

Performance-Improvement Project: Increasing Nursing Knowledge of the Impact of Sugammadex in Female Patients Taking Steroidal Contraceptives

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Purpose: *This process-improvement project improved postoperative education for female patients by facilitating the development of a topic-specific education program to improve knowledge and confidence among perianesthesia nurses in a military treatment facility.*

Design: *An educational program was developed and presented which reviewed the impact sugammadex has on steroidal contraceptive efficacy, evidence-based postoperative teaching strategies, and specific patient education recommendations for female sugammadex-exposed patients taking steroidal contraceptives.*

Methods: *Effectiveness was measured by comparing nurses' baseline knowledge and confidence scores before and immediately after presentation of the educational program. These results were then compared with 2-week reassessments to determine if lasting improvements were achieved.*

Findings: *Statistically significant increases in knowledge and confidence were achieved upon both postintervention assessments.*

Conclusions: *Interactive evidence-based educational interventions can effectively create sustained increases in knowledge and confidence among health care professionals which translates into improved postoperative patient education.*

Keywords: *sugammadex, contraceptive efficacy, continuing nursing education, postanesthesia teaching.*

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THE FOOD AND DRUG ADMINISTRATION approved sugammadex (Bridion) for use in the United States in December 2015. It has now become widely available in many health care facilities for use in a variety of patient populations.¹ This medication reverses the effects of the aminosteroid neuromuscular blocking medications, specifically rocuronium and vecuronium.² Sugammadex has been safely used since 2008 on over nine million patients in Europe and Australia.^{3,4} Before the approval of sugammadex, anticholinesterase medications in combination with anticholinergic medications have traditionally been used to reverse the effects of neuromuscular blocking agents, such as rocuronium and vecuronium. When compared to these other agents, sugammadex reverses rocuronium and vecuronium with significantly faster recovery times, decreased incidence of residual neuromuscular blockade in the postoperative period, and no occurrences of emergent reintubation. Unlike the traditional medications that are used to reverse the effects of neuromuscular blocking medications, sugammadex can be administered to reverse neuromuscular blockade in 2 minutes compared with an estimated 30-minute interval until reversal with other agents.³ The ability to rapidly reverse neuromuscular blocking medications can dramatically decrease morbidity and mortality in difficult airway scenarios, especially the critical cannot-intubate and cannot-ventilate scenarios.³ Adverse postoperative outcomes, such as postoperative nausea and vomiting and increased myocardial oxygen demand that can result from pharmacodynamic effects of traditional neuromuscular blocking medications, are also significantly reduced by the use of sugammadex.^{3,5}

Background

Sugammadex reverses the effects of rocuronium and vecuronium by encapsulating the aminosteroid molecules. Once the aminosteroid molecule is encapsulated, it becomes physiologically inactive, and the resulting molecular complex is ultimately renally eliminated.² Although sugammadex has a high affinity for rocuronium and vecuronium, it can also encapsulate progesterone and estrogen. Progesterone levels can be decreased up to 34% in females after the administration of 4 mg per kilogram of sugammadex, described as

being equivalent to one missed dose of a steroidal contraceptive.² Sugammadex dosages can range from 2 mg per kilogram to 16 mg per kilogram; however, currently no data exist on the impact of other dosages of sugammadex on progesterone levels. Steroidal contraceptives are available in oral, topical, injectable, and implantable formulations and can contain only progestin, a synthetic form of progesterone, or be combined with ethinyl estradiol.⁶ Progesterone and the synthetic form progestin prevent ovulation and alter the production and release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), resulting in the impedance of follicular development.⁶ Although one dose of a steroidal contraceptive can decrease serum levels of LH and FSH, 7 days of consistent daily administration is required to reduce serum LH and FSH levels to adequately repress follicular development.⁶ Subsequently, females taking steroidal contraceptives are at risk of unintended pregnancy after the administration of sugammadex, and it is recommended that alternative means of nonhormonal contraception be implemented for at least 7 days.⁴

Unintentional pregnancy can have lasting and devastatingly negative effects on mothers, children, and families that are difficult to quantify. Unintended pregnancies negatively impact mission readiness, adds significant cost burden to military health care, can lead to unhealthy lifestyle behaviors of service members, and are associated with, and have the potential to add to psychological distress among patients and their families.^{7,8}

The individual cost of an uncomplicated unintentional pregnancy can range from an average of \$31,000 for a vaginal delivery up to an average of \$51,000 for a cesarean section.⁷ Health care expenditures dramatically increase if any complications to the mother or fetus occur.

