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A Randomised Controlled Trial Comparing Sugammadex versus Neostigmine for Reversal of Vecuronium - Induced Neuromuscular Block in Geriatric Patients

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Abstract

Background: Geriatric patients undergoing general anaesthesia carry an elevated risk of residual neuro muscular block because of age-related physiological decline and altered pharmacokinetics. Neostigmine, the conventional reversal agent, has a ceiling effect and cholinergic side effects, whereas Sugammadex selectively encapsulates amino steroid neuromuscular blockers. Evidence specific to vecuronium reversal in the elderly remains limited.

Aim: To compare the efficacy and Haemodynamic safety of Sugammadex versus Neostigmine for reversal of vecuronium-induced neuromuscular block in geriatric patients.

Methods: This prospective, randomised, controlled study was conducted in the Department of Anaesthesiology and Critical Care, Gauhati Medical College and Hospital (CTRI/2025/02/080445) over one year (February 2025–February 2026). One hundred and six patients aged ≥60 years, ASA grade II, undergoing surgery under general anaesthesia were randomised (block randomisation, sealed-envelope allocation concealment) into two equal groups. Group A (n=53) received Neostigmine 0.05 mg/kg with Glycopyrrolate 0.01 mg/kg; Group B (n=53) received Sugammadex 2 mg/kg intravenously, both administered at a moderate block (train-of-four [TOF] count 2–3). Neuromuscular monitoring used acceleromyography at the ulnar nerve. The primary outcome was time to TOF ratio ≥0.9; secondary outcomes were time to extubation, time to shift to the post-anaesthesia care unit (PACU), and perioperative Haemodynamic changes.

Results: Baseline demographic and surgical characteristics were comparable between groups. Sugammadex achieved significantly faster reversal (4.08±2.26 vs 10.5±3.73 min; p<0.001), extubation (6.08±2.26 vs 12.5±3.73 min; p<0.001), and PACU transfer (8.08±2.26 vs 14.5±3.73 min; p<0.001) than Neostigmine. A transient but statistically significant rise in heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure occurred at 3 minutes after reversal in the Neostigmine group (p < 0.001), attributed to the vagolytic action of Glycopyrrolate; values normalised thereafter. Oxygen saturation and sedation (RASS) scores were comparable between groups.

Conclusion: Sugammadex achieves significantly faster neuromuscular reversal, earlier extubation, and quicker PACU transfer than Neostigmine in geriatric patients, with greater Haemodynamic stability. Sugammadex may be preferred as the reversal agent of choice in elderly patients receiving vecuronium-based neuromuscular blockade.

Keywords: Sugammadex, Neostigmine, Vecuronium, Geriatric Anaesthesia, Neuromuscular Block Reversal, Train-Of-Four Ratio.

Introduction

The global population aged ≥60 years is projected to rise from 10% to 22% by 2050, making the elderly an increasingly prominent surgical population[1]. Aging brings physiological decline, reduced organ reserve, higher co morbidity burden, and Hepatorenal alterations that change the pharmacokinetics and pharma co dynamics of an aesthetic drugs[2,3]. Adequate neuro muscular blockade is essential for tracheal intubation and optimal surgical conditions, but a single in tuba ting dose of a non-depolarising muscle relaxant can leave residual paralysis for over two hours [4-7]. Reversal agents are therefore routinely used to prevent residual neuromuscular block and postoperative pulmonary complications [8].

Neostigmine, an acetyl cholinesterase inhibitor, remains the conventional reversal agent, but it exhibits a ceiling effect beyond which increasing the dose does not improve reversal, cannot reliably reverse deep block, and produces cholinergic side effects such as bradycardia, broncho constriction, and excessive secretions that require co - administration of an anti cholinergic such as Glycopyrrolate[9,10].

Sugammadex, a modified γ - cyclodextrin, selectively encapsulates amino steroid neuromuscular blocking agents - principally rocuronium and, to a lesser extent, vecuronium - forming an inactive complex without Muscarinic side effects or the need for anti cholinergic [12].

Geriatric patients have altered drug handling: reduced hepatic blood flow and glomerular filtration slow vecuronium clearance, while diminished cardio vascular reserve and autonomic dysfunction increase susceptibility to reversal - related Haemodynamic instability [2,13-17].

