



Original Research Article

Comparison of efficacy and safety profile of sugammadex versus neostigmine for reversal of rocuronium induced neuromuscular blockade in elective lumbar spine surgeries: A prospective randomized controlled trial

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Abstract

Background and Aim: Effective reversal of neuromuscular blockade is essential to prevent postoperative complications such as residual paralysis and respiratory distress. Neostigmine has long been used for this purpose, but its side effects and slower onset have prompted interest in alternatives like Sugammadex. This study assessed the effectiveness and safety of Sugammadex (2 mg/kg) compared to Neostigmine (50 µg/kg) in reversing rocuronium-induced neuromuscular blockade in patients undergoing planned lumbar spine surgery under neurosurgical anesthesia in India. The research focused on evaluating the reversal capabilities of these two agents in this specific clinical setting.

Materials and Methods: This prospective, randomized controlled trial included 80 patients (ASA Class 1–3) who were administered rocuronium (1.2 mg/kg) for endotracheal intubation, with supplemental doses given as required. Neuromuscular blockade (NMB) was assessed using train-of-four (TOF) monitoring. Upon reappearance of the second twitch, participants were randomly allocated to receive either Sugammadex or neostigmine with glycopyrrolate. The primary outcome measure was the recovery time required for the TOF ratio to reach 0.9.

Results: Patients receiving sugammadex had a geometric mean recovery time of 1.85 minutes (95% CI: 1.5–2.1), compared to 5.88 minutes (95% CI: 2.9–8.9) for neostigmine. Sugammadex was well tolerated, with no serious adverse events or instances of residual or recurrent NMB noted.

Conclusion: Sugammadex facilitated a significantly faster recovery from NMB than neostigmine, achieving recovery approximately three times quicker in the studied population. It was well tolerated, with no serious adverse events, and demonstrated a favourable safety profile in this clinical setting.

Keywords: Neostigmine; Neuromuscular blockade; Neuromuscular blocking agents; Neuromuscular blockade reversal; Rocuronium; Sugammadex; TOF ratio.

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1. Introduction

General anaesthesia with endotracheal intubation is the most commonly used technique in over 80% of surgical procedures across various medical specialties. A critical component of this approach is the use of neuromuscular blocking agents (NMBAs), which induce muscle relaxation to facilitate tracheal intubation and optimize surgical access. By paralyzing the vocal cords, NMBAs ensure the safe insertion of the endotracheal tube while preventing involuntary movements and spontaneous respiration during surgery.¹

Muscle relaxants are categorized into depolarizing agents, such as succinylcholine, and non-depolarizing agents, including steroid-based and benzylisoquinoline compounds. Non-depolarizing agents generally present fewer side effects, such as allergic reactions, but carry a significant risk of postoperative residual curarization (PORC). Incomplete reversal of NMBAs can lead to postoperative residual paralysis (PORP), a potentially dangerous condition characterised by persistent muscle weakness. This condition significantly increases the risk of complications and adverse outcomes, with residual neuromuscular blockade identified clinically

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when the train-of-four (TOF) ratio remains below 0.9, indicating inadequate recovery of neuromuscular function following NMBA use.²

The complications of PORP can be severe, including regurgitation from weakened sphincter muscles, hypoxia, airway obstruction, generalized muscle weakness, and difficulty with speech and swallowing. Preventing PORP primarily involves the pharmacologic reversal of NMBAs, traditionally achieved using cholinesterase inhibitors.³ The development of quantitative neuromuscular monitoring in the 1970s shifted the focus from subjective clinical assessments to objective measures, greatly improving the monitoring of neuromuscular blockade.⁴

Neostigmine, often combined with anticholinergic agents like atropine or glycopyrrolate, remains the standard treatment for reversing neuromuscular blockade. These inhibitors increase acetylcholine levels at the neuromuscular junction, enhancing competition for muscle nicotinic receptors. While effective, they can cause side effects such as bradycardia, bronchoconstriction, dry mouth, and tachycardia. Additionally, cholinesterase inhibitors may struggle to reverse deeper levels of blockade reliably, often failing to achieve a TOF ratio of 0.9 within a practical timeframe.⁵

