

"Comparison Of Sugammadex And Neostigmine For Reversal Of Rocuronium-Induced Neuromuscular Blockade In Patients Undergoing General Anaesthesia: A Randomized Controlled Trial"

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Abstract

Background and aims: Postoperative residual neuromuscular blockade remains a significant concern following utilisation of neuromuscular blocking agents during general anaesthesia. A selective relaxant binding agent, sugammadex, has been introduced as rapid reversal agent to aminosteroidal neuromuscular blockers like rocuronium. This research was aimed to compare efficacy and safety of sugammadex and neostigmine in reversal of neuromuscular blockade caused by rocuronium.

Materials and Methods: This prospective, double-blinded randomized controlled trial (RCT) has been held in 74 adult patients (ASA I-II) undergoing elective surgery under general anaesthesia. Participants have been randomized into 2 groups: sugammadex 2mg/kg (Group S, n=37) and neostigmine 50µg/kg having glycopyrrolate (Group N, n=37). Quantitative neuromuscular monitoring using acceleromyography has been employed. Primary outcome has been time from administration of reversal agent to recovery of train-of-four (TOF) ratio ≥ 0.9 . Secondary outcomes involved time to sustained head lift and hand grip, as well as incidence of postoperative adverse events.

Results: Baseline characteristics were comparable between groups, with no significant differences in age ($p = 0.556$), gender ($p = 0.244$), procedure duration ($p = 0.25$), or rocuronium dose ($p = 0.29$). Sugammadex produced significantly faster recovery: TOF 0.9 at 2.6 ± 1.5 min versus 4.3 ± 1.9 min ($p < 0.001$). Clinical tests of neuromuscular recovery were in favour of sugammadex :head-lift at 3.0 ± 2.2 min versus 6.2 ± 3.2 min ($p < 0.001$), and hand-grip at 3.2 ± 2.3 min versus 6.5 ± 3.6 min ($p < 0.001$) which showed positive correlation with TOF ratio ($r = 0.72$, $p < 0.001$). Adverse effects were markedly fewer with sugammadex (10.8% vs. 40.5%, $p = 0.003$).

Conclusion: Sugammadex provides more reliable and faster reversal of rocuronium-induced neuromuscular blockade having earlier clinical recovery and fewer adverse effects compared with neostigmine. It represents a clinically advantageous option for neuromuscular blockade reversal in routine anaesthetic practice.

Keywords: Sugammadex; Rocuronium; Neostigmine; Neuromuscular blockade; Train-of-four monitoring

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1. Introduction

General anaesthesia is characterised by unconsciousness, analgesia, amnesia, muscle relaxation and involves attenuating autonomic responses to noxious stimuli. Muscle relaxation is one of these components, and it plays an important role in process of tracheal intubation, optimum surgical exposure, controlled ventilation. This is

achieved by utilisation of neuromuscular-blocking agents (NMBAs), that are administered to the neuromuscular junction to produce different depths of paralysis.¹ Rocuronium, an aminosteroidal NMBA, is widely used in clinical practice because of its rapid onset, predictable pharmacological profile, and suitability for rapid sequence induction.²

However, utilisation of neuromuscular blocking agents is associated with postoperative residual neuromuscular blockade (RNMB), which may lead to impaired airway protection, hypoventilation, aspiration, delayed recovery, and increased postoperative morbidity. Approximately 20–40% of patients in the recovery room may demonstrate incomplete neuromuscular recovery, particularly when reversal or adequate monitoring is omitted.³

Accurate neuromuscular monitoring is therefore essential for safe anaesthetic practice. Peripheral nerve stimulators and TOF monitoring enable clinicians to titrate intraoperative NMBA dosing, determine the appropriate timing of reversal, and confirm adequate recovery (TOF ratio ≥ 0.9). Quantitative monitoring methods including acceleromyography (AMG) provide objective measurements of muscle response and are considered more reliable than subjective clinical tests. AMG devices measure acceleration of adductor pollicis muscle following ulnar nerve stimulation and are widely used in clinical settings because of their practicality and availability.^{4–6}

