

Research Article

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Titrating Sugammadex to Reverse Neuromuscular Blockade to $\geq 90\%$ Train-of-Four-Ratio

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ABSTRACT

Introduction: In January 2023, the American Society of Anesthesiologists (ASA) published its first practice guideline on monitoring and antagonism of neuromuscular blockade, recommending quantitative monitoring and a Train-Of-Four Ratio (TOFR) of 90% or greater before extubation. The ASA called for further investigation into the appropriate dosing of Sugammadex.

Methods: This was a prospective, single-arm (non-randomized) dose-finding/titration study conducted from August 2023 to February 2024. Neuromuscular blockade was measured with a TwitchView Electromyographic (EMG) monitor. Patients with TOFR below 40% at reversal received Sugammadex in 20-mg increments every three minutes until TOFR reached 90% or greater; those with TOFR 40%-89% received Neostigmine and were excluded. Of the 130 patients who consented, 105 completed the protocol. Sugammadex dose was correlated with Rocuronium dose using Pearson correlation and linear regression.

Results: Of 105 patients, 102 (97%) required less than the FDA-recommended dose of 2, 4, or 16 mg/kg; 2 patients required the recommended dose, and 1 patient required more. Seventy patients (67%) required 100 mg or less, and 19 patients (18%) required 40 mg or less. Sugammadex dose correlated significantly with Rocuronium dose ($r=0.423$, $r^2=0.179$, $P<.001$) but not with weight or depth of block.

Conclusions: The Sugammadex dose required to achieve a TOFR of 90% or greater was determined by the total Rocuronium dose, not by weight or block depth. It was substantially lower than the FDA recommended dose in most patients. These findings support a Rocuronium-based dosing methodology and reinforce the need for quantitative monitoring, rather than fixed weight-based dosing, to individualize reversal.

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Received: September 30, 2026; **Accepted:** October 06, 2026; **Published:** October 14, 2026

Introduction

In January 2023, the American Society of Anesthesiologists (ASA) published its first-ever practice guideline for the monitoring and antagonism of neuromuscular blockade. The ASA concluded that quantitative neuromuscular monitoring and achieving a $\geq 90\%$ Train-of-Four Ratio (TOFR) were goals to be met prior to extubation. Regarding Sugammadex, the ASA recommended further investigation into its appropriate mg/kg dose and the use of ideal versus total body weight at various depths of neuromuscular blockade [1]. The following study may be helpful to anesthesia departments and providers through a reduction in Sugammadex underdosing, a reduction in Sugammadex overdosing, reducing costs, and improving patient safety through the elimination of residual neuromuscular blockade.

Currently, there are two recommendations regarding Sugammadex dosing. The first recommendation is from the Food and Drug Administration (FDA). The FDA prescribing information guides providers to administer 2mg, 4mg, or 16 mg/kg of Sugammadex, depending on the depth of neuromuscular blockade at the time of reversal [2]. The second recommendation is from the ASA. The ASA guideline advises returning patients to $\geq 90\%$ TOFR [1].

It may be difficult for the anesthesia provider to meet both Sugammadex dosing recommendations. When following the ASA's $\geq 90\%$ TOFR recommendation, the anesthesia provider will either administer Sugammadex above or below the FDA-recommended dosing. When following the FDA's recommendation, the patient could be extubated with residual paralysis ($<90\%$ TOFR) or receive more Sugammadex than necessary to achieve $\geq 90\%$ TOFR. Since TOFR $\geq 90\%$ is a clear and quantifiable goal, the

dose required to achieve this in milligrams per kilogram (mg/kg) is unlikely to be exactly the FDA-recommended 2, 4, or 16 mg/kg dose.

A previous Sugammadex titration protocol administered 50mg of Sugammadex every five minutes until the patient returned to $\geq 90\%$ TOFR. That study yielded surprising results, most notably, that the required Sugammadex dose was usually less than the manufacturer's recommendation. Also, the prior study determined that the Sugammadex dose could not be predicted from the train-of-four response immediately prior to reversal [3]. To contribute further research in this area, this study was conducted between August 1, 2023, and February 29, 2024, at the University of Mississippi Medical Center (UMMC) in Jackson, MS. The University of Mississippi Medical Center is the only level one trauma center in the state of Mississippi. The study enrolled 130 surgical patients who provided signed informed consent stating that, if Sugammadex was indicated for reversal, they would receive 20 mg Sugammadex boluses every three minutes until achieving $\geq 90\%$ TOFR. The researchers chose the smaller 20 mg Sugammadex doses to improve dosing precision compared with prior studies, while still maintaining a reasonable reversal duration [3]. Of the 130 consented patients, 105 received the Sugammadex dosing protocol, and 25 did not receive the Sugammadex dosing protocol, due to exclusion criteria. Of the 105 patients who received the dosing protocol, 102 required less than the FDA-recommended dose of either 2, 4, or 16 mg/kg at the time of reversal. Two of the 105 patients required the FDA-recommended dose, and one patient required more than the FDA-recommended dose.

