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Is Dexamethasone 4mg a More Effective Anti-Emetic than Dexamethasone 8mg for the Prevention of Early Post-Operative Nausea and Vomiting in Women Undergoing Laparoscopic Gynecological Surgery?

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IS DEXAMETHASONE 4MG A MORE EFFECTIVE ANTI-EMETIC THAN DEXAMETHASONE 8MG FOR THE PREVENTION OF EARLY POST-OPERATIVE NAUSEA AND VOMITING IN WOMEN UNDERGOING LAPAROSCOPIC GYNECOLOGICAL SURGERY?

by

Steven Blake Doyle

Abstract of a Capstone Project
Submitted to the Graduate School
and the Department of Advanced Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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ABSTRACT

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Postoperative nausea and vomiting (PONV) is a common problem in the surgical setting. It affects as much as 20 to 80 percent of patients undergoing surgery (D'souza, Swami, & Bhagwat, 2011). PONV can lead to increased patient costs and recovery time by causing the patient to stay in the healthcare facility for a longer period of time. A retrospective cohort study was completed to examine whether or not there was a significant difference between patients who received 4mg and 8mg of dexamethasone in the incidence of PONV. All patients studied received ondansetron intraoperatively as their primary anti-emetic. English-speaking patients who met the following inclusion criteria were included in the retrospective chart review: those who are female, those who have undergone laparoscopic gynecological surgery and received dexamethasone, those who are non-smokers, and those who are aged 18-60 with an American Society of Anesthesiologists (ASA) score of II or less. Patients that met the following exclusion criteria were not counted towards the chart review: those who are an ASA III or above, those who did not follow the recommended fasting time prior to surgery, those with a history of motion sickness, those with a history of PONV, those who are taking routine anti-emetics, those whose are deaf, those who are blind, those who are smokers, and

those outside the age range for 18-60 years. Statistical analysis using a Chi-Square test was used to evaluate whether the patients receiving 4mg of dexamethasone experienced more PONV that those who received 8mg.

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A Capstone Project
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December 2015

DEDICATION

I would like to thank my beautiful wife, Avery Doyle, for being patient with me throughout my education. She has been with me since day one of nursing school, and I am blessed to have her with me throughout my pursuit of higher education.

In addition, I would like to thank my parents and family members. I love and miss you all, and will be happy to be closer to home once I complete my education.

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologists
CTZ	Chemoreceptor Trigger Zone
EMAR	Electronic Medication Administration Record
EPIC	Electronic Patient Integrated Care
IRB	Institutional Review Board
PACU	Post anesthesia Care Unit
PONV	Postoperative Nausea and Vomiting
SPSS	Statistical Package for the Social Sciences

CHAPTER I

INTRODUCTION

Statement of the Problem

Post-operative nausea and vomiting (PONV) is a common problem in the surgical settings. It affects as much as 20 to 80 percent of patients undergoing surgery (D'souza, Swami, & Bhagwat, 2011). Sustained vomiting is one of the most frequent causes of unexpected hospital admission of patients from ambulatory surgery centers (Yao, Fontes, & Malhotra, 2012). PONV contributes to additional problems such as anxiety, patient dissatisfaction, dehydration, muscular fatigue, and delayed recovery.

PONV has many different triggers. History of PONV, female gender, laparoscopic procedures, opioids, being a non-smoker, and duration of surgery have all been linked to increased incidence of PONV (Miller & Pardo, 2011). The chemoreceptor trigger zone (CTZ) located in the brainstem is believed to be responsible for nausea and vomiting. The CTZ contains opioid, serotonin, histamine, dopamine, and muscarinic acetylcholine receptors, which when triggered, cause nausea and vomiting (Barash et al., 2013). The CTZ, vagal nerve, and vestibular organs send signals to the vomiting center in the medulla leading to PONV (Barash et al., 2013). A multimodal drug therapy approach can be effective in blocking stimulation of the receptors of the CTZ, thus preventing PONV.

There are many different approaches to preventing PONV. One particular method that is popular is treating PONV prophylactically with the anti-emetic drug ondansetron. It has been reported that many patients have greater fear of PONV than they do of experience pain as a result of their procedure (Sweeny, 2003). If left untreated, the

incidence PONV varies greatly amongst populations being studied, with an occurrence rate of 20-30% in the general surgical population and as high as 70-80% in high-risk surgical populations (Jee, Yoon, & Jang, 2010).

There are many different factors that can make a patient more or less susceptible to experiencing PONV. Many of these risk factors can be identified by a thorough pre-anesthetic evaluation with a complete history and physical. One factor which can be assessed is being obese. Obese patients have a higher incidence of PONV than non-obese patients (Sweeny, 2003). Some explanation for this could be that anesthetic medications could be deposited in adipose tissues and be released while the patient is in the recovery room. Other problems with having a larger body size can be that larger people have increased resting stomach volumes. The more volume one has in their stomach, the more likely it is for that person to have an incidence of vomiting.

Gender plays a role in determining the risk factor of PONV. Women are four times more likely to have PONV than men (Sweeny, 2003). This is even more likely to occur in younger women due to the fact that the incidence of PONV also decreases with age (Sweeny, 2003). These are major reasons why the proposed study is focusing on women undergoing general anesthesia as the population of interest in regards to PONV since they are more likely to experience it than men.

