



The Relationship between the Sugammadex Use and Postoperative Reintubation in the Absence of Neuromuscular Monitoring

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Background: Evidences show that sugammadex may facilitate extubation after surgery. Applying neuromuscular monitoring in general anesthesia may prevent postoperative reintubation. However, routine general anesthesia does not always include neuromuscular monitoring. Therefore, we investigated the relationship between the sugammadex use and postoperative reintubation in the absence of neuromuscular monitoring. **Methods:** We conducted a retrospective analysis of the incidence of postoperative reintubation in the operating room (OR) or postanesthesia care unit following sugammadex use in the absence of neuromuscular monitoring that involved a large number of patients over 4 years (from January 2017 to August 2020). Postoperative reintubation was applied for patients who had peripheral oxygen saturation <90% despite being given 6 L/min oxygen with a face mask. Patients with perioperative neuromuscular monitoring, renal or hepatic failure, electrolyte imbalance, body mass index over 35, incomplete data, and age under 20 years were excluded. All data from the ORs' database and anesthesia records were analyzed. **Results:** Of 6582 patients receiving sugammadex, 6313 were included in this study. Two confirmed cases of postoperative reintubation were detected, with an incidence of 0.03% (2 of 6,313). As of the type of surgery, a 34 years old male received elective thoracic surgery, and another 66 years old male received elective urological surgery. No long-term pulmonary sequelae were found. **Conclusion:** This study suggests that the occurrence of postoperative reintubation following sugammadex (2–4 mg/kg) use is rare even in the absence of neuromuscular monitoring. Further large prospective studies are required to validate the findings of this study.

Key words: Sugammadex, general anesthesia, reintubation, neuromuscular monitoring, postoperative residual curarization

INTRODUCTION

Sugammadex is a cyclodextrin molecule that encapsulates and inactivates rocuronium and vecuronium. As a result, any degree of neuromuscular block produced by rocuronium or vecuronium can be rapidly and completely reversed without autonomic effects.¹ Sugammadex has been demonstrated to shorten extubation time, resulting in improvement of operating room (OR) turnover in clinical anesthesia settings.² Among a generalizable cohort of adult patients undergoing inpatient surgery at American hospitals, the use of sugammadex was associated with a clinically and statistically significant lower incidence of major pulmonary complications.³

Therefore, sugammadex may be a useful factor for the enhanced recovery after surgery protocol.^{2,3} Such assessments require the aid of appropriate neuromuscular transmission (NMT) monitoring devices.⁴

However, Kirmeier *et al.*⁵ concluded that “the use NMT monitoring could not decrease this risk of postoperative pulmonary complications. In addition, the use of quantitative NMT monitoring in 4182 patients compared with qualitative NMT monitoring in 2686 patients was seemingly not associated with a reduced risk of postoperative pulmonary complications.”⁶

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Yazar *et al.*⁷ also reported that the incidence of postoperative reintubation were found to be 1.7% even with administration of sugammadex and NMT monitoring. Moreover, a recent report shows that the use of quantitative NMT monitoring alone does not preclude residual neuromuscular block.⁸

In fact, most Australian and New Zealand anesthesiologists, 19.3% European anesthesiologists, and 9.4% American anesthesiologists never use NMT monitoring for the management of neuromuscular blocking agents (NMBAs).^{9,10} In Taiwan, routine clinical anesthesia does not usually include NMT monitoring by its inconvenience, or unreliable due to the patient's inappropriate hand position during surgery and emergence. Moreover, this is also not uncommon elsewhere in the world.^{2,10-14}

To the best of our knowledge, the relationship between sugammadex without perioperative NMT monitoring and postoperative reintubation has not been well demonstrated. Therefore, this retrospective study aims to evaluate the incidence rate of postoperative reintubation following sugammadex use in the absence of NMT monitoring, in routine clinical practice, and any kind of surgery.

MATERIALS AND METHODS

This study was approved by the Ethics Committee (TSGHIRB No: A202105042) of Tri-Service General Hospital (TSGH), Taipei, Taiwan (Chairman, Professor Yu Mu Hsien) on February 22nd, 2021. All methods were performed in accordance with the relevant guidelines and regulations by domestic IRB.