Methods

This prospective, single-arm (non-randomized) dose-finding/titration study was approved by the Institutional Review Board at UMMC. While adhering to both the ASA guidelines and interdepartmental policy, patients with a TOFR $< 40\%$ at the time of reversal would be administered Sugammadex until a TOFR $\geq 90\%$ was achieved [1]. Patients who had a TOFR between 40-89% at the time of reversal were administered Neostigmine and Robinul, and those patients were excluded from the study. Randomization or patient grouping was not possible because the researchers could not predict which patients would have a TOFR below 40% at the time of reversal. The type of surgery was not controlled for and included orthopedic, general, urological, ear, nose, and throat, vascular, plastic, thoracic, oncologic, and neurosurgical procedures. At the end of the procedure, the patient's temperature was recorded, and the level of neuromuscular blockade was determined using a TwitchView™ Electromyography (EMG) neuromuscular monitor. Prior to emergence, a member of the research team would assess the patient, determine eligibility, and, when applicable, conduct the Sugammadex dosing protocol. When preparing Sugammadex for administration, eight milliliters (ml) of normal saline was mixed with two ml of Sugammadex (100 mg/ml) in a ten ml syringe. The final concentration of Sugammadex was 20 mg/ml. When deemed appropriate, the Sugammadex dosing protocol would be administered. The Twitchview™ stimulation frequency was set to every 15 seconds. A timer was started, and 20 mg (one ml) doses of Sugammadex were administered at three-minute intervals while the level of neuromuscular blockade was monitored; a subsequent dose of Sugammadex was administered if the TOFR was below 90%. This dosing protocol was repeated until a TOFR $> 90\%$ was achieved. Lastly, the total time to achieve TOFR $\geq 90\%$ and the percentage of muscle recovery prior to extubation were recorded.

Neuromuscular blockade was measured using the TwitchView™

EMG monitor. Each TwitchView™ electrode array was placed on either the patient's left or right upper extremity along the ulnar nerve, and the depolarization of the adductor pollicis muscle was measured. Monitoring was initiated after the patient was sedated but before administering the neuromuscular blocking agent (NMBA), Rocuronium. Unlike previous studies, the milli-amps (mA) delivered by the TwitchView™ EMG monitor were not controlled for [3]. Per the TwitchView™ EMG manufacturer's recommendations, the monitor was allowed to go through its optimization process and choose the appropriate mA for each patient. While 48 mA was the most common current chosen by the monitor, the mA applied to the patient could range from one to 80 mA.

- **Inclusion Criteria Included:** (a) Patients between the ages of 18 and 99 years old, (b) Both Genders, (c) All Races, (d) All Ethnicities, (e) English Speaking, and (f) All Surgical Procedures requiring a non-depolarizing neuromuscular block performed within the setting of the University of Mississippi Medical Center operating rooms.
- **Exclusion Criteria Included:** (a) Patients who require interpreters, (b) Patients with Pre-Existing Neuromuscular Disorders, (c) A Serum creatinine level > 1.5 mg/dL, and (d) Any history of difficult intubation or emergent airway rescue situation.

For this study, the researchers developed and used the Sugammadex dosing protocol below for each patient.

- Follow the ASA recommendations of extubating patients only after achieving $> 90\%$ TOFR
- If the patient is below 40% TOFR at the time of reversal, administer 20mg of Sugammadex every three minutes until $\geq 90\%$ TOFR is achieved (patients who were 40-89% TOFR at the time of reversal received Neostigmine and Robinul, and were excluded from the study)
- Record the neuromuscular relaxant drug and dose that had been administered at the time of reversal
- Record the patient's height, weight, gender, body mass index, ASA classification, and temperature at the time of reversal
- Record the corresponding depth of neuromuscular blockade at the time of each reversal dose
- Record the amount of Sugammadex (in mg) that was required to achieve $\geq 90\%$ TOFR
- Record the mg/kg equivalent by dividing the number of milligrams by the patient's weight
- Record the time between the first Sugammadex dose and achieving $\geq 90\%$ TOFR
- Record the percent (%) recovery of muscle function prior to extubation.