The type of surgical procedure can also have a major influence of PONV. Gynecological and abdominal surgery patients are at a much greater risk of PONV than patients undergoing other surgery types such as bone fracture repair. Some procedures that are commonly associated with PONV are strabismus surgery, ear surgery, laparoscopy, orchiopexy, ovum retrieval tonsillectomy, and breast surgery (Butterworth,

Mackey, & Wasnick, 2013). Considering which type of surgical procedure the patient is undergoing can aid the anesthetist in making an assessment of how much the patient is at risk for PONV.

The type of anesthetic used and the duration of the procedure also can play a role in determining the risks of PONV. The longer the procedure, the greater the chance for PONV. General anesthesia has a greater incidence of PONV. Nitrous oxide has also been linked to increased incidence of PONV, as well as the use of opioids for pain management (Sweeny, 2003).

There are several things, such as age, gender, duration of surgery, and body weight that cannot be controlled by the anesthetist to prevent the incidence of PONV. However, there are some factors that can be controlled such as fluid replacement and which anesthetic agents are used throughout the procedure (Sweeny, 2003) . It is important to note how much fluid the anesthetist is giving the patient during the pre-operative, intraoperative, and postoperative state. Although there have been numerous studies seeking to define fluid strategy, anesthetists giving liberal, standard, or restrictive amounts of fluids have not been able to consistently improve postoperative outcomes (Butterworth, Mackey, & Wasnick, 2013). As always, when considering fluid resuscitation, the anesthetist should consider the patient's comorbidities such as cardiovascular history when selecting a fluid resuscitation strategy.

The anti-emetic drug ondansetron is a popular drug of choice for most anesthetists in preventing and treating PONV. Ondansetron selectively block serotonin 5-HT receptors with minimal to no effect on dopamine receptors (Butterworth, Mackey, & Wasnick, 2013). 5-HT receptors appear to play an important role in the initiation of the

vomiting reflex. These receptors are located outside of the blood-brain barrier, which are activated by substances such as anesthetics and opioids (Butterworth, Mackey, & Wasnick, 2013). Thus the use of ondansetron is very effective in offsetting the emetic effects of most drugs given during anesthesia. Ondansetron is metabolized in the liver via cytochrome P-450 enzymes, and it is important to consider the dosage in patients who have any signs of liver failure as to avoid toxicity (Butterworth, Mackey, & Wasnick, 2013). Ondansetron in a dosage of 4mg has been seen to be just as effective as 8mg when it is administered in the post-anesthesia care unit for treatment of nausea and vomiting (Nagelhout & Plaus, 2014).

Dexamethasone is a glucocorticoid steroid drug that has been found to be an effective treatment in reducing the incidence of PONV, given alone or in combination with other anti-emetic drugs (Nagelhout & Plaus, 2014). Dexamethasone should be given immediately after induction instead of at the end of surgery, and the mechanism of action in preventing PONV is unknown (Butterworth, Mackey, & Wasnick, 2013). The beneficial effects of dexamethasone in preventing PONV could be secondary to its long duration of action, which can last up to 24 hours (Nagelhout & Plaus, 2014). Dexamethasone in doses as small as 4mg has been shown to be as effective as ondansetron in reducing the incidence of PONV (Butterworth, Mackey, & Wasnick, 2013). Dexamethasone at a dosage of 4mg and 8mg have been shown to prevent PONV (D'souza, Swami, & Bhagwat, 2011). Dexamethasone is commonly supplied in 4mg/1ml vials.

As with ondansetron, dexamethasone is also metabolized in the liver via cytochrome P-450 enzymes. Adverse effects of single dose of dexamethasone have not

been reported, however, patients who are sensitive to steroid administration, such as patients with diabetes, should be considered carefully as steroids have a tendency to increase blood glucose levels (Nagelhout & Plaus, 2014). Dexamethasone also acts in the inhibition of prostaglandin synthesis thus preventing swelling, which could prove especially useful to surgeons and anesthetists during neck and airway procedures (Nagelhout & Plaus, 2014).

Conceptual and Theoretical Framework

The use of prescriptive theory, including its basic tenets, assumptions, and theory parts, will serve as a theoretical framework for the capstone project involving the use of dexamethasone intravenously for the prevention of post-operative nausea and vomiting. Future practice implications of prescriptive theory are abundant, as most experiments measuring interventions can be applied to prescriptive theory.

Prescriptive theory is a subclass of a group of theories known as middle range theories. When theorists produced middle-range theories, they chose conceptual models that align with his or her own expectations of the world. Many middle range theories are created from the same conceptual model (Butts & Rich, 2011). According Butts and Rich, "Many middle-range theories are needed to deal with all of the phenomena encompassed by any one conceptual model because each theory deals with only a limited aspect of the total reality encompassed by a conceptual model" (p.36). Middle-ranged theories can further be broken down into subclasses. McKenna and Slevin outlined four types of scientific categories, descriptive, explanatory, prescriptive, and finally prescriptive theory (Butts & Rich, 2011). Prescriptive theory prescribes evidence and uses knowledge utilization that looks beyond the predictive cause-and-effect

relationships. Prescriptive theory builds on other the other subclasses of middle-range theory that consists of descriptive, explanatory, and predictive theory (Butts & Rich, 2011). The adaptation of prescriptive theory could aid clinicians by providing evidence of cause-and-effect relationships between interventions, such as intravenous administration of dexamethasone, to predict outcomes like the prevention of PONV. In other words, prescriptive theory addresses aspects of therapeutic interventions. This capstone project, as previously described, will be addressing a pharmacological intervention in the prevention of PONV. The administration of dexamethasone to prevent PONV uses prescriptive theory by exploring cause-and-effect relationships, and investigating whether or not the intervention of administering dexamethasone intravenously is effective in preventing PONV. Evidence of the effectiveness or ineffectiveness of these interventions will be noted in order to influence current practice.

