

Genitourinary Specific Findings

While no studies were found in the literature search specifically related to impact of dexamethasone dosing on blood glucose levels in patients undergoing genitourinary procedures, several of the larger trials and studies provided a breakdown of results with different surgical populations. The Corcoran et al. (2021b) randomized controlled trial found that neither the 4 mg or 8 mg dose produced excessive hyperglycemia in the following data: the control group had 4 patients from gynecological surgeries and 6 patients from urology surgeries; the dexamethasone 4 mg group had 5 patients from gynecological and 6 patients from urology; and the dexamethasone 8 mg group had 5 patients from gynecological and 9 patients from urology. Conversely, a study which had much higher numbers of patients that underwent gynecologic or urologic procedures was the Low et al. (2015) retrospective study which had found that dexamethasone, specifically 8 to 10 mg, was associated with a significant increase in blood glucose levels. This study solely compared patients with pre-existing type II diabetes and the impacts of 4 mg vs 8-10 mg dosing. A total of 143 patients undergoing gynecological procedures and 73 patients undergoing urologic procedures were included in the dexamethasone 4 mg group, while 64 patients undergoing gynecologic and 47 patients undergoing urologic were included in

the dexamethasone 8-10 mg group. Unfortunately, analysis of each specific surgical procedure group and the response to blood glucose concentration was not provided for either of these studies to allow comparison of gynecologic and urologic groups to the entirety of the study of implications of dexamethasone dosing on blood glucose levels.

In regard to the effect of dexamethasone on blood glucose levels in genitourinary patients specifically, Murphy et al. (2014) conducted the one randomized trial found in the literature search that focused solely on the gynecologic surgical patient population. While this study provided data for the effect of 4 mg vs 8 mg of dexamethasone on blood glucose levels, exclusion criteria was notable for listing type II diabetes. While not including diabetic patients, gynecological surgery patients had no differences in hyperglycemic events in either the control, 4 mg of dexamethasone, or 8 mg of dexamethasone groups. Further research would need to be conducted to see if these results in gynecologic patients remain similar when looking at those with and without type II diabetes.

Additional Benefits of Dexamethasone in the Genitourinary Population

While studies over the past few decades have shown that dexamethasone plays a role in prevention of PONV, additional studies have taken place to determine if there are any further benefits to administration of dexamethasone in the perioperative period. A few studies mentioned additional benefits consisting of analgesic effects, improved recovery, and anti-inflammation. De Oliveira et al. (2011) compared the quality of recovery in patients who had received dexamethasone 0.1 mg/kg, dexamethasone 0.05 mg/kg, and saline within a randomized controlled trial. The findings were in favor that the dose of 0.1 mg/kg of dexamethasone resulted in reduced: opioid use, sore throat, muscle pain, and nausea. A similar study by Pauls et al. (2015), which looked at quality of recovery scores of women who had undergone gynecologic

procedures, determined that 8 mg of dexamethasone resulted in improved patient-reported recovery scores compared to those who didn't receive dexamethasone.

Adverse Effects

Chronic steroid use can be associated with increased infection risk, making practitioners question if a single dose of dexamethasone is associated with increased risk of wound infection post-surgery. Multiple researchers have considered infection when looking at studies regarding dexamethasone use. Gali et al. (2012) sought to determine if administration of dexamethasone increased rates of infection following urogynecologic surgery. Through multivariable statistical analysis of a retrospective chart review, there was no association found between single-dose dexamethasone use and postoperative UTIs or wound infections in this patient population (Gali et al., 2012). In the PADDI trial, a randomized controlled trial with groups receiving 8 mg of dexamethasone or a placebo, results showed surgical-site infections of 8.1% in the dexamethasone group and 9.1% in the placebo group (Corcoran et al., 2021a). This study didn't show a breakdown for genitourinary procedures in particular, but did include data on patients with pre-existing diabetes, and the results remained consistent that rates of surgical site infections were lower in the dexamethasone group than the placebo, 11.1% and 14%, respectively.

