

SCHOLARLY PROJECT: SUGAMMADEX AND HORMONAL BIRTH CONTROL
EDUCATION

By

Madison Gallo

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Approved By:

Lufei Young, PhD, ACNP-BC
School of Nursing

Zhuo Job Chen, PhD
School of Nursing

Danielle Brown DNAP, CRNA
CMC Nurse Anesthesia Program Faculty

Scott Strassels, PharmD, PhD
Atrium Health

Crystal Piper, MPH, MHA, PhD
Public Health Sciences Department

ABSTRACT

MADISON GALLO. Scholarly Project: Sugammadex and Hormonal Birth Control Education.
(Under the Direction of DR. LUFEI YOUNG, PH.D., ACNP-BC)

Background

Sugammadex is one of the most used agents to reverse surgery induced neuromuscular blockade. It also reduces hormonal contraceptive effectiveness. There is limited evidence about developing effective education of the interaction between Sugammadex and birth control pills in post anesthesia care unit (PACU) nurses who are responsible to provide discharge education to patients taking hormonal contraceptives.

Purpose

The purpose of the project is to examine the effect of a web-based education on PACU nurses' awareness and knowledge about the interaction between Sugammadex and hormonal contraceptives.

Methodology

A quasi-experimental study with pretest posttest design was conducted in a southeast healthcare facility. An animated educational video was designed to enhance the knowledge about the interaction between Sugammadex and hormonal contraceptives. An online survey was performed to assess the change of pre and post education knowledge score.

Results

The study included 27 PACU nurses. Age was associated with pretest score ($b = 0.04$, $p = .010$). Older participants were likely to have higher pre-intervention score. There was a significant pretest -posttest difference on Question 1 (the mechanism of action of Sugammadex) ($\chi^2 = 7.72$, $p = .005$) and total score (3.93 ± 1.00 vs. 4.55 ± 0.67 , $t = 2.81$, $p = .011$).

Conclusion

The web-based education is effective to improve PACU nurses' knowledge of the drug interaction between Sugammadex and hormonal contraceptives. The finding may help the development of discharge teaching in surgical patients taking hormonal contraceptives.

Keywords: Sugammadex, hormonal contraceptives, post anesthesia care unit (PACU) nurses

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LIST OF ABBREVIATIONS

PACU	Post Anesthesia Care Unit
PICO	Population, Intervention, Control, Outcomes
QR	Quick Response
SPO	Structure, Process, Outcome
CRNA	Certified Registered Nurse Anesthetist

CHAPTER I: INTRODUCTION

1.1 Background and Significance

Sugammadex is a drug that provides a rapid and dose-dependent reversal of profound neuromuscular blockade. More specifically, Sugammadex is a cyclodextrin that binds selectively to the steroidal neuromuscular blocking agents where it encapsulates and inactivates the neuromuscular blocking agent in the plasma, rendering it incapable of binding with receptors. Sugammadex is the most ideal reversal agent on the market right now due to its ability to reverse any depth of neuromuscular blockade. Dubovoy et al. (2020) developed a retrospective observational study conducted across 24 institutions in the United States to discover the prevalence of Sugammadex use. Researchers discovered that out of 934,798 cases that received a neuromuscular blocking agent, an average of 40% of the cases were administered Sugammadex.

Sugammadex is a highly effective neuromuscular blocking reversal agent, but it has one very important drug-drug interaction: hormonal contraception. Similar to the effects Sugammadex has on neuromuscular blocking agents, it also binds progesterone with a strong affinity and may reduce the efficacy of hormonal contraceptives. According to Hartman et al. (2019), “this interaction binds the prostatic compound found in many hormonal contraceptives, decreasing the plasma level of progesterone” (p. 352). Richardson and Raymond (2020) state “studies indicate that Sugammadex binds progesterone, thereby reducing hormone levels to an extent that is equivalent to missing doses of oral contraceptives” (p. 1632). The FDA label for Sugammadex contains a warning, advising that women taking hormonal contraception use a back-up contraceptive method or abstinence for seven days after exposure to Sugammadex. According to Daniels and Abma (2018), approximately 26% of women aged 15 to 49 use hormonal birth control and “the most common contraceptive methods currently being used were

female sterilization (18.6%), oral contraceptive pill (12.6%), long-acting reversible contraceptives (10.3%), and male condoms (8.7%)” (p. 2). Lazorwitz et al. (2019) conducted a retrospective chart review at the University of Colorado Hospital and found the following:

Where out of 1000 charts reviewed, 134 were found to be women utilizing hormonal contraception at the time of Sugammadex exposure. After review of the documentation, it was revealed that only one patient received counseling. They also found one patient who did not receive education regarding Sugammadex endured an unintended pregnancy within three months of Sugammadex administration (p. 296).

Unintended pregnancy can have serious health consequences to the mother and the baby. These health risks include low birthweight, increased risk of postpartum depression, and physical or psychological abuse. “Up to half of women who experience pregnancy due to contraception failure opt for termination” (Richardson & Raymond, 2020, p. 1633). Pregnancy termination may be accompanied by psychological discomfort, depression, and posttraumatic stress disorder in addition to facing escalating access difficulties (Richardson & Raymond, 2020).

Approximately 37% of pregnancies resulting in live births in the U.S. are unintended (Mosher et al., 2012). The effects of an unintended pregnancy on one's health, finances, and relationships if carried to term are also significant (Richardson & Raymond, 2020). According to the World Health Organization (2019), “globally, 74 million women living in low and middle-income countries have unintended pregnancies annually. This leads to 25 million unsafe abortions and 47,000 maternal deaths every year.” According to The Commonwealth Fund, maternal morbidity conditions such as hypertensive disorders, hemorrhage, gestational diabetes mellitus, and mental health conditions cost around 32.3 billion dollars from conception through age five, with the healthcare system enduring over half of these costs (O’Neil et al., 2021).