Purpose

The purpose of this project was to determine how the exposure to an educational program describing the effects of sugammadex on contraceptive efficacy affects knowledge and confidence among perianesthesia nurses who provide postoperative patient education compared with their current knowledge and confidence.

Organizing Framework

The Iowa Model of Evidence-Based Practice to Promote Quality Care was the framework used for the design of the project.⁹ Upon identification of a problem-focused trigger, a team was formed to compile current evidence on the topic, synthesize the literature findings, and develop assessment and implementation methodologies to bridge the gap of evidence-based knowledge and current practices.

Literature Review and Appraisal

A literature search was completed in the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Uniformed Services University of Health Sciences' (USU) Power Search, Cochrane Library, Trip, National Institute of Health's (NIH), PubMed, and the American Association of Nurse Anesthetists (AANA). The search terms used included Sugammadex, Bridion, postoperative patient education, and contraceptive sugammadex.

Upon initial literature search, there was limited available literature discussing efficacious postoperative teaching methodologies regarding the reduced efficacy of steroidal contraceptives when female patients receive sugammadex. Therefore, articles that specifically discussed the effect sugammadex has on progesterone or steroidal contraceptives and articles that discussed efficacious postoperative education strategies were included in the literature review.

Inclusion criteria for articles included those with a publication date within the previous 10 years in peer-reviewed journals and available in English. Articles were excluded if the postoperative education intervention that was being evaluated included any preoperative education interventions.

Our literature search identified 1,345 potential articles. There were 69 duplicate articles eliminated. Four articles were excluded because they were not peer reviewed. One article was rejected because it was published before 2007. Three articles were not available in English and were also excluded. All article titles were reviewed for appropriateness, resulting in the elimination of 1,221 articles, yielding a total of 47 articles to be reviewed. The remaining articles were read,

and 34 articles were eliminated, resulting in 13 articles ultimately meeting our inclusion criteria. These articles were read in their entirety, reviewed, and described in [Figure 1](#).

Each article that described their intervention, variables, findings, level of evidence, and quality of evidence was included and summarized in [Table 1](#).^{4,10-21} The level of evidence for each article was based on the type of study design used in the article.²² The Association of Family Physicians' Strength of Recommendations Taxonomy guidelines were used to determine the quality of evidence for each article. The ratings include "A" for studies that were focused on patient outcomes, "B" that had significant limitations within the design, or "C" that had inadequate design or were expert opinions.

Of the 13 articles, two articles discussed the study of postoperative patient education. One article was a systematic review that resulted in improved patient knowledge and retention of postoperative education when education was individualized, delivered using more than one format, delivered in two or more sessions, and occurred in an individual setting.¹¹ The second article was a case study rated "C" which resulted in improved knowledge and satisfaction when individualized patient discharge instructions were provided.¹⁷

The remaining 11 articles described the potential impact sugammadex has on progesterone or steroidal contraceptives. Eight articles were evidence-based reviews of sugammadex: two were rated as "B" and six were rated as "C". All eight articles described the potential decreased efficacy that sugammadex can have on progesterone, steroidal contraceptives, and resulting risk for unintended pregnancy. Two B-rated articles directly measured the potential impact of sugammadex on progesterone. One article found up to a 34% reduction in progesterone, whereas the other article found no effect on human progesterone levels when sugammadex was administered.