Summary of Results

As evidenced by the synthesis of results, the literature has conflicting findings regarding the impact of dexamethasone dosing on blood glucose levels in type II diabetic patients. Additionally, there need to be additional studies for genitourinary surgical patients in particular to truly understand the implications of dexamethasone dosing with this specific surgical population. While some of the studies found a transient increase in blood glucose levels, they

also emphasized the importance of dexamethasone utilization for additional benefits including antiemetic, anti-inflammatory, and analgesic which is an important factor to consider when looking at future studies.

Literature Review Conclusion

With conflicting literature regarding the impact of dexamethasone on blood glucose, particularly in diabetic patients, it is worth noting that a survey study has been performed to assess anesthesia providers' perceptions of dexamethasone administration usage in the intraoperative area (Corcoran & Edwards, 2015). Of the 333 survey responses – 65.5% of the providers who utilized medications for PONV prophylaxis administered dexamethasone. Additionally, 71.5% of the anesthesia providers who responded to the survey indicated concern for hyperglycemia in diabetic patients, however only 6.6% of the responses believed hyperglycemia to be a concern for nondiabetic patients. No additional studies were found regarding surveys of anesthesia providers' beliefs with dexamethasone for comparison to the Corcoran and Edwards (2015) results. This review of literature has revealed many discrepancies in regard to perioperative dosing of dexamethasone. The literature concludes that there are multiple factors to take into consideration when dosing dexamethasone perioperatively and depend greatly on the patient's clinical status, medical optimization, degree of preoperative glycemic control with HbA1C status, and provider preference.

Conceptual Framework

This project utilized the SPO conceptual framework, alternatively known as the Donabedian model, named after Avedis Donabedian who formulated this framework as a means for evaluating quality of medical care in the 1960s (Agency for Healthcare Research and Quality, 2015). The SPO model serves as a framework for examining and evaluating quality of health

care, with the three steps being: S-structure, P-process, and O-outcome. Donabedian emphasized the importance of the connection between structures, processes, and outcomes; therefore utilizing this model allows for relationships between the PICO, methodology, and outcomes to be identified. In this quality improvement project, the SPO model was utilized to evaluate the impact of dexamethasone dosing in type II diabetics. The structure (S) of this project included the full-service community hospital location and three different surgical patient populations being reviewed, consisting of type II diabetic patients undergoing either genitourinary, orthopedic, or bariatric procedures. The process (P) involved completing a literature review and subsequently a chart review to gain insight into the effects of dexamethasone dosing on blood glucose levels in the postoperative period. The outcome (O) of this QI project was to disseminate the findings on the effects of dexamethasone dosing in type II diabetic patients to anesthesia providers and provide further recommendations.

CHAPTER III: METHODOLOGY

Project Design

This was a quality improvement (QI) project that followed the SPO conceptual framework model and served to provide updated information to anesthesia providers regarding the effect of intraoperative dexamethasone dosing on blood glucose levels in type II diabetic patients undergoing genitourinary procedures. This was part of a larger QI project which focused on patients undergoing three different types of surgical procedures; this project focused specifically on the implications of dexamethasone dosing in genitourinary procedures. The project utilized a descriptive design and included a current literature review and synthesis along with a chart review and data analysis. IRB approval was obtained from both the Wake Forest School of Medicine and the University of North Carolina at Charlotte.

Setting

The selected hospital setting for this quality improvement project is a 196-bed, full-service community hospital located in a major metropolitan area in North Carolina. The hospital contains sixteen operating rooms and provides surgical access for orthopedics, spine, electroconvulsive therapy, endoscopy, gastric bypass, general, vascular, total joint, urological, and women's pelvic health, using regional block modalities, monitored anesthesia care (MAC), and general anesthetic techniques. This institution serves a metropolitan community of over 800,000 people of adult and geriatric age groups (U.S. Census Bureau, 2021). It staffs approximately 30-40 certified registered nurse anesthetists (CRNAs) total and utilizes a care team model under anesthesiologist (MDA) supervision. The ORs run 45-50 cases daily on average, 65% being orthopedics, 15% general/bariatrics, 10% vascular, 5% neurospine, and 5% neurology. In total there are approximately 10,800 cases performed annually. The average

number of genitourinary cases performed are 5.8 daily, 29 weekly, and 116 monthly. Bariatric case numbers are 1.3 daily, 9 weekly, and 36 monthly. The orthopedic case numbers are 9.4 daily, 66 weekly, and 264 monthly as of February 2023.