Relevant information was retrieved from the medical records and the electronic database of TSGH. A single-center retrospective study involved adult patients under general anesthesia with sugammadex use was conducted from January 2017 to August 2020 in Taipei, Taiwan. 6,313 patients with the American Society of Anaesthesiologists (ASA) score of I–III who had undergone elective or nonelective surgery under general anesthesia with sugammadex use in the absence of NMT monitoring were included. The exclusion criteria were perioperative NMT monitoring use, renal or hepatic failure, electrolyte imbalance, body mass index over 35, incomplete data, and age under 20 years. Following these criteria, a total of 269 patients were excluded from this study [Figure 1].

No premedication was given before anesthesia induction. Routine monitoring, including noninvasive blood pressure, electrocardiography (lead II), pulse oximetry, and end-tidal carbon dioxide (EtCO₂), was established for each patient. Direct radial arterial blood pressure and a central venous catheter were used in patients undergoing major surgery.

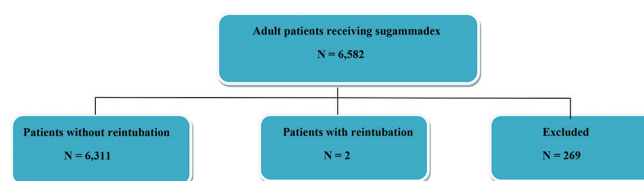


Figure 1: Flow diagram detailing the selection of patients included in the retrospective analysis. 269 patients were excluded due to perioperative neuromuscular monitoring use, renal or hepatic failure, electrolyte imbalance, body mass index over 35, incomplete data, and age under 20 years

Before anesthesia induction, all IV infusion lines were examined. Anesthesia was induced using fentanyl (1–2 µg/kg) or remifentanyl (0.5–1 µg/kg), propofol (1–2.5 mg/kg), and rocuronium (0.6 mg/kg) in all cases.

Anesthesia was maintained with target-controlled infusion (TCI) (Fresenius Orchestra Primea; Fresenius Kabi AG, Bad Homburg, Germany) using propofol at an effect-site concentration (Ce) of 3.0–4.0 µg/mL in the propofol-based total intravenous anesthesia (TIVA). Patients with TIVA received FiO₂ of 50%–100% oxygen at a flow rate of 0.3 L/min. Patients with inhalation anesthesia (INHA), the desflurane vaporizer was set between 4% and 10% in 50%–100% oxygen at a flow of 0.3 L/min, or the sevoflurane vaporizer was set between 2% and 4% in 50%–100% oxygen at a flow of 1.0 L/min in a closed breathing system. Repetitive boluses of rocuronium (0.1–0.2 mg/kg) and fentanyl (0.5–1 µg/kg) (or continuous infusion of remifentanyl with TCI) were given as necessary throughout the operation. No routinely NMT monitoring was applied during surgery.¹⁵⁻²¹ INHA or maintenance of the Ce with TCI using propofol was adjusted downward and upward by 0.5%–2% or 0.2–0.5 µg/mL, respectively, when needed based on the hemodynamics. The level of EtCO₂ was kept at 35–45 mmHg by adjusting the ventilation rate with a maximum airway pressure <30 cm H₂O with a 5 cmH₂O positive end expiratory pressure. The bispectral index (BIS)-guided protocol was conducted in high-risk surgical patients.²² The BIS monitor (BISTM, Medtronic, Covidien, USA) was within the range of 40–60 and used in hemodynamic instability, low maintained Ce of propofol Ce, previous history of alcoholism, previous history of awareness, low body weight (body mass index; BMI ≤18), poor functional activity (<4 metabolic equivalents or ejection function <35%), and as per patients' request. Besides, 2.5–5.0 mg of midazolam was administered for prevention intraoperative awareness when higher propofol Ce (>6 µg/mL) was required for a patient to lose consciousness.

At the end of the skin closure, the lungs were ventilated with 100% oxygen at a fresh gas flow of 6 L/min. Once spontaneous breathing returned, reversal of neuromuscular function was achieved by administering sugammadex (2–4 mg/kg) by the anesthesiologist in charge to prevent residual paralysis. When

the patient regained consciousness by name with spontaneous and smooth respiration, the endotracheal tube was removed. Patients were sent to the post-anesthesia care unit (PACU) or intensive care unit and were assessed after surgery by the anesthesiologist in charge.