Monea and Thomas (2011) state “taxpayers financed a total of about 1.25 million unintended pregnancies in 2001 and that the average cost per publicly financed unintended pregnancy ranges from about \$7,700 to about \$10,000” (p. 90).

1.2 Problem Statement

Women of childbearing age who receive Sugammadex perioperatively are not receiving proper education about the need for secondary birth control for up to seven days postoperatively. One of the reasons patients do not receive proper medication education is the lack of knowledge, competency, and confidence in post-anesthesia care unit (PACU) nurses when it comes to providing patient medication education (Dahlberg et al., 2022). Unintended pregnancy may occur in women of reproductive age who receive Sugammadex during the perioperative period and who are not properly informed about the need for supplemental birth control for up to seven days after the procedure. At the study site, there were no standardized and evidence-based guidelines specifying nursing education regarding the delivery of discharge instructions about Sugammadex drug interactions.

1.3 Purpose of the Project

To address these clinical issues, the purpose of this project was to examine the effectiveness of a web-based provider education program on PACU nurses’ knowledge about the drug-drug interaction between Sugammadex and hormonal contraception. The project was to highlight the need for a standardized web-based education program centered around Sugammadex and its adverse effects on hormonal contraceptives. Empowering nurses with proper education can lead to accurate dissemination of discharge teaching and ultimately promotes positive patient outcomes.

1.4 Clinical Question

Compared to current nursing education, is a web-based education program more effective at improving the knowledge on the drug-drug interaction between Sugammadex and hormonal contraception in PACU nurses who are providing Sugammadex discharge teaching for childbearing age women?

CHAPTER II: LITERATURE REVIEW

2.1 Existing Guideline and Education Program

While it seems intuitive to educate patients and nurses about the risks of pregnancy after receiving Sugammadex, there is a lack of a formalized process to address the issue of effective postoperative discharge teaching regarding Sugammadex and hormonal birth control. Three articles in current literature suggest an education program designed to improve nurses' knowledge and counseling rate regarding drug-drug interactions with hormonal contraceptives (Hartman et. al., 2021; O'Driscoll & Parrott 2019; David et al., 2023). In a performance improvement project conducted at a Naval Hospital the investigators looked at the efficacy of an interactive education program to improve knowledge and confidence among peri anesthesia nurses and after education was provided, they found a significant increase in confidence scores among the participants (O'Driscoll & Parrott, 2019). Hartman et al. (2021) found similar results in their study of 59 post anesthesia care unit (PACU) nurses at a tertiary hospital. David et al. (2019) conducted a similar study with a different drug that affects hormonal contraception, Aprepitant (Emend), and found a significant increase in nursing knowledge after implementing an educational in-service.

The results of these studies indicate that delivering a standardized educational program may enhance the PACU nurses' capacity to communicate important details regarding drug-drug interactions such as the requirement that patients utilize a supplementary method of birth control. Expanding the search to find education programs designed to teach nursing staff about drug interactions with contraceptives proved to be unsuccessful. This suggests a gap in the literature and a need for the implementation of a standardized process aimed at increasing nurses' knowledge regarding drug-drug interactions.

2.2 Evaluation of Effectiveness

Researchers implemented a pre and posttest design to assess knowledge improvement among PACU nurses (Hartman et. al., 2021; O'Driscoll & Parrott 2019; David et al., 2023). The questions were the same for the pretest and posttest. All studies performed immediate posttest following a face-to-face educational in-service and subsequent posttest to assess for long-term learning. O'Driscoll and Parrott (2019) performed their subsequent posttest 2 weeks following education in contrast to David et al. (2023) who performed theirs 90 days after education. The longest duration between education and subsequent post testing was performed by Hartman et al. (2021) at 30 weeks. O'Driscoll and Parrott (2019) and David et al. (2023) employed a multiple-choice format with five questions via paper format and seven questions sent out via email, respectively. In contrast, Hartman et al. (2021) developed a five question 5-point Likert scale to assess nursing knowledge via email. All the studies showed increased scores on the posttests as compared to the pretests. Utilizing the pretest-posttest design, researchers were able to conclude that educational in-services empower PACU nurses with the knowledge and confidence to provide effective discharge teaching. The addition of subsequent post testing further proved the longevity of the educational sessions.

2.3 Effectiveness of Web-based Programs

Technology advancements like web-based education have improved nurses' ability to learn new information by offering engaging content in a flexible setting. The abundance of computer-facilitated learning alternatives suggests that nurses are becoming more interested in this type of learning. Berger et al. (2009) conducted a study and gave the participants the choice between a web-based format versus a face-to-face format and out of 1661 participants, 1544 chose the web-based training style. Learner's enjoyment of the material is essential to their

participation and motivation of learning new concepts. Several studies found that learners who participated in web-based continuing education conveyed satisfaction with the educational format (Harris et al., 2022; Moattari et al., 2014; Berger et al., 2009). In a study involving around 6,000 participants, over 80% indicated satisfaction with the web-based training (Harris et al., 2022). Likewise, a Quasi-experimental research study was performed across 5 teaching hospitals and discovered similar satisfaction rates among participants regarding the web-based training format at over 80% (Moattari et al., 2014). Berger et al. (2009) questioned participants on their satisfaction with the web-based training and the results were 72% of participants indicated that they were satisfied. However, Rosvall and Carlson, (2017) and Bond et al. (2017) experienced criticism from their participants noting a lack of face-to-face interaction with colleagues and received suggestions for combining both formats for the best educational experience.

Not only are web-based programs favored for their flexibility, but they are also a cost-effective alternative to traditional face-to-face learning. Multiple studies have shown that web-based programs offer a beneficial alternative to classroom teaching (Berger et al., 2009; Rosvall & Carlson, 2017; Lim & Yeojin, 2021). Due to the large number of nurses needing continuing education, Berger et al. (2009) found that web-based training was the most cost-effective method. Utilizing a convergent mixed-method design, Rosvall and Carlson (2017) also discovered that educating large groups through web-based training is the most flexible and cost-effective strategy. Researchers also found “learning in digital environments allows the individual to study at his/her own pace since the educational material is available 24 hours a day” (Rosvall & Carlson, 2017, p. 4778). In a randomized control trial conducted across three hospitals, Lim and Yeojin (2021) found “unlike offline training, web-based education has the advantages of greater accessibility and self-directed repetitive learning without limitations regarding time and

place” (p. 2). Web-based learning offers many advantages to learners and facilities and is seen as an effective means of education.