For several decades, neostigmine has been the standard pharmacological agent used for reversal of non-depolarising neuromuscular blockade (NMB) in India. Although effective at moderate depths of blockade, neostigmine has several limitations. It cannot reliably reverse deep blockade, recovery may be slow or

incomplete, and the drug may produce muscarinic adverse effects including bradycardia, bronchospasm, increased secretions, gastrointestinal disturbances.^{7,8} Anticholinergic agents such as glycopyrrolate are therefore co-administered to counteract these effects, although they may themselves cause tachycardia, blurred vision, and dry mouth. Residual paralysis may still occur despite neostigmine administration.⁹

These limitations led to the development of sugammadex, modified γ -cyclodextrin that provides novel mechanism for reversal of aminosteroidal NMB. Sugammadex acts by encapsulating free rocuronium or vecuronium molecules in plasma, thereby rapidly reducing their availability at the neuromuscular junction. This mechanism enables rapid as well as predictable reversal of even deep NMB without the cholinergic adverse effects associated with neostigmine.^{10,11} Several international studies have demonstrated that sugammadex results in faster recovery to TOF ratio ≥ 0.9 and lower incidence of RNMB.^{12–15} Despite these advantages, evidence from India, particularly from South India, remains limited [16–18]. Local comparative data are therefore necessary to guide clinical decision-making in routine anaesthetic practice. The present study has been conducted comparing with safety as well as efficacy of sugammadex and neostigmine for reversal of rocuronium-induced NMB using quantitative neuromuscular monitoring.

2. Methods

Study design and setting

This prospective, double-blinded, parallel-group RCT having 1:1 allocation ratio has been held in “Department of Anaesthesiology at SRM Medical College Hospital and Research Centre, Kattankulathur, Tamil Nadu, India”. Study has been conducted over 18 months, from June 2024 to November 2025.

Participants

Adult patients aged 18 to 65 yrs having “American Society of Anesthesiologists (ASA)” physical status I or II who have been scheduled to experience elective surgical procedures under general anaesthesia requiring rocuronium-induced neuromuscular blockade have been eligible for inclusion.

Patients have been excluded if they had known hypersensitivity to sugammadex, neostigmine, or rocuronium; renal impairment; neuromuscular disorders; significant hepatic dysfunction; pregnancy or lactation; anticipated difficult airway; utilisation of medications known to interfere with neuromuscular transmission; or a body mass index greater than 35kg/m². All eligible participants have been provided with detailed information about study and a written informed consent has been obtained before enrolment.

Sample size calculation and sampling method

Sample size has been calculated as per earlier study by Jones RK et al., which compared reversal times between sugammadex and neostigmine.¹⁹ Using expected effect size of 0.81, significance level of 5%, and study power of 90%, minimum required sample size has been estimated to be 33 participants in every group.

To account for potential attrition rate of 10%, sample size has been increased to 37 patients per group, resulting in a total study population of 74 participants.

No interim analyses or stopping guidelines were planned for this study.

Randomisation and blinding

A computer-generated randomization sequence has been utilised to randomly assign participants in 1:1 ratio to one of two study groups. An investigator who has not been involved in patient recruiting, intraoperative management, or outcome evaluation created the allocation sequence using a computer-based random number generator.

Allocation concealment has been ensured utilising sequentially numbered opaque sealed envelopes prepared by independent investigator. After enrolment, the appropriate envelope was opened and the assigned intervention was prepared.

Group S received sugammadex 2mg/kg, whereas Group N received neostigmine 50µg/kg with glycopyrrolate.

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Study followed a double-blind design. Study drugs have been prepared in identical syringes by an independent anaesthesiologist who hasn't been involved in intraoperative management or postoperative assessment. Both patient and investigator responsible for recording neuromuscular recovery parameters remained blinded to group allocation throughout study period.