The study has a sample size of 130 consented patients. Of the 130 consented patients, 105 patients received the Sugammadex dosing protocol, and 25 patients were excluded due to the following factors:

- The patient spontaneously reversed the neuromuscular blocking agent and returned to TOFR $\geq 40\%$ by the time of surgical closure. In these instances, the patients received neuromuscular reversal with Neostigmine and Robinul.
- The patient spontaneously reversed the neuromuscular blocking agent and returned themselves to TOFR $\geq 90\%$ by the time of surgical closure. In these instances, the patients emerged from anesthesia without neuromuscular reversal agents being administered.

TwitchView™ malfunction. Occasionally, erroneous and/or inconsistent data were displayed on the TwitchView™ monitor.

These malfunctions could include, but are not limited to:

- Faulty/broken monitor or cables
- Faulty electrode array
- Human errors
- Patient conditions
- After consent, one patient's surgery unexpectedly continued late into the night, and a researcher was not present on emergence.
- After consent, three patients' surgeons changed the procedure, and no neuromuscular blocking agent was required.
- Upon induction, one patient's TwitchView™ touchscreen display remained on the default screen and would not progress into startup mode.
- Upon emergence, one patient's neuromuscular depth was a post-tetanic count (PTC) 0, but this was subsequently attributed to erroneous data capture.
- Upon emergence, one patient was qualified for the protocol, but a nurse anesthesia resident inadvertently administered an initial dose of 100 mg of Sugammadex instead of the 20 mg protocol dose.
- Upon the emergence of one patient, the researcher was with a patient in the intensive care unit and did not make it back to the operating room in time to conduct the protocol.
- During emergence, one patient emerged quickly, and the team felt it was inappropriate to continue the dosing protocol. The protocol was abandoned, the FDA-recommended dose of Sugammadex was administered, and the patient was extubated without complication.
- Toward the end of one surgery, the TwitchView data became erratic and inconsistent shortly after the dosing protocol had been initiated. Upon untucking the patient's arms, the probe was found to be mispositioned. The probe was repositioned, the data regained consistency, and the patient's TOFR was 95%. By this time, 60 mg of Sugammadex had been administered, and it was unclear exactly when the patient had exceeded 90%.
- Six patients spontaneously recovered to $\geq 90\%$ TOFR, and no neuromuscular reversal agents were given.
- Eight patients spontaneously reversed to $\geq 40\%$ TOFR; Neostigmine and Robinul were given, and 90% TOFR was achieved.
- One patient spontaneously reversed to 49% TOFR, and Neostigmine and Robinul were administered. After waiting 10 minutes, 88% TOFR was achieved. Sugammadex 20 mg was administered, achieving 96% TOFR, and the patient was successfully extubated.

Statistical Analysis

The study consisted of 105 patients. The primary endpoint was time to TOFR ≥ 0.9 . The patients were divided into two groups based on the train-of-four (TOF) at the end of the surgical procedure. There were 19 patients in the group TOF < 0 (PTC 0-15), and 86 patients in the group TOF 1- TOF 4 [1%-39%]. MedCalc statistical software (version 13.3) and VassarStats were used to analyze the data. Summary statistics, including mean and standard deviation, were calculated for different parameters in the study. Student's t-test was used for quantitative data, and confidence intervals with a $P < 0.05$ were considered statistically significant.

The time from the first dose of Sugammadex to the initial depth of neuromuscular blockade and to achieving a TOFR ≥ 0.9 was measured. The dose-response relationship with body weight was analyzed using correlation statistics, with dose as the independent variable. Effective dose was interpolated from regression models for TOF 1- TOF 4 [1%-39%], TOF < 1 , and TOF regardless of depth.