Despite growing evidence for Sugammadex in adults, data specific to vecuronium reversal in elderly patients remain limited. This study was undertaken to compare the efficacy and Haemodynamic safety of Sugammadex versus Neostigmine for reversal of vecuronium-induced neuromuscular block in geriatric patients. The null hypothesis was that there is no difference in recovery time to a TOF ratio ≥0.9 between the two reversal agents in this population.

Aims and Objectives

The primary objective was to compare the recovery time from administration of the reversal agent (Sugammadex or Neostigmine) to a TOF ratio ≥0.9 in geriatric patients undergoing general anaesthesia with vecuronium-based neuromuscular blockade. Secondary objectives were to compare (1) time to extubation, (2) time to shifting the patient from the operating room to the PACU, and (3) Haemodynamic changes following administration of the reversal agent.

Materials and Methods

Study design and setting: This was a prospective, randomised, controlled study conducted in the operating theatres of the Department of Anaesthesiology and Critical Care, Gauhati Medical College and Hospital, Guwahati, over one year (13 February 2025 to 28 February 2026), after Institutional Ethics Committee clearance (MC. No.: 190/ 2007/ pt - II/ August, 2024/54, dated 27/09/2024) and written informed consent from all participants. The trial was prospectively registered with the Clinical Trial Registry of India (CTRI/ 2025/ 02/ 080 445).

Participants: Patients aged ≥60 years, of either sex, ASA physical status I or II, undergoing elective or emergency surgery under general anaesthesia, were screened. Exclusion criteria were refusal of consent, known or suspected neuromuscular disease, anticipated difficult intubation, known drug sensitivity, personal/family history of malignant hyperthermia, and known chronic kidney or liver disease.

Sample size: Based on Mraovic et al. [34], who reported a mean time to TOF ratio ≥0.9 of 26.3±17.5 minutes with Neostigmine, a sample of 48 patients per group was required to detect a clinically relevant difference in recovery time with 5% significance and 80% power. Allowing for a 10% dropout, 53 patients per group (total n=106) were enrolled.

Randomisation and blinding: Of 300 patients screened, 180 did not meet eligibility criteria and 14 declined participation, leaving 106 patients who were randomised using computer-generated, variable-block randomisation with sealed-envelope allocation con cealment into Group A (Neostigmine, n=53) and Group B (Sugammadex, n=53).

An aesthetic protocol: All patients underwent a standard pre-an aesthetic evaluation and were kept nil per oral for 8 to 10 hrs. In the operating room, standard monitoring was established, and body temperature was maintained above 35°C. Premedication comprised intravenous Glycopyrrolate 40 mcg/ kg and fentanyl 1 mcg/kg after 3 minutes of pre-oxygenation. Anaesthesia was induced with propofol 1-2 mg/kg.

Neuromuscular monitoring was performed by acceleromyography, with surface electrodes over the Ulnar nerve and supra maximal train-of-four stimulation delivered every 15 seconds, recording the evoked response of adductor pollicis. Neuromuscular blockade was induced with vecuronium 0.1 mg/kg and maintained at a moderate block (TOF count 1–2) with vecuronium 0.015 mg/kg maintenance boluses. Anaesthesia was maintained with sevoflurane (MAC 0.8–1.0, FiO2 0.37) in nitrous oxide–oxygen (2:1), with a tidal volume of 6–8 mL/kg. Ondansetron 0.1 mg/kg was given approx imately 20 minutes before reversal for antiemetic pro phylaxis.

Intervention: At the end of surgery, when the TOF count reached 2–3 twitches, patients received either Injection Neostigmine 0.05 mg/kg (maximum 5 mg) with Glycopyrrolate 0.01 mg/kg (maximum 2 mg) intravenously (Group A) or Injection Sugammadex 2

mg/kg intravenously (Group B), each diluted in 10 mL normal saline.

Heart rate, systolic and diastolic blood pressure, and ECG rhythm were recorded every minute until TOF ratio ≥0.9 was sustained for three consecutive measurements. Extubation required TOF ratio ≥0.9 together with eye opening, hand grip, and head lift to command. The Richmond Agitation–Sedation Scale (RASS) [37] was used to assess sedation at baseline and after extubation.

Outcomes: The primary outcome was recovery time, defined as the interval from reversal agent administration to a TOF ratio ≥0.9. Secondary outcomes were time to extubation, time to shift from the operating room to the PACU, and haemodynamic changes (heart rate, systolic/diastolic blood pressure, mean arterial pressure, SpO2, and RASS score) relative to baseline, recorded at 1, 3, and 5 minutes after reversal.