Reaching the target audience effectively is vital to assure their competency so they can deliver patient-centered care. Liaw et al. (2016) found that the knowledge and abilities of hospital nurses in assessing, managing, and reporting were dramatically improved by a web-based educational program. Several studies found that in comparison to face-to-face learning, web-based learning was just as effective (Berger et al., 2019; Lahti et al., 2014). Berger et al. (2019) discovered that “the achievement of learning objectives with web-based instruction has been reported to be similar with that of traditional face-to-face instruction for equivalent participants” (p. 128). Lahti et al. (2014) found that there were no statistically significant differences between the web-based learning participants and the face-to-face learning participants in terms of comprehension. Nursing comprehension is the first step in ensuring effective patient comprehension of discharge teaching.

2.4 Development and Implementation of Patient Education

There are barriers preventing patients from understanding the side effects of Sugammadex. One obstacle is the timing of discharge teaching. According to Hartman et al. (2021), anesthesia providers do not know if Sugammadex will be given until the time of surgery which leads to inconsistency in discharge teaching to women of childbearing age. Patients receive many medications throughout the perioperative area which leads to unpredictable recall. Hospitals are challenged to determine when teaching is most effective and at what point of the perioperative continuum should these patients receive this vital information. “Current recommendations are to wait up to two hours after the end of anesthesia

to deliver discharge instructions and that verbal instructions should be supplemented with written instructions” (Hartman et al., 2021, p. 352).

Given the various degrees of health literacy among patients and caregivers, understanding discharge instructions is a crucial factor to consider. DeSai et al. (2021) states, “studies have shown that approximately one-third of Americans have low health literacy” (p. 1). A patient’s health literacy can determine whether they are compliant with discharge instructions. In this instance, non-compliance can lead to adverse events, such as pregnancy. There have been many studies aimed at uncovering effective discharge teaching strategies. Implementing standardized discharge processes that focus on nurse’s expertise in the delivery of postoperative teaching is important for patient retention.

One method that has been supported by substantial evidence is the teach back method. This approach involves asking patients to rephrase teaching material previously discussed to determine adequacy of teaching. This method has been shown to significantly increase patient comprehension, validate information, and enhance health outcomes (Nurhayati et al., 2019; Hartman et al., 2021). In addition to the teach back method, written instructions are a great supplement and resource for patients upon discharge. “The Joint Commission recommends a fifth grade reading level for all health care documents” (Hartman et al., 2021, p. 352). Simplicity is a crucial component in enhancing comprehension of discharge materials. To categorize discharge instructions, simplification is characterized as using shorter sentences, simpler terms, bullet points, and bolded font (Choudhry et al., 2019). Simplifying discharge instructions, eliminating medical jargon, and utilizing the teach back method are all effective strategies for increasing patient comprehension and ultimately decreasing the risk of adverse events.

2.5 Conceptual/Theoretical Framework

Donabedian's quality framework, also known as Structure-Process-Outcome (SPO), was used to guide this quality improvement project. The SPO model has been widely utilized in healthcare quality research for six decades (Ayanian & Markel, 2016). This model is flexible and comprehensive enough to be applied in various healthcare organizations. It consists of three interrelated concepts. First, the structures of healthcare are defined as the physical and organizational aspects of care settings. Second, the processes of patient care are positioned in the middle of the model because they rely on the structures to provide resources and mechanisms for healthcare providers to carry out patient care activities. The third concept, on the far right, is the outcomes of patient care.

In the context of this project, the 'structure' referred to the level 1 trauma center PACU selected for this study. The 'process' involved developing and implementing a web-based education program on the drug-drug interaction between Sugammadex and hormonal contraceptives. Therefore, the specific 'outcome' was the increased nursing knowledge (see Appendix B). Patient outcomes depend on the quality of care delivered to the patients. Discharge teaching plays a vital role in providing high-quality care to surgical patients. It is reported that the frequency and quality of discharge teaching is significantly associated with the knowledge and competency of PACU nurses regarding drug information (Hayajneh et al., 2020). To improve patient outcomes, an online education program was developed to enhance PACU nurses' knowledge, competency, and confidence in providing accurate, evidence-based, and patient-centered discharge drug education.

CHAPTER III: METHODS

3.1 Study Design

A quantitative, quasi-experimental project was conducted using a pretest posttest design. The project included 3 phases: 1) pre-education survey, 2) web-based education session, and 3) post-education survey. The purpose of this project was to examine the effectiveness of a web-based provider education program on PACU nurses' knowledge regarding the drug-drug interaction between Sugammadex and hormonal contraception. The project investigated the following PICOT question: Compared to current nursing education (C), is a web-based education program (I) more effective in improving knowledge about the drug-drug interaction between Sugammadex and hormonal contraception (O) in PACU (T) nurses who provide discharge teaching for childbearing age women receiving Sugammadex (P)? The scores on pre- and post-education tests were compared to assess intervention effect. SQUIRE 2.0 guidelines were used to organize and report project findings (SQUIRE, 2020). Institutional Review Board approvals were obtained from both the study site and the university prior to the implementation of the project (Appendix C and D).