Table 1: Statistical Analysis

Parameter	Value
Pearson correlation coefficient (r)	0.4228
r ²	0.1788
P-value	0.000007007
Covariance	545.2656
Sample size (n)	105
Statistic	4.7354

Table 2: Body Mass Index (BMI) – P = 0.63

Parameter	N	BMI kg $\pm$ SD	CI (95%)	CI (99%)
PTC 0-15	19	29.9 $\pm$ 8.20	$\pm$ 1.7	$\pm$ 2.34
TOF 1- TOF 4 [1%-39%]	86	28.9 $\pm$ 6.24	$\pm$ 3.43	$\pm$ 4.76

Table 3: Sugammadex Dose – P = 0.002

Parameter	N	Rocuronium Dose (mg $\pm$ SD)	Rocuronium Dose (mg $\pm$ SD)	CI (99%)
PTC 0-15	19	76.8 $\pm$ 42.9	$\pm$ 5.43	$\pm$ 7.20
TOF 1- TOF 4 [1%-39%]	86	67.4 $\pm$ 11.7	$\pm$ 20.7	$\pm$ 28.4

Table 4: Rocuronium Dose – P = 0.373

Parameter	N	Rocuronium Dose (mg $\pm$ SD)	CI (95%)	CI (99%)
PTC 0-15	19	76.8 $\pm$ 42.9	$\pm$ 5.43	$\pm$ 7.20
TOF 1- TOF 4 [1%-39%]	86	67.4 $\pm$ 11.7	$\pm$ 20.7	$\pm$ 28.4

Table 5: Time to 97% - P = 0.003

Parameter	N	Time to 97% (min $\pm$ SD)	CI (95%)	CI (99%)
PTC 0-15	19	17.0 $\pm$ 6.50	$\pm$ 3.13	$\pm$ 4.29
TOF 1- TOF 4 [1%-39%]	86	11.8 $\pm$ 6.04	$\pm$ 1.32	$\pm$ 1.75

Table 6: Rocuronium mg/kg – P = 0.09

Parameter	N	Rocuronium (mg/kg $\pm$ SD)	CI (95%)	CI (99%)
PTC 0-15	19	1.00 $\pm$ 0.47	$\pm$ 0.26	$\pm$ 0.36
TOF 1- TOF 4 [1%-39%]	86	0.78 $\pm$ 0.39	$\pm$ 0.06	$\pm$ 0.08

Table 7: Sugammadex mg/kg – P = 0.001

Parameter	N	Sugammadex (mg/kg $\pm$ SD)	CI (95%)	CI (99%)
PTC 0-15	19	1.55 $\pm$ 0.39	$\pm$ 0.21	$\pm$ 0.30
TOF 1- TOF 4 [1%-39%]	86	1.03 $\pm$ 0.56	$\pm$ 0.13	$\pm$ 0.17

Table 8: Rocuronium / Sugammadex mg/kg – P = 0.04

Parameter	N	Rocuronium/Sugammadex (mg/kg)/(mg/kg)	CI (95%)	CI (99%)
PTC 0-15	19	0.68 $\pm$ 0.33	$\pm$ 0.19	$\pm$ 0.26
TOF 1- TOF 4 [1%-39%]	86	0.91 $\pm$ 0.49	$\pm$ 0.10	$\pm$ 0.14