Population and Subjects

The sample population included type II diabetic patients of ASA status I-III, male or female, between the age of 35-75 that underwent a genitourinary procedure which lasted less than 4 hours. A total of forty-nine charts were collected and analyzed which met the inclusion and exclusion criteria that will be explained further below.

According to the United States Census Bureau, of the over 800,000 estimated population within the Charlotte metropolitan area, 44.7% are white, 35.2% are black or African American, 0.4% are American Indian and Alaska Native, and 6.5% are Asian (U.S. Census Bureau, 2021). Additionally, the estimated percentage of persons in poverty is 11.6%, an estimated 14.1% are under 65 without health insurance, and 5.5% of those under 65 have a disability.

Intervention

This quality improvement (QI) project sought to document the effects of intraoperative dexamethasone dosing and its effect on perioperative blood sugar in the patient undergoing genitourinary surgery. Dexamethasone is well documented in the literature for its positive effects on postoperative analgesia through decreasing narcotic consumption, postoperative nausea vomiting (PONV) prevention, assistance with mitigating the body's stress response to surgery, and anti-inflammatory effects. Despite this, it is often withheld out of concern for effects on type II diabetic glycemic control postoperatively. The goal was to provide the documented effects on perioperative glycemic control as well as disseminate updated evidence-based data to current

anesthesia providers. This project analyzed retrospective data on perioperative glycemic levels on patients who received varying doses of dexamethasone (if at all).

Methodology

Data Collection

The method of this quality improvement project consisted of a chart review via data collected by an electronic health record data collection champion and quality officer at a metropolitan hospital system. Information and data were collected in a chart review of surgical patients with type II diabetes undergoing genitourinary procedures at a full-service community hospital. This quality improvement project had a comparative design that included patients' preoperative hemoglobin A1C (HbA1C) results in addition to all serum glucose levels during or following their surgical procedure. A hemoglobin A1C 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. This information was compared to other patients undergoing the same type of 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 was the lack of control of confounding variables, but efforts were made to be descriptive in the inclusion and exclusion criteria to minimize these variables.

Inclusion and Exclusion Criteria

The age requirement for this quality improvement project included type II diabetic surgical patients undergoing genitourinary procedures at the full-service community hospital site between the ages of 35-75. Other inclusion criteria included patients scheduled for procedures less than four hours, patients with a documented preoperative HbA1C reading within the last twelve months ranging from 6.5-9%, patients who are non-pregnant, and patients with an ASA classification of I, II, or III. Patients had 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 blood glucose levels were examined in the chart review. In order to minimize confounding variables, exclusion criteria were also defined. This project excluded patients with type I diabetes, patients on chronic steroid therapy, patients who took any prescribed antihyperglycemic medications the day of the procedure, and all patients with significant comorbidities that qualified 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 an ASA V status is defined as, “A moribund patient who is not expected to survive without the operation.” (ASA, 2020).

The total number of charts reviewed were forty-nine random samples from the genitourinary 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 within the larger QI project that was performed. Data were coded and given appropriate markers once 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. As dexamethasone is a medication given for a variety of uses intraoperatively, different doses were 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 were then analyzed and reported on with the developed mean changes, standard deviations, and ranges. HbA1C levels were reported on as well to assess for any commonalities among patients who might have had a larger hyperglycemic response to intraoperative doses of dexamethasone. Having this portion of data to review offered the chance to report on the level of significance a single dose of dexamethasone has on a type II diabetic patient undergoing a genitourinary procedure.