3.2 Sample/population

The study used a convenience sample that consisted of approximately 45 PACU nurses at a level one trauma center. The reason PACU nurses were chosen as the study participants was that PACU nurses primarily provided patient education at discharge. The hypothesis was that increased knowledge among PACU nurses about the drug interaction of Sugammadex might lead to a higher quality and frequency of patients' education on drug interactions prior to discharge. This, in turn, could potentially reduce preventable birth control failures due to a lack of awareness about the need for a secondary form of birth control for up to seven days after the

administration of Sugammadex. The study included PACU registered nurses with any amount of experience working full or part time in the adult PACU. The study excluded registered nurses employed in the pediatric PACU and any ancillary staff who was not responsible for patient discharge teaching.

3.3 Setting

This quality improvement project was implemented at a level one trauma center in the southeastern United States. The level one trauma center has 874 total beds and performs approximately 150 anesthetics per day throughout 37 operating rooms and over 20 non-operating room anesthesia (NORA) sites. The adult PACU consists of 37 beds. Historically, Sugammadex has been used approximately 1,500 times per year in female patients between the ages of 18-65 at this hospital.

3.4 Intervention

For the web-based education, an animated educational video was designed. The website Animaker (2015) was used to create the animated educational video. Animaker is a video animation software that utilizes fully customizable characters and templates that users can produce animated videos with. Once the animated educational video was created it was embedded into Survey Monkey. The video began with an introduction to Sugammadex, followed by Sugammadex's mechanism of action, side effects, drug-drug interactions, and patient teaching recommendations. The video consisted of sound and subtitles to accommodate different learning styles. The content validity of the education intervention was established by the dissertation committee member who was a licensed pharmacist with doctoral level education and extensive teaching experience, as well as Certified Registered Nurse Anesthetist (CRNA) faculties. The video was available in English. It took participants approximately five minutes to complete.

Participants accessed the video via a quick response (QR) code with a smartphone device.

Participants were given six weeks to access the educational session.

The following strategies were used to enhance and maintain the intervention fidelity. For study design, a clear and detailed intervention protocol was developed that outlined specific education components and expected outcomes. Standardized education materials that align with the intervention protocol was developed. To improve the intervention fidelity, all team members participated in developing online surveys and web-based education modules. To ensure the delivery and receipt, the average time spent on completing the online education modules was regularly monitored and scheduled team meetings were used to identify and troubleshoot any challenges encountered by the participants in completing the online learning module. Emails were sent to encourage active participation and completion and provided guidance on how to access the web-based learning module. The emails also identified areas that may need further clarification. For enactment, the online animated video encouraged participants to apply the knowledge and skills they gained into their clinical practice. By addressing each of these components in the design, training, delivery, receipt, and enactment stages of the educational intervention, the intervention fidelity was improved, ensuring that the intervention was implemented as intended and produced meaningful outcomes.

3.5 Data Collection

Both pre- and post-education surveys were constructed to collect participants' demographic and clinical information including gender, age, years of experience, and educational background. The subsequent portion of both surveys comprised five questions to assess PACU nurses' knowledge of Sugammadex, its effects on hormonal contraception, and their current practice in providing Sugammadex related discharge teaching. One question was in

yes or no format, whereas the other four questions were multiple choice format (See Appendix A). A scoring system was utilized to quantitatively measure the survey responses. All surveys were scored the same. A correct answer was given a one and an incorrect answer was given a zero. The content validity of the surveys was confirmed by all committee members and CRNAs before being distributed. The pre-education survey was administered among PACU nurses before the education intervention to assess their baseline knowledge of Sugammadex. Survey Monkey was used to create and administer surveys. The users had access to the pre-education survey test by scanning the provided QR code. Following the pre-education survey, participants completed self-paced online educational material. Immediately following the educational session, participants were prompted to complete a post-education survey, which was identical to the pre-education survey. The survey results were collected electronically via a QR code that was linked to Survey Monkey's website. All responses submitted through Survey Monkey were confidential and collected in real time. Once the data collection period ended, all responses were made anonymous.

To increase participation and completion rates, weekly emails were sent out. Once a week, an email was sent to the PACU manager providing an update on the project's current participation count. The PACU manager encouraged staff to participate during their daily huddle sessions. At the study site, there were 45 total PACU nurses. Twenty-seven participated in the project. Out of these 27 participants, 22 completed both the pre and posttest. The completion rate was 81% at the study site.

3.6 Data Management and Security

The online education module was preset to only show the computer IP address the participants used to complete the learning module. Each participant was assigned a unique study

ID, which was used for data entry, tracking, and analysis. Each participants' ID was stored in a secured, IRB approved web-based folder. This web-based folder is password protected and only accessible by the project personnel. A consent form was provided to participants prior to completing the module. This consent informed participants that their years of experience and provider role will be used for study purposes. Participants were reassured that their identity remained confidential and secure.

Furthermore, Survey Monkey, an online password protected site, was utilized to store data. Survey Monkey was only accessible to the project personnel, the sponsor of this research, IRB, and any other persons required by law. Both university and the participating healthcare facilities shared a uniform policy on the protection of patient privacy that satisfied all the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The project team abided by both organizations' policies, and strictly adhered to the detailed human subject protection regarding data analysis, which was utilized throughout this project period to preserve participants' privacy and security. Participants were provided the option to opt out of participating in the project.

3.7 Data Analysis/evaluation plan

All statistical analyses were performed using R version 4.0.2 with a significance level of 0.05 (De Micheaux, 2013). Pre-analysis data screening was performed prior to statistical analysis to examine coding errors, outliers, and data skewness to determine if any data cleaning procedures were needed. Coding errors often occur when the questionnaires are used as assessment tools. To reduce coding errors, the statistician was consulted, and statistical procedures were used to recode the study questionnaires. Additionally, the missing data caused by unanswered questions was reviewed for patterns that would introduce bias in the result.

Participants were asked to go back and fill out the questionnaires completely. If some data items remained missing, these issues were resolved via consultation with the statistician and major advisor.

Descriptive statistics (means, standard deviations, or median, interquartile range, or number, percentages, and frequencies) were calculated for all variables. Demographic characteristics of the study population were analyzed as means and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables. All statistical tests were 2-tailed. The variables were checked for normality and the mean and standard deviation was used as a measure of central tendency since the data are normally distributed.

