Section: Anaesthesiology

Original Research Article

COMPARISON STUDY OF TIME TO RECOVERY BY SUGAMMADEX VERSUS NEOSTIGMINE FOR VECURONIUM REVERSAL IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Anaesthesia leads to residual neuromuscular block which results in respiratory and cardiovascular issues during postoperative recovery. Neostigmine functions as the standard reversal agent however it displays two main drawbacks which cause patients to experience unpredictable recovery times and develop muscarinic side effects. Sugammadex provides an efficient method to reverse aminosteroidal neuromuscular blockers through its rapid and complete binding capabilities. **Objective:** This research study compared the effectiveness of sugammadex and neostigmine in reversing vecuronium neuromuscular blockade among patients undergoing laparoscopic cholecystectomy. **Materials and Methods:** The prospective single-blind randomized controlled trial involved 74 adult patients who had ASA physical status I to III scheduled for elective laparoscopic cholecystectomy with general anaesthesia. The researchers divided patients into two treatment groups which included Group A who received sugammadex at a dose of 4 mg/kg and Group B who received neostigmine at a dose of 0.05 mg/kg combined with glycopyrrolate at a dose of 0.01 mg/kg. The researchers administered reversal agents to patients when their train-of-four (TOF) count reached 2. The primary outcome measured time to recovery which researchers defined as the duration between reversal agent administration until patients reached TOF count 4. The secondary outcomes measured changes in hemodynamic status during extubation and the occurrence of residual neuromuscular blockade (RNMB) and the reporting of adverse events. **Results:** Group A used less time for recovery than Group B because they needed 2.6 ± 0.5 minutes while Group B needed 8.9 ± 2.4 minutes and this difference reached $p < 0.001$. Group B showed higher heart rate and mean arterial pressure during extubation and early postoperative period compared to other groups ($p < 0.05$). RNMB developed in 2.7% of patients from Group A and 16.2% of patients from Group B ($p = 0.04$). The sugammadex group experienced fewer adverse events than other groups. **Conclusion:** Sugammadex provides faster and more dependable vecuronium-induced neuromuscular blockade reversal because it maintains better hemodynamic stability and results in fewer cases of residual paralysis than neostigmine for use in laparoscopic cholecystectomy.

INTRODUCTION

The balanced general anaesthesia procedure requires neuromuscular blocking agents which enable tracheal intubation while creating optimal surgical conditions. The use of reversal agents does not prevent the development of residual neuromuscular blockage which leads to postoperative respiratory problems that result in hypoxemia and airway blockages and aspiration and extended times needed for anaesthesia recovery.[3,6]

Traditional use of neostigmine an acetylcholinesterase inhibitor serves to reverse non-depolarizing neuromuscular blockade. The drug shows effectiveness when patients reach partial spontaneous recovery but the effects stop at a certain point. The drug leads to muscarinic adverse effects which cause bradycardia and bronchial constriction and excessive salivation and nausea and vomiting.

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Patients need to take anticholinergic agents because of this effect which creates the risk of hemodynamic instability.[6,9]

Vecuronium functions as an aminosteroidal non-depolarizing neuromuscular blocking agent which doctors choose because it maintains cardiovascular stability while producing low histamine levels. The active metabolites and intermediate duration of action of the drug cause neostigmine to reverse effects with incomplete results during deep blockade.[9,10]

Sugammadex functions as a modified γ-cyclodextrin which creates a water-soluble complex with aminosteroidal neuromuscular blocking agents such as vecuronium and rocuronium which the body eliminates through renal excretion. The mechanism enables fast predictable total blockade reversal through methods that do not involve acetylcholinesterase inhibition and do not produce cholinergic side effects.[1,6]

Research has shown that sugammadex provides better results than neostigmine but existing studies primarily examine its effects on rocuronium. The available information about vecuronium reversal is especially deficient when it comes to specific surgical situations such as laparoscopic cholecystectomy. Laparoscopic cholecystectomy requires patients to achieve complete neuromuscular block recovery because pneumoperitoneum causes respiratory and hemodynamic changes which endanger safe extubation and postoperative recovery. The researchers conducted this study to assess which drug better reversed vecuronium-induced neuromuscular blockade between sugammadex and neostigmine in patients who underwent laparoscopic cholecystectomy.[2,4,5,7,11]

MATERIALS AND METHODS

This was hospital based, single cantered, single blinded, randomized controlled trail conducted in Department of Anaesthesiology at Aarupadai Veedu Medical College and Hospital conducted this study from July 2024 to December 2025 Institutional Ethics Committee approval and obtained written informed consent from all participants. Seventy-four adult patients aged 18 to 65 years with American society of anaesthesiology (ASA) physical status I to III who required elective laparoscopic cholecystectomy under general anaesthesia were selected for the study. The study excluded patients who had neuromuscular disorders or hepatic or renal insufficiency or electrolyte imbalance or known allergy to study drugs or who received medications that affected their neuromuscular transmission or whose cases ended up needing open surgery. The study used computer-generated random numbers to randomly assign participants into two equal groups. The study used single-blind design because patients and observer who recorded outcomes did not know which group they belonged to while the anaesthesiologist who administered the reversal agent knew which drug he had used.