Sugammadex has emerged as a novel solution to the limitations of cholinesterase inhibitors. Specifically effective against amino steroid non-depolarizing blockers like rocuronium and vecuronium, Sugammadex forms an irreversible complex with rocuronium, which is then eliminated by the kidneys. This method provides a fast and reliable reversal of neuromuscular blockade, eliminating the risk of postoperative residual curarisation (PORC) and avoiding muscarinic side effects. Research demonstrates that Sugammadex reverses rocuronium-induced neuromuscular blockade significantly faster than neostigmine, making it a preferred option for improving patient recovery and safety.⁶

This study aimed to compare the safety and effectiveness of Sugammadex versus neostigmine in reversing neuromuscular blockade, focusing on the time required for complete neuromuscular recovery, as measured by the attainment of a TOF ratio ≥ 0.9 . The research specifically targets Indian adult neurosurgical patients undergoing elective lumbar spine surgeries under general anaesthesia at a tertiary healthcare facility.

2. Materials and Methods

This randomized, comparative, prospective study was conducted over 18 months, following approval from the Institutional Ethics Committee (SVEIC/ON/Medi/BNPG 21/Sep/ 2215). A total of 80 adult patients (ages 18–65) scheduled for elective lumbar spine surgeries and classified as American Society of Anaesthesiologists physical status I, II, or III were enrolled after obtaining informed consent.

Patients with known allergies to the study drugs, pregnancy, compromised liver or renal function, muscular dystrophies, or medications affecting the neuromuscular junction were excluded.

Randomization was performed using a random number table generated by Microsoft Excel, with an independent statistician overseeing central randomization to maintain blinding. Two anaesthesiologists, not involved in patient care or data collection, prepared and coded the reversal agents, which were administered by clinical staff unaware of group assignments (Consort: Figure-1).

A comprehensive pre-anaesthetic evaluation was conducted one day before surgery, including measurements of height, weight, vital signs (pulse rate, blood pressure, respiratory rate, and temperature), and a systemic examination (respiratory, cardiovascular, gastrointestinal, and central nervous systems). Blood tests, including complete blood count, serum urea, creatinine, liver function tests, and ECG, were performed. Patients were kept nil by mouth for six hours prior to induction.

Upon arrival in the operating theatre, an intravenous line was established, and Ringer lactate infusion was initiated. ECG, pulse rate, blood pressure, and SpO₂ were continuously monitored, along with baseline measurements for the current required to achieve a TOF (Train of Four) ratio of 4/4. Electrodes for monitoring the TOF were positioned over the ulnar nerve at the wrist: the distal black (negative) electrode at the wrist crease, and the proximal red (positive) electrode placed 3–6 cm above along the ulnar nerve's path.

Patients were premedicated with Inj. glycopyrrolate (0.004 mg/kg IV), Inj. ondansetron (0.1 mg/kg IV), Inj. midazolam (0.02 mg/kg IV), and Inj. fentanyl (50 mcg/kg IV). Pre-oxygenation with 100% oxygen was performed via a face mask for 3 minutes. The qualitative PNS monitor was used prior to the administration of neuromuscular blockers to verify electrode placement and baseline current, which was then multiplied by three to determine the supramaximal current for the neuromuscular blockade.

Induction was performed with intravenous Inj. propofol (2 mg/kg), followed by tracheal intubation after administering Inj. rocuronium (1.2 mg/kg). Anaesthesia was maintained with O₂, N₂O, isoflurane, and maintenance doses of rocuronium (0.2 mg/kg). During surgery, patients were continuously monitored for heart rate, non-invasive BP, ECG, and oxygen saturation after intubation. Neuromuscular blockade was assessed using the PNS qualitative neuromuscular monitoring of the adductor pollicis muscle, and the TOF ratio was measured at supramaximal current (three times the baseline milliamperes). Neuromuscular blockade was monitored every 15 seconds following rocuronium administration, and the time for TOF to decrease from 4/4 to 0/4 was recorded. Supplemental doses of rocuronium were administered at the discretion of the

anesthesia provider to maintain moderate neuromuscular blockade (TOF < 1/4), with TOF response checked every 15 minutes.