Study procedure

Once in operation room, standard monitoring was done which included non-invasive blood pressure, electrocardiography, pulse oximetry, temperature, End-tidal CO₂. Neuromuscular monitoring has been conducted with the help of acceleromyography (STIMPOD NMS450) of adductor pollicis muscle after the ulnar nerve stimulation and the supramaximal stimulus threshold was identified.

All patients received premedication with glycopyrrolate (5–10 µg/kg), ondansetron (0.1 mg/kg), and midazolam (0.1 mg/kg). After adequate preoxygenation, anaesthesia has been induced utilising propofol (2–3 mg/kg) and fentanyl (2–3 µg/kg). Rocuronium 0.6 mg/kg has been provided to facilitate tracheal intubation. Anaesthesia has been maintained having 1:1 mixture of oxygen and nitrous oxide, having sevoflurane at minimum alveolar concentration of 1.

Additional boluses of rocuronium (0.1 to 0.2 mg/kg) were administered intraoperatively whenever second twitch reappeared during TOF monitoring.

When number of TOFs had reached four or the TOF ratio was within the range of 0.7 at the completion of the surgery, the reversal agent was given as per the randomisation of the sequence. Neuromuscular recovery was assessed using acceleromyography until adequate recovery was achieved.

Patients who met standard clinical and neuromuscular extubation criteria (TOF ratio of 0.9) were then extubated and transferred to postoperative recovery room, where they were further observed.

Outcome measures

Primary outcome

Primary outcome has been time from administration of reversal agent to recovery of TOF ratio ≥ 0.9 .

TOF responses have been recorded every 15 secs during first 3 mins, every 30 seconds between three and five minutes, and at one-minute intervals thereafter until recovery was achieved.

Secondary outcomes

Secondary outcomes were postoperative neuromuscular recovery measured by clinical tests like sustained head lift of five seconds and sustained hand grip of five seconds. These measures were carried out at 15, 30 and 45 min and at one hour after the extubation.

Simultaneous TOF ratio measurements were recorded to detect any late-onset RNMB.

Adverse events such as hypotension, cough, tachycardia, bradycardia, nausea, vomiting, excessive salivation have been monitored and recorded in postoperative recovery period.

Statistical analysis

After entering all of the data into Microsoft Excel, it was analysed utilising "Statistical Package for Social Sciences (SPSS)" version 29. Categorical variables have been shown as frequencies and percentages, although continuous variables was given as mean $\pm$ standard deviation. Independent t-test has been utilised comparative groups for continuous data, while chi-square test has been utilised for categorical variables analysis. Statistical significance is defined as p-value < 0.05 .

Ethical approval

This research has been done with approval of "Institutional Ethics Committee of SRM Medical College Hospital and Research Centre (IEC No: SRMIEC-ST0724-1714, dated 05 November 2024)", all the procedures were performed according to principles of Declaration of Helsinki.

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Figure 1: A 2ml Sugammadex vial(100mg/ml) used in the study