Method of Data Collection

As part of the chart review, charts were flagged of patients undergoing the aforementioned surgical procedure at the full-service community hospital that underwent a surgery lasting less than four hours. Lab results included any serum glucose readings as well as any HbA1C levels available from the preoperative, intraoperative, and postoperative period. The opportunity to review home medications allowed for proper review of data collected to assess trends, rule out patients on chronic steroid therapy, and identify oral antihyperglycemic agents that may have been taken on the day of surgery – excluding patients from being eligible for chart review. Dexamethasone dosing intraoperatively was imperative for review to examine the trends of dosing among anesthesia providers and assess any significance in different dosing. The chart reviews of the dexamethasone dosing provided information on any hyperglycemic changes that may have resulted with dexamethasone dosing among type II diabetic surgical patients. Serum

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

Confidentiality

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 at the metropolitan hospital system and the appropriate confidential patient markers were assigned. Since the electronic medical records supplied several personal details, the only materials reviewed for this quality improvement project were the necessary markers for inclusion and exclusion criteria. These markers comprised of 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 (just the latest HbA1C level), and the intraoperative anesthetic record. Further efforts to maintain anonymity involved identifying patients by initials rather than names, preventing any distribution of medical records beyond group members, securely storing data on password protected laptops that were pre-approved by the hospital facility to access patient health information, and identifying data by surgical group. Once all data were secured and logged, all other patient identifiers were terminated to maintain anonymity, and a codebook was utilized to organize data from all charts with de-identified code numbers. Additionally, all other data were coded using a secure algorithm only accessible to immediate team members.

Timeline for Data Collection

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 applications for the institution and UNC Charlotte began. IRB

approval from the institution was granted on July 11th, 2023. IRB approval from UNC Charlotte was granted on August 4th, 2023. With the IRB approval for both Wake Forest and UNC-Charlotte, the data collection process and chart review commenced. A meeting took place with an electronic health record data collection champion on September 8th, 2023 to go over the chart review process and run the electronic medical records report with all members of the larger QI project group. After this meeting, 10 days were spent reviewing all charts, finalizing chart filters, and entering all necessary data into a de-identified codebook. The data collection for the chart review was completed by September 18th, 2023. For the data analysis and evaluation process, the codebook was sent to Dr. Job Chen, who assisted with statistical analysis, on September 19th, 2023. The statistical analysis report was returned to members of the QI project team on October 6th, 2023 for data analysis and evaluation. Compilation of data analysis, evaluation, and comparison to the findings from the synthesis of literature occurred from October 6th, 2023 to October 18th, 2023. The resulting discussions regarding limitations, implications, and recommendations were finalized by the end of November, 2023, prior to the doctoral defense on December 8th, 2023.

Data Analysis and Evaluation

After the data collection period and chart review were finished, the data needed to be statistically analyzed and evaluated. 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 resource and assisted in obtaining statistical values from the data collection provided via the chart review.

There were several factors that were pulled from the chart review in efforts to gain a better understanding of the role of dexamethasone dosing in type II diabetic patients undergoing genitourinary procedures. An integral factor that was related to the PICO question and aimed at identifying if intraoperative administration of dexamethasone affects postoperative blood glucose levels compared to preoperative blood glucose levels. To analyze the differences in postoperative and preoperative blood glucose levels, *t*-test statistical analysis was completed to determine if there was any statistical difference or level of significance regarding dexamethasone dosing and increases in blood glucose concentrations. Furthermore, an area of interest regarding the implications of different dosing of dexamethasone (for example 4 mg vs 8 mg) was noted after conducting the literature review. As a result of this area of interest found within current literature, additional data analysis was performed to determine if there were any statistically significant differences in blood glucose concentrations based on the dosage of dexamethasone individuals received intraoperatively. This data analysis was performed and evaluated with t-test statistics to evaluate any areas of significance in regard to dexamethasone dosing in type II diabetic patients.

CHAPTER IV: CHART REVIEW RESULTS

Sample Characteristics

The original electronic chart review report that was run for the full-service community hospital and anesthesia records included 8.567 results. These results were narrowed down using filters tailored to follow inclusion and exclusion criteria. Filters included: the dates of January 1st, 2023 to September 10th, 2023, ASA I-III status, age 35-75, surgical service urology, HbA1C 6.5-8.9, history of type II diabetes, and length of surgery 0-240 minutes. After application of filters, a total of 51 charts were available for review and data collection. Out of the 51 charts, two charts were excluded due to patients being on continuous insulin drip infusions, bringing the total charts reviewed with data collection to a sample size of 49.

