IMPLEMENTATION OF AN INTRAOPERATIVE COGNITIVE AID TO GUIDE SUGAMMADEX USE FOR PHARMACOLOGIC REVERSAL OF NEUROMUSCULAR BLOCKADE

by

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ABSTRACT

MICHAEL THOMAS PLEVA Implementation of an Intraoperative Cognitive Aid to Guide Sugammadex Use for Pharmacologic Reversal of Neuromuscular Blockade. (Under the direction of DR. STEPHANIE WOODS)

The incidence of residual neuromuscular blockade (rNMB) following general anesthesia remains as high as 60%, placing patients at an increased risk of developing postoperative pulmonary complications (PPCs) (Saager et al., 2019). PPCs are associated with increased readmission rates, hospital length of stay, and overall morbidity and mortality (Kirmeier et al., 2019). A quality improvement project was conducted to examine anesthesia providers' current practice using sugammadex compared to evidenced base practice guidelines revealed throughout a comprehensive literature review. An anonymous survey was distributed among anesthesia providers throughout a level one trauma center to identify their current practice and knowledge regarding the use of sugammadex. Seventy-seven anesthesia providers completed the survey. Ninety-seven percent of providers correctly identified that sugammadex interferes with hormonal birth control, while only 58.7% were found to correctly dose sugammadex according to the patient's actual body weight. Thirty-seven percent of anesthesia providers revealed they avoid administering sugammadex in patients with kidney disease. A cognitive aid was developed and placed throughout the operating rooms, targeting knowledge gaps identified in the survey. This quality improvement project recommends continuing the analysis of current practice trends, as this will help inform and promote best practices consistent with contemporary literature.

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DEDICATION

This doctoral project work is dedicated to my wife, as you have been a constant source of support and encouragement during all the challenges over the last two and a half years of nurse anesthesia school. This work is also dedicated to my parents, as you have given me the foundation to achieve what I have and what I hope to achieve in the future. Thank you everyone for the unconditional love and support.

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LIST OF ABBREVIATIONS

CRNA	Certified Registered Nurse Anesthetist
ESRD	End Stage Renal Disease
FDA	Food and Drug Agency
NMB	Neuromuscular blockade
PDSA	Plan, Do, Study, Act
PPCs	Postoperative Pulmonary Complications
REPS	Residual Paralysis Prediction Score
rNMB	Residual Neuromuscular Blockade
SRNA	Student Registered Nurse Anesthetist
TEG	Thromboelastogram
TOF	Train of Four
TOFC	Train of Four Count
TOFR	Train of Four Ratio

Section I: Introduction

Background

Intraoperative muscle paralysis is often needed to optimize surgical exposure, facilitate tracheal intubation, and control patients' ventilation. The incidence of residual neuromuscular blockade (rNMB) following general anesthesia remains as high as 60% despite advancements in neuromuscular blockade (NMB) monitoring modalities and the introduction of novel pharmacologic reversal agents (Saager, 2019). Multiple studies cite an association between the pulmonary function impairment attributed to residual neuromuscular blockade and increased critical postoperative pulmonary complications (PPCs) (Kheterpal et al., 2020; Rudolph et al., 2018; Leslie et al., 2021; Saager et al., 2019). Anesthesia providers must exercise vigilance to attenuate the incidence of residual paralysis and negative sequelae. Proper identification of patients at elevated risk for developing rNMB and appropriate dosing of pharmacologic reversal agents are essential elements of competent clinical practice.

Sugammadex is a selective relaxant-binding agent developed for direct reversal of aminosteroidal NMBAs approved by the FDA in 2015 (U.S Food and Drug Administration, 2015). Because complete recovery of the NMJ prior to extubation is vital for high-risk patients, sugammadex is often the first-line reversal strategy. Rudolph et al. (2018) created the first residual neuromuscular block prediction score (REPS) to classify high-risk patients according to ten predictors (Rudolph et al., 2018). Although sugammadex can rapidly reverse deep NMB, there are clinical indicators for use and providers must be aware of potential adverse events.

Problem Statement

Residual paralysis following general surgery is a significant risk factor implicated in the development of major postoperative pulmonary complications PPCs. According to a multicenter, prospective study conducted by Kirmeier et al. (2019), found that patients demonstrating a train of four ratio (TOFR) less than 0.9 exhibited impaired respiratory control during hypoxia, increased risk for airway obstruction, and higher aspiration rates. PPCs such as respiratory failure, the need for reintubation within 24 hours, and pneumonia are associated with pathophysiologic, financial, and emotional burdens by increasing hospital length of stay, the number of readmissions, and overall morbidity and mortality. Kirmeier et al. (2019), revealed approximately 5% of adult patients undergoing non-cardiac surgery will experience a major PPC, resulting in increased mortality and $100,000 in additional costs per occurrence. Reducing the incidence of rNMB is a key, modifiable risk factor to improve postoperative outcomes for patients and healthcare systems.

Several studies implicate considerable variation in provider reversal management and individual pharmacologic variability as important influencers for rNMB (Ji et al., 2021; Murphy et al., 2018; Saager et al., 2019). There is a lack of standardization by anesthesia providers regarding the dosing of reversal agents according to the determined depth of neuromuscular paralysis.

Purpose

This project is a part of a larger quality improvement project regarding the overall management of neuromuscular blockade that includes peripheral nerve stimulator monitoring (Stovall, 2022) and reversal with neostigmine (Cornette, 2022). The specific aim of this quality improvement project was to identify current practice for the use of sugammadex as a reversal

agent at a level one trauma center with 46 fully functional operating rooms. The goal of the larger quality improvement project was to create a cognitive aid as an intraoperative reference guide for managing neuromuscular blockade. Once current practice habits were identified, practice trends and evidence-based guidelines from the synthesis of the literature were used to inform the creation of a cognitive aid.