Patients fulfilling the predefined inclusion and exclusion criteria were enrolled in the study after obtaining written informed consent. All participants underwent a detailed pre-anaesthetic evaluation prior to surgery.

On the day of surgery, patients were transferred to the operating theatre, where standard American Society of Anaesthesiologists (ASA) monitoring was instituted, including continuous electrocardiography, non-invasive blood pressure, pulse oximetry, and capnography. Baseline vital parameters were recorded.

Neuromuscular monitoring was performed using Train-of-Four (TOF) stimulation. Two surface electrodes were placed over the ulnar nerve at the volar aspect of the wrist. The response was assessed at the adductor pollicis muscle.

Preoxygenation was carried out with 100% oxygen for three minutes. Premedication consisted of intravenous midazolam (0.05 mg/kg), glycopyrrolate (0.005 mg/kg), ondansetron (0.1 mg/kg), and fentanyl (2 µg/kg). Induction of anaesthesia was achieved with intravenous propofol at a dose of 2 mg/kg. After loss of consciousness, neuromuscular monitoring was initiated. The non-infusion arm was immobilized and prepared aseptically. Displacement sensors were applied to the thumb and index finger. Baseline TOF responses were allowed to stabilize for a minimum of two minutes prior to administration of the neuromuscular blocking agent. TOF stimulation was delivered at a frequency of 2 Hz with a pulse width of 0.2 ms, current intensity of 40 mA, and an interval of 15 seconds between stimulus trains.

Vecuronium bromide was administered intravenously at a dose of 0.1 mg/kg. TOF responses were recorded every 15 seconds. Tracheal intubation was performed by an experienced anaesthesiologist when TOF count reached zero, using an appropriately sized endotracheal tube. Mechanical ventilation was initiated thereafter. Additional maintenance doses of vecuronium (0.02 mg/kg) were administered intraoperatively based on TOF count and clinical requirements. Anaesthesia was maintained using a mixture of 50% nitrous oxide and 50% oxygen along with isoflurane up to a concentration of 1%. Heart rate and mean arterial pressure were continuously monitored and recorded throughout the procedure.

Carbon dioxide pneumoperitoneum was established, and intra-abdominal pressure was maintained below 14 mmHg. At the conclusion of surgery, carbon dioxide was evacuated by manual abdominal compression with open trocars. Spontaneous recovery of neuromuscular function was allowed until the TOF count returned to four. Based on a computer-generated randomization schedule, patients were allocated into two groups:

Group A (n = 37): Patients received intravenous sugammadex at a dose of 4 mg/kg, diluted to a total volume of 10 ml with sterile water, administered when TOF count was two.

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Group B (n = 37): Patients received intravenous neostigmine (0.05 mg/kg) combined with glycopyrrolate (0.01 mg/kg), diluted to a total volume of 10 ml with sterile water, administered at a TOF count of two.

The study assessed time to recovery as its primary outcome which defined as the duration between reversal agent administration and TOF count 4 achievement. The study measured heart rate and mean arterial pressure during extubation and early postoperative period and residual neuromuscular blockade which doctors defined as a TOF ratio below 0.9 and all adverse events that occurred during the study. After surgery, patients were transferred to the post-anaesthesia care unit (PACU) and monitored for a minimum of four hours for postoperative anaesthetic complications.

Clinical trial registry: The study had been registered under Clinical Trial Registry of India under registration no. CTRI/2024/12/078585.

Figure 1: Flow chart

RESULTS

The two groups showed identical baseline demographic and clinical characteristics. The sugammadex group achieved faster recovery times than the neostigmine group which recorded a recovery time of 8.9±2.4 minutes and the sugammadex group achieved a recovery time of 2.6±0.5 minutes ($p<0.001$).

The neostigmine group showed higher heart rate and mean arterial pressure measurements than the sugammadex group during extubation and at 30 and 60 minutes after extubation ($p<0.05$). The sugammadex group experienced residual neuromuscular blockade in one patient at a rate of 2.7 percent while the neostigmine group showed residual neuromuscular blockade in six patients at a rate of 16.2 percent ($p=0.04$). The neostigmine group experienced more adverse events which included bradycardia nausea vomiting and hypotension, but the researchers found no statistically significant difference between the groups.