The primary outcome assessment tested the incidence of postoperative reintubation, which was detected by the patients who had peripheral oxygen saturation <90% despite being given 6 L/min oxygen with a face mask in the OR and PACU following surgery. In addition, we evaluated the patients' characteristics (age, sex, height, weight, ASA), and the type of anesthesia or surgery. Medical information of the patients, along with the results of the postoperative evaluation, were analyzed. Data are presented as the mean and standard deviation of a number of patients. The statistical analysis was performed using Sigmapstat 3.5 (Systat Software Inc, San Jose, CA, USA) for Windows.

RESULTS

Out of 6582 patients assessed for eligibility, 6313 were enrolled in this study. Table 1 summarizes the characteristics of the patients and the type of surgery. Two cases of postoperative reintubation were detected, corresponding to an incidence of 0.03% (2/6313). The average age was 62.4 ± 8.5 years old, the height was 164.7 ± 9.7 cm, and the weight was 63.7 ± 8.2 kg. A total of 3242 men and 3071 women were enrolled in the study. Furthermore, the study included 643 ASA I patients, 4308 ASA II patients, and 1362 ASA III patients. There were 4931 (78.1%) patients under INHA, and 1382 (21.9%) patients under TIVA. Duration of surgery was 153.1 ± 80.5 min, and total dose of rocuronium was 72.6 ± 32.9 mg. The analysis of two patients with postoperative reintubation was summarized in Table 2. During the analysis period, the other 66 years old male (height of 163 cm and weight of 65 kg) underwent postoperative reintubation due to severe laryngospasm following administration of 100 mg sugammadex under unintubated trachea, but endotracheal tube was extubated few minutes later without any sequelae.²³

Case 1

A 34-year-old ocular myasthenia gravis male (height of 174 cm and weight of 64 kg; treated with oral pyridostigmine 60 mg three times a day) was scheduled for video-assisted thoracic surgery with removal of mediastinal tumor. Initially, we tried to use NMT monitoring perioperatively, however, there was no available NMT monitoring at that time. Fortunately, the patient's hemodynamics were stable and SpO₂ 99% to 100% (with 100% oxygen at a flow rate of 1 L/min.) during the surgery, and the procedure was

Table 1: Characteristics of the patients and surgery (*n*=6313)

Total cohort eligible number	<i>n</i> (%)
Age (years)	62.4±8.5
Height (cm)	164.7±9.7
Weight (kg)	63.7±8.2
Sex (male/female)	3242/3071
ASA (I/II/III)	643/4308/1362
Type of anesthesia	
Inhalation	4931 (78.1)
TIVA	1382 (21.9)
Surgical modality	
Elective	5890 (93.3)
Nonelective	423 (6.7)
Type of surgery	
General surgery	1156 (18.3)
Colorectal surgery	442 (7.0)
ENT surgery	334 (5.3)
Orthopedic surgery	778 (12.3)
Thoracic surgery	747 (11.8)
Cardiovascular surgery	25 (0.4)
Neurosurgery	572 (9.1)
Urological surgery	585 (9.3)
Gynecologic surgery	635 (10.1)
Oral and maxillofacial surgery	99 (1.6)
Plastic surgery	186 (2.9)
Ophthalmologic surgery	754 (11.9)
Duration of surgery (min)	153.1±80.5
Total dose of rocuronium (mg)	72.6±32.9

Data shown as mean±SD or *n* (%). ASA=American Society of Anesthesiologists; TIVA=Total intravenous anesthesia; ENT=Ear, nose and throat; SD=Standard deviation

performed smoothly. The duration of surgery was about 3 h, and the total dose of rocuronium was 70 mg. After the operation, sugammadex ×200 mg was administered to facilitate the recovery of spontaneous respiration as he emergence from anesthesia. When the patient regained consciousness and the endotracheal tube was extubated. However, dyspnea and desaturation happened following extubation immediately. Sugammadex-induced laryngospasm,²³ or postoperative myasthenic crisis²⁴ was highly suspected. He was reintubated (without vocal cord edema or laryngospasm at that time) in the OR, and postoperative myasthenic crisis was diagnosed by the neurologist. After emergent treatment, he was sent to the intensive care unit. After 5 times of plasma exchange, the patient was successfully extubated. Finally, he discharged without any sequela [Table 2].