Theoretical Framework

The Plan, Do, Study, Act (PDSA) model was used for this quality improvement project related to the current knowledge and practice surrounding the use of sugammadex. The PDSA model is used extensively under the Institute for Healthcare Quality Improvement (IHI) to implement change or improve existing processes to improve patient care (McBride & Tietze., 2018). The cyclical nature of the PDSA components emphasizes continual analysis and refinement of changes.

The "plan" was completed by a thorough review of the literature to create a validated survey to assess current knowledge and practice habits among anesthesia providers for managing reversal of neuromuscular blockade using sugammadex. The "do" consisted of distributing the 8-item survey via SurveyMonkey to all anesthesia providers.

The "study" component analyzed the survey responses to identify trends surrounding NMB reversal using sugammadex among anesthesia providers. The results were collected and exported via SurveyMonkey. Data points were aggregated to determine common themes for improvement in clinical practice. The evidence synthesis plus model helped integrate evidence-based practice guidelines focused on areas of needed improvement identified in the survey findings into a concise cognitive aid. The final "act" component of the PDSA model formulated

the cognitive aid. The cognitive aid was placed on the anesthesia machine in operating rooms for an intraoperative reference.

Clinical Question

In adult surgical patients requiring neuromuscular paralysis, how does best-practice evidence in the literature, compared to current knowledge and practice on the pharmacological reversal of neuromuscular blockade using sugammadex, inform management of neuromuscular blockade?

Section II: Literature Review

A literature review was conducted using the search terms “neuromuscular blockade,” “residual paralysis”, “sugammadex”, “postoperative pulmonary complications”, “reversal”, “general anesthesia” and “delayed emergence”. An extensive electronic search was completed using multiple databases, including PubMed, Science Direct, Cochrane Database of Systematic Reviews (CDSR), and CINAHL Complete. Relevant, peer-reviewed articles and research published from 2012 through 2021 with full-text availability in the English language were included. Studies that included non-human subjects, patients less than 18 years of age, emergency and outpatient surgery were excluded.

Indications for Use

Complete recovery of the neuromuscular junction prior to extubation is vital for high-risk patients, and sugammadex is often the first-line reversal strategy. In 2015, the FDA approved sugammadex as the first selective agent to reverse aminosteroidal neuromuscular blockade (NMB) (U.S Food and Drug Administration, 2015). Sugammadex reverses NMB by encapsulating rocuronium or vecuronium, creating a concentration gradient between the plasma and the neuromuscular junction –moving the nondepolarizing muscle blocker away from the muscle tissue (Chandrasekhar et al., 2021). If quantitative monitoring is unavailable, the train of four count (TOFC) is the best indication for the use and dosing of sugammadex. The U.S Food and Drug Administration (2015) recommended 2 mg/kg if there are two train of four (TOF) twitches and 4 mg/kg if there are no TOF twitches but at least two post-tetanic twitches. 16 mg/kg can be given immediately after an induction dose of rocuronium if the patient cannot be ventilated or intubated.

Administration and Dosing

While the FDA recommended dosing of sugammadex according to the patient's actual body weight, studies have attempted to prove that using the ideal body weight or adjusted body weight is just as efficient while more economical. A randomized control trial discovered that doses of 0.5-1 mg/kg of sugammadex were just as effective as the standard 2 mg/kg dose (Duranteau et al., 2021). Mostoller et al. (2021) developed a randomized clinical trial studying the pharmacokinetics of sugammadex when dosed by actual weight versus ideal body weight in morbidly obese patients. Researchers found that patients with a BMI >40 have 50% less sugammadex in their plasma when dosed according to their ideal body weight rather than actual body weight. Badaoui et al. (2016) concluded that ideal body weight plus 35-50% in obese patients was sufficient to reverse deep neuromuscular blockade. None of the forenamed studies observed rNMB and agreed sugammadex dosing based on actual body weight leads to a faster reversal of neuromuscular blockade.

Contraindications

Although sugammadex can rapidly reverse deep NMB, providers must be aware of the relative precautions related to its use. Given that sugammadex is eliminated through the kidneys, patients with a creatinine clearance of less than 30ml/min are not considered candidates for sugammadex (Chandrasekhar et al., 2021). The U.S Food and Drug Administration (2015) recommended against the use of sugammadex in severe renal failure patients and stated that no dosage adjustments in patients with moderate renal dysfunction are necessary. However, a recent systematic review conducted by Kim et al. (2021) found that the administration of sugammadex is safe for end-stage renal disease (ESRD) patients. The authors' concluded reversal was slightly

slower in ESRD patients, no patients exhibited rNMB, and hemodialysis effectively removed the sugammadex-rocuronium complex (Kim et al., 2021).

Administration of sugammadex has raised concern due to its potential correlation with coagulopathy leading to increased postoperative blood loss. In a large retrospective study, Moon et al. (2018) found no significant differences among PT/INR & PTT after patients received 4 mg/kg of sugammadex. Chang et al. (2021) revealed similar findings but took an additional step assessing a thromboelastogram (TEG) in a randomized, double-blind control trial. When investigators administered 4 mg/kg of sugammadex, the coagulation time (K time) increased by 17% compared to the control group. All other TEG parameters were within normal limits. In another large randomized, double-blind trial, Rahe-Meyer et al. (2014) administered 4 mg/kg of sugammadex and found only a transient increase in PT/INR and PTT. However, these patients received thromboprophylaxis as they were undergoing orthopedic surgery. All studies found no increase in postoperative blood loss when sugammadex was administered. However, Tas et al. (2015) saw an increase in postoperative blood loss among the sugammadex group following septoplasty; there was no clinical significance to this finding. More clinical trials are needed to clarify the effect sugammadex has on the coagulation pathway.