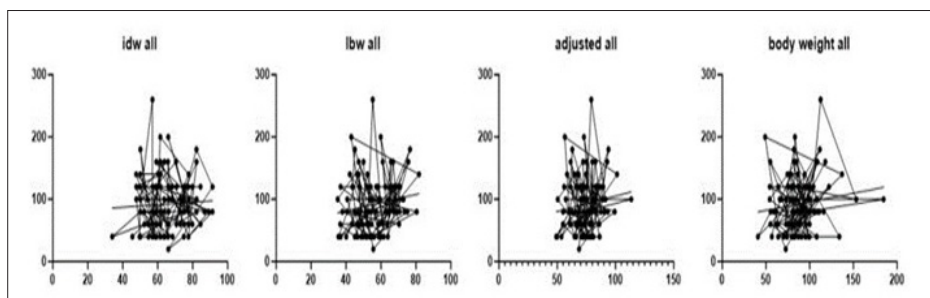


Figure 1: Weight All

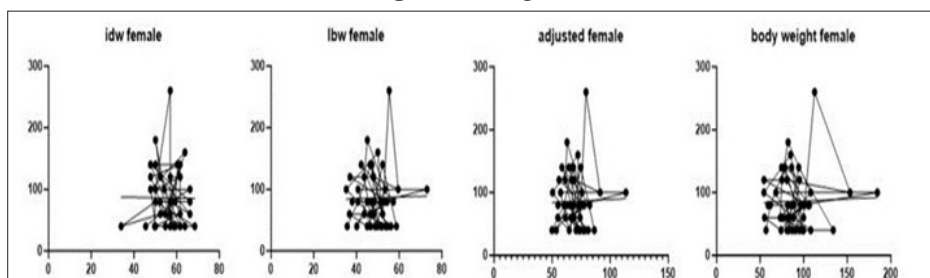


Figure 2: Weight Female

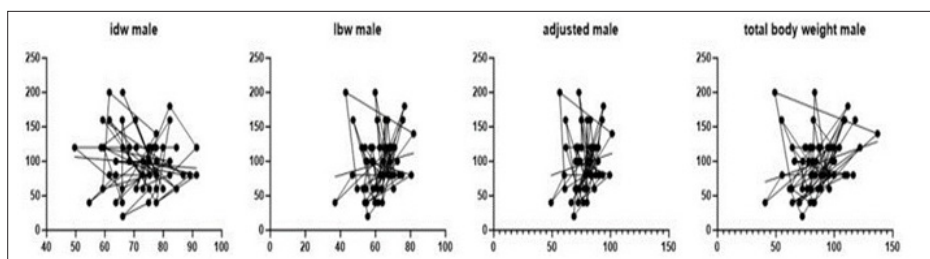


Figure 3: Weight Male

Dose of Rocuronium to Sugammadex

When grouping all patients, regardless of their depth of neuromuscular block at the time of reversal, the Pearson correlation indicated a significant, medium positive relationship between X and Y ($r(105) = .423$, $p < .001$). Equation of the line $y = 0.631 * X + 49.92$, where X = rocuronium.

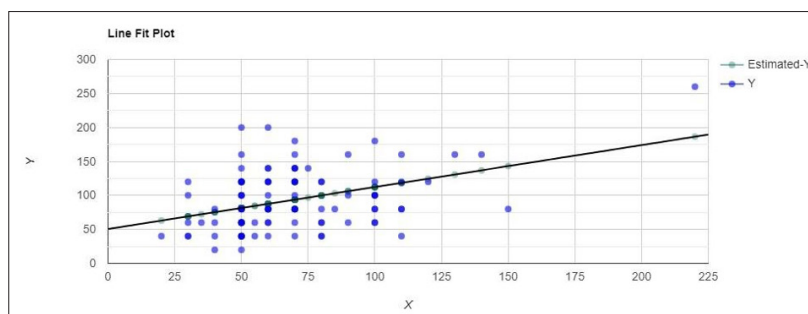


Figure 4: Line Fit Plot 1 - Equation of the Line Considering All Samples Regardless of Depth Sugammadex Dose (mg) = $0.631(\text{Roc dose mg}) + 49.92$

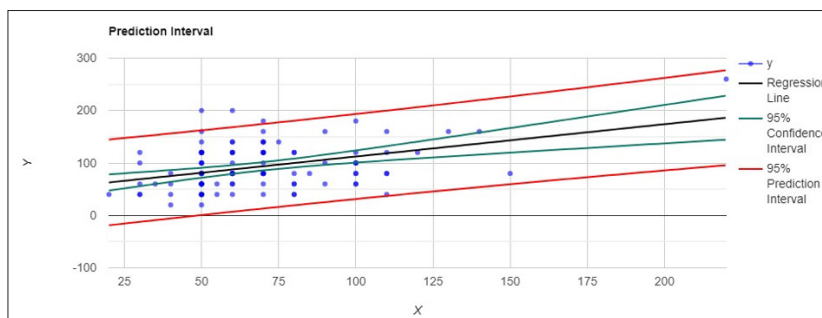


Figure 5: Prediction Interval 1 - Prediction Interval for All Samples Regardless of Depth

When grouping patients by depth (TOF 1–TOF 4 [1%–39%]), the Pearson correlation indicated a significant, medium-sized positive relationship between X and Y ($r(105) = .423$, $p < .001$). Equation of the line $y = 0.5654 * X + 48.15$, where X = rocuronium