The χ^2 were performed to describe and compare frequencies. The Student t-test were utilized to test for significant differences between pre and post-survey scores. Pearson's correlation coefficients were used to determine the relationships between key concepts. Univariate and multivariate logistic regression or linear regression analyses were performed to determine the relationships between the pretest and posttest.

3.8 Timeline

The project's subject matter was determined and settled upon in December 2022. Subsequently, a comprehensive literature review was undertaken in February 2023, providing a strong foundation for the project's direction. In April 2023, the proposal defense was successfully accomplished, marking a significant milestone in the project's progression. Following this accomplishment, the necessary approvals from both the clinical site and the university Institutional Review Boards were secured in July 2023. Data collection and the implementation of the intervention were carried out during the month of August and the early part of September

2023. By mid-October 2023, the data analysis was completed, and the project report was generated, as detailed in Appendix E.

CHAPTER IV: RESULTS

4.1 Sample Description

A total of twenty-seven individuals participated in this study. The total amount of possible participants was 45, corresponding with a 60% participation rate. While 27 participants completed the pretest survey it is important to note that only 22 participants completed the posttest survey. Among the participants, 85.2% were female and 14.8% were male. The participants' ages ranged from 25 to 63 years, with a mean age (M) of 44.56 and a standard deviation (SD) of 12.18. The median (Mdn) age was 48 years (see figure 1). In terms of years of professional experience, participants reported a range of 1 to 33 years, with a mean (M) of 12.04 and a standard deviation (SD) of 10.22. The median (Mdn) years of experience were 9. Regarding educational background, 14.8% of participants held an associate degree, 81.5% had a bachelor's degree, and 3.7% had a master's degree.

The analysis revealed a statistically significant association between age and pretest scores ($b = 0.04$, $p = .010$). Specifically, older participants tended to score higher on the pretest, suggesting that age is a predictor of success in answering pretest questions. In contrast to the observed relationship between age and pretest scores, no significant associations were found between other demographic variables (i.e., gender, education level, and years of experience) on either pretest or posttest scores. The p-values for these variables were all greater than 0.081, indicating that gender, education level, and years of experience did not significantly influence

participants' performance on the pretest or posttest.

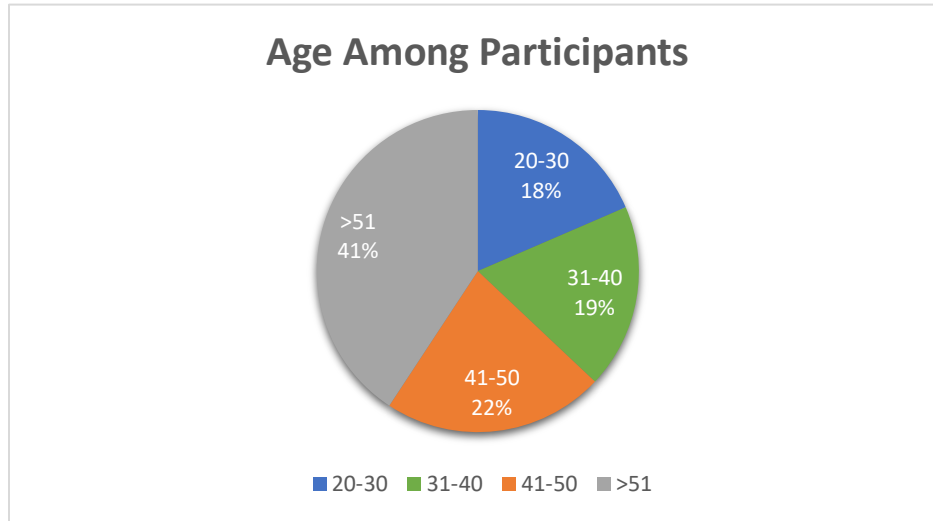


Figure 1. Age among participating participants

4.2 Primary Findings

Table 1. Pretest and posttest comparison for each question and total score

	Pretest (n = 27) % correct	Posttest (n = 22) % correct	p-value
1. What is the mechanism of action of Sugammadex?	33.3	77.3	.006
2. Which form of birth control does Sugammadex NOT affect?	85.2	90.9	.865
3. If given Sugammadex, how long should women of childbearing age use additional birth control for?	92.6	95.5	1.00
4. How does Sugammadex render hormonal birth control ineffective?	96.3	100	1.00
5. Do you offer additional discharge teaching about Sugammadex to women of childbearing age?	85.2	95.2	.513
Total score	3.93 (1.00)	4.55 (0.67)	.011

Note. p-values for the individual questions were based on chi-squared tests. The p-value for testing total score difference was based on paired t-test.

Table 1 provides a detailed breakdown of the percentage of correct answers for each question in the study. It highlights the specific areas of improvement and shows a notable and

significant difference in pretest-posttest performance on Question 1, as indicated by a chi-square statistic ($\chi^2(1) = 7.72, p = .005$). Question 1 on the survey assessed PACU nurses' knowledge of the specific mechanism of action of Sugammadex. The significant increase in correct answers on this question of the posttest demonstrates the effectiveness the educational intervention has had on nurses' knowledge of Sugammadex. The other 4 questions provided in the survey did not show a statistical difference between pretest-posttest scores (see figure 2). Although Question 1 exhibited the most significant enhancement in scores between the pretest and posttest, it concurrently displayed the lowest posttest score among the five questions. This observation implies a deficiency in understanding the pharmacodynamics of Sugammadex.