Statistical Analysis

Data were analysed using SPSS version 25 and Graph Pad Prism. The Shapiro–Wilk test assessed normality. Continuous variables meeting normality assumptions were compared using the independent-samples t-test; non-normally distributed variables were compared using the Mann-Whitney U test. Categorical variables were compared using the chi-square test. A p-value <0.05 was considered statistically significant and <0.001 highly significant.

Results

Of 300 patients screened, 106 eligible patients were enrolled and completed the study — 53 in the Neostigmine group (Group A) and 53 in the Sugammadex group (Group B); 180 did not meet eligibility criteria and 14 declined participations. Baseline demographic and surgical characteristics were statistically comparable between the two groups (Table 1).

Table 1: Baseline demographic and surgical characteristics

Parameter	Neostigmine group (n=53)	Sugammadex group (n=53)	Statistic	p-value
Mean age (years)	66.0 ± 6.58	67.2 ± 5.51	Mann-Whitney	0.101
Male : Female	32 : 21	26 : 27	$\chi^2 = 1.37$	0.242
ASA grade II (%)	53 (100%)	53 (100%)	—	—
Mean weight (kg)	60.7 ± 7.65	59.2 ± 6.18	t = 1.12	0.266
Duration of surgery (min)	68.0 ± 32.5	64.1 ± 31.4	Mann-Whitney	0.679
Total vecuronium dose (mg)	7.75 ± 1.51	7.58 ± 1.25	Mann-Whitney	0.538

The commonest procedure overall was laparoscopic cholecystectomy (45.2%), followed by exploratory laparotomy (24.5%) and Hernioplasty (13.2%); the distribution of surgery types did not differ significantly between groups (χ^2=12.2, p=0.430).

Table 2: Primary and secondary time-based outcomes

Outcome	Neostigmine group (min)	Sugammadex group (min)	t-value	p-value
Time to TOF ratio ≥0.9 (primary outcome)	10.5 ± 3.73	4.08 ± 2.26	10.7	<0.001

Time to extubation	12.5 ± 3.73	6.08 ± 2.26	10.7	<0.001
Time to shift to PACU	14.5 ± 3.73	8.08 ± 2.26	10.7	<0.001

Sugammadex achieved reversal to a TOF ratio ≥0.9 approximately 61% faster than Neostigmine, with correspondingly earlier extubation and PACU transfer (all p<0.001).

Table 3: Haemodynamic parameters at key time points (mean ± SD)

Parameter	Time point	Neostigmine group	Sugammadex group	p-value
Heart rate (bpm)	Baseline	88.6 ± 4.56	89.5 ± 3.43	0.271
Heart rate (bpm)	3 min post-reversal	99.8 ± 5.33	90.7 ± 4.20	<0.001
Systolic BP (mmHg)	Baseline	124 ± 12.0	126 ± 10.3	0.446
Systolic BP (mmHg)	3 min post-reversal	146 ± 14.3	138 ± 10.3	<0.001
Diastolic BP (mmHg)	Baseline	87.8 ± 7.91	87.9 ± 6.74	0.906
Diastolic BP (mmHg)	3 min post-reversal	83.6 ± 8.20	79.7 ± 7.72	0.013
MAP (mmHg)	Baseline	99.8 ± 6.44	101 ± 5.59	0.571
MAP (mmHg)	3 min post-reversal	104 ± 6.27	99.0 ± 6.21	<0.001
SpO2 (%)	Baseline	96.6 ± 1.42	97.0 ± 1.26	0.171
SpO2 (%)	3 min post-reversal	97.1 ± 1.63	96.8 ± 1.60	0.232

At all recorded time points except 3 minutes after reversal, heart rate, systolic and diastolic blood pressure, and MAP were statistically comparable between groups. At 3 minutes post-reversal, the Neostigmine group showed a significant transient rise in all Haemodynamic parameters (p<0.001 for heart rate, systolic BP and MAP; p=0.013 for diastolic BP), which returned to baseline by 5 minutes. This was attributed to the anti cholinergic (vagolytic) action of Glycopyrrolate rather than a direct effect of Neostigmine. SpO2 did not differ significantly between groups at any time point; three patients(two Neostigmine, one Sugammadex) transiently desaturated to 93% in the immediate post-reversal period, all of whom improved with supportive management.

Pre- and postoperative RASS sedation scores were similar between groups (Mann-Whitney p=1.0 and p=0.425, respectively), suggesting comparable levels of consciousness recovery with both reversal strategies.