Review of Literature

Included in this section is a narrative review of literature concerning the use of dexamethasone in the prevention of PONV within various populations. The online database CINAHL and PubMed, were used to search for articles related to the clinical question at hand. The word “dexamethasone” was entered into line one, the words “postoperative nausea and vomiting” were entered into line two, and the word “women” was entered into line three. A total of 91 articles were found from CINAHL and 71 articles from PubMed. Ten articles were used exclusively for the literature review that exclusively included the population of women aged 18 or older undergoing general anesthesia.

Gynecological surgery is considered a high risk factor for PONV (D'souza, Swami, & Bhagwat, 2011). A quantitative study by D'souza, Swami, and Bhagwat (2011) compared the use of intravenous dexamethasone and ondansetron for the prevention of PONV in young women undergoing laparoscopic gynecological surgery. Ninety-three women were randomly divided into 3 groups. One group received 4mg dexamethasone, another group 8 mg dexamethasone, and the final group received 4 mg of ondansetron. A PONV score was used as an assessment tool during the first 24 hours after surgery.

The incidence of PONV during the 24 hour postoperative period was highest amongst the group that received 4 mg ondansetron within the first 3 hours postoperatively. In the dexamethasone 4 mg groups, the request for rescue antiemetic drugs was significantly lower than in the dexamethasone 8mg group and the ondansetron 4mg group. Based on this study, it can be suggested that dexamethasone is an efficient cost effective drug for the prophylaxis of PONV, and the dexamethasone at a dosage of 4mg was most effective amongst this population.

Laparoscopic surgeries are the second most common cause of PONV (Maddali, Fahr, Fahr, & Zarrough, 2003) A comparison of dexamethasone with ondansetron against metoclopramide and dexamethasone for the prevention of PONV amongst female patients undergoing laparoscopic diagnostic gynecological surgery was examined by Maddali, Mathew, Fahr, and Zarroug (2003). Their research was conducted in the form of a perspective, randomized, double-blind study. One-hundred twenty women were given either saline (group 1), 8mg of dexamethasone with 10mg of metoclopramide (group 2), or 8mg dexamethasone with 4mg of ondansetron (group 3). There were no significant

differences amongst the group's mean age, mean weight, duration of procedure, or duration of stay in the post anesthesia care unit (PACU). The patients were assessed for PONV every hour for 6 hours, then every 2 hours for 6 hours, and finally every 4 hours for the final 12 hours.

Between the three groups, the results of the study were most favorable for the patients in group 3. The patients in group 1 suffered the highest incidence of nausea at 45%, followed by group 2 at 40%, and group 1 at 17.5%. Interestingly enough, patients in group 1 did not suffer from vomiting, while 35% of group 2 and 10% of group 1 had incidence of vomiting. The researchers concluded that the use of dexamethasone with ondansetron as an efficient, cost-effective, and easily available way to prevent PONV than the use of dexamethasone with metoclopramide (Maddali, Fahr, Fahr, & Zarrough, 2003).

The use of dexamethasone vs ketorolac for the prevention of PONV in women undergoing laparoscopic gynecologic surgeries was examined in a by Rimaitis, Svitojute, and Macas (2010). The researchers compared 153 women with American Society of Anesthesiologists (ASA) physical status score of I-II undergoing laparoscopic gynecological procedures. The women were divided into 3 random groups, a dexamethasone group, a ketorolac group, and a control group. The dosage of dexamethasone given was 4mg, while the ketorolac group received 30mg of ketorolac, and the control group received no medication at all. There were no significant demographic differences found within the population. Thirty-seven of the patients registered had a history of migraines. Fifty-nine and one-half percent of these patients suffered from PONV, while only 12.9% of patients without a history of migraine

headaches reported PONV. Of the groups examined, the dexamethasone group had 13.8% of patients reporting PONV, while the ketorolac group had 37.3% of patients report PONV, and the control group suffered a rate of 58.9% of patients reporting PONV. The researchers concluded that history of migraine headache is an independent risk factor for PONV, 4 mg of dexamethasone during induction of anesthesia showed a significant difference in the reduction of PONV, and that the use of ketorolac during induction reduced the risk of PONV.

It is well known that ondansetron is an effective anti-emetic drug. Yuksek, Alici, Erdem, and Cesur (2003) sought to compare ondansetron vs dexamethasone for the prevention of PONV in women undergoing laparoscopic gynecological surgery. The study consisted of women aged 19-62 years old undergoing general anesthesia for laparoscopic gynecological surgery. Patients with BMI > 35, history of gastric reflux were excluded. All patients completed the study.