CONSORT 2010 Flow Diagram

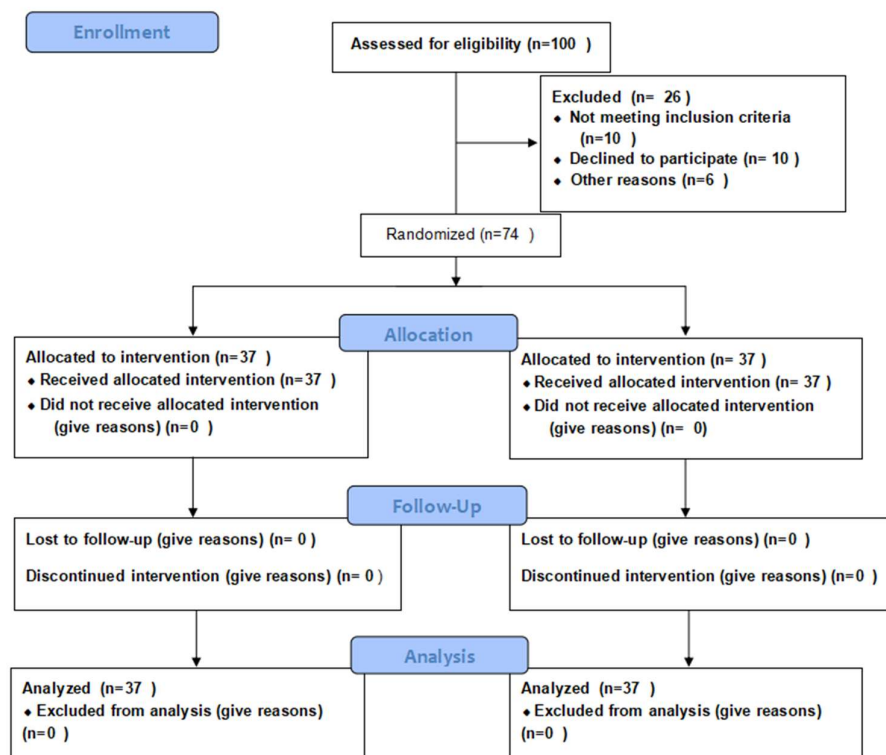


Figure 2: Consort Flow Diagram

3. Results

Table 1: Demographic characteristics of study participants

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Variable	Sugammadex (N = 37)	Neostigmine (N = 37)	Test Statistic	P value
Age (years)				
<20	5 (13.5%)	3 (8.1%)	Chi-square = 2.081	0.556
20–40	17 (45.9%)	14 (37.8%)		
40–60	14 (37.8%)	17 (45.9%)		
>60	1 (2.7%)	3 (8.1%)		
Gender				
Female	20 (54.1%)	15 (40.5%)	Chi-square = 1.355	0.244
Male	17 (45.9%)	22 (59.5%)		

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Procedure Duration (min)	98.9 ± 23.3	94.9 ± 27.9	T = 0.679	0.25
Rocuronium Dosage (mg)	37.2 ± 4.8	36.5 ± 5.6	T = 0.556	0.29

Table 1 demonstrates baseline population along with clinical characteristics of participants involved in the study. No statistically significant differences have been found among sugammadex and the neostigmine groups in terms of gender, age distribution, duration of surgery or overall dose of rocuronium. These findings indicate that the two groups were comparable at baseline.

Table 2: Comparison of time taken to reach TOF 0.9 between groups

Time Taken to reach TOF 0.9 (min)	Mean	Std. Deviation	T value	P value
Sugammadex	2.6	1.5	-4.365	<0.001*
Neostigmine	4.3	1.9		

*Statistically significant at 5% level of significance

The comparison of time required to attain TOF ratio ≥ 0.9 between two groups is shown in Table 2. Mean recovery time has been significantly shorter in sugammadex group (2.6±1.5 minutes) compared with neostigmine group (4.3±1.9 mins), demonstrating faster reversal of NMB with sugammadex ($p < 0.001$).