Methods

Ethical Considerations

The chairman of the institutional review board evaluated this project and concluded that it was

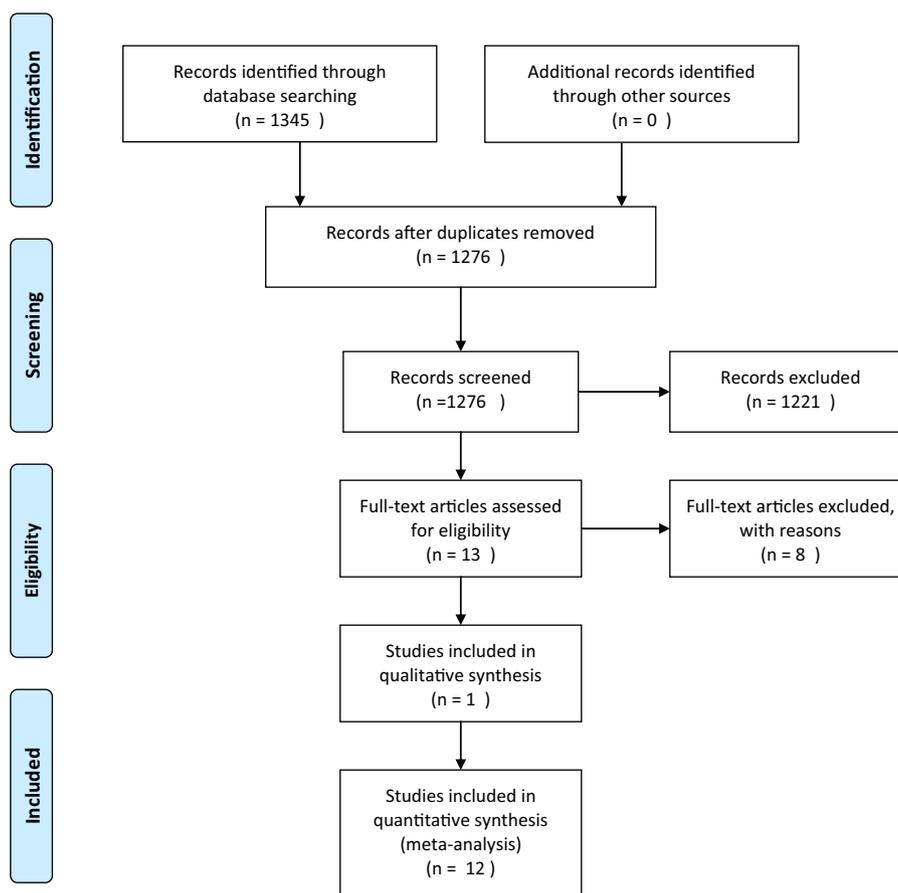


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. This figure is available in color online at www.jopan.org.

a performance-improvement project that did not meet the criteria for a full-committee review. Furthermore, the facility executive board also authorized this evidence-based practice project. No individually identifiable information was collected or recorded. Participation was voluntary, and all testing materials were shredded after scores were recorded. The risk of violating privacy or confidentiality of the participants was minimal.

Context

This evidence-based performance-improvement project was conducted at a small-sized military treatment facility within the United States. The hospital has six operating rooms, fifteen medical surgical beds, and performs over 2,000 surgical procedures annually. At the time of the project, the hospital employed 25 perianesthesia regis-

tered nurses. Sugammadex was available for use by anesthesia practitioners before and during this evidence-based educational project implementation.

Intervention

An educational presentation was developed through collaboration with project team members, addressing the pharmacokinetics, pharmacodynamics, and the side effects of sugammadex including the impact on serum progesterone levels and subsequent impact on steroidal contraceptive efficacy. In addition, evidence-based postoperative teaching strategies that enhance patient knowledge and retention were presented to improve the delivery of postoperative patient education. Specific evidence-based patient education recommendations for female patients taking steroidal contraceptives were also addressed.