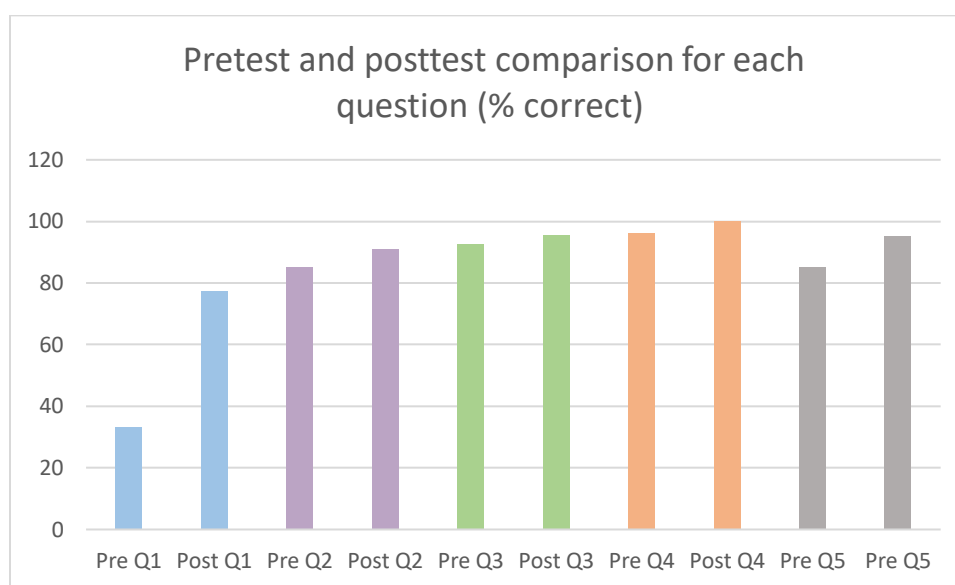


Figure 2. Pretest and posttest comparison for each question

Question 2 was used to assess the knowledge of which birth controls can be rendered ineffective by Sugammadex. This was important because patients may be on hormonal birth control not taken by mouth, so PACU nurses need to be aware of these other forms that could potentially be affected by Sugammadex. Though the percentage correct for this question was high on the pretest, there was not a significant improvement in scores for this question.

Question 3 was used to assess nursing knowledge of the length of time patients need to use other forms of birth control if administered Sugammadex. It is important for PACU nurses to understand this to provide the correct education to their patients. The high scores yielded on both the pretest and posttest represent understanding of this critical issue and do not provide any statistical evidence to this project.

Question 4 assessed nursing knowledge of the exact method of birth control ineffectiveness if given Sugammadex. This question is a potential question asked by patients or their family members. Patient educators having this knowledge could empower them to educate their patients. Statistical analysis did not show a significant difference in pretest and posttest scores, however the 100% correct on the posttest, does imply adequate nursing knowledge of this topic.

Additionally, question 5 did not show statistical difference in pretest scores versus posttest scores. This question was used to assess if nurses felt it was important to give educational instruction to patients about the interaction of Sugammadex and their birth control. This was a yes or no question. The correct answer was deemed “yes” for statistical analysis. This question shows a high percentage of nurses providing discharge teaching to their patients about Sugammadex to women of childbearing age.

When comparing the final scores of the pretest and posttest, overall, the average number of correct answers increased from 3.93 out of 5 (SD = 1.00) on the pretest to 4.55 out of 5 (SD = 0.67) on the posttest (see figure 3). This difference was statistically significant, as indicated by a paired t-test ($t = 2.81$, $p = .011$).

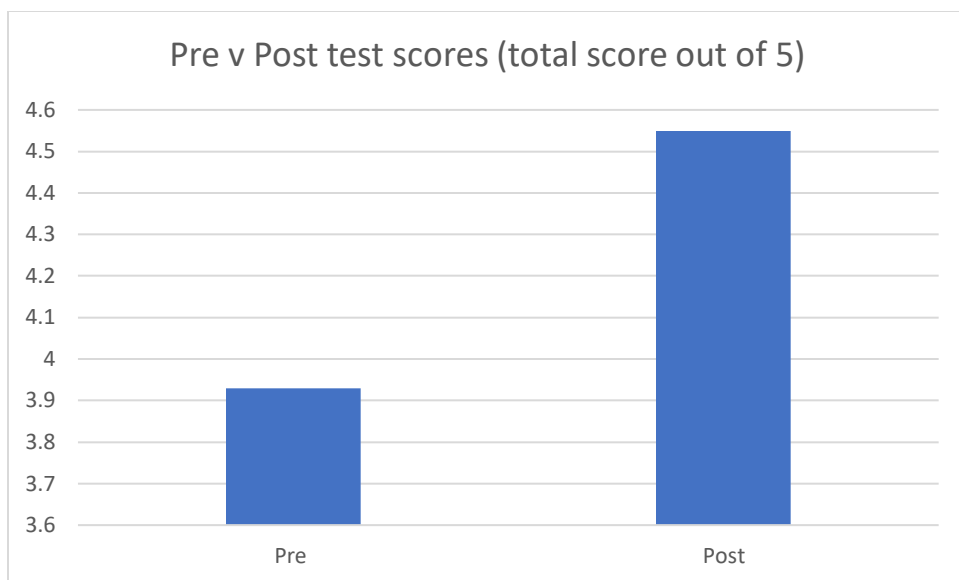


Figure 3. Pretest scores versus posttest scores (total score)

CHAPTER V. DISCUSSION

5.1 Summary

This quality improvement (QI) project marked a significant milestone as it was the first documented endeavor to assess the impact of a web-based educational module on the knowledge of Post-Anesthesia Care Unit (PACU) nurses concerning the potential drug-drug interaction between Sugammadex and hormonal contraceptives. Despite the FDA's inclusion of a warning about this interaction in the drug label, studies have revealed that less than 1% of women using hormonal contraceptives had received adequate education on this matter (Devov et al., 2023; Lazorwitz et al., 2020). The absence of proper education exposes female patients on combined oral contraceptive pills and Sugammadex to the risk of unwanted pregnancies. One contributing factor to this gap in medication education is the limited knowledge, competence, and confidence among the nursing staff, who bear the responsibility of imparting medication-related information (Dahlberg et al., 2022). In a concerted effort to enhance the quality and frequency of patient medication education, this project sought to investigate the effectiveness of a web-based educational program aimed at PACU nurses. The primary outcome of this study indicated that the web-based education initiative was not only feasible but also highly effective in improving PACU nurses' overall comprehension of the drug-drug interaction between Sugammadex and hormonal contraception.