Table 2: Analysis for two cases with postoperative reintubation following sugammadex use in the absence of neuromuscular monitoring

	Past history	Surgical procedure	Cause analysis
Case 1 (34 years old male; ASA III)	Myasthenia gravis	VATS with removal of mediastinal tumor	Occurrence of postoperative myasthenic crisis after administration of sugammadex
Case 2 (66 years old male; ASA II)	Hypertension	Flexible ureteroscopy	Disconnection of the intravenous line while administration of sugammadex

ASA=American Society of Anesthesiologists; VATS=Video-assisted thoracic surgery

Case 2

A 66-year-old male, with a height of 171 cm and weight of 89 kg, underwent an elective left side retrograde intrarenal surgery using the flexible ureteroscope, due to suspected urothelial cancers. He was classified as ASA physical status II due to a medical history of hypertension. The anesthesia and operation proceeded uneventfully, and the hemodynamics were stable. The duration of surgery was about 34 min, and the total dose of rocuronium was 50 mg. At the end of the surgery, we used sugammadex $\times 200$ mg to reverse neuromuscular function and prevent residual paralysis once spontaneous breathing returned, however, disconnection of the intravenous line was noted during the administration of sugammadex. After the administration of uncertain dose of sugammadex, the patient regained consciousness by name with spontaneous respiration, the endotracheal tube was removed and the patient was sent to the PACU for further care. However, dyspnea and desaturation happened while arrival of PACU. He was reintubated (without vocal cord edema or laryngospasm at that time) in the PACU. After emergent treatment with another dose of sugammadex $\times 200$ mg, dyspnea and desaturation were improved, and residual paralysis was diagnosed. Subsequently, he was successfully extubated in the PACU and sent to the general ward. Finally, he discharged without any sequela [Table 2].

DISCUSSION

In the present medical center, the incidence of postoperative reintubation following sugammadex use in the absence of NMT monitoring was 0.03%, which was similar with recently reported rates (0%) under sugammadex use without NMT monitoring.^{2,11} Our results are similar with the recent studies^{2,11} due to the use of 100–200 mg (2–4 mg/kg) of sugammadex being the most common standard dose without NMT monitoring in our institution. Park *et al.*² demonstrated that there was no occurrence of postoperative reintubation in patients ($n = 68$) receiving sugammadex in the absence of NMT monitoring by use of sugammadex $\times 2$ –4 mg/kg in laryngeal microsurgery. Iwasaki *et al.*¹¹ also reported that there was no occurrence of postoperative reintubation in patients ($n = 952$)

receiving sugammadex in the absence of NMT monitoring by use of 200 mg of sugammadex being the most common “standard” dose. However, Domenech *et al.*²⁵ reported that 16% (3/19) patients receiving 2–4 mg/kg sugammadex without NMT monitoring developed postoperative neuromuscular blockade without mention of the incidence of postoperative reintubation. Moreover, Kotake *et al.*²⁶ reported that the risk of train-of-four (TOF) ratio <0.9 after tracheal extubation after 2–4 mg/kg sugammadex remains as high as 9.4% in a clinical setting in which NMT monitoring was not used, but no postoperative reintubation was found ($n = 117$). As our two cases are uncommon (postoperative myasthenic crisis and disconnection of intravenous line), therefore, our results revealed that 2–4 mg/kg of sugammadex without NMT monitoring is safe in general population.

Kao *et al.*²⁷ reported that 0.09% patients ($n = 2164$) receiving sugammadex with NMT monitoring underwent postoperative reintubation due to negative-pressure pulmonary edema. Yazar *et al.*⁷ reported that 1.7% patients ($n = 60$) receiving sugammadex with NMT monitoring underwent postoperative reintubation. A multicenter matched cohort study conducted by Kheterpal *et al.*³ reported that 0.8% (189/22,856) patients suffered from postoperative respiratory failure and reintubation following sugammadex use, and 70.9% (16,215/22,856) patients were under NMT monitoring (without subgroup analysis). Domenech *et al.*²⁵ also reported that the use of intra-operative NMT monitoring and sugammadex were associated with a lower incidence of residual neuromuscular blockade (without mention of the incidence of postoperative reintubation), with calculated odds ratios of 0.04 and 0.18, respectively. Accordingly, the use of NMT monitoring even when sugammadex is used for antagonism of rocuronium-induced neuromuscular block is recommended.²⁶ However, in the current study, the incidence of postoperative reintubation were lower (0.03%) than previously reported rates (0.09%–1.7%) under sugammadex use with NMT monitoring.^{3,7,27}