Table 1. Evidence Table

Citation	Intervention	Variables	Findings	Level of Evidence	Evidence Quality
Cada et al. ⁴	Evidence-based review of sugammadex	Review of the pharmacokinetics and pharmacodynamics for sugammadex	Decreased efficacy of progesterone and is equivalent to missing one dose or several doses of steroidal contraceptives increasing the risk for unintended pregnancy	VII	C
Dalton and Van Hasselt ¹⁰	Clinical opinion	Communication of reduced efficacy of contraceptives if sugammadex is given	N/A	VII	C
Fredericks et al. ¹¹	Systematic review	Methods to increase patient knowledge and retention of postoperative education	Increased patient knowledge and retention of postoperative education when individualized information is delivered using more than one format, in two or more sessions, and in individual setting.	I	A
Gunduz Gulet et al. ¹²	Evidence-based review of sugammadex	Comparison of the effect of sugammadex with that of neostigmine/atropine on steroidal hormone levels	No affect on serum progesterone level in humans	II	B
Hogg and Mirakhur ¹³	Evidence-based review of sugammadex	Review of the pharmacokinetics and pharmacodynamics for sugammadex	Decreases contraceptive efficacy and equivalent, taking a steroidal contraceptive 12 hours after scheduled daily dose	VII	C
Kipps ¹⁴	Clinical opinion	Optimization of contraceptive methodology implementation based on individual patient factors	Use of contraceptive medication can be based on ethical, religious, socioeconomic, cultural, and medical factors	VII	C
Kovac ¹⁵	Evidence-based review of sugammadex	Review of the pharmacokinetics and pharmacodynamics of sugammadex	Progesterone and estrogen can have a 2% to 22% affinity for sugammadex	VII	C
Mirakhur ¹⁶	Evidence-based review of sugammadex	Exploration of dosages and effects of sugammadex	Predictive reduction in unbound progesterone of up to 34% and is equivalent to a 12-hour delay in contraceptive administration	VII	C

Ortoleva ¹⁷	Case study	Efficacy of customized discharge instructions compared with physician hand-written discharge instructions	Anecdotal improvement in discharge instruction understanding, patient satisfaction compliance, and staff satisfaction	VII	C
Rex et al. ¹⁸	Evidence-based review of sugammadex	Review of the pharmacokinetics/ pharmacodynamics for sugammadex	Decreased serum progesterone by approximately 30% and is equivalent to taking a steroidal contraceptive 12 hours after scheduled daily dose	VII	C
Schaller and Fink ¹⁹	Evidence-based review of sugammadex	Review of the pharmacokinetics/ pharmacodynamics for sugammadex	Decreased efficacy of steroidal contraceptives and progesterone level equivalent to missing one dose of medication increasing the risk for unintended pregnancy	VII	C
Smart and Gallagher ²⁰	Clinical opinion	N/A	N/A	VII	C
Zwiers et al. ²¹	Evidence-based review of sugammadex	Measurements of heat absorption or production synthesized through a mathematical model to assess the efficacy of sugammadex	34% reduction in free etonogestrel and equivalency of missed dose of steroidal contraceptives to one missed dose	IV	B

The educational presentation began after baseline knowledge and confidence levels on these topics were assessed among perianesthesia nurses. Knowledge and confidence levels were reassessed immediately after the educational presentation and again after 2 weeks.

Baseline knowledge and confidence scores were assessed immediately after the educational intervention and compared with subsequent knowledge and confidence assessments to determine the effectiveness of the educational intervention. Baseline knowledge and confidence scores were also compared to the 2-week reassessment knowledge and confidence scores to determine if a lasting improvement was achieved.

Measures

The written knowledge and confidence assessments were developed by university-affiliated certified registered nurse anesthetists. The baseline assessment consisting of four multiple-choice questions and one true-or-false question (Figure 2). The subsequent assessments consisted of the same five multiple-choice questions. The questions evaluated knowledge on the pharmacokinetics, pharmacodynamics, and other effects of sugammadex in addition to postoperative patient education strategies to improve knowledge retention. Confidence levels for every answer were assessed on an 11-point Likert scale (0% to 100% increasing by 10% intervals).