5.2 Interpretation

The central clinical question guiding this project assessed whether a web-based educational program improves nursing knowledge concerning the effects of Sugammadex on birth control effectiveness during the discharge teaching process. This question was addressed using the total scores of the pretests and posttests. The statistically significant improvement of

scores between the pretest and posttest ($p = .011$) underscore the efficacy of the educational video in enhancing the PACU nurses' understanding of the effects of Sugammadex on birth control. The increase in the number of correct answers reflects a valuable knowledge improvement of the nurses in this critical area, potentially improving patient care and safety.

Question 1 of the survey, "What is the mechanism of action of Sugammadex?", provides insight into the PACU nursing knowledge of the pharmacodynamics of Sugammadex. The pretest score of 33% shows a deficiency in this valuable knowledge. This lack of knowledge may lead to a decreased level of confidence among nurses, potentially hindering their capacity to effectively educate patients. Improvement of scores for question 1 on the posttest after the intervention demonstrates comprehension of the material. This knowledge can be important for nurses' confidence in providing the proper discharge instructions. While question 1 of the survey showed significant improvement after the intervention, the posttest scores show room for improvement.

This project demonstrates the effectiveness of the web-based education program in improving PACU nurses' knowledge of the drug-drug interaction between Sugammadex and hormonal contraception, as indicated by a statistically significant increase in posttest scores. Other studies, such as O'Driscoll & Parrott (2019), Hartman et al. (2021), and David et al. (2019), where educational programs were implemented have also shown to enhance nurses' knowledge in various contexts. These studies align with this project's outcomes, supporting the effectiveness of education programs in improving knowledge. The significant improvement in knowledge about Sugammadex aligns with the literature's emphasis on the necessity of providing education in this area.

This QI project revealed a statistically significant association between age and pretest scores, suggesting that older participants tended to score higher on the pretest. Other literature has not suggested this association; therefore, this finding provides additional insights into the influence of age and pre-intervention test scores.

The findings of this quality improvement project align with the broader literature in demonstrating the effectiveness of education programs in improving nurses' knowledge in healthcare settings. It specifically showcases the impact of a web-based education program on PACU nurses' knowledge regarding Sugammadex and hormonal contraception, addressing a significant gap in the literature. Additionally, it provides new insights into the influence of age on pretest scores and emphasizes the need for tailored education programs to improve knowledge in specific areas. These findings contribute to the existing body of literature on healthcare education and medication knowledge. Improving nurses' knowledge of the pharmacodynamics of specific drugs, can lead to more consistent education for patients and increased awareness about the interactions Sugammadex has with hormonal birth control. These results encourage the importance of ongoing education and training in healthcare settings to ensure the highest standards of patient care are maintained.

5.3 Limitations

There are several limitations in this project. The project employed a pretest-posttest study design. The most significant limitation of this type of design is the lack of a control group, potentially introducing bias and threats from confounding factors. The results may not be generalizable to all healthcare settings, as it was a QI project conducted in one institution. A small convenient sample of PACU nurses was used from one urban hospital, which could affect the validity of the results. The study is limited by measuring the short-term effect of the online

education program. Due to feasibility and time constraints, this project was unable to assess the long-term effect of the online education program. The study focused on the impact of a web-based educational intervention as a single factor. Other potential confounding variables, such as prior knowledge or additional educational activities outside of the study, were not accounted for. The project primarily focused on knowledge improvement as measured by the pretest and posttest. It did not assess whether this knowledge translated into actual behavior changes or improved patient outcomes. Pediatric PACU nurses were excluded due to IRB approval would take even longer because the “pediatric” word in the proposal would require further investigation. Additionally, giving birth control related teaching to pediatric patients is not the same as teaching adult patients. The education module developed would not be applicable to the younger patient population.

To address these limitations and enhance the internal validity of the project, several efforts were made. Appropriate statistical methods were used to analyze the data, which included paired t-tests and chi-square tests to evaluate differences between pretest and posttest scores and to identify areas of improvement. Using a pretest-posttest design helped control for individual differences between participants and allowed for an evaluation of changes within the same group. The project reported detailed demographic information about the participants, which helps readers understand the characteristics of the sample. Overall, while the project has limitations, the efforts to mitigate potential sources of bias and confounding demonstrate a commitment to internal validity. However, it is important to recognize that addressing some of these limitations in future research could further strengthen the study's findings and applicability.

5.4 Recommendations

The Conduction of larger-scale replication studies involving a more diverse sample of PACU nurses across multiple healthcare settings would help validate the effectiveness of web-based educational programs in different contexts and among a broader range of healthcare professionals. Furthermore, designing and implementing randomized controlled trials with control groups to assess the true impact of web-based education on knowledge improvement would provide stronger evidence of causality and control for confounding variables. Future research could consider incorporating objective measures or observations to validate self-reported knowledge levels. Enhancement of the project could be done by conducting a more comprehensive assessment of the effectiveness of the educational intervention, including its impact on nurses' confidence and communication skills in educating patients about medication interactions. Moreover, a long-term follow-up assessment would provide insights into the sustainability of the education intervention's impact. Additionally, Extended research to assess whether knowledge gained translates into changes in clinical practice, such as improved patient counseling or a reduction in unintended pregnancies. This would link knowledge improvement to real-world outcomes.

5.5 Implication

Nurses constitute an indispensable component of the perioperative healthcare team, contributing significantly to patient care during the recovery phase and subsequent stages. Their pivotal role in discharge teaching is attributable to their unique capacity for personalized patient care. Among the perioperative team, PACU nurses invest unparalleled time and attention in direct patient care. This extended interaction affords nurses invaluable insights into individual patients' educational backgrounds, enabling them to customize discharge instructions at an intricate, case-specific level, thus ensuring optimal comprehension. The study underscores the

importance of ongoing education for PACU nurses on the drug-drug interaction between Sugammadex and hormonal contraceptives. Healthcare institutions should consider implementing web-based education programs or other effective educational interventions to ensure nurses are well-informed.