According to current literature, sugammadex has a high affinity for progesterone and decreased the effectiveness of oral contraceptives (Chandrasekhar., 2021). A single dose of sugammadex is comparable to missing one dose of oral contraceptives. Therefore, females who received sugammadex should plan to use alternative forms of contraception for seven days (U.S Food and Drug Administration., 2015). A study conducted by Lazorwitz et al. (2020) found less than 1% of women using hormonal contraception had proper documentation of counseling concerning the need for alternative forms of birth control following the administration of

sugammadex. This finding indicates a lack of knowledge among these anesthesia providers surrounding the drug interaction between hormonal contraception and sugammadex.

To date, hypersensitivity is the only absolute contraindication for the administration of sugammadex. In a double-blind, placebo-controlled study, researchers administered sugammadex to 448 volunteers. Sugammadex given at 4 mg/kg of sugammadex caused 0.7% of the participants to experience mild to moderate hypersensitivity compared to 4.7% who received 16 mg/kg. One participant became anaphylactic following a dose of 16 mg/kg of sugammadex (de Kam et al., 2018). In addition to a higher dose, repeated exposure to sugammadex increased the risk of hypersensitivity, as revealed in Min et al. (2018a), a double-blind, randomized control trial with 375 volunteers. As participants received their second, third, and fourth dose of sugammadex, the incidence of hypersensitivity increased. One participant became anaphylactic after receiving 16 mg/kg of sugammadex (Min et al., 2018a). Both Min et al. (2018a) and de Kam et al. (2018) studied healthy volunteers without prior administration to rocuronium or vecuronium. Min et al. (2018b) conducted a retrospective analysis of 3,519 subjects who underwent general anesthesia with neuromuscular blockade. The investigators found a low incidence of hypersensitivity (0.385%) related to the administration of sugammadex and no confirmed cases of anaphylaxis.

High-Risk Patient Characteristics

Anesthesia providers must exercise vigilance to identify patients at high risk for developing rNMB. Pietraszewski & Gaszyński. (2013) conducted an observational study that discovered the geriatric population as a high-risk factor for rNMB. Of 184 geriatric patients, 44% exhibited a TOFR below 0.7 compared to 20% of the 231 patients between 19-57. Several physiological and anatomical changes affect the geriatric population as there is a decrease in the

volume of distribution for hydrophilic drugs and a decrease in renal and hepatic function. Consequently, this dramatically alters the pharmacokinetics as the liver metabolizes and the kidney excretes the aminosteroidal neuromuscular blockers (Nagelhout, 2018). Pietraszewski & Gaszyński. (2013) further explains that elderly patients have an increased sensitivity to nondepolarizing neuromuscular blockers due to a greater distance between the pre-and post-synaptic clefts and a decrease in acetylcholine efflux throughout the neuromuscular junction. The authors recommended that the standard dose of rocuronium geriatric patients decrease by 30%, similar to the 30% decrease in the clearance rate of rocuronium in this population (Pietraszewski & Gaszyński., 2013).

In addition to the elderly population, Stewart et al. (2016) showed that 48%, 38.3%, and 36.3% of patients undergoing open abdominal, laparoscopic, and procedures less than 90 minutes, respectively, were found to have rNMB. Open abdominal operation required a profound neuromuscular block until the procedure was completed to facilitate closure of the abdominal fascia. This method delayed the reversal of the paralysis (Stewart et al., 2016). Laparoscopic procedures required a deep neuromuscular block throughout the procedure to reduce intra-abdominal pressures (Sun et al., 2021). Short procedures requiring paralysis did not allow adequate time for spontaneous recovery of the neuromuscular junction with a TOFR >0.9 (Stewart et al., 2016).

Saager et al. (2019) conducted a blinded, multicenter cohort study examining 250 adult patients undergoing elective abdominal surgery. Statistically, significant evidence was noted between rNMB and a BMI >30, male gender, and an ASA class three. While the studies above found geriatric patients were more likely to exhibit rNMB, the RECITE study found no correlation between age and rNMB (Saager et al., 2019).

Rudolph et al. (2018) created the residual neuromuscular block prediction score (REPS) to classify high-risk patients according to ten predictors. The ten predictors identified were hepatic failure, neurological disease, high doses of neostigmine, metastatic tumors, females, procedures <120 minutes, aminosteroidal neuromuscular blocking agents administered, BMI >35, no nurse anesthetist present, and an experienced surgeon. Some risk factors align with previously mentioned literature; however, there are discrepancies between gender and BMI as discussed in Saager et al. (2019) and procedure time as listed in Stewart et al. (2016). Also, the REPS score does not consider geriatrics a substantial risk for rNMB, in contrast to Stewart et al. (2016) and Pietraszewski & Gaszyński. (2013). The REPS was more accurate in predicting rNMB compared to the train of four count (TOFC), and a high REPS (>4) was associated with PPCs, 30-day readmission, and increased hospital length of stay (Rudolph et al., 2018). The recent development of REPS reinforces the need to understand further critical risk factors that influence rNMB. However, as the first predictive scale of its kind, REPS will need to be independently validated by an outside group using a larger cohort.