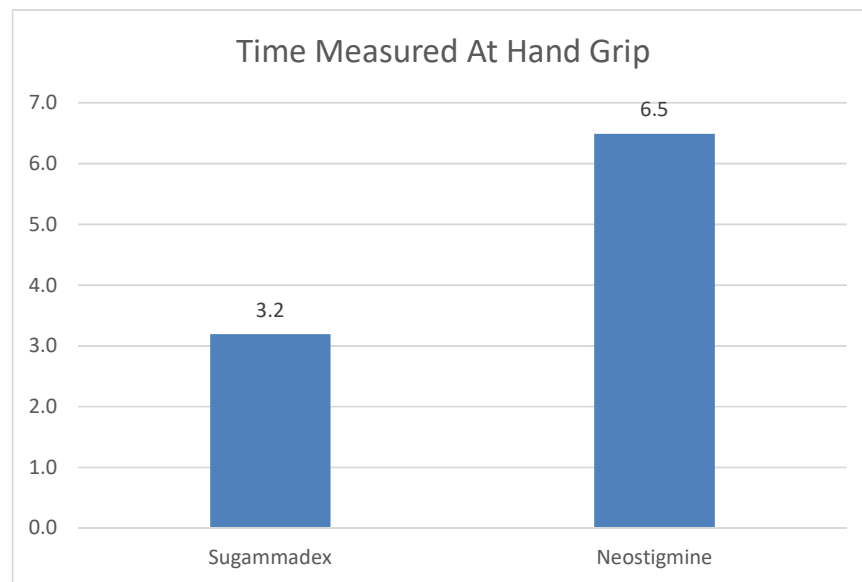


Figure 3: Comparison of time measured at hand grip between groups

The time required to achieve sustained hand grip for five seconds is shown in Figure 3. Patients receiving sugammadex achieved sustained hand grip significantly earlier than those receiving neostigmine (3.2±2.3 mins vs. 6.5±3.6 minutes; $p < 0.001$).

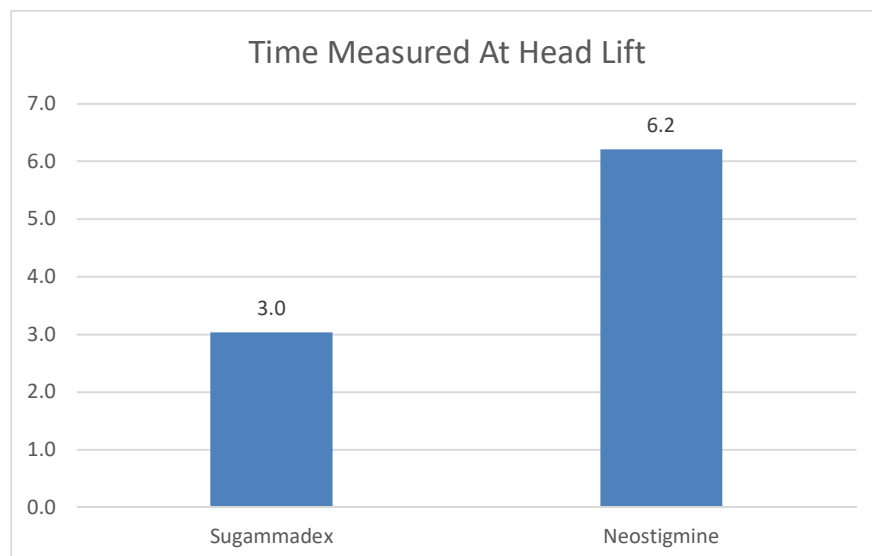


Figure 4: Comparison of time measured at head lift between groups

Similarly, the time required to achieve sustained head lift for five seconds is presented in Figure 4. Recovery was significantly faster in the sugammadex group (3.0 ± 2.2 minutes) than in neostigmine group (6.2 ± 3.2 minutes; $p < 0.001$).

Table 3: Comparison of side effects between group

Side effects	Group				Total		P value
	Sugammadex		Neostigmine				
	N=37	%	N=37	%	N=74	%	
Desaturation	0	0.0%	2	5.4%	2	2.7%	0.473
Cough	1	2.7%	3	8.1%	4	5.4%	0.607
Excess salivation	0	0.0%	4	10.8%	3	4.1%	0.123
Hypotension	1	2.7%	2	5.4%	3	4.1%	1
Bradycardia	0	0.0%	2	5.4%	2	2.7%	0.473
Vomiting	2	5.4%	2	5.4%	4	5.4%	1
Overall side effects	4	10.8%	15	40.5%	19	26.7%	0.003*

*Statistically significant at 5% level of significance

Table 3 shows the comparison of side effects between the Sugammadex and Neostigmine groups. The comparison of side effects between the Sugammadex and Neostigmine groups shows that most individual adverse events, including desaturation, cough, excess salivation, hypotension, bradycardia, and vomiting, did not differ significantly between the two groups ($p > 0.05$). None of the patients developed late onset residual neuromuscular blockade. Overall, side effects were more common in the Neostigmine group 15 (40.5%) compared to the Sugammadex group 4 (10.8%). The incidence of side effects shows statistically significant difference between groups ($P=0.003$). This suggests that Sugammadex is associated with a lower overall risk of side effects and may be better tolerated than Neostigmine.