Of the forty-nine charts that were reviewed, the following describes some of the sample demographics that were collected. Ages ranged from 49 to 75 years old, with a mean age of 65.76 years old. When looking at ASA status, 0% had an ASA I status, 20.4% had an ASA II status, and 79.6% had an ASA III status. Surgery length consisted of a range from 31 to 136 minutes, with the mean length being approximately 67 minutes. All forty-nine charts reviewed involved patients undergoing some form of cystoscopy procedure and intervention.

In regard to dexamethasone dosage: 36.7% of the sample did not receive any dexamethasone at all, 34.7% received a 4 mg dose, 26.5% received an 8 mg dose, and 2% received a 10 mg dose. Almost two-thirds of the sample received a dose of dexamethasone between 4 or 8 mg.

Chart Review Results

Table 1 depicts the range in dexamethasone dosing and associated preoperative, postoperative, and changes in blood glucose. As evidenced by all included *p*-values in Table 1,

there were no significant changes in postoperative blood glucose levels with any dose, from 0 mg to 10 mg, of dexamethasone. Overall, in all forty-nine patients, there was no significant change in blood glucose levels post-operatively (*t = 0.92, p = 0.361)* and this was regardless of if dexamethasone was administered at all, or in any of the various dosages administered.

Table 1: Dexamethasone Dose, Preoperative Blood Glucose Levels, & Postoperative Blood Glucose Levels

Dose (mg)	**Sample Size**	**Preop BG**	**Postop BG**	**BG Change**	**p-value**
0 *(Standard Deviation)*	n = 18	138.8 *(37.1)*	139.7 *(39.9)*	0.4 *(23.6)*	0.956
4 *(Standard Deviation)*	n = 17	128.1 *(28.1)*	131.2 *(22.6)*	-3.5 *(19.5)*	0.534
8 *(Standard Deviation)*	n = 13	127.8 *(23.8)*	129.1 *(23.4)*	-5.6 *(12.4)*	0.280
10 *(Standard Deviation)*	n = 1	204 *(NA)*	173 *(NA)*	-31 *(NA)*	NA
Overall Total	n = 49	133.8 *(32.2)*	135.4 *(30.8)*	-3.1 *(20.1)*	0.361

Important note: p-values were based on paired t-tests.

When analyzing results based on the sample demographics that were discussed prior, statistical analysis indicated that changes in blood glucose were not associated with any of the

demographic factors collected. These include: age, ASA status, HbA1C levels, and surgery length, all of which are outlined in Table 2 with their respective t-values and p-values.

Table 2: Sample Demographics and Blood Glucose Change

Demographic	**Range (Mean/SD)**	**Change in BG *t*-value**	**Change in BG *p*-value**
Age	49-75 *(65.76/6.50)*	-1.43	0.160
ASA Status	II-III *(frequency: 10 ASA II, 39 ASA III)*	0.13	0.901
Surgery Length	31-136 *(66.73/24.15)*	1.29	0.208
HbA1c	6.5-8.9	0.46	0.648

The chart review results demonstrated that for genitourinary procedures, there were no significant changes in blood glucose levels based on demographic factors collected. Additionally, the dose selected for dexamethasone administration had no significant impact on blood glucose levels in the postoperative period. It is important to note that with this chart review, for postoperative blood glucose readings 71.4% (n=35) had a postoperative blood glucose reading while 28.6% (n = 14) did not have a postoperative blood glucose reading documented in the chart. These charts were still analyzed to determine if there was any association between dexamethasone dosing and the addition or lack of a postoperative reading

and statistical analysis concluded there was no association (t-value = 1.15, p-value = 0.257). It is not clear why 14 charts didn't have a postoperative blood glucose reading, as this is a standard of care to obtain a reading in the post anesthesia care unit for any patient diagnosed with type II diabetes recovering from surgery.