Sugammadex vs. Neostigmine

The recent FDA approval of a direct-acting reversal agent with a unique mechanism of action fueled numerous studies analyzing the differences between neostigmine and sugammadex and the respective clinical practice implications. Collectively, many studies agree on the benefits of a more rapid and effective reversal devoid of the unwanted muscarinic effects with sugammadex compared to neostigmine. A Cochrane systematic review examined 41 studies, including 4206 participants. Hristovska et al. (2017) concluded that sugammadex is more efficient at reversing neuromuscular blockade than neostigmine. Sugammadex was 6.6 times faster than neostigmine in achieving a TOFR >0.9 when the TOFC accounted for two twitches

and 16.6 times faster when the patient was under deep paralysis (Hristovska et al., 2017). Geldner et al. (2012) conducted a randomized control trial including 140 patients, revealing that sugammadex provided a superior reversal compared to neostigmine. In addition to sugammadex being 3.4 times faster than neostigmine, 94% of the patients who received sugammadex recovered within five minutes of administration, compared to 20% of the patients treated with neostigmine (Geldner et al., 2012). Hristovska et al. (2017) found use of sugammadex caused 40% fewer adverse events, including PONV, bradycardia, and the need for supplemental oxygen, when compared to neostigmine.

Although there is literature favoring sugammadex over neostigmine, several studies have also failed to identify a definitive link between a greater reduction in adverse pulmonary outcomes with sugammadex compared to neostigmine. In a prospective, double-blinded randomized control trial, Kim et al. (2019) found no significant differences in the Postoperative Quality Recovery Scale at 15 min and 40 min after surgery between patients receiving neostigmine or sugammadex. These results were reinforced in a large, prospective observational study conducted by Kirmeier et al. (2019) that collected data from 22,308 patients. Neither the use of sugammadex or neostigmine for neuromuscular blockade reversal was associated with better pulmonary outcomes. Furthermore, Abola et al. (2020) conducted a randomized control trial and found no difference in the patients' inspiratory spirometry score regardless of whether the patient received neostigmine or sugammadex. In this study, the hand strength, extubation time, and discharge readiness were all comparable across the neostigmine and sugammadex groups. Notably, a limitation to this study was the higher percentage of patients in the neostigmine group that were reversed with two to four twitches, inferring that the neostigmine group had a less profound neuromuscular block (Abola et al., 2020). Finally, in Japan, where

sugammadex is used routinely used on most patients, researchers conducting a multicenter observational study found that, in the absence of neuromuscular monitoring and after reversal with sugammadex, 9.4% of patients still had a TOFR<0.9 after extubation (Kotake et al., 2013).

Summary of Findings

Residual neuromuscular blockade and subsequent adverse respiratory events prevent patients' optimal postoperative recovery. Anesthesia providers are responsible for inducing, maintaining, and adequately reversing muscle paralysis.

A Cochrane systematic review illustrated that sugammadex has superior efficacy than neostigmine. Yet, its inflated cost and limited number of studies on the adverse effects have led to hesitancy for its consistent use. The U.S Food and Drug Administration (2015) recommended 2 mg/kg if there is a TOFC of two or more and 4 mg/kg if there is a TOFC of zero with at least two post tetanic twitches. Compared to the standard dosing of neostigmine, Hristovska et al. (2017) concluded that sugammadex was 6.6 times faster and caused 40% fewer side effects than neostigmine. The contraindications for the use of sugammadex deserve additional attention. A robust debate with inconsistent findings exists throughout the publications as to whether sugammadex increases bleeding, is related to hypersensitivity, and how a patient with renal dysfunction is affected by sugammadex.

Section III: Methodology

Project Design

This project followed the evidence synthesis plus project model and served as the first steps in translating research into practice related to reversal of neuromuscular blockade using sugammadex (Bonnel & Smith, 2018). This project included a comprehensive review and synthesis of contemporary literature and analysis of survey data of current clinical practice surrounding the use of sugammadex. After integrating knowledge gained from the literature review and survey findings, evidence-based guidelines were delivered to anesthesia providers through an easily accessible cognitive aid to guide best practices for the reversal of neuromuscular blockade reversal using sugammadex.

Setting

The survey was distributed to the anesthesia providers at a level one trauma center. The institution is distinguished as a certified transplant center for heart, kidney, liver, and pancreas. Innovative technology at the institution provides the opportunity for many surgical procedures performed using minimally invasive laparoscopic or robotic surgical approaches. While these less-invasive approaches offer numerous benefits, including decreased pain and a shorter hospital stay, surgeons must rely upon precision to achieve successful outcomes (Barash et al., 2017). Such precision typically warrants the use of pharmacologic muscle relaxation to avoid inadvertent patient movement that could jeopardize damaging surrounding organs. Appropriate management of neuromuscular blockade is integral to achieving optimal patient outcomes, as paralytic use is a common daily practice for anesthesia providers.

Subjects

This project utilized convenience sampling method with anesthesia staff receiving a survey related to current practices on reversing neuromuscular blockade with sugammadex. The providers self-selected whether they chose to complete the survey. As a result of the method chosen, the project's findings did not extend to the general population of anesthesia providers– only to those who participated in the research (Stratton, 2021).

The sample consisted of anesthesia staff. Student Registered Nurse Anesthetists (SRNAs) were excluded from participation. Based on the current staffing census, the potential population included 212 anesthesia providers—165 Certified Registered Nurse Anesthetists (CRNAs) and 47 Anesthesiologists. Demographics among anesthesia providers were anonymous in the survey. Data obtained related to the sample population included academic degree and years since completion of anesthesia training.

Intervention

The survey findings aimed to identify the current practice of anesthesia providers surrounding neuromuscular blockade reversal with sugammadex. Once current practice habits were identified, the investigator analyzed trends and integrated evidence-based guidelines from the synthesis of the literature to inform the creation of a cognitive aid that serves as an intraoperative reference to neuromuscular blockade reversal. Specifically, the cognitive aid focuses on the pharmacological reversal of neuromuscular blockade using sugammadex, and is in a clear, easy-to-access location on the anesthesia machine as an intraoperative reference tool.