At the end of the surgery, neuromuscular blockade reversal was performed only when the TOF was $\geq 2/4$. In the 'N' group, Inj. neostigmine (0.05 mg/kg) and Inj. glycopyrrolate (0.008 mg/kg) were used, while in the 'S' group, Inj. Sugammadex (2 mg/kg) was administered. After the reversal agents were given, TOF responses were assessed every 30 seconds for the first 3 minutes, then every minute thereafter until a TOF count of 4/4 was achieved. Once adequate neuromuscular reversal was confirmed, patients were extubated and transferred to the postoperative recovery area.

The primary outcome measure was the time taken for complete neuromuscular recovery (TOF ratio ≥ 0.9). Secondary outcomes included: (1) the need for additional reversal doses to achieve TOF 4/4, (2) the incidence of postoperative residual curarization (PORC), and (3) the occurrence of adverse events such as nausea/vomiting, hemodynamic instability (bradycardia, tachycardia, hypotension), respiratory complications (dyspnoea, respiratory depression), neurological symptoms (drowsiness, dizziness, blurred vision), and other reactions (shivering, dry mouth, dysgeusia, rigor, hypersensitivity).

Prior to the study, a power analysis was conducted to determine the required sample size based on recovery time from NMB. With a two-sided type I error of 5% and a study power of 80%, a mean sample size of 40 patients per group was calculated to be sufficient to detect a difference of 50% or more in recovery time between the two groups, based on the study by Fiorda Diaz J et al.²

Data were systematically collected, compiled, and analysed. Numerical variables were reported as means and standard deviations, while categorical variables were presented as frequencies and percentages. Statistical analysis was performed using the unpaired Student's t-test for numerical variables and the chi-square test for categorical variables, with $p < 0.05$ considered statistically significant.

3. Results

A total of 80 patients were enrolled in the trial, with 40 randomized to Group S and 40 to Group N. Demographic characteristics, including gender, age, race, ASA physical status, and preoperative diagnosis, were comparable between groups as shown in **Table 1**. The mean ages were 44.38 ± 12.03 years for Group N and 47.7 ± 13.53 years for Group S ($p = 1$). Group N had 60% males, while Group S had 42% females. The median body mass index (BMI) was similar in both groups. Participants included ASA-I (25%), ASA-II (55%), and ASA-III (20%) in Group N, and ASA-I (10%), ASA-II (45%), and ASA-III (45%) in Group S.

A qualitative peripheral nerve stimulator (PNS) with a Train of Four (TOF) feature was used for neuromuscular monitoring. The positive (red) electrode was placed proximally, and the negative (black) electrode distally on the wrist crease to stimulate the ulnar nerve and assess adductor pollicis muscle twitches. Preoperatively, the baseline current for 4/4 twitches was recorded, with the supramaximal current set at three times the baseline. In Group N, the mean baseline current was 18.65 ± 2.06 mA, and the supramaximal current was 56.03 ± 6.2 mA. In Group S, these values were 18.18 ± 2.11 mA and 54.53 ± 6.33 mA, respectively as shown in **Table 2**.

During induction with Rocuronium (1.2 mg/kg), TOF COUNT was assessed. Both groups (N and S) achieved similar intubating conditions in 1.5 minutes, similar to Succinylcholine (2 mg/kg) as shown in **Table 3**.

Intraoperatively, TOF count was measured every 15 minutes and maintenance doses of 0.2 mg/kg of rocuronium were given on appearance of single twitch (TOF count of 1/4 from 0/4) on stimulating via peripheral PNS attached.

Analysis of the complete dataset revealed a statistically significant difference in recovery times between the two groups ($p < 0.0001$). The sugammadex group demonstrated markedly faster neuromuscular recovery, achieving a TOF ratio of 0.9 (four palpable twitches) in a geometric mean time of 1.85 minutes (95% CI: 1.5-2.1 minutes). In contrast, the neostigmine group required significantly longer, with a mean recovery time of 5.88 minutes (95% CI: 2.9-8.9 minutes).