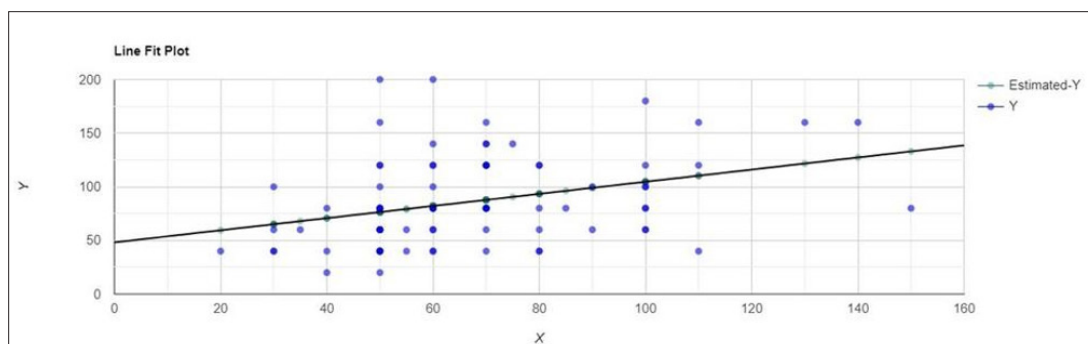


Figure 6: Line Fit Plot 2 - Equation of the Line for TOF 1 - TOF 4 [1%-39%] - Sugammadex dose (mg) = $0.5654 (\text{Roc dose mg}) + 48.15$

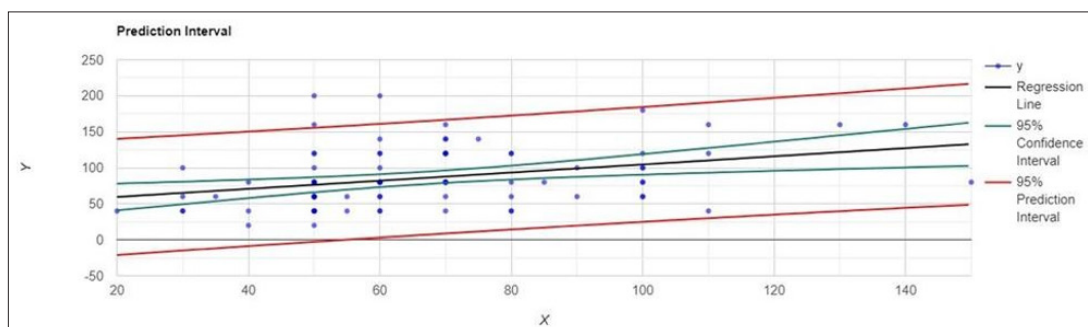


Figure 7: Prediction Interval 2 – for TOF 1 – TOF 4 (1% - 39%)

When grouping patients by depth PTC 0-15, the Pearson correlation indicated a significant medium-sized positive relationship between X and Y ($r(105) = .423$, $p < .001$).