Data Collection

Data was collected using an eight-item multiple-choice survey. Two of the eight questions surveyed current practice, while the remaining six questions surveyed current knowledge surrounding the use of sugammadex. Five of the eight questions were true or false, while the remaining three questions were multiple choice. Surveys were sent to CRNAs and anesthesiologists using the SurveyMonkey platform. Anesthesia providers received an email reminder of the upcoming survey with detailed instructions on how to access the survey link via QR code. The QR code was posted in anesthesia breakrooms, call rooms and on anesthesia machines throughout twenty-two operating rooms. These operating rooms were chosen due to their high volume of muscle paralysis. The survey's primary goal assessed the reversal of neuromuscular blockade with sugammadex among anesthesia providers at the level one trauma center. Subsequently, the data obtained was used to identify facility-specific education needs to inform the development of the cognitive aid. The validity of the survey questions was determined according to approval from the appointed clinical expert and OR leadership.

Timeline for Data Collection

Data was collected following IRB approval from the institution and UNC Charlotte. Prior to dispersing the survey, a brief description of the project was presented during an anesthesia grand round meeting on July 14th, 2022. Data collection began with the survey distribution on August 29th, 2022. The survey was open for completion for one month, from August 29th to September 29th, 2022. A reminder to complete the NMB survey was sent on September 21st, 2022, September 27th, 2022, and September 29th, 2022. Survey results were analyzed, along with findings from the synthesis of the literature, to develop the cognitive aid from September 29th to

October 30th, 2022. The finalized and approved cognitive aid was implemented throughout the operating rooms of a level one trauma center.

Data Management Strategies and Confidentiality of Data

De-identification of survey responses ensured confidentiality of the information gathered. Academic degree and years since completing anesthesia training was the only demographic information survey participants were asked to provide. Participants were asked to check a box if they consent for investigators to use their de-identified responses for analysis in the final project report. Investigators were not able to track responses to any individual provider. Data sharing during the project was limited to members of the project committee.

Data Analysis and Evaluation

The success of the initial survey was measured by evaluating the responsiveness of anesthesia providers. The returned surveys identified areas with high training needs and was one measure of success in achieving the goal of creating a valid cognitive aid. The survey yielded a 36.3% return rate from anesthesia providers.

Data analysis was completed with descriptive statistics of the 8-question survey given to anesthesia providers. The SurveyMonkey results were exported directly using Microsoft Excel and statistical analysis was completed with the assistance of a statistician. Each participants' response was distributed utilizing a frequency-count table. This table provided the opportunity to review individual responses to survey questions providing an average response to questions regarding sugammadex on the survey (Bonnel & Smith., 2018). A frequency count was calculated for the total population and subgroups based on their years of experience and degree of education. Organizing the data in this manner allowed the review of the numeric data patterns

for individuals and collective group responses. Logistic regression was calculated to associate years of experience with performance on questions throughout the survey.

The survey used a score of 80% to differentiate survey responses. Questions that did not meet this benchmark within the sample were considered a focal point within the cognitive aid. After interpreting both the survey data and synthesizing the relevant literature, an educational cognitive aid detailing the best practices for the pharmacologic reversal of neuromuscular blockade with sugammadex was developed. This method is consistent with the evidence synthesis plus project model.

Section III: Project Finding

Sample Demographics

Demographical data within this survey consisted of the degree of education and years of experience among participating anesthesia providers. Seventy-seven anesthesia providers completed the survey. Most providers held a Master of Nurse Anesthesia Degree (n=57), while the remaining providers held a Doctoral of Nurse Anesthesia Degree (n=11) or were physician anesthesiologists (n=9) (see figure 1). Thirty-seven providers have practiced for five years or less, 14 providers with 6-10 years of experience, 15 providers with 11-20 years of experience, and 11 providers with more than 20 years of experience (see figure 2).

Figure 1

Degree of education among participating anesthesia providers

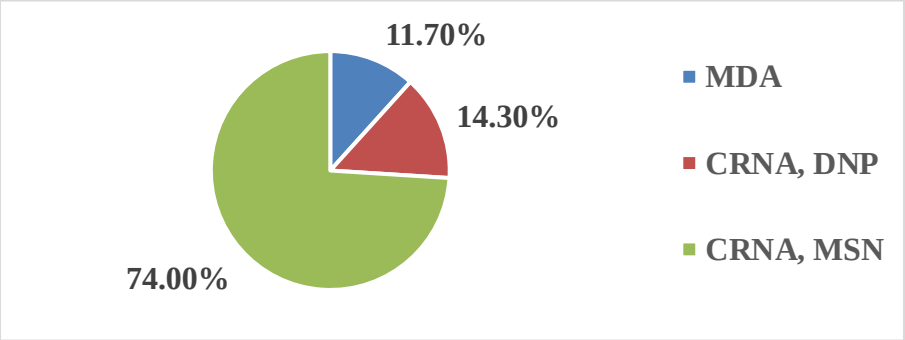
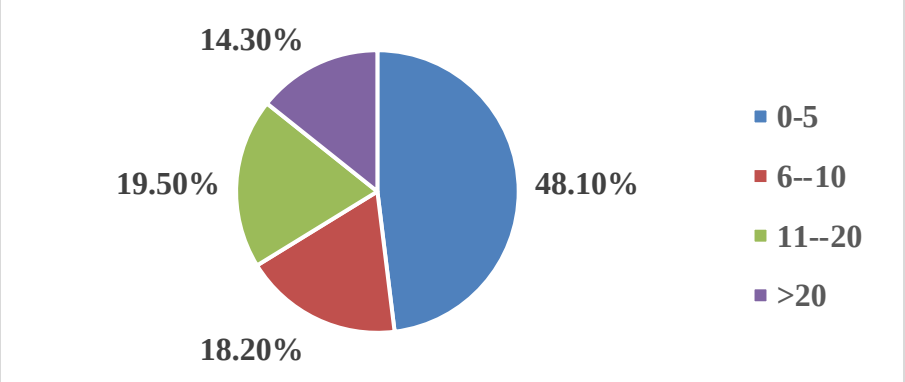