The findings demonstrate statistically significant differences ($p < 0.0001$), clearly indicating Sugammadex's clinical superiority over neostigmine in neuromuscular blockade reversal. As evidenced in **Table 3** and **Figure 2**, Sugammadex achieves significantly faster recovery times (1.85 vs 5.88 minutes), confirming its enhanced pharmacodynamic profile for rapid neuromuscular function restoration.

In comparing adverse events post-extubation, Inj. Sugammadex was well tolerated, with only one case of nausea ($n=1$) out of 40 and no residual neuromuscular blockade. In contrast, Inj. Neostigmine had one inadequate reversal and three cases of complications: bronchospasm ($n=1$), nausea ($n=1$), and vomiting ($n=1$), out of 40 patients. (**Table 4**)

Table 1: Demographic and baseline characteristics of patients*

Parameter	Group N	Group S	t	p-value
	Mean \pm SD	Mean \pm SD		
Age (Years)	44.38 \pm 12.03	47.7 \pm 13.53	1.160	0.2497
Weight (kg)	58.28 \pm 7.47	58.15 \pm 6.78	-0.0815	0.9353
	Group N	Group S	Chi Square	p-value
Gender	Frequency (%)	Frequency (%)		
Male	24 (60%)	23 (57.5%)	0.000	1.000
Female	16 (40%)	17 (42.5%)		
ASA			Chi Square	P-value
I	10 (25%)	4 (10%)	6.818	0.0331
II	22 (55%)	18 (45%)		
III	8 (20%)	18 (45%)		

*Numerical variables reported as Mean \pm Standard Deviations, and categorical variables as frequencies and percentages. Statistical analysis done by the unpaired Student's t-test comparing numerical variables, while the chi-square test used for categorical variables, with $p < 0.05$ considered significant.

Table 2: Baseline and supramaximal current:[§]

Parameter	Group N	Group S	t	p-value
	Mean \pm SD	Mean \pm SD		
Baseline Current (mAmp)	18.65 \pm 2.06	18.18 \pm 2.11	-1.008	0.3166
Supramaximal Current (mAmp)	56.03 \pm 6.2	54.53 \pm 6.33	-1.071	0.2876

[§] Values are presented as mean \pm SD. Statistical analysis was done by the unpaired Student's t-test comparing numerical variables, with $p < 0.05$ considered significant (mAmp= milli Amperes)

Table 3: Induction and Reversal TOF count monitoring (in minutes):[#]

Parameter	Group N (Neostigmine)	Group S (Sugammadex)	t	p-value
	Mean \pm SD	Mean \pm SD		
Induction TOF Monitoring (in minutes)	1.51 \pm 0.21	1.59 \pm 0.25	1.550	0.1253
Reversal TOF Monitoring (in minutes)	5.88 \pm 2.99	1.85 \pm 0.26	-8.492	P < 0.0001

[#]Values are presented as mean \pm SD. Statistical analysis was done by the unpaired Student's t-test comparing numerical variables, with $p < 0.05$ considered significant. It took approximately 1.5 minutes in both the groups to take TOF count from 4/4 to 0/4 in induction with Rocuronium, while for reversal, Patients in Group-N took more time than those in Group-S for TOF count to go from 2/4 to 4/4.

Table 4: Comparison of complications seen with neostigmine versus Sugammadex.[@]

Complications	Group N	Group S	Chi Square	p-value
	Frequency (%)	Frequency (%)		
Needed Neostigmine Supplementation	1 (2.5%)	0 (0%)	3.12	0.5379
Nausea	1 (2.5%)	1 (2.5%)		
Nausea, Vomiting	1 (2.5%)	0 (0%)		
Bronchospasm	1 (2.5%)	0 (0%)		
Nil	36 (90%)	39 (97.5%)		

[@] Categorical variables shown as frequencies and percentages. Statistical analysis done by the chi-square test.