CHAPTER V: DISCUSSION

Implications for Practice

This QI project sought to identify the impact of dosage level of dexamethasone on postoperative blood glucose levels in type II diabetic patients undergoing genitourinary procedures. In both the literature review and chart review, several implications for practice were identified. In the PADDAG trial (Corcoran et al, 2021b) results concluded that both 4 mg and 8 mg doses did not cause excessive hyperglycemia in patients with well controlled diabetes when compared to those who received no dexamethasone. Similar findings to that of the PADDAG trial were found within this chart review, as there was no significant increase in blood glucose levels for any group (those who received 0 mg, 4 mg, 8 mg, or 10 mg of dexamethasone). Another randomized clinical trial which had comparable findings noted that there was no statistical difference between the increase in blood glucose levels of patients who received dexamethasone and those who did not; however, in this trial all groups noted an increase in blood glucose levels, but it was found that dexamethasone administration didn't play a role in the increase (Murphy et al., 2014). Comparatively, for this chart review it was found that blood glucose levels actually declined by 3.1 points overall when looking at preoperative vs postoperative levels; however, with a $p = 0.361$, these results were not statistically significant.

While all of the previously mentioned results affirmed that dexamethasone administration did not have a significant impact on postoperative blood glucose levels, there were several studies within the literature that demonstrated a correlation between dexamethasone and increases in blood glucose. One such example was a retrospective database analysis which found a dose of 8-10 mg to be associated with significantly greater increases in blood glucose when compared to 4 mg (Low et al., 2015). The literature review results concluded that there was

variability in both dexamethasone dosing and response of blood glucose levels within the type II diabetic population, pointing to an indication that further studies are warranted on this topic to better understand and analyze trends.

It is important to note that this QI project was part of a larger overarching QI project where additional populations of bariatric procedures and orthopedic procedures were reviewed utilizing the same inclusion criteria and chart review design. Gabhart (2023) found there to be a significant increase in immediate postoperative blood glucose compared to preoperative blood glucose levels within the bariatric procedure population who received a dose of 4-10 mg of dexamethasone. Additionally, in the review of the bariatric procedure population there were additional data collected for 24-hour postoperative blood glucose levels, where there was no significant difference in those levels compared to the preoperative levels (Gabhart, 2023). When reviewing the results of the orthopedic procedures population, Walker (2023) concluded that "dexamethasone dosing had a significant effect on the change of blood glucose levels with a higher dose leading to a greater increase in blood glucose levels ($t = 4.55$, $p < .001$)" (p. 16). Both the bariatric and orthopedic procedures populations had more findings of significance associated with dexamethasone dosing and increased blood glucose levels as compared to the genitourinary group. One possible conclusion for these differing results from the genitourinary procedure population was the average length of surgery. As all forty-nine procedures in the GU group consisted of various cystoscopy procedures, there was a shorter length of surgery, with an average length of approximately 67 minutes. To compare, the orthopedic procedure group had an average length of approximately 90 minutes and a range from 12 to 238 minutes (Walker, 2023) while the bariatric procedure group had an average length of approximately 120 minutes (Gabhart, 2023). Additionally, as cystoscopy procedures aren't as involved as most of the

orthopedic and bariatric procedures which were reviewed, another possible conclusion could be that the stress response from surgery itself was less, resulting in lower increases in blood glucose levels postoperatively.

Limitations

Notably, there were some limitations to be discussed for this QI project. There was a limited number of charts that were reviewed; due to location and lack of procedure variability, the genitourinary procedures were limited to that of cystoscopies with interventions. An additional limitation involved the time constraint due to the project timeline. It became clear within the literature review and the chart review that there is a need for understanding the reasoning behind anesthesia providers' choices due to the variability of dexamethasone dosing given to type II diabetic patients, but this was not able to be reviewed via the retrospective chart review. Further project limitations included that almost two-thirds of the sample received a dose of dexamethasone between 4 or 8 mg, so there wasn't an even distribution among 0, 4, 8, or 10 mg doses to be able to compare results more accurately between dosing categories. A final limitation to note was that 14 of the 49 charts included in this chart review did not have a postoperative blood glucose reading obtained at all once in the PACU and it was not clear why there was no reading, as this is a standard of care to obtain for patients diagnosed with type II diabetes recovering from surgery.