Analysis

All collected data were entered into the statistical software program StatCrunch (Pearson Education, released 2007) after being reviewed for accuracy and completeness. Each test was scored with the same criteria. Incorrect answers were recorded as "0," and correct answers were recorded as "1." All test scores were totaled on a zero-to-five numerical scale, with higher scores reflecting a higher number of questions correctly answered. Mean confidence scores for each test were calculated for every preceding knowledge question.

Descriptive statistics and tests of normality and homogeneity were analyzed to determine the characteristics of the sample. The Kruskal-Wallis One-

way analysis of variance by ranks was used to assess the impact the educational intervention had on knowledge and confidence levels among perianesthesia nurses with respect to the pharmacokinetics and pharmacodynamics of sugammadex, effects on steroidal contraceptives, and essential aspects of efficacious postoperative patient education strategies.

Results

A total of 24 perianesthesia registered nurses received the educational intervention. All data points were complete for each assessment.

Before the educational intervention, 12 of the 24 participants did not know that sugammadex could alter serum progesterone levels, increasing the risk for unintended pregnancies in females who continue to take steroidal contraceptives. Only four participants were able to correctly indicate the mechanism of action for sugammadex.

Statistically significant increases in knowledge were observed immediately after the educational intervention ($n = 24$, $P < 0.0001$, median pretest score = 3, median immediate post-test scores = 5, follow-up post-test scores = 5) (Figure 3). Every participant could accurately identify the impact sugammadex has on progesterone, and 22 participants correctly indicated the pharmacokinetics of sugammadex immediately after the educational intervention. The increase in knowledge on these topics was retained in the subsequent knowledge assessment performed 2 weeks later ($n = 24$, $P < 0.0001$, median subsequent post-test score = 5) (Figure 3).

Increased confidence scores were also statistically significant immediately after the educational intervention ($n = 24$, $P < 0.0001$, median pretest confidence = 46%, median immediate post-test confidence = 98%) and remained significantly increased upon reassessment 2 weeks later ($n = 24$, $P < 0.0001$, median subsequent post-test confidence = 90%), as depicted in Figure 4. One participant indicated that before the educational intervention, they had no confidence in their knowledge of the topics that would be presented. Subsequent reported confidence scores were no less than 70% immediately after the educational intervention.