Figure 2

Years of experience among participating anesthesia providers



Survey Results

Table 1

Survey findings on current practice related to sugammadex

Item	Descriptor	Frequency	Percent correct
Sugammadex not used with creatine clearance < 30 ml/min.	True **False**	*n* = 29 *n* = 48	62.3
Hesitant to use Sugammadex with coagulopathic patients.	True **False**	*n* = 9 *n* = 67	88.2
Sugammadex is dosed according to the patients' _____ body weight.	**Actual** Ideal Adjusted No difference	*n* = 45 *n* = 19 *n* = 10 *n* = 3	58.4
Patients must use alternative forms of birth control for seven days if receiving sugammadex.	**True** False	*n* = 75 *n* = 2	97.4
Hemodialysis removes sugammadex/rocuronium molecular complex.	**True** False	*n* = 63 *n* = 14	81.8
More bradycardia is seen with sugammadex than neostigmine.	True **False**	*n* = 8 *n* = 69	89.6
Clinical indicator for the use of sugammadex that is not listed in the Omnicell.	**Unable to assess TOF** Cannot ventilate Clinical concern documented in EHR Failure to intubate after rocuronium or vecuronium when ventilation without airway protection is contraindicated Inadequate reversal using neostigmine.	*n* = 66 *n* = 9 *n* = 12 *n* = 27 *n* = 8	85.7
Hypersensitivity to sugammadex increases with _____ and _____.	**Repeated administration** **Doses of 16mg/kg** Renal Impairment Pediatric Patients	*n* = 44 *n* = 55 *n* = 23 *n* = 20	37.7

The frequencies for each item on the survey are reported in Table 1. Most of the sample population answered the following four questions correctly, meeting the 80% benchmark. Seventy-five (97.4%) anesthesia providers stressed that patients using hormonal contraception should use alternative birth control methods for seven days following the administration of sugammadex. Hemodialysis effectively removing the sugammadex/rocuronium molecule was answered correctly by 63 (81.8%) anesthesia providers. Sixty-nine (89.6%) anesthesia providers answered that significant bradycardia occurs with neostigmine more often than sugammadex. Finally, 85.7% of anesthesia providers correctly chose that the inability to assess the TOFC during surgery is not an indicator of the use of sugammadex.

Forty-eight (62.3%) anesthesia providers reported administering sugammadex in patients with a creatine clearance of less than 30ml/min, while 29 (37.7%) refrained from administering sugammadex in this patient population. Only nine (11.8%) providers were hesitant to administer sugammadex to coagulopathic patients, as most anesthesia providers do not consider coagulopathy when planning to administer sugammadex.

The following question was a pick-two multiple-choice question, regarding what two factors have led to an increased incidence of hypersensitivity. Forty-one anesthesia providers (53.2%) answered one of the two options correctly, and seven (9.1%) providers answered both responses incorrectly. Only 37.7% of anesthesia providers correctly answered that repeated drug administration and doses of 16 mg/kg increase the risk for hypersensitivity when using sugammadex (n=29).

When asked about dosing sugammadex, forty-five (58.4%) anesthesia providers agreed with the current literature, reporting using actual body weight to dose sugammadex. Nineteen anesthesia providers (24.7%) answered ideal body weight, 10 (13%) answered adjusted body

weight, and three (3.9%) claimed it made no difference how you dosed sugammadex. Logistic regression results indicated a significant association between years of experience and correctly dosing sugammadex. This finding indicates that more years of experience reduced the odds of correctly choosing actual body weight to dose sugammadex (odds ratio = 0.29, $p < .001$). There were no other significant associations with the remaining questions on the survey.

Section IV: Discussion

Implications

Anesthesia providers must be aware of new evidence surrounding the use of sugammadex in patients with poor kidney function, which deviates from the FDA recommendation in 2015 when sugammadex first became available. While the Food and Drug Administration recommends against the use of sugammadex in patients with severe renal failure, a systematic review conducted by Kim et al. (2021) found that sugammadex was safe in patients with end-stage renal disease (ESRD). Nearly 60% of providers acknowledged administering sugammadex to patients with a creatinine clearance of less the 30ml/min. Kim et al. (2021) also revealed that hemodialysis removes the sugammadex and rocuronium complex, as approximately 80% of the anesthesia provider agreed with this finding in the literature.

Most anesthesia providers (88.2%) reported no concern about administering sugammadex in coagulopathic patients. At the same time, Chang et al. (2021), Moon et al. (2018), and Tas et al. (2015) found no clinically significant increase in post-operative blood loss when sugammadex was administered. Providers must be mindful that sugammadex can transiently increase PT/INR and PTT, as found in a study conducted by Rahe-Meyer et al. (2021). It appears safe to administer sugammadex in patients without increasing their risk for bleeding. However, more research is needed on coagulopathic patients receiving sugammadex.

The administered dose of sugammadex according to weight is managed differently among participating anesthesia providers. Duranteau et al. (2021), Mostoller et al. (2021), and Badaoui et al. (2016) found no residual neuromuscular blockade regardless of how sugammadex is dosed. These three studies reported that dosing sugammadex using actual body weight led to faster reversal of neuromuscular blockade. The Food and Drug Agency (2015) recommends

using actual body weight. Only 58.4% of participating providers dose sugammadex according to the actual body weight. The remaining providers reported using suboptimal dosing regimens, implying an area that needed improvement among current practices within the facility.

Close to all providers responded that patients using hormonal contraception should use alternative birth control methods for seven days following the administration of sugammadex, a finding that is consistent with a study by Chandrasekhar (2021) and the Food and Drug Administration (2015). An essential consideration for anesthesia caregivers is providing post-operative counseling to use alternative forms of birth control for the following week. A future recommendation would be to assess whether anesthesia providers offer this information during the transfer of patient care.