Recommendations

This QI project served as a starting point for beginning to understand the implications of a commonly administered intraoperative medication, dexamethasone, and its effects with different dosages on type II diabetic patients. It is recommended that future projects include analyzing anesthesia providers' reasonings on their selected doses of dexamethasone in this

patient population. By sending a questionnaire and survey to anesthesia providers regarding what factors determine their selected dosage of dexamethasone and comparing that to chart reviews, there could be more insight into this topic and to gain a better understanding of reasoning behind the vast variability in dosing of this common medication.

Additionally, there is currently no standard protocol for guidelines regarding dexamethasone dosing in type II diabetic patients undergoing surgery at the hospital system where this quality improvement project was performed. Further studies with an emphasis on larger samples, additional procedure populations, and at different clinical locations would be useful to gain more information in understanding what significance there is for dexamethasone dosing in different surgical populations in regard to influence on blood glucose levels. These recommendations would be useful to eventually allow for a clinical practice guideline to assist anesthesia providers in their decision-making for dexamethasone dosages intraoperatively, in the hopes to improve quality of care for type II diabetic patients undergoing surgical procedures.

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APPENDIX A: UNCC IRB APPROVAL LETTER

CHARLOTTE
DIVISION OF RESEARCH

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 B: WAKE FOREST IRB APPROVAL LETTER

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

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.

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

APPENDIX C: DATA COLLECTION PLAN FOR CHART REVIEW

Data Collection Plan For Chart Review: Intraoperative Dexamethasone Dosing in Type II Diabetic Patients

Setting:
-Atrium Health Mercy

Patient characteristics/inclusion criteria:
-Type II diabetes diagnosis
-Age 35-75
-ASA status I, II, or III
-Non pregnant

Surgical types: *surgery lasting less than 4 hours*
-Orthopedics (excluding spine)
-Bariatric
-Genitourinary

Data needed:
-35 random samples from each surgical type
-Pre-operative HbA1C reading within 12 months prior to surgery (6.5-9% to be included)
-Any preoperative blood glucose reading (including the time taken)
-Immediate postoperative blood glucose reading (time taken)
-Any additional blood glucose readings (if any during intraoperative period as well as any blood glucose readings for admitted patients during hospitalized post-surgical period)
-Patient age
-Patient gender
-Patient ASA status
-Home medication list (to assess for oral antihyperglycemic use, chronic steroid therapy, etc.)
-If patient received dexamethasone - what dose and what time
-Induction time, anesthesia stop/handoff time

Exclusion Criteria:
-ASA IV or V
-Patients who took anti-hyperglycemic agents day of surgery
-Patients on chronic steroid therapy
-HbA1C >9% or <6.5%

APPENDIX D: EXCEL CODEBOOK

A	B	C	D	E	F
					Codebook: Dexamethasone Dosing in Type II Diabetic Patients
De-Identified Number	Received Dexamethasone?	Dose of Dexamethasone	Time of Dexamethasone Adminsitration	Pre-Operative Blood Glucose	Time of Pre-Operative BG Reading
100					
101					
102					
103					
104					
105					

G	H	I	J	K
s // Associated Keys: Column A: De-identified number: 100s = orthopedic surgical subgroup, 200s = bariatric surgical subgroup, 300s = genitourinary surgical sul				
Post-Operative Blood Glucose	Time of Post-Operative BG Reading	Amount of Change Preop BP to Post BG (mEq/dL)	Pre-Operative HgBA1C	Age

L	M	N	O	P	Q
ıbgroup; Column B: Received Dexamethasone: 0 = no, 1 = yes					
Length of surgery	ASA Status	Last BG within 24 hours if available	Time for Last BG within 24 hours	Amount of Change Preop BP to 24 hr BG (mEq/dL)	Type of Surgery