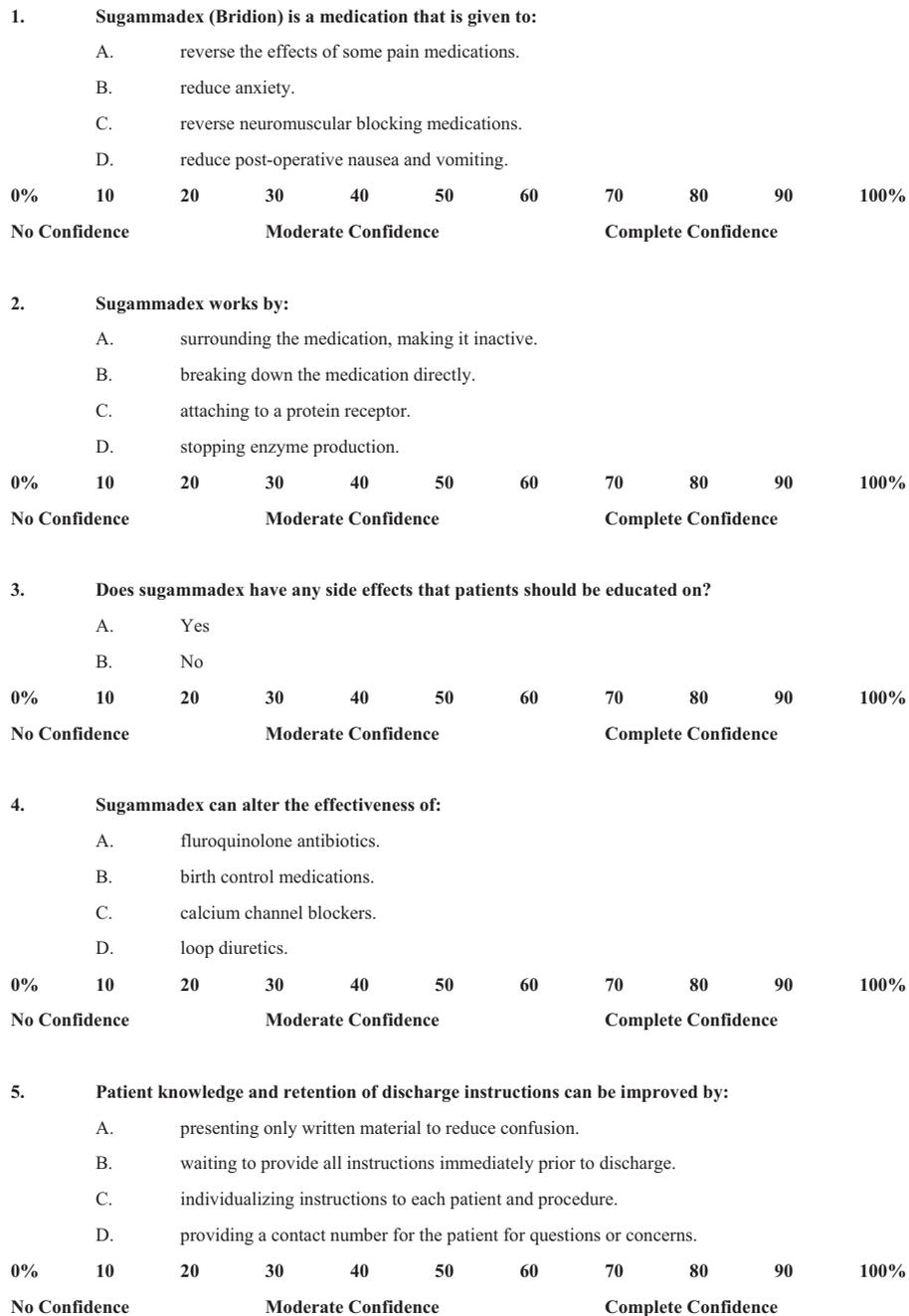


Figure 2. Knowledge and confidence assessment.

Discussion

Each educational intervention was facilitated by the same subject-matter expert using identical materials and visual aids and covered the same information in a consistent order as to maintain the uniformity of the information presented. The educational intervention was presented in a

manner to appeal to visual and auditory learners in an interactive format. The presentation was direct and brief, detailing essential aspects of the effects of sugammadex and evidence-based postoperative patient education strategies. Through this engaging and varied presentation style, learners were able to significantly increase their knowledge and confidence regarding these