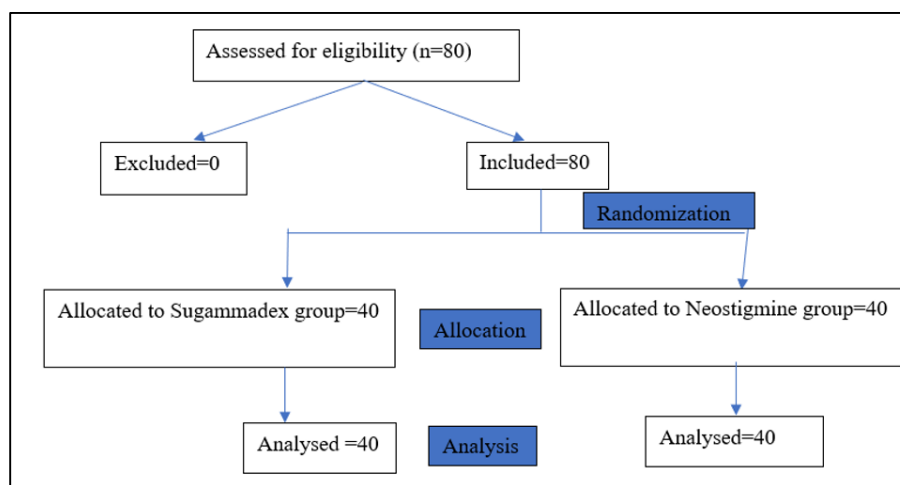


Figure 1: Consort flow diagram

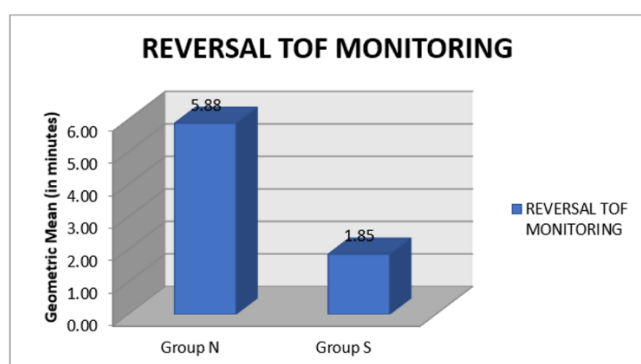


Figure 2: Reversal TOF monitoring

4. Discussion

Our results indicate that Indian subjects undergoing lumbar spine surgeries and receiving sugammadex for neuromuscular blockade reversal reached a TOF ratio 0.9 faster than patients receiving neostigmine with glycopyrrolate. This finding has been consistently reported in previous studies.⁷⁻¹⁴

Illman et al. studied 50 patients, comparing sugammadex (2 mg/kg) to neostigmine (50 mcg/kg) for reversing rocuronium-induced neuromuscular blockade. The mean time to achieve a TOFR of 0.9 was significantly shorter for sugammadex (1.7 ± 0.7 minutes) than for neostigmine (13.3 ± 5.7 minutes, $P < 0.001$), supporting sugammadex as a faster and more reliable reversal agent.¹⁵

Sacan et al. reported that patients receiving sugammadex achieved TOF ratios of 0.7, 0.8, and 0.9 significantly faster than those given edrophonium or neostigmine ($p < 0.05$). Sugammadex also showed higher predictability for achieving TOF 0.9 within 5 minutes as compared to neostigmine for deep (1-2 PTC) neuromuscular blockade reversal (98% vs. 11%).¹²

Geldner et al. compared recovery from rocuronium-induced neuromuscular blockade using sugammadex during deep blockade versus neostigmine at moderate blockade in

140 laparoscopic surgery patients. Sugammadex (4 mg/kg) led to recovery 3.4 times faster than neostigmine (50 mcg/kg plus atropine), with times of 2.4 minutes and 8.4 minutes, respectively. From the last rocuronium dose to recovery, times were 13.3 minutes for sugammadex and 35.2 minutes for neostigmine, highlighting superior efficacy of Sugammadex in reversing neuromuscular blockade.¹⁶

Grintescu et al. studied 34 laparoscopic cholecystectomy patients, finding that sugammadex (2 mg/kg) led to significantly faster recovery times than neostigmine (50 mcg/kg) for moderate neuromuscular blockade, with times of 1.2 ± 0.8 minutes versus 16.7 ± 6.9 minutes ($p < 0.05$).¹⁷