The 60 participants were randomly divided into 3 equal groups, one receiving 4mg ondansetron, the other 8mg dexamethasone, and the last given saline. There was a significant difference seen between the groups during the first 3 hours after surgery. Ondansetron was found to be significantly more effective than dexamethasone and saline. Dexamethasone did not prevent PONV nor did saline within the first 3 hours. In fact, there were no significant differences found between the two. Based on this study, one could suggest that dexamethasone was ineffective in preventing early PONV, and ondansetron is the better choice to prevent PONV within the first 3 hours after surgery.

Laparoscopic cholecystectomy is a very common laparoscopic abdominal procedure. While many studies have focused on the use of dexamethasone in

laparoscopic gynecological procedures, Choi, Jo, J. Lee, W. Lee, and Shim (2012) sought to compare the use of dexamethasone 8mg, ramosetron 0.3 mg, and dexamethasone 8mg combined with ramosetron 0.3mg in women undergoing laparoscopic cholecystectomy. The researchers randomly assigned 120 women into 3 groups, each receiving one of the mentioned drug regimens. The participants' ages ranged from 21 to 64 years old, and had an ASA status of I-II. The researchers concluded that the combination of both dexamethasone and ramosetron was most effective in prevention of PONV, with 93% of participants showing complete response, followed by ramosetron at 78% and dexamethasone at 70%.

Breast surgery under general anesthesia has been linked to an increased incidence of PONV. It is estimated that 60- 80% of patients having a mastectomy procedure with axillary dissection experience PONV (Fujii, 2006). Dr. Yoshitaka Fujii (2006) reviewed the use of dexamethasone as well as other traditional, non-traditional, and non-pharmacological preventative measures for PONV for women undergoing mastectomy procedures. Fujii concluded that dexamethasone is effective for the prevention of PONV for patients undergoing a mastectomy, especially during the first 24 hours, and that dexamethasone is particularly effective when given in addition to other anti-emetics.

Fujii later used the knowledge gained from the review to collaborate with Dr. Masahiro Nakayama (2007) to conduct a double-blind placebo-controlled trial to determine the effectiveness of dexamethasone for the prevention of PONV and the reduction of analgesic requirement in patients undergoing a mastectomy. Ninety women aged 40-66 with no history of gastrointestinal disease, history of PONV, or motion

sickness were randomly divided into three groups, one receiving 4mg dexamethasone, another 8mg of dexamethasone, and the last a placebo.

Within 24 hours after the procedure, 33% of the dexamethasone 4mg patients experienced PONV, followed by 27% in the dexamethasone 8mg group, and 67% in the placebo group. The use of indomethacin as a pain reliever was requested by 83% of the placebo group, 70% of those who received 4mg dexamethasone, and 45% of the participants who received 8mg dexamethasone. The researchers suggested that dexamethasone at a dosage of 8mg was most effective in decreasing the incidence of PONV and pain in women undergoing general anesthesia for mastectomy.

Motion sickness has been shown to cause an increased risk for PONV in the patient undergoing general anesthesia (Lee, Lai, Lin, Huang, & Lin, 2002). Lee et al.(2002) completed a double-blind, placebo-controlled study in which 168 female patients, half of which had a history of motion sickness, undertaking laparoscopic gynecological surgery were randomly divided into 2 groups and given 8mg of dexamethasone or saline immediately before induction of anesthesia.

The results of the study yielded complete response to dexamethasone in 80.5% of patients with history of motion sickness and 37.5% of patients with history of motion sickness who received saline. In contrast, a complete response to dexamethasone was found in 83.3% of patients without history of motion sickness and 53.7% of those receiving saline. Calculation of efficacy within the subgroups showed dexamethasone was 45.3% more effective in patients with a positive history of motion sickness. In conclusion, Lee et al. found that dexamethasone is effective in both groups of patients

and that there were more favorable outcomes amongst patients who received dexamethasone with a history of motion sickness.

Surgery type and population are not the only risk factors for PONV, the use of narcotic drugs in the perioperative period can increase the risk of PONV. A quantitative study by Young, Yoon, and Jang (2010) compared the use of ondansetron with dexamethasone vs metoclopramide with dexamethasone in patients undergoing gynecologic procedures who were also receiving fentanyl intravenous-patient controlled analgesia. A total of 100 patients were randomly divided into two groups. One group received 5mg dexamethasone after induction, and then was given 4 mg ondansetron at the end of the procedure, while the other group was given 5 mg of dexamethasone after induction with 20 mg metoclopramide at the end of the procedure.

The results of the study found no significant differences between the two treatment modalities. The incidence of PONV was 44% in the group that received ondansetron and dexamethasone, and 38% in the group that received metoclopramide and dexamethasone. Both treatment modalities appeared to be effective in the prevention of PONV.