The POPULAR study reported that 17,150 patients received NMBAs, but in more than 10,000 of these patients, NMT monitoring was not applied, and the extubation of their tracheas was based solely on clinical criteria. Moreover, approximately one-third of the patients who received NMT monitoring were extubated with a TOF ratio <0.9 .⁵ In STRONGER study, 35.7%

(16,336/45,712) patients did not receive NMT monitoring in American adult patients undergoing inpatient surgery.³ In this study, there were 29.1% of patients received sugammadex without NMT monitoring during surgery.³ It is thus difficult to state that the routine use of NMT monitoring is necessary in general anesthesia. A more relevant conclusion should be to reinforce the fact that while inadequate or inappropriate NMT monitoring management, NMBAs could lead to severe adverse events.⁵ Cammu *et al.*²⁸ showed that between 2012 and 2018, the management of NMBAs in a single-center, they revealed that NMT monitoring use in the OR had increased over time, however, 14% residual neuromuscular blockade remained apparent in the PACU. Even if monitored, patients receiving sugammadex had a TOF ratio between 0.7 and 0.9 in the PACU, it might result from the inappropriate practice of neuromuscular blockade management.²⁸ The lack of appropriate dosing of sugammadex and the lack of checking the TOF ratio before extubation of the endotracheal tube could be the reasons for the residual neuromuscular blockade in the PACU in the abovementioned study.²⁸ We agree that the failure to recognize residual neuromuscular blockade could ultimately be attributed to a failure to monitor neuromuscular blockade or a lack of understanding of neuromuscular pharmacology.²⁹ Accordingly, we suggest that the use of quantitative NMT monitoring alone does not preclude residual neuromuscular blockade and the improvements in the interpretation of NMT monitoring may be necessary.

The most common reason for postoperative reintubation after sugammadex use might be old age (≥ 75 years).⁷ In our case 1, a 34 years old patient encountered postoperative myasthenic crisis and postoperative reintubation even after administration sugammadex $\times 200$ mg. For this high-risk patient, the use of NMT monitoring was strongly recommended.³⁰ However, no NMT monitoring was available at that time, and it was against our principle of using NMT monitoring in patients with neuromuscular disease.³⁰ Finally, even under NMT monitoring, the symptoms of postoperative myasthenic crisis could not be improved by the administration of sugammadex due to exhaustion of the muscles with postoperative residual neuromuscular blockade (defined as a TOF ratio < 0.9).^{31,32} In our case 2, a 66 years old patient underwent reintubation due to the disconnection of the intravenous line during the administration of sugammadex. Thus, the patient might receive inappropriate dose of sugammadex and suffer from postoperative residual neuromuscular blockade, and it was an avoidable malpractice. Inconsistently, our two cases were < 75 years, and further investigation was needed for validation of other common reasons of postoperative reintubation after sugammadex use.

This study has a few limitations. First, the study is a retrospective analysis in a single medical center. The

additional, well-designed, multicentral studies are required to investigate this phenomenon further. Second, a previous study reported that old age patients were more likely to experience postoperative reintubation after sugammadex use.⁷ However, the association between the patient's age and postoperative reintubation following sugammadex use is not determined in the present study, and additional studies will be necessary to establish the association. Finally, we did not conduct the analysis of postoperative reintubation following sugammadex use with NMT monitoring. In our hospital, we only use NMT monitoring in self-paid sugammadex for high-risk patients such as obese patients (BMI > 35),³³ patients with obstructive sleep apnea,³⁴ patients undergoing high-risk eye surgery including keratoplasties and pars plana vitrectomies,³⁵ patients with chronic obstructive pulmonary disease,³⁶ and patients with neuromuscular disease, due to lack of neuromuscular monitoring.³⁰ Moreover, most cases receiving sugammadex with NMT monitoring are high-risk eye surgery patients. It may be a confounding factor in the analysis of postoperative reintubation following sugammadex use with NMT monitoring, and further investigation is necessary.

CONCLUSION

This single-center retrospective study suggests that the incidence of postoperative reintubation after sugammadex use is very low even in the absence of NMT monitoring.

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Conflicts of interest

There are no conflicts of interest.

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