Woo et al. evaluated rocuronium-induced neuromuscular blockade reversal in 118 Korean patients, comparing sugammadex ($n=59$) and neostigmine ($n=59$). The mean recovery time to a TOF ratio of 0.9 was 1.8 minutes for sugammadex and 14.8 minutes for neostigmine ($p < 0.0001$). Mild-to-moderate adverse events were reported: sugammadex caused bradycardia ($n=1$) and headache ($n=3$), while neostigmine was associated with headache ($n=2$), nausea ($n=1$), rash ($n=1$), hypotension ($n=1$), and recurrence of NMB ($n=1$).¹⁸

Our study shows Sugammadex is superior to Neostigmine and Glycopyrrolate for reversing neuromuscular blockade, evidenced by shorter recovery and extubation times ($p < 0.0001$) achieving a TOF ratio of 0.9 (four palpable twitches) in a geometric mean time of 1.85 minutes (95% CI: 1.5-2.1 minutes) in contrast to the neostigmine group with a mean recovery time of 5.88 minutes (95% CI: 2.9-8.9 minutes). Faster reversal of neuromuscular blockade leads to early recovery of muscle tone, reducing postoperative complications. Stimulation of muscle spindles activates spinal motoneurons and cerebral arousal centers especially RAS (reticular activating system) (afferentation theory).^{19,20}

Khuenl-Brady et al. found similar incidences of general muscle weakness as in our study in patients receiving

Sugammadex or neostigmine.²¹ In our study, one patient in group N needed supplemental neostigmine for complete reversal, while all patients in group S achieved adequate muscle power with sugammadex, showing no residual or recurrent neuromuscular blockade.

Hsiao-Cheng Chang et al. demonstrated that Sugammadex effectively reversed deep neuromuscular block from rocuronium, providing prompt recovery and improved surgical conditions. Compared to the indirect agent neostigmine, Sugammadex had fewer adverse effects. Their retrospective review revealed that Sugammadex resulted in significantly lower rates of postoperative vomiting (POV) and urinary retention (POUR), with heart rate reduced by 7.253 ($P < 0.0001$) and mean arterial pressure by 5.213 ($P < 0.0001$). The incidence of POV and POUR was substantially higher in the neostigmine group, highlighting Sugammadex's superior safety and hemodynamic stability.²² Cholinesterase inhibitors like neostigmine are commonly used for reversing neuromuscular blockade but are less effective in deep blockade situations. They require anticholinergic drugs like atropine, glycopyrrolate to mitigate side effects such as bradycardia, hypotension, and postoperative nausea.^{23–26} However, these anticholinergics can inhibit bladder contraction, increasing the risk of postoperative urinary retention.^{27,28}

The overall incidence of postoperative complications in our study was 12.5%. An episode needing neostigmine supplementation for post-reversal residual blockade and an episode of bronchospasm was reported in Group N only, whereas a higher incidence of postoperative nausea and vomiting was observed in Group N ($n=2$) compared to Group S ($n=1$) (5% versus 2.5%).

Sugammadex provides a distinct advantage over traditional agents by not interfering with the acetylcholinesterase receptor system. This enables faster and more predictable reversal of neuromuscular blockade, reducing the incidence of residual block and optimizing healthcare resources.^{31–33} While spontaneous recovery from rocuronium-induced neuromuscular blockade is possible without antagonists, it occurs at a significantly slower rate. Sugammadex, however, specifically reverses steroidal muscle relaxants like rocuronium, whereas neostigmine is required for reversing agents such as atracurium, Cisatracurium, or mivacurium.⁵

The study's limitations include the failure to account for variables such as the length of the surgical procedure, the time elapsed since the last rocuronium dose, or the doses of concurrent anaesthetics, which may influence the outcomes.

5. Conclusion

Sugammadex (2 mg/kg) provides a significantly faster geometric mean recovery time compared to Neostigmine (50 µg/kg) plus Glycopyrrolate in patients given Rocuronium as

a neuromuscular blocking agent. Sugammadex is nearly three times faster in reversing neuromuscular blockade and is found to be safer, with minimal side effects and no instances of residual or recurrent neuromuscular blockade in the studied Indian population.

6. Source of Funding

None.

7. Conflict of Interest

None.

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