The practitioner controls when to give medication. Correct timing of administration of medication is essential to achieving the desired effects. Wang, Ho, Tzeng, and Tang (2000) sought to determine optimal timing of the administration of dexamethasone for the prevention of PONV. 120 ASA I-II women ages 35-45 scheduled for total abdominal hysterectomy participated in a randomized, double-blind, placebo-controlled study. Those with a positive history of gastrointestinal disease or prior use of antiemetics in the last 48 hours were excluded. The patients were randomly divided into 3

groups. Group 1 was given 10mg of dexamethasone prior to induction of anesthesia, group 2 received 10 mg dexamethasone after tracheal extubation, and group 3 only received saline. Within 2 hours post-operatively, only 8% of patients in group 1 needed rescue anti-emetics, followed by 30% of group 2 and 35% of group 3. Incidence of PONV during the first two hours post-operatively was present in 15% of group 1, 45% of group 2, and 53% of group 3. During hours 2-24 PONV was reported in 25% of group 1, 28% of group 2, and 55% of group 3. Based on these results, it is clear to see that dexamethasone should be given immediately before induction of anesthesia to achieve maximum efficacy in the prevention of PONV.

In conclusion, numerous studies have indicated that dexamethasone is an efficient drug for the prevention of PONV in women undergoing general anesthesia. Dexamethasone at dosages of 4 and 8mg have both been shown to be effective, and giving dexamethasone as an adjunct to ondansetron or other traditional antiemetics shows favorable results. Evidence supports that dexamethasone is effective at preventing PONV in high risk patients with history of motion sickness. It is most beneficial to give dexamethasone at the induction of anesthesia, rather than at the end of surgery. None of the studies reviewed reported any incidence unwanted side effects.

CHAPTER II

METHODOLOGY

Target Outcome

The desired outcome of this capstone project is to determine whether or not there is a significant difference between the dosages of dexamethasone in regards to the prevention of PONV by completing a retrospective chart review. The knowledge gained could help anesthesia providers determine the most effective dosage of dexamethasone for their patients, which could in turn lead to cost savings by reducing the time spent in the PACU, and result in greater patient satisfaction through the reduction of PONV. If no significant difference is found, one could suggest that 4mg be administered instead of 8mg in order to use less medication.

Population

Fifty patient charts that met the inclusion criteria were selected from patients that had laparoscopic gynecological surgery at a level 2 regional trauma center in the Southeastern United States. Each patient selected received ondansetron during the intraoperative period. English speaking patients who meet the following inclusion criteria were included in the retrospective chart review: those who are female, those who have underwent laparoscopic gynecological surgery and received dexamethasone, those who are non-smokers, and those who are aged 18-60 with an ASA of II or less. Patients that met the following exclusion criteria were not counted towards the chart review: those who are an ASA III or above, those who did not follow the recommended fasting time prior to surgery, those with a history of motion sickness, those with a history of PONV,

those who are taking routine anti-emetics, those whose are deaf, those who are blind, those who are smokers, and those outside the age range for 18-60 years.

Barriers

Clinical limitations to the accuracy of this retrospective chart review could include that some patients are simply more prone to PONV than others. The use of a retrospective chart study does not allow the researchers to give direct interventions, or finely control the amount of drugs and intravenous fluids given throughout the administration of anesthesia. Duration of surgical procedures can also vary, even if the surgeon is performing the same procedure on two different patients. As mentioned earlier, the longer the duration of surgery, the higher risk the patient is for PONV. There was difficulty finding an adequate number of patients that had received 4mg dexamethasone compared to 8mg. Eight mg dexamethasone was used by substantially more providers at the host site. A larger sample could have been obtained had there been a greater number of patients who received 4mg of dexamethasone.

Setting

A regional hospital in the Southeastern United States will serve as the setting for the retrospective chart review. The hospital provides a large variety of surgical services for its surrounding community. There are many surgeons who routinely perform laparoscopic gynecological surgery within the setting. The hospital uses Electronic Patient Integrated Care (EPIC), which is an electronic health record used to store patient records. The use of EPIC was an additional bonus as it provided quick access to numerous medical records allowing the researcher to efficiently collect the sample.

Research Approaches

A retrospective chart review was completed in order to compare the outcomes of the two medications. A retrospective review involves the researcher looking at a group of patients who did or did not experience an event such as PONV. In the case of the study, the incidence of PONV was examined among 2 different groups of patients, one who received 4mg dexamethasone, and the other who received 8mg. A retrospective review prevents the researcher from making direct interactions to the patients being studied. This approach is deemed safe and appropriate as it allows anesthesia providers to care for their patients in the way they prefer, and does not directly influence patient care. Data was collected using the data collection form attached at the end of this paper. All data was de-identified to protect patients' protected private information. Statistical Package for the Social Sciences (SPSS) was used to make a statistical analysis which compared the data by using a chi-square test to determine whether or not there is a significant difference between the two dosages of medications in regards to early PONV.

Sampling

After given approval by the Institutional Review Board (IRB) at The University of Southern Mississippi and the capstone setting, a retrospective chart review was completed in order to collect data. Patients' charts were searched using EPIC software. Patient sensitive information was not recorded. The patient summary page on EPIC was first used to see if the patient met the inclusion criteria. This page gives general demographic information on the patient, and gives a snapshot of their overall health such as co-morbidities, age, history of PONV or motion sickness, smoking status, and ASA score as given by the anesthesia provider that interviewed them prior to their procedure.