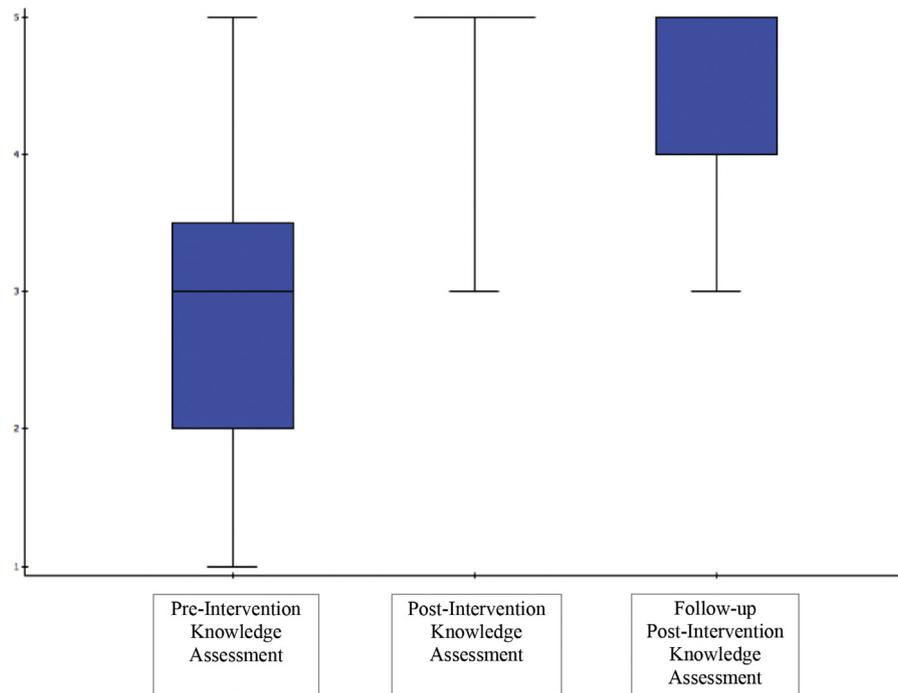


Figure 3. Knowledge assessment results. This figure is available in color online at www.jopan.org.

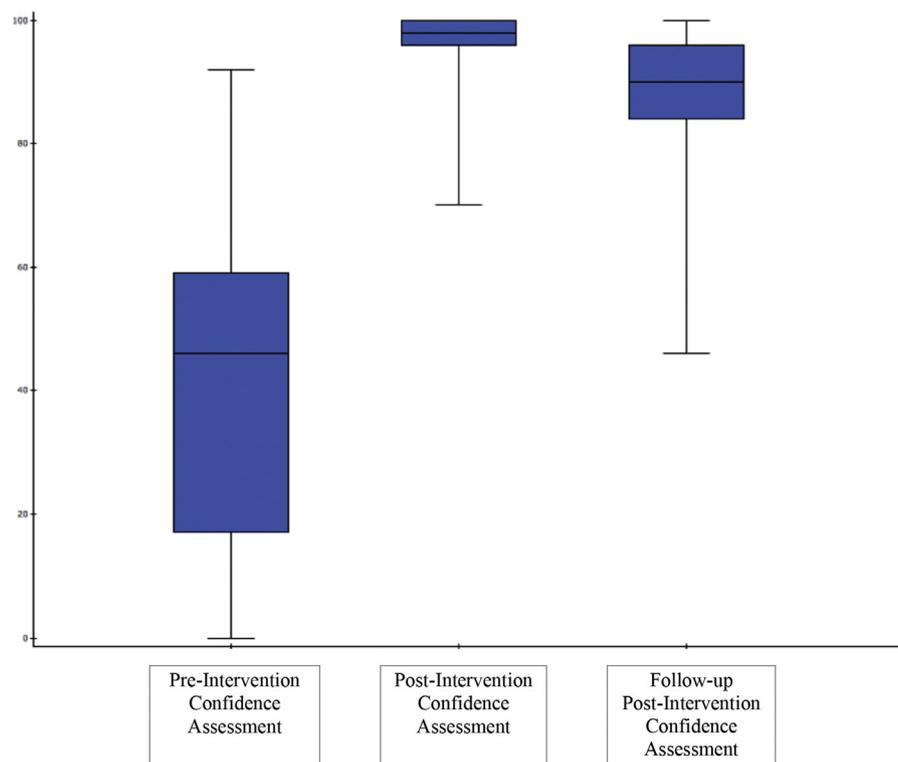


Figure 4. Confidence assessment results. This figure is available in color online at www.jopan.org.

topics and retain the information. The significant retention in knowledge and confidence supports the effectiveness of concise evidence-based educational interventions that were delivered using interactive teaching formats.

Military treatment facilities are uniquely challenged with high staff turnovers due to repeated location reassignments. Practice-change sustainment can be difficult in this environment. In an effort to ensure an enduring evidence-based practice change, a proposed addition in the facility's electronic health record will be submitted so that the appropriate discharge instructions to female patients taking steroidal contraceptives who have received sugammadex are automatically provided during follow-up postoperative education.

Limitations

The limitations of this project include a small sample size and a large variance of professional experience. There were not enough patients who met

the criteria to receive this specific postoperative discharge education to properly power a study and to determine the ultimate impact on patient education.

Conclusion

Interactive evidence-based educational interventions can effectively create sustained increases in knowledge and confidence among health care professionals. When information is presented in a succinct and meaningful format to the audience, participants can learn and retain the knowledge presented and feel empowered to use that information to improve the care their patients receive.