Based on the survey findings and the current literature, three areas surrounding sugammadex are included in the cognitive aid. Sugammadex administration in patients with kidney disease is cited, as new evidence suggests that sugammadex is safe in this patient population. Second, as most providers know, sugammadex interferes with hormonal birth control. It is vital to remind providers of the need for postoperative counseling for nonhormonal methods of birth control during the transfer of patient care. Lastly, appropriate sugammadex dosing is included in the cognitive aid. Dosing according to the patient's actual body weight and the number of twitches recorded in the TOFC is consistent with current evidence-based practice.

Strengths

This quality improvement project consisted of a small sample size at a single academic center. Due to the small sample size, data was quickly aggregated, leading to the implementation of the cognitive aid in a relatively brief period. Another strength was that the survey identified needs specific to the facility. Different facilities often have different devices or methods of

monitoring. Only including one facility allowed observers to perform analysis on survey questions from providers with the same monitors, medications, and resources. This helped to create a more tailored and applicable cognitive aid.

Several survey recruitment strategies were utilized throughout the data collection phase. Email reminders were sent to anesthesia providers, and the quality improvement project was presented to anesthesia providers to increase survey participation. QR codes were located throughout several operating rooms to increase awareness and ease accessibility of the survey. Finally, institutional approval was only needed at one healthcare facility.

Limitations

A limitation of this study is that it lacks relevance to other healthcare institutions, as it was a single survey sent to one group of anesthesia providers at one academic center. Although the tailored approach helped increase the usefulness of the cognitive aid at the identified facility, it reduced the relevance and reach to other healthcare facilities. Another challenge was survey participation. Investigators aimed for a 60% response rate among anesthesia providers, and unfortunately, only 36.3% of providers responded. Many other surveys were distributed by SRNAs during this time, potentially leading to survey fatigue among respondents.

In addition, investigators cannot determine whether survey participants only submitted one response, an issue resolved by having participants identify themselves. Identification of duplicate participant responses can be made by requiring anesthesia providers to provide their email addresses affiliated with their institution, and responses can be limited to one email address. Finally, there is no validated method of determining which information should be included in the cognitive aid.

Recommendations

There are both short- and long-term recommendations for this project. One recommendation is to obtain more expert input to validate the survey. Another suggestion is to balance the number of true or false questions and multiple-choice questions more evenly. Adding more multiple-choice questions also comes with a requisite increase in time to complete the survey; both need balanced. Additionally, questions in which respondents answered at least 90% correctly should be re-evaluated. Lastly, it is recommended that the survey be distributed while no other surveys are being sent to anesthesia providers.

In the weeks to months following the cognitive aid distribution, observers recommend collecting provider feedback regarding the cognitive aid. This would include feedback on usability, accessibility, and resourcefulness. Continuing evaluation and analysis of current practice trends are recommended as new literature, neuromuscular blockade management modalities, and facility guidelines evolve. This will help inform and promote practice consistent with current literature and best practice.

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Appendices

Appendix A: Neuromuscular Blockade Management Survey

Current Practice

1. Sugammadex is typically not used in patients with a creatinine clearance less than 30 ml/min.
    a. True
    b. False
2. I am hesitant to administer sugammadex in coagulopathic patients.
    a. True
    b. False
3. Sugammadex is dosed according to the patients'_____ in order to achieve a faster reversal of neuromuscular blockade.
    a. Actual Body Weight
    b. Ideal Body Weight
    c. Adjusted Body Weight
    d. It does not make a difference
4. Which of the following clinical indicators for the use of sugammadex are not currently listed in the Omnicell?
    a. Unable to assess TOF due to surgical limitations
    b. Can't intubate/Can't ventilate
    c. Clinical concern documented in EHR
    d. Failure to intubate after rocuronium or vecuronium when ventilation without airway protection is contraindicated
    e. Inadequate reversal using neostigmine.

Current Literature

1. Patients using hormonal birth control methods who have received sugammadex should be advised to use an alternate form of birth control for seven days.
    a. **True**
    b. False
2. Hemodialysis can effectively remove a rocuronium/sugammadex molecular complex.
    a. True
    b. False
3. A greater degree of clinically significant bradycardia occurs with sugammadex administration compared to neostigmine.
    a. True
    b. False
4. Recent literature ~~data~~ suggests that the incidence of a hypersensitivity reaction to sugammadex increases with (select all that apply):
    a. Repeated administration
    b. Doses of 16 mg/kg
    c. Renal impairment
    d. Pediatric patients