Once that patient was deemed to have met all inclusion criteria and none of the exclusion criteria, the intraprocedure record was accessed. The intraprocedure flowsheet provided the researcher with the anesthetic agent used, amount of dexamethasone given, amount of neostigmine given, intravenous fluids given, duration of anesthetic, and whether or not ondansetron was given intraoperatively. After the patient was deemed to have been given the appropriate intraoperative regimen for the study, the researcher then viewed the PACU flowsheet record to the PACU in and out times. The electronic medication administration record (EMAR) was then accessed to determine if any ondansetron or promethazine was given during the patient's time in the PACU. This served as an indicator for the researcher for PONV in the PACU because these medications are only given if the patient is experiencing nausea or vomiting.

In summary, de-identified relevant data, including patient age, gender, race, anesthetic agent used, intravenous fluid administered, duration of anesthetic, and the occurrence of early PONV in the post anesthesia care unit as evidenced by the administration of rescue anti-emetics ondansetron and promethazine was collected. Fifty patient charts were reviewed to compare dosages of dexamethasone used for each patient. The two samples, one consisting of patients receiving 4mg dexamethasone, and the other consisting of patients receiving 8mg of dexamethasone, were compared. Frequency of PONV in the PACU among ages 18-30, 30-40, 40-50, and 50-60 was recorded. PONV in the PACU amongst race and inhalation agent used were also examined. Pre-op medications were also recorded as well as past history of PONV and motion sickness. Intraoperative fluids given, amount of neostigmine, ondansetron, and dexamethasone administered were also recorded and analyzed.

The pre-existing data collected from the healthcare facility for the project contained protected patient health information. All information was kept confidential throughout the collection and analysis of data. Patient identifiers such as the patient medical record numbers were not recorded. After all data was recorded and statistical analysis was completed, all data collection forms were shredded as requested by the IRB.

CHAPTER III

ANALYSIS OF DATA

The goal of this capstone project was to perform a retrospective chart review to determine whether or not there was a significant difference between two dosages of dexamethasone in the prevention of PONV in the PACU. A Pearson's chi-square test was used to determine whether or not there was a statistical significant difference. Demographic data was also collected as well as incidence of PONV among dosages of neostigmine and anesthetic agents used.

Statistical Analysis

A Pearson's chi-square test was completed using SPSS to make a statistical analysis. The chi-square test helps distinguish whether or not there is a statistically significant difference when comparing two different groups receiving the same interventions. The chi-square test can provide the probability that the outcome and exposure of an event are independent (Peat, Barton, & Elliott, 2012). In this particular case, the fisher's exact value was the most relevant value due to the fact that the incidence of PONV was less than 5 in each group. The Fisher's exact test is generally used when one or more cells in a 2 x 2 table have an expected count of less than 5 (Peat, Barton, & Elliott, 2012). A hypothesis and null hypothesis were created for the capstone project. The hypothesis stated that there is a decreased incidence of early PONV in patients receiving 8mg of dexamethasone vs 4mg of dexamethasone. The null hypothesis stated that there is not a decreased incidence of early PONV in patients receiving 8mg of dexamethasone vs 4mg of dexamethasone. The level of significance α a probability of rejecting a true null hypothesis. An α value of 0.05 was used to analyze the data.

Results

The retrospective review was completed at the approved healthcare facility in the Southeastern United States. A convenience sample of 50 charts spanning February 2015 to September 2015 were analyzed. Inclusion criteria included those who are female, those have underwent laparoscopic gynecological surgery and received dexamethasone, those who are non-smokers, and those who are aged 18-60 with an ASA of II or less. Exclusion criteria were not counted towards the chart review: those who are an ASA III or above, those who did not follow the recommended fasting time prior to surgery, those with a history of motion sickness, those with a history of PONV, those who are taking routine anti-emetics, those whose are deaf, those who are blind, those who are smokers, and those outside the age range for 18-60 years. All data was de-identified during the collection process and destroyed after data analysis was complete. The following tables summarize demographic data and findings within the sample group. Patient ages, ethnicity, inhalation agent used, and amount of neostigmine were all examined.

Table 1

Patient Age and Incidence of PONV

Age	PONV 4mg	No PONV 4mg	PONV 8mg	No PONV 8mg
18-29	1	1	0	1
30-39	0	10	0	9
40-49	1	7	3	8

Table 1 (continued).

50-60	0	5	0	4

Of the 50 patients examined, most of the patients fell between the age groups of 30-49. This was anticipated before data collection began, as with most laparoscopic GYN procedures such as hysterectomies and tubal ligations are performed on this age group. Ethnicities of the recorded sample is illustrated in Table 2.

Table 2

Incidence of PONV among Ethnicity

Ethnicity	PONV 4mg	No PONV 4mg	PONV 8mg	No PONV 8mg
White	1	18	3	17
Black	1	5	0	5

Table 3

Incidence of PONV among Inhalation Agent

Inhalation Agent	Sevoflurane	Desflurane
PONV	2	3
No PONV	35	10

The use of sevoflurane at the capstone project data collection facility was clearly the inhalation agent of choice by the anesthesia providers. It is interesting to note that a large proportion of the patients who received desflurane experienced PONV in the PACU. 23% of those who received desflurane experienced PONV, while only 5.4% of those who received sevoflurane were positive for PONV in the PACU. The researcher took notice of this outlier, however, due to the small sample size of this capstone, it would not be a good candidate for statistical analysis of PONV among anesthetic agent used.