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References

1. Highlights of Prescribing Information: Bridion (Sugammadex). Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022225lbl.pdf. Accessed December 11, 2017.
2. Et T, Topal A, Erol A, Tavlan A, Kılıçaslan A, Uzun ST. The effects of sugammadex on progesterone levels in pregnant rats. *Balkan Med J*. 2015;32:203-207.
3. Ledowski T. Sugammadex: What do we know and what do we still need to know? A review of the recent (2013 to 2014) literature. *Anaesth Intensive Care*. 2015;43:14-22.
4. Cada DJ, Levien TL, Baker DE. Sugammadex. *Hosp Pharm*. 2016;51:585-596.
5. Koyuncu O, Turhanoglu S, Ozbakis Akkurt C, et al. Comparison of sugammadex and conventional reversal on postoperative nausea and vomiting: a randomized, blinded trial. *J Clin Anesth*. 2015;27:51-56.
6. Rivera R, Yacobson I, Grimes D. The mechanism of action of hormonal contraceptives and intrauterine contraceptive devices. *Am J Obstetrics Gynecol*. 1999;181:1263-1269.
7. Heitmann RJ, Mumford SL, Hill MJ, Armstrong AY. Estimated economic impact of the levonorgestrel intrauterine system on unintended pregnancy in active duty women. *Mil Med*. 2014;179:1127-1132.
8. Barton K, Redshaw M, Quigley MA, Carson C. Unplanned pregnancy and subsequent psychological distress in partnered women: A cross-sectional study of the role of relationship quality and wider social support. *BMC Pregnancy and Childbirth*. 2017;17.
9. Titler MG, Kleiber C, Steelman VJ, et al. The Iowa model of evidence-based practice to promote quality care. *Crit Care Nurs Clin North America*. 2001;13:497-509.
10. Dalton J, Van Hasselt G. Sugammadex – time of onset: 9 months. *Anesthesiology*. 2016;71:115-116.
11. Fredericks S, Guruge S, Sidani S, Wan T. Postoperative patient education: a systematic review. *Clin Nurs Res*. 2010;19:144-164.
12. Gunduz Gul G, Ozer AB, Demirel I, Aksu A, Erhan OL. The effect of sugammadex on steroid hormones: A randomized clinical study. *J Clin Anesth*. 2016;34:62-67.
13. Hogg RMG, Mirakhor RK. Sugammadex: a selective relaxant binding agent for reversal of neuromuscular block. *Expert Rev Neurother*. 2009;9:599-608.
14. Kipps S. History taking for women's contraception. *Pract Nurs*. 2013;24:78-83.
15. Kovac AL. Sugammadex: the first selective binding reversal agent for neuromuscular block. *J Clin Anesth*. 2009;21:444-453.
16. Mirakhor RK. Sugammadex in clinical practice. *Anesthesiology*. 2009;64:45-54.
17. Ortoleva C. An approach to consistent patient education. *AORN J*. 2010;92:437-444.
18. Rex C, Bergner UA, Pühringer FK. Sugammadex: a selective relaxant binding agent providing rapid reversal. *Curr Opin Anaesthesiol*. 2010;23:461-465.
19. Schaller SJ, Fink H. Sugammadex as a reversal agent for neuromuscular block: an evidence-based review. *Core Evid*. 2013;8:57-67.

20. Smart A, Gallagher J. Clinicians and women's learning package on sugammadex (Bridion) and hormonal contraceptives. *Aust Nurs Midwifery J.* 2015;22:52.

21. Zwiers A, van den Heuve M, Smeets J, Rutherford S. Assessment of the potential for displacement interactions

with sugammadex: a pharmacokinetic pharmacodynamic modeling approach. *Clin Drug Investig.* 2011;31:101-111.

22. LoBiondo-Wood G, Haber J. *Nursing Research: Methods and Critical Appraisal for Evidence-Based Practice*, 6th ed. St. Louis, MO: Mosby Elsevier; 2006.

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