4. Discussion

Baseline characteristics including age distribution, gender, procedure duration, and total rocuronium dosage were comparable between the groups, indicating appropriate randomization and minimizing the influence of confounding variables.

In recent research, recovery to TOF ratio ≥ 0.9 occurred significantly faster in sugammadex group than in the neostigmine group (2.6 ± 1.5 minutes v/s 4.3 ± 1.9 mins; $p < 0.001$). These findings indicate that sugammadex provides more rapid pharmacological reversal of rocuronium-induced NMB.

Similar findings have been reported by studies like Garg A et al., who demonstrated recovery times of 2.29 ± 1.12 minutes with sugammadex compared with 8.72 ± 1.5 minutes with neostigmine, while Mallipudi S et al., reported recovery times of 2.1 ± 0.5 minutes versus 12.8 ± 3.2 minutes respectively.^{14,20} Mahajan N et al. also observed significantly faster recovery with sugammadex (2.6 ± 0.8 minutes) compared with neostigmine (12.4 ± 3.1 minutes).¹³ These findings closely correspond with the magnitude and direction of the effect observed in the present study, supporting the consistent superiority of sugammadex for rapid reversal of NMB.

Even in more complex surgical settings, sugammadex has demonstrated similar advantages. Deana C et al. reported recovery times of 9.4 ± 4.6 minutes with sugammadex compared with 34.6 ± 24.9 minutes with neostigmine in patients undergoing liver transplantation.¹⁵ Similarly, studies in ambulatory surgery and patients with respiratory disease have also shown markedly faster reversal with sugammadex.^{18,21} These findings indicate that the pharmacodynamic advantage of sugammadex is consistent across different clinical settings.

The Cochrane review by Hristovska et al. reported that sugammadex reverses moderate NMB approximately 6.6 times faster and deep blockade up to 16.8 times faster than neostigmine.²² The use of a TOF ratio ≥ 0.9 as the benchmark for adequate recovery, which was adopted in the present study, is also consistent with international neuromuscular monitoring guidelines and facilitates valid comparisons across studies.^{23,24}

In contrast Abola RE et al. and Kumar VM et al. did not observe statistically significant differences in certain recovery endpoints.^{2,25} However, these discrepancies are likely attributable to variations in study design, depth of blockade at reversal, sample size, and timing of postoperative assessment rather than true equivalence between the two drugs.

The faster recovery observed with sugammadex can be explained by its unique pharmacological mechanism. Sugammadex encapsulates circulating rocuronium molecules, rapidly reducing their free plasma concentration and thereby reversing NMB directly. In contrast, neostigmine acts indirectly by inhibiting acetylcholinesterase and increasing acetylcholine concentration at the neuromuscular junction, a process that is dependent on partial spontaneous recovery and therefore inherently slower.²⁶

In the present study clinical indicators of neuromuscular recovery also favoured sugammadex. Patients receiving sugammadex achieved sustained head lift and sustained hand grip significantly earlier than those receiving neostigmine. The mean time to sustained hand grip was 3.2 ± 2.3 minutes in sugammadex group compared with 6.5 ± 3.6 minutes in neostigmine group, while sustained head lift occurred at 3.0 ± 2.2 minutes and 6.2 ± 3.2 minutes respectively ($p < 0.001$).

These results suggest that the rapid pharmacological reversal achieved with sugammadex translates into earlier restoration of clinically relevant muscle strength, which is essential for safe extubation and prevention of postoperative respiratory complications.