Below, table 4 shows the amount of the paralytic reversal drug neostigmine was given to each patient. Neostigmine is the most commonly used paralytic reversal agent used, but it is believed to increase the incidence of PONV (Nagelhout & Plaus, 2014). In the 5 incidences of PONV, 3 received 3 mg of neostigmine, and 2 received 4 mg of neostigmine. It is interesting to note that the 6 patients from this sample who received 5 mg of neostigmine, which is the maximum recommended dosage, did not experience PONV.

Table 4

Total Neostigmine Patients Received

Neostigmine (mg)	PONV	No PONV
0	0	9
1	0	1
2	0	4
3	3	11

Table 4 (continued).

4	2	14
5	0	6

The data presented in table 5 below is indicative of the sample used in this study. There were a total of 50 subjects analyzed during this retrospective chart review, 25 patients receiving 4mg of dexamethasone and 25 patients receiving 8mg of dexamethasone. The incidence of PONV in the PACU occurred almost equally across groups. 2 patients receiving 4mg experienced PONV while 3 patients receiving 8mg experienced PONV. This accounts for 8% and 12 % of the groups being analyzed respectively. Of all the patients measured from the population, 10% of the total experienced PONV in the PACU

Table 5

Dexamethasone PONV Cross Tabulation

			PONV		
			Yes	No	Total
Dexamethasone	4mg	Count	2	23	25
		% within Dexamethasone	8.0%	92.0%	100.0%
		% within PONV	40.0%	51.1%	50.0%
		% of Total	4.0%	46.0%	50.0%

Table 5 (continued).

8mg	Count	3	22	25
	% within Dexamethasone	12.0%	88.0%	100.0%
	% within PONV	60.0%	48.9%	50.0%
	% of Total	6.0%	44.0%	50.0%
Total	Count	5	45	50
	% within Dexamethasone	10.0%	90.0%	100.0%
	% within PONV	100.0%	100.0%	100.0%
	% of Total	10.0%	90.0%	100.0%

The Pearson's chi-square test below, where (N=50, df=1)= .222, p=.067, allows the researcher to determine whether or not there is a statistically significant difference between the two different dosages of dexamethasone in regards to PONV in the PACU among the sample. The chi-square test for association was completed. Since two of the cells were less than 5 due to the incidence of PONV being low, there was no statistical association using the Pearson Chi-Square value. Instead, the Fisher's Exact Test was used in which it yielded a 1.0 on the 2 sided test and a 0.500 on the 1 sided test. These results yielded no statistically significant relationship among the two dosages of dexamethasone in the reduction of PONV.

Table 6

Chi Square Tests

	Value	df	Asymptotic Significance (two-sided)	Exact Sig. (two-sided)	Exact Sig. (one-sided)
Pearson Chi-Square	.222[a]	1	.637		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.224	1	.636		
Fisher's Exact Test				1.000	.500
Linear-by-Linear Association	.218	1	.641		
N of Valid Cases	50				

a. df=degrees of freedom. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.50.

b. Computed only for a 2x2 table

CHAPTER IV

SUMMARY

The purpose of this capstone project was to complete a retrospective chart review to help determine whether or not there was a significant difference between two dosages of dexamethasone and the reduction of PONV in the PACU. After all data was analyzed, it was concluded that there was no statistically significant difference between the incidences of PONV in the PACU among the sample provided. It is interesting to note that of the 13 patients that were given desflurane, 23% experienced PONV in the PACU. Of the 50 patients in the sample, only ten percent experienced PONV in the PACU. As stated earlier, PONV affects as much as 20% to 80% of patients undergoing surgery. This was a relatively lower than expected total due to the fact that the women analyzed in the study were considered having a very high risk for PONV.

Recommendations

Although the sample size was relatively small and only covered a short time period, it is recommended that the findings of this paper be further investigated, especially in terms of PONV and anesthetic agent being used. According to the clinical site pharmacy, dexamethasone is supplied to the clinical site in single dose 4mg vials that cost $2.50 per vial. While this is not a high cost for a single administration, the compounded cost of thousands of vials could be substantial, especially at a busy surgery center. One could argue that since there was no statistically significant difference between the two dosages of dexamethasone in this sample, that the anesthesia provider administer just 4mg of dexamethasone for the prevention of PONV in order to conserve

medication and reduce overall costs. This point can further be argued since there are studies reporting that 4mg of dexamethasone has been found to be just as effective in the reduction of PONV as 8mg. However, as all anesthesia providers know, not all cases call for the same medication regimens. For procedures where swelling may be a concern, giving 8mg of dexamethasone may be more suitable since it would aid in the reduction swelling and still help reduce PONV.

Conclusion

In conclusion, this retrospective chart review produced no statistically significant difference between 4mg of dexamethasone and 8mg of dexamethasone in the reduction of PONV in the PACU within the sample provided. One could argue based on this sample that the administration of 4mg was just as efficient as 8mg in the reduction of PONV. If supply is low or cost is an issue, the use of 4mg dexamethasone could be used as an effective adjunct in anti-emetic therapy. Currently, PONV will continue to be a problem for patients undergoing surgery. A holistic approach in the prevention of PONV, where fluids are monitored, amount of neostigmine is considered, and appropriate receptors in the CTZ are blockaded is a good approach for anesthetist in the prevention of PONV.