Equation of the line $y = 0.5677 * X + 80.59$, where X = rocuronium

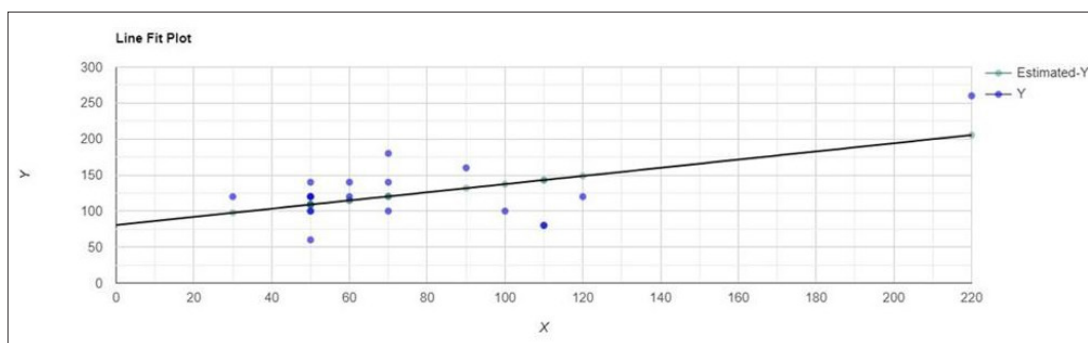


Figure 8: Line Fit Plot 3 - Equation of the line for PTC 0-15

Sugammadex dose (mg) = $0.5677 (\text{Roc dose mg}) + 80.59$

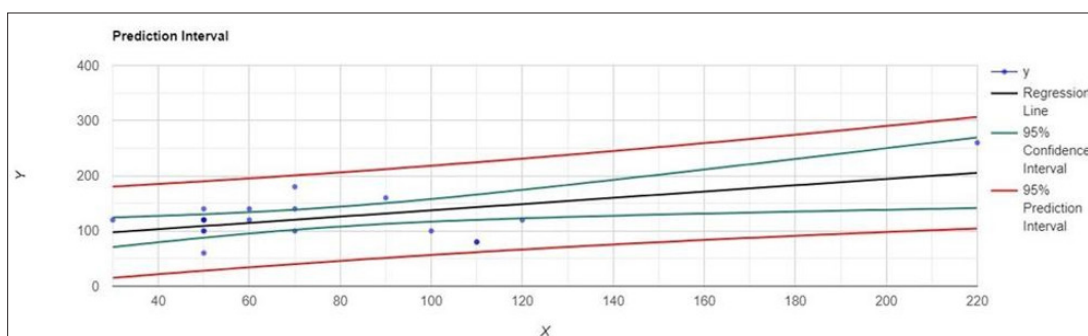


Figure 9: Prediction Interval 3 - Prediction Interval for PTC 0-15

Discussion

The researchers determined that the dose of Sugammadex required to achieve neuromuscular reversal was dependent on the total amount of Rocuronium administered, regardless of the depth of neuromuscular block at the time of reversal. This conclusion is further supported by Sugammadex mechanism of action, which involves binding to Rocuronium molecules in a 1:1 ratio [3,4]. While depth of neuromuscular block is thought to be directly correlated to the amount of Rocuronium administered, factors including the effect Rocuronium has on each patient, as well as the patient's natural metabolism of Rocuronium, are both variable and unpredictable. This inter-patient variability results in the observed phenomenon that two similar patients can receive the same dose of Rocuronium yet have various depths of neuromuscular block.

Furthermore, the researchers determined that the degree of reversal diminished with each additional dose of Sugammadex administered. Initially, the possibility of varying concentration gradients was the leading theory behind this finding. This theory is supported by prior pharmacokinetic studies showing that neuromuscular blocking agents (NMBA) molecules escape the synaptic cleft and enter the plasma due to the concentration gradient created after unbound NMBA molecules are encapsulated by Sugammadex [5]. Upon further review of the literature, the researchers believe that it is less likely associated with a concentration gradient and more with binding affinity. The binding affinity of Rocuronium to Sugammadex is defined as a binding constant (K_a) of 25×10^6 M⁻¹ [6]. The binding affinity of Rocuronium to the acetylcholine receptor, however, has yet to be defined. It is plausible to assume that Rocuronium's affinity for the receptor is either greater than or, at a minimum, equivalent to its affinity for Sugammadex. This would explain the plateau and corresponding weaker responses with repeated doses of Sugammadex. To elaborate further, there would be fewer free Rocuronium molecules available to bind, and the remaining molecules would need to dissociate spontaneously. They would likely be replaced by acetylcholine before binding to Sugammadex. As the concentration of acetylcholine increases, which is made difficult by its rapid metabolism by acetylcholinesterase, the concentration would once again favor the binding of acetylcholine over Rocuronium, leaving the remaining molecules to be either chelated by Sugammadex or metabolized by the liver [7-10].

This prospective, single-arm (non-randomized) dose-finding/titration study was designed to explore the reversal of Rocuronium. The researchers made no efforts to guide the anesthetic technique or the use of Rocuronium. The doses of Rocuronium and other agents administered to patients in this study reflect the variability in anesthetic techniques among providers. This study determined the following:

- **No Correlation to Weight:** The dose of Sugammadex required for patients was not correlated with weight in any measure (actual, ideal, lean, or adjusted).
- **No Correlation to Depth:** Amongst anesthesia providers, it is generally known that increased administration of neuromuscular blocking agents (NMBAs) results in greater neuromuscular block depth. If an anesthesia provider administers additional Rocuronium and then follows the FDA-recommended dosing, the guidelines do not increase the recommended Sugammadex dose. The depth of neuromuscular block achieved after administering an NMBA varies widely among patients and appears to be an individualized, independent factor.