The study emphasizes the need for standardized and comprehensive patient education regarding the interaction between Sugammadex and hormonal contraceptives. Nursing staff should be equipped to provide patients with accurate information and advice to ensure patient safety. Collaboration between different healthcare professionals, including nurses, pharmacists, and anesthesia providers, is essential in addressing medication interactions. Interprofessional education and collaboration can lead to better patient care.

Future research should assess the long-term impact of knowledge gained through educational programs on nurses' behavior and patient outcomes. This can provide insights into the sustainability of knowledge improvement. These implications for practice and further study aim to promote continuous improvement in healthcare education, patient safety, and the quality of care provided by healthcare professionals. They emphasize the importance of evidence-based educational interventions and interprofessional collaboration to enhance patient outcomes.

5.6 Conclusions

This quality improvement initiative underscores the ongoing educational requirements for nurses involved in post-operative patient discharge instruction. It is crucial that patients who have been administered Sugammadex during the perioperative phase receive essential information regarding the medication and its potential interactions with hormonal birth control. The educational material, developed by anesthesia experts and disseminated through

web-based videos to nurses in the Post-Anesthesia Care Unit (PACU), have proven to enhance their knowledge, ultimately contributing to improved patient outcomes.

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APPENDIX A: SURVEY QUESTIONS

Demographic questions:

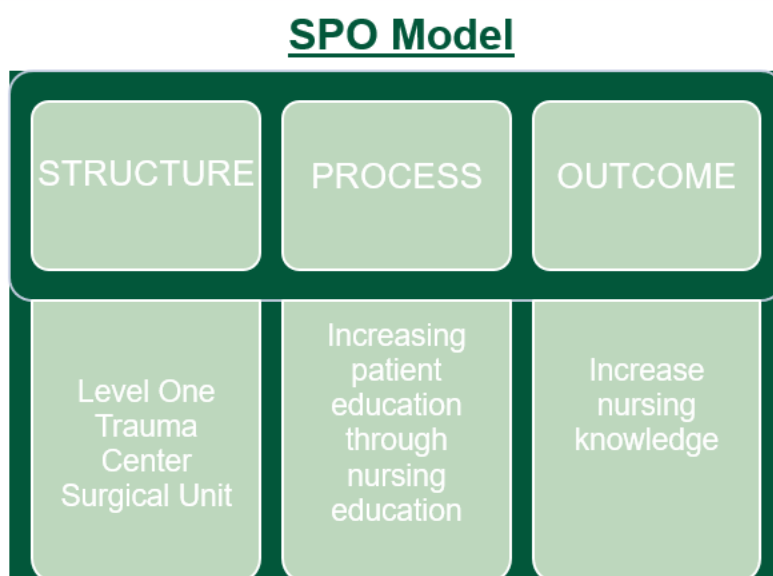
1. What is your gender?
 - a. Male
 - b. Female
 - c. Non-binary
2. What is your age?
 - a. FILL IN THE BLANK
3. How many years of experience do you have as a PACU nurse at Atrium?
 - a. FILL IN THE BLANK
4. What is your educational background?
 - a. Associate's degree
 - b. Bachelor's degree
 - c. Master's degree
 - d. Doctorate degree

Survey Questions:

1. What is the mechanism of action of Sugammadex?
 - a. It opens up sodium channels to allow entrance of sodium into the nerve ending
 - b. It adheres to postsynaptic cholinergic receptors of the motor end plate
 - c. It encapsulates the steroidal neuromuscular blockers and prevents them from binding to Nicotinic receptors
 - d. It noncompetitively binds to the NMDA receptor and blocks the influx of calcium

2. Which form of birth control does Sugammadex NOT affect?
 - a. Hormonal Intrauterine device (IUD)
 - b. Oral birth control
 - c. Nexplanon
 - d. Condom
3. If given Sugammadex, how long should women of childbearing age use additional birth control for?
 - a. 3 days
 - b. 7 days
 - c. 24 hours
 - d. 28 days
4. How does Sugammadex render hormonal birth control ineffective?
 - a. It encapsulates the progesterone and estrogens contained within hormonal birth control
 - b. It encapsulates the sodium contained within hormonal birth control
 - c. It prevents ovulation
 - d. It promotes follicular development.
5. Do you offer additional discharge teaching about Sugammadex to women of childbearing age?
 - a. Yes
 - b. No

APPENDIX B: SPO MODEL



APPENDIX C: UNCC IRB LETTER



To: Ashley Burch
University of North Carolina
at Charlotte

From: Office of Research Protections and Integrity

Approval Date: 21-Jul-2023

RE: Notice of Determination of Exemption

Exemption Category: 1

Study #: IRB-24-0008

Study Title: Sugammadex and Hormonal Birth Control

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](#).

APPENDIX D: WAKEFOREST SCHOOL OF MEDICINE IRB LETTER

MEMORANDUM

To: Danielle Brown
Atrium/Carolinas Healthcare System

From: Douglas Yoder, Chair
Institutional Review Board

Date: 6/22/2023

Subject: Exempt Protocol: IRB00097769
Sugammadex and Hormonal Birth Control Education- A Quality
Improvement Project

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

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

The Wake Forest School of Medicine IRB is duly constituted, has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonisation (ICH) E6, Good Clinical Practice (GCP), as applicable. WFSM IRB is registered with OHRP/FDA; our IRB registration numbers are IRB00000212, IRB00002432, IRB00002433, IRB00002434, IRB00008492, IRB00008493, IRB00008494, and IRB00008495.

WFSM IRB has been continually fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2011.



APPENDIX E: TIMELINE