APPENDIX A

FORREST GENERAL HOSPITAL IRB APPROVAL LETTER

FORREST GENERAL HOSPITAL

DATE:	June 12, 2015
TO:	Steven Doyle, BSN Nursing
FROM:	Forrest General Hospital Institutional Review Board
STUDY TITLE:	[766250-1] Is Intravenous Dexamethasone 4mg a More Effective Anti-Emetic than Dexamethasone 8mg for the Prevention of Early Post-Operative Nausea and Vomiting in Women Undergoing Laparoscopic Gynecological Surgery?
IRB REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	June 10, 2015
REVIEW CATEGORY:	Exemption category # *B4*

Thank you for your submission of New Project materials for this research study. Forrest General Hospital Institutional Review Board has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will put a copy of this correspondence on file in our office.

If you have any questions, please contact Michele Stanley at 601-288-4324 or mstanley@forrestgeneral.com. Please include your study title and reference number in all correspondence with this office.

APPENDIX B

THE UNIVERSITY OF SOUTHERN MISISSIPPI IRB APPROVAL LETTER

THE UNIVERSITY OF
SOUTHERN MISSISSIPPI

INSTITUTIONAL REVIEW BOARD
118 College Drive #5147 | Hattiesburg, MS 39406-0001
Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
  Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 15072003
PROJECT TITLE: Is Intravenous Dexamethasone 4mg a More Effective Anti-Emetic than Dexamethasone 8 mg for the Prevention of Early Post-Operative Nausea and Vomiting in Women Undergoing Laparascopic Gynecological Surgery?
PROJECT TYPE: New Project
RESEARCHER(S): Steven Blake Doyle
COLLEGE/DIVISION: College of Nursing
DEPARTMENT: Advanced Practice/Anesthesia
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Expedited Review Approval
PERIOD OF APPROVAL: 09/14/2015 to 09/13/2016
Lawrence A. Hosman, Ph.D.
Institutional Review Board

APPENDIX C

DOCTOR OF NURSING PRACTICE ESSENTIALS

The Essentials of Doctoral Education of Advanced Nursing Practice

I. Scientific Underpinnings for Practice

- The use of prescriptive theory to assess cause and effect relationships. The administration of dexamethasone 4mg vs 8mg in the prevention of PONV uses cause and effect relationships to draw a conclusion based on patient outcomes. The knowledge gained from these outcomes can be used to influence anesthesia practice.

II. Organizational and Systems Leadership for Quality Improvement and Systems Thinking

- Research supports that the use of dexamethasone is effective in the prevention of PONV. The use of dexamethasone for prevention of PONV could improve patient outcomes, and quality of hospital stay when the patient does not suffer from symptoms of PONV.

III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice

- Evidence supports that dexamethasone decreases the incidence of PONV in women undergoing general anesthesia. Once the retrospective chart review is completed, data collected could influence current practice.

IV. Information Systems/Technology and Patient Care Technology for the Improvement of Transformation of Health Care

- The use of research databases searched during the literature review will provide evidence used to help determine best practice use of

dexamethasone for the prevention of PONV. The use of EPIC during the retrospective chart review will also put emphasis on patient care technology.

V. Health Care Policy for Advocacy in Health Care

- Evidence shows that dexamethasone prevents PONV in women undergoing general anesthesia. This information could help influence anesthesia providers to create facility policies involving the use of dexamethasone for the prevention of PONV.

VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes

- At the conclusion of the capstone projects, interprofessional collaboration will occur as the results are shared with local anesthesia providers that could be used to improve patient population health outcomes.

VII. Clinical Prevention and Population Health for Improving the Nation's Health

- PONV is a common occurrence in the surgical setting, and is more likely to occur in women undergoing general anesthesia. Decreased incidence of PONV will reduce costs for the patient and healthcare facility providing care. The use of dexamethasone can help achieve this.

VIII. Advanced Nursing Practice

- This capstone puts emphasis on the use of the evaluation of evidence-based literature to make a clinical decision for treatment in the prevention of PONV demonstrating advanced levels of clinical judgment to improve patient outcomes.

APPENDIX D

ASA PHYSICAL STATUS CLASSIFICATION SYSTEM

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BM < 40), well controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part) (American Society of Anesthesiologists, 2015)

APPENDIX E

DATA COLLECTION FORM

Identification # _____ Procedure Date __/__/____

Age _____ Sex M / F Ht. _____ Wt. _____ BMI _____

Ethnicity _____ Smoker Y/N ASA _____

Current Medications

_____

Past Medical History_____

Past Anesthesia Complications

_____

Preoperative Medications_____

Anes Start _____ Anes End _____ Total Anes _____

Surgery Start _____ Surgery End _____ Total Surgery _____

Intraoperative:

ETT size_____ Inhalation agent used _____

Time	Medication	Dose
	Ondansetron	
	Dexamethasone	
	Neostigmine	

IVF type: _____

EBL _____ml

PACU:

PACU Vital Signs:

BP _____ HR _____ Temp _____

PACU time in: _____

Time	Medication	Dose
	Ondansetron	
	Promethazine	

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