Appendix B: Demographics

Figure 1

Degree of education among participating anesthesia providers

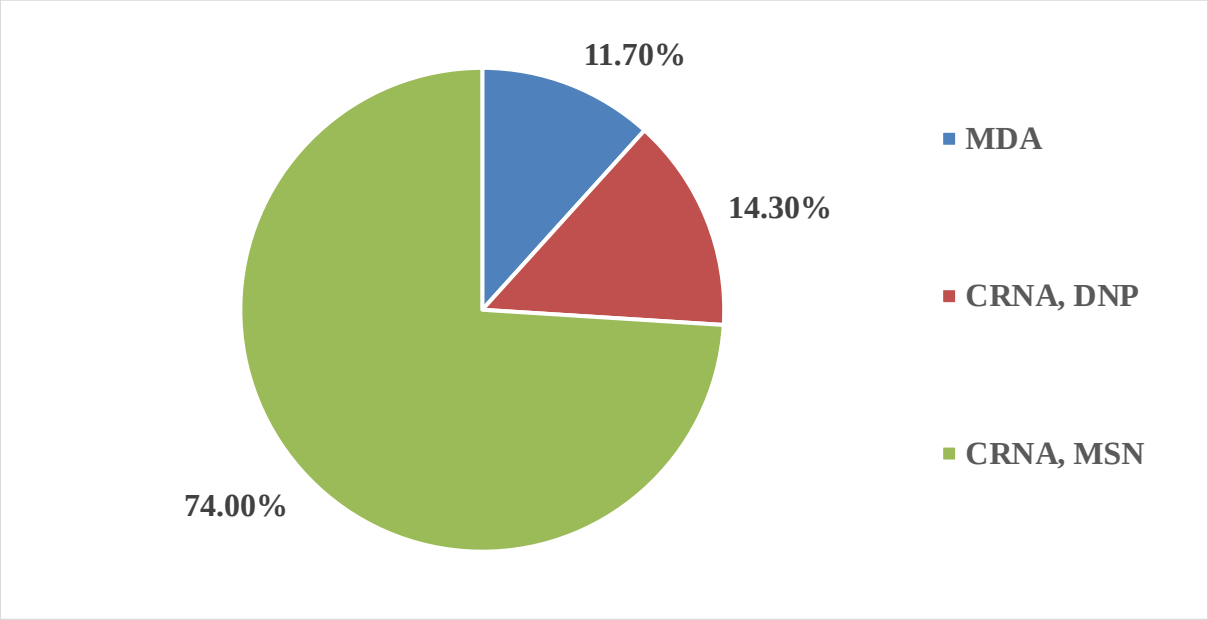
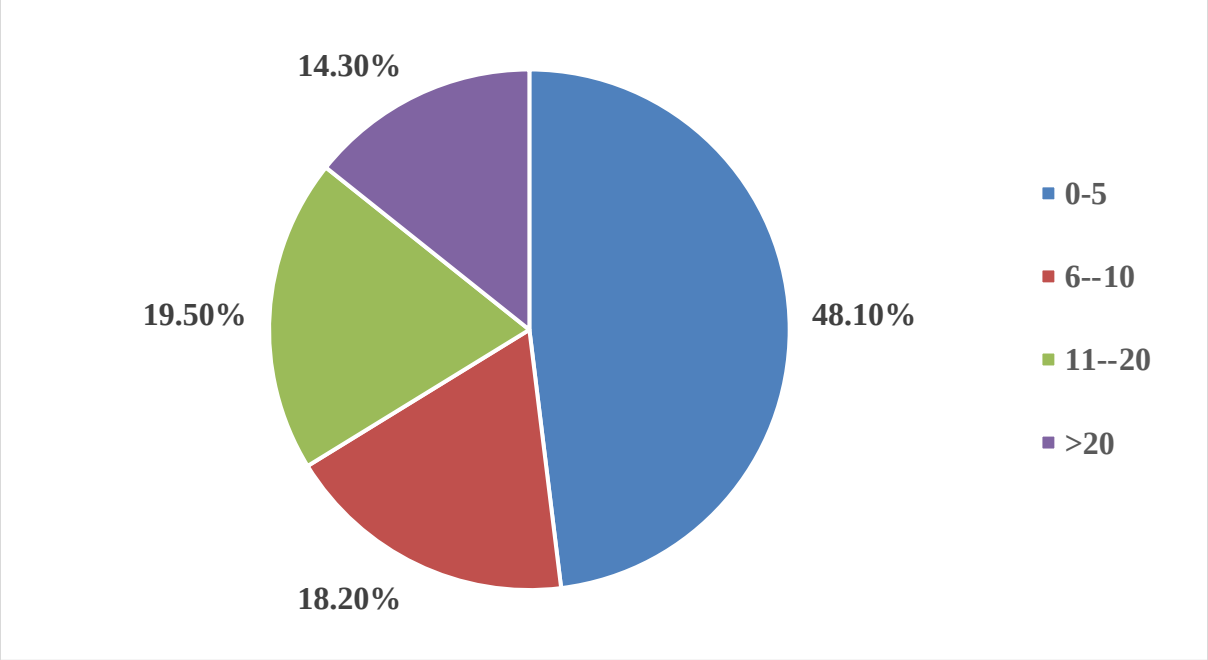


Figure 2

Years of experience among participating anesthesia providers



Appendix C: Survey Results

Table 1

Findings on current practice related to sugammadex

Item	Descriptor	Frequency	Percent correct
Sugammadex not used with creatine clearance < 30 ml/min.	True **False**	*n* = 29 *n* = 48	62.3
Hesitant to use Sugammadex with coagulopathic patients.	True **False**	*n* = 9 *n* = 67	88.2
Sugammadex is dosed according to the patients' _____ body weight.	**Actual** Ideal Adjusted No difference	*n* = 45 *n* = 19 *n* = 10 *n* = 3	58.4
Patients must use alternative forms of birth control for seven days if receiving sugammadex.	**True** False	*n* = 75 *n* = 2	97.4
Hemodialysis removes sugammadex/rocuronium molecular complex.	**True** False	*n* = 63 *n* = 14	81.8
More bradycardia is seen with sugammadex than neostigmine.	True **False**	*n* = 8 *n* = 69	89.6
Clinical indicator for the use of sugammadex that is not listed in the Omnicell.	**Unable to assess TOF** Cannot ventilate Clinical concern documented in EHR Failure to intubate after rocuronium or vecuronium when ventilation without airway protection is contraindicated Inadequate reversal using neostigmine.	*n* = 66 *n* = 9 *n* = 12 *n* = 27 *n* = 8	85.7
Hypersensitivity to sugammadex increases with _____ and _____.	**Repeated administration** **Doses of 16mg/kg** Renal Impairment Pediatric Patients	*n* = 44 *n* = 55 *n* = 23 *n* = 20	37.7