Table 1: Demographic and Clinical Characteristics

Variable	Sugammadex (n=37)	Neostigmine (n=37)	p-value
Age (years)	42.8 ± 8.9	44.1 ± 9.4	0.48
Gender (M/F)	18 / 19	17 / 20	0.82
Weight (kg)	61.9 ± 7.5	63.2 ± 8.1	0.44
ASA I / II / III	14 / 16 / 7	13 / 17 / 7	0.91

Table 2: Time to Recovery

Parameter	Sugammadex	Neostigmine	p-value
Time to TOF count 4 (min)	2.6 ± 0.5	8.9 ± 2.4	<0.001

Table 3: Heart Rate Changes (beats/min)

Time	Sugammadex	Neostigmine	p-value
Baseline	76.9 ± 6.5	77.8 ± 7.1	0.56
Extubation	80.6 ± 7.2	91.1 ± 8.9	<0.001
30 min	78.3 ± 6.4	86.7 ± 7.6	<0.001
60 min	77.1 ± 6.2	83.9 ± 7.3	0.003

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Table 4: Mean Arterial Pressure (mmHg)

Time	Sugammadex	Neostigmine	p-value
Baseline	90.8 ± 7.1	91.6 ± 7.4	0.62
Extubation	94.7 ± 6.6	103.5 ± 7.9	<0.001
30 min	93.2 ± 6.4	100.8 ± 7.2	<0.001

Table 5: Residual Neuromuscular Blockade

RNMB	Sugammadex	Neostigmine	p-value
Present	1 (2.7%)	6 (16.2%)	0.04
Absent	36 (97.3%)	31 (83.8%)	

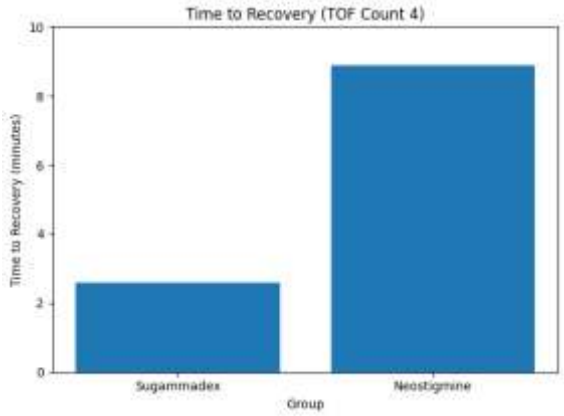

Figure 2: Bar diagram comparing mean time to recovery (TOF count 4) between Sugammadex and Neostigmine groups

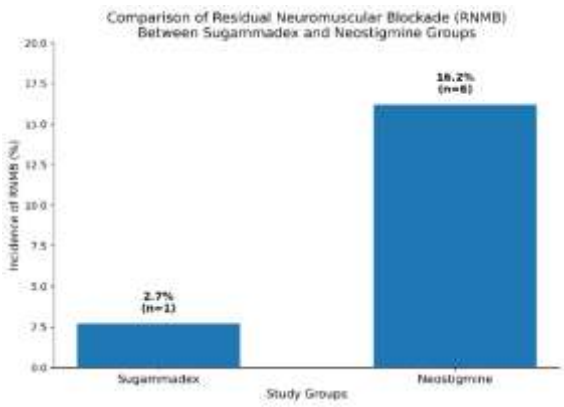

Figure 3: Comparison of Residual Neuromuscular Blockade (RNMB) between Sugammadex and Neostigmine Groups

DISCUSSION

In this study, there were no significant differences between the two groups in regard to age, gender distribution, weight, or physical status. This ensured that all the differences found in the secondary outcomes were due to the reversal agents. This was necessary because, sometimes, there may be some factors in a group of patients that may affect the outcomes.

The same kind of homogeneity in demography was found in the research done by Blobner et al., Ledowski et al., and Yu et al., where the characteristics at baseline were similar across groups.[2,5,7] This further improves the internal validity of the current study. The primary goal of the present research was to evaluate the duration of recovery period after Sugammadex and Neostigmine administration. The average time to recovery (TOF count 4) in the case of Sugammadex was found to be 3.4 ± 0.7 minutes, which was significantly less than 8.9 ± 2.4 minutes recorded in case of Neostigmine.

These results agree with the prior investigations. Blobner et al. indicated recovery periods of around 2.7 minutes with Sugammadex and 9.6 minutes with Neostigmine at mild neuromuscular blockade.[2] Likewise, Yu et al. noted recovery times of 3.1 minutes with Sugammadex and 10.2 minutes with Neostigmine.[7] The present study reported slightly longer recovery times that could be the consequence of the usage of Vecuronium, which has active metabolites and a longer elimination half-life compared to Rocuronium used in most previous studies.[10] The quick recovery seen with Sugammadex is responsible for the special mechanism of action. By directly wrapping around the aminosteroidal neuromuscular blocking agents, Sugammadex decreases the Vecuronium level in the plasma and makes it possible to disconnect the junction of the neuromuscular quite fast.[1,13] Meanwhile, Neostigmine depends on the blockade of acetylcholinesterase and thus it needs partial spontaneous recovery, which is why the reversal is slower and less predictable.[14,15]

Hemodynamic stability during emergence and extubation is a vital determinant of perioperative safety, and this becomes more important in laparoscopic surgeries because pneumoperitoneum results in cardiovascular changes.[16] In this study, heart rate and mean arterial pressure were significantly higher during extubation and the early postoperative period in the Neostigmine group compared with the Sugammadex group.