- **Time Matters:** The researchers noted that after a dose of Sugammadex, neuromuscular function improved rapidly and consistently for approximately five minutes. The speed of neuromuscular recovery then begins to slow; improvement continues for approximately ten minutes, after which no further improvement is observed. Once the recovery from Sugammadex ceases, it would be reasonable to expect that the patient's spontaneous recovery via metabolism of the remaining NMBA would continue, allowing for the typical, steady improvement in neuromuscular function over time. The researchers noted a case example, in one patient, the anesthesia provider administered Sugammadex well before surgical closure, and no further spontaneous recovery from neuromuscular block was observed until approximately one hour after Sugammadex administration.
- **Diminishing Returns:** The researchers noted that with each additional 20 mg dose of Sugammadex, neuromuscular block recovery was progressively reduced.
- **Regression:** Regression (recurarization) was observed in one of the 105 patients, similar to findings in other studies [3]. This one patient was at a PTC of one at the time of Sugammadex reversal, and the patient achieved 100% TOFR after 80 mg Sugammadex. Over the next 17 minutes after 100% TOFR, the patient regressed to 80% TOFR. After dropping to a TOFR of 80%, the patient then, over the next 37 minutes, began to spontaneously recover back to 90%, without any additional neuromuscular reversal agents. Since it is estimated that only one of every 25,000,000 bound Sugammadex/rocuronium complexes will disassociate, it seems unlikely that recurarization is due to dissociation [4].
- **Reversing patients from PTC 0:** With Sugammadex, three of the 105 patients were reversed from a PTC of 0, and there is currently no FDA dosing recommendation for that level of neuromuscular block. Despite the common moniker of "complete neuromuscular blockade," it is still possible for patients to move and breathe at all depths of neuromuscular block, including PTC 0 [1-8]. If a patient's neuromuscular block is a PTC of 0, and additional Rocuronium is administered, the next TwitchView measurement will still be a PTC of 0. This scenario makes any dosing recommendation based on depth of neuromuscular block even more challenging. Ward recently proposed the "Bergin Zone" theory, which suggests that multiple depths within a PTC of 0 cannot be detected by current monitoring technology. Ward's theory also postulates that those depths, and their subsequent reversal, will not be static as the continued measurement of a PTC of 0 would suggest, but would be just as fluid and dynamic as a PTC of one to 15 and a TOF of one to four [9].

This study had several limitations. During the statistical analysis, other potentially vital data points were identified, including Rocuronium re-dosing and the timing between re-dosing and neuromuscular reversal. Also, the researchers did not consider potential medications that could affect acetylcholine (its release or breakdown), or comorbidities that could affect the number of nicotinic acetylcholine receptors (positively or negatively), such as burns, immobilization, or myasthenia gravis [11-13].

Regarding Sugammadex, the ASA recommended further investigation into its appropriate mg/kg dose and the use of ideal versus total body weight at various depths of blockade [1]. The data analysis of this study provides many avenues for future research. Future research could explore additional data points, including age; the timing of Rocuronium dose(s) during the anesthetic; the timing of Sugammadex administration relative to the last

Rocuronium dose; review of medications; the effects of anesthetic gases; comorbidities; hepatic function; and renal function. Also, the standardization of Rocuronium dosing in terms of mg/kg or a Rocuronium infusion titrated to a predetermined depth of blockade. Given the single-center, non-randomized design of this study, prospective validation of the proposed dosing equations in a larger, multicenter cohort is warranted before adoption into routine clinical practice.

Conclusion

This prospective, single-arm dose-finding study demonstrates that the Sugammadex dose required to achieve a TOFR of 90% or greater is determined primarily by the total Rocuronium dose administered, rather than by patient weight or the depth of neuromuscular block at the time of reversal. In most patients, the Sugammadex dose was substantially lower than the FDA's weight-based recommendations, suggesting that fixed 2, 4, or 16 mg/kg dosing frequently overestimates the Sugammadex actually needed for adequate reversal. The regression equations derived from this cohort offer a Rocuronium-based alternative to weight-based dosing that may help anesthesia providers individualize reversal, reduce unnecessary drug cost, and avoid both under- and overdosing. These findings reinforce the ASA's 2023 guidance that quantitative neuromuscular monitoring, rather than weight-based dosing alone, should guide the decision to extubate. Given the single-center, non-randomized design of this study, prospective validation of the proposed dosing equations in a larger, multicenter cohort is warranted before adoption into routine clinical practice.

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