Similar findings have been reported by studies like Chauhan AP et al who demonstrated faster restoration of neuromuscular function with sugammadex, while delayed recovery with neostigmine was associated with transient postoperative weakness.¹² Similarly, Mehta S et al. reported that all patients receiving sugammadex were able to successfully perform the five-second head lift test in the recovery room.²⁷

However, not all studies have demonstrated statistically significant differences in later postoperative muscle strength measurements. Abola RE et al. reported similar hand grip strength at 30, 60, and 120 minutes after reversal.²⁵ This may be explained by the fact that by these later time points neuromuscular recovery following neostigmine may have already occurred, thereby minimizing detectable differences between the two groups. Early recovery measurements, such as those used in the present study, may therefore be more sensitive in demonstrating the pharmacodynamic advantage of sugammadex.

In the present study, most individual adverse events such as desaturation, cough, excess salivation, hypotension, bradycardia, and vomiting occurred infrequently and didn't demonstrate statistically significant differences among groups. However, overall incidence of side effects has been significantly lower in sugammadex group. These findings suggest that sugammadex has a more favorable safety profile. Similarly, Mahajan N et al. reported lower rates of bradycardia, postoperative nausea and vomiting, and residual paralysis with sugammadex compared with neostigmine.¹³ Dong V et al. also found higher rates of bradycardia and increased secretions in the neostigmine group, reflecting its parasympathomimetic effects.²⁸

Meta-analytic data have likewise shown that sugammadex is associated with fewer adverse events, particularly bradycardia, postoperative nausea and vomiting, and RNMB.²⁵ Nevertheless, some studies have reported comparable overall adverse event rates between the two drugs, although the types of complications differed.^{14,21}

The lower incidence of adverse events with sugammadex can be explained pharmacologically. Neostigmine increases concentration of acetylcholine at nicotinic and muscarinic receptors, which result in cholinergic adverse effects of bronchospasm, bradycardia, secretions. In comparison, sugammadex does not affect the cholinergic system and thereby avoiding these parasympathomimetic effects because it acts as direct encapsulation of rocuronium.

In such a way, outcomes of recent studies demonstrate that sugammadex is more predictable and faster in terms of reversing the NMB that is caused by rocuronium than neostigmine. This rapid pharmacological recovery was accompanied with earlier restoration of clinical meaningful muscle strength and reduced overall adverse events. These findings support growing body of evidence indicating that sugammadex represents more effective and well-tolerated option for NMB reversal in routine anaesthetic practice.

5. Limitations

There are limitations to consider when evaluating outcomes of such study. Study has been held in single tertiary care centre and may not generalisable to other institutions with diverse populations. or anaesthetic procedures. Even though the sample size was large enough to identify differences in the primary outcome, relatively modest number of participants might not have allowed identification of uncommon adverse effects of the reversal agents. The primary evaluation of neuromuscular recovery was conducted during early postoperative period; hence, no evaluation of long-term respiratory or functional outcomes was assessed. Moreover, the neuromuscular monitoring has been performed at adductor pollicis with the help of acceleromyography, which, although widely accepted, is not necessarily representative of the recovery patterns of other muscle groups, including the diaphragm or upper airway muscles.

6. Conclusion

The present RCT demonstrates that sugammadex provides more reliable and faster reversal of rocuronium-induced NMB than neostigmine in patients undergoing general anaesthesia. Recovery to TOF ratio ≥ 0.9 occurred significantly earlier having sugammadex, and this rapid objective recovery was accompanied by earlier restoration of clinically relevant muscle function, including sustained head lift and hand grip strength. In addition, greater proportion of patients in sugammadex group experienced uncomplicated recovery with fewer overall adverse effects seen when compared to neostigmine. These results indicate that sugammadex has a more predictable and clinically beneficial alternative to reversal of rocuronium-induced NMB in routine practice of anaesthesia.

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