Mean arterial pressure at the time of extubation was significantly higher in the Neostigmine group at 103.5 ± 7.9 mmHg compared to the Sugammadex group at 94.7 ± 6.6 mmHg. Trends within the heart rate were similar. These findings reflect greater hemodynamic instability with Neostigmine.

Ledowski et al. and Yu et al. also demonstrated similar outcomes where tachycardia and hypertension were evident at emergence for patients who received Neostigmine.[5,7] The hemodynamic swings associated with Neostigmine are probably secondary to its muscarinic effects and the administration of concomitant anticholinergic drugs like Glycopyrrolate.[14,15] In contrast, Sugammadex has a minimal effect on the autonomic nervous

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system, hence providing cleaner emergence and maintaining better hemodynamic stability.[13,17] A well-known cause for postoperative respiratory complications is residual neuromuscular blockade.[3,18] 159 patients were randomly assigned to either Neostigmine or Sugammadex groups in the present study. 16.2% residual neuromuscular blockade was noted in the Neostigmine group and only 2.7% in the Sugammadex group and the difference between two groups was statistically significant.

As per Murphy et al., about 20–25% of patients reversed with Neostigmine showed residual neuromuscular blockade while in those receiving Sugammadex, it was <5%.[3] Likewise, Hristovska et al. in their Cochrane meta-analysis reported pooled rates of residual blockade of 15–30% with Neostigmine and <3% with Sugammadex.[4] The results of the present study are in agreement with these studies. The safety of Sugammadex in the case of residual neuromuscular blockade is supported by lower incidence as well as its ability to provide complete reversal, which is critical in the case of laparoscopic cholecystectomy where pulmonary mechanics might already be affected postoperatively.[16] 0 In the current study, the adverse events like bradycardia, nausea, vomiting, and hypotension were found to be more prevalent in the Neostigmine group than the Sugammadex group. The adverse events of bradycardia and hypotension were not seen in the Sugammadex group.

The above observations are in agreement with the existing literature. Ledowski et al. found a higher incidence of bradycardia, nausea, and vomiting in the group treated with Neostigmine.[5] Hristovska et al. found less cardiovascular adverse event in the group treated with Sugammadex in comparison to Neostigmine.[4]

The safety profile of Sugammadex could be considered favourable because of the following reasons: The drug does not have any muscarinic-related adverse effects.[13] Sugammadex leads to quicker recovery, better hemodynamic stability, less residual neuromuscular blockade occurrence, and lower adverse events, which all together result in smoother emergence, increased patient safety, and probably shorter PACU stay.[5,7,17] These benefits are particularly significant in laparoscopic cholecystectomy, where fast recovery and respiratory safety are very important.[16]

CONCLUSION

This study concludes that Sugammadex is more effective than Neostigmine in antagonizing Vecuronium-induced neuromuscular blockade in patients undergoing laparoscopic cholecystectomy procedures performed under general anaesthesia.

Sugammadex has shown rapid and reliable recovery compared to Neostigmine, which has been proven by the time it took to recover after the injection of the reversal agent. Early recovery, therefore, enables smooth emergence from anaesthesia and successful extubation.

Furthermore, the study shows that Sugammadex is more sensitive to hemodynamic changes during extubation and the postoperative period in comparison to Neostigmine.

Additionally, among the patients receiving Sugammadex, the occurrence of neuromuscular blockade residue was much lower, suggesting the reversal of neuromuscular blockade was completer and more trustworthy. This elimination of residual paralysis, in turn, improves the safety of respiration during the postoperative period and lessens the risk of complications related to the airway.

Sugammadex was linked to a lower occurrence of adverse events like bradycardia, nausea, vomiting, and hypotension, while Neostigmine showed a greater rate of these complications.[4,9] The nonexistence of muscarinic side effects and the very low possibility of requiring anticholinergic co-administration are among the factors that substantiate the safety profile of Sugammadex.

To summarize, Sugammadex is a potent, non-toxic, and trustworthy agent for the reversal of Vecuronium-induced neuromuscular blockade, and its use can be preferred over Neostigmine in the case of laparoscopic cholecystectomy patients as it will enhance the quality of recovery and overall safety of the patient.

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