Discussion

In this randomised controlled trial of 106 geriatric patients receiving vecuronium-based neuromuscular blockade, Sugammadex produced markedly faster reversal to a TOF ratio ≥0.9 than Neostigmine (4.08 ± 2.26 vs 10.5 ± 3.73 min; a 61% reduction), which translated into earlier extubation (105.6% faster) and quicker PACU transfer. These findings are concordant with prior randomised trials in elderly cohorts: Khuenl-Brady et al. [27] reported an 84.9% faster reversal with Sugammadex after vecuronium in adults, Mraovic et al. [34] found an 84.8% faster reversal in patients ≥ 65 years undergoing spine surgery with rocuronium, and Vested et al. [36] reported a 74.3% faster reversal in patients ≥ 75 years undergoing robotic surgery. Similarly, Ellison et

al. [26] and Yang et al. [35] documented substantially faster extubation with Sugammadex (73.3% and 83.3% faster, respectively).

Demographic and surgical variables (age, sex, weight, ASA grade, surgery type, duration, and vecuronium dose) were well balanced between groups, minimising confounding and strengthening the internal validity of the observed treatment effect.

Haemodynamic parameters were comparable at baseline and at most post-reversal time points; however, a transient but statistically significant rise in heart rate, systolic and diastolic blood pressure, and MAP occurred in the Neostigmine group at 3 minutes after reversal, resolving by 5 minutes. Neostigmine is well known to cause cholinergic side effects such as bradycardia and arrhythmias, necessitating co-administration of an anti cholinergic such as Glycopyrrolate, which has a similar onset time and is preferred over atropine because it does not cross the blood-brain barrier [10]. We attribute the transient tachycardia and hypertension in Group A to the vagolytic action of Glycopyrrolate rather than to Neostigmine itself, a pattern also reported by Togioka et al.[32] in a study of geriatric patients undergoing prolonged surgery. Elderly patients have reduced vital capacity, blunted hypoxic and hypercapnic ventilatory responses, arterial stiffness, diminished cardiac reserve, and dysautonomia, all of which heighten vulnerability to reversal - agent induced cardiovascular perturbation[2]. Sugammadex, requiring no anti cholinergic co-administration, therefore offers a comparatively more haemodynamically stable reversal option in this vulnerable population.

Sedation scores (RASS), assessed before induction and after extubation, were similar between groups, consistent with Batistaki et al. [22], who found no difference in post operative cognitive dysfunction between Sugammadex and Neostigmine, and with Aho et al. [21], who showed that BIS/entropy elevations after either reversal agent reflect electromyographic artefact rather than true awareness. Neostigmine was dosed at 0.05 mg/ kg with Glycopyrrolate 0.01 mg/ kg, consistent with recommendations for moderate block reversal [10].

Neostigmine exhibits a well-recognised ceiling effect beyond 60–80 mcg/kg, beyond which further dosing does not enhance reversal because acetyl cholinesterase is already substantially inhibited - a particular concern in elderly patients, who have a higher baseline prevalence of residual neuromuscular block [17]. Sugammadex, by contrast, acts through stoichiometric encapsulation of the amino steroid neuromuscular blocker rather than enzyme inhibition, and its dosing is depth-dependent (2 mg/kg for moderate block, 4 mg/kg for deep block, 16 mg/kg for immediate reversal) [12,19]. Consistent with earlier vecuronium-specific trials by Khuenl-Brady et al. [27] and Lemmens et al.[28], our results confirm that Sugammadex provides reliable and rapid reversal of vecuronium - induced block even in an elderly cohort with reduced Hepatorenal clearance.

Limitations

This study was conducted at a single centre and restricted to ASA grade II patients, which may limit generalisability to higher-risk elderly patients (ASA III–IV) or those with hepatic or renal impairment, who were excluded. Long-term outcomes such as postoperative pulmonary complications, 30-day readmission, and cost-effectiveness were not assessed and warrant evaluation in future multicentric trials.

Conclusion

In geriatric patients undergoing vecuronium-based neuromuscular blockade, Sugammadex achieved

significantly faster reversal to a TOF ratio ≥ 0.9, earlier extubation, and quicker PACU transfer compared with Neostigmine, along with greater Haemodynamic stability in the immediate post-reversal period. These findings support the preferential use of Sugammadex as the reversal agent of choice in elderly patients receiving amino steroid neuromuscular blockers, particularly where rapid, predictable recovery and cardiovascular stability are clinically important.

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