

## Original Research Article

# COMPARISON OF TWO DIFFERENT DOSES OF SUGAMMADEX 2mg Vs. 4mg AS A REVERSAL AGENT IN LAPAROSCOPIC CHOLECYSTECTOMY UNDER GENERAL ANESTHESIA

Anubha<sup>1</sup>, Vinod Kumar Yadav<sup>2</sup>, Ashish Tyagi<sup>3</sup>, Rahul Singh Paraliya<sup>4</sup>

<sup>1</sup>PG 3<sup>rd</sup> year, Santosh Medical College Hospital, India.

<sup>2</sup>Associate Professor, Santosh Medical College Hospital, India.

<sup>3</sup>Associate Professor, Santosh Medical College Hospital, India.

<sup>4</sup>Consultant, General Medicine, Park Hospital, Paschim Vihar, India.

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## Corresponding Author:

**Dr. Anubha,**  
PG 3<sup>rd</sup> year, Santosh Medical College  
Hospital, India.  
Email: anubhakumari90@gmail.com

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## ABSTRACT

**Background:** Neuromuscular blocking agents (NMBAs), such as rocuronium, are commonly used for intubation and in surgical conditions. Sugammadex, a selective relaxant binding agent, provides rapid reversal of neuromuscular blockade (NMB), unlike traditional agents. **Objective:** This study compares the effects of Sugammadex at doses of 2 mg/kg and 4 mg/kg in patients undergoing laparoscopic cholecystectomy, focusing on neuromuscular recovery and extubation time.

**Materials and Methods:** A two-year observational study at Santosh Medical College included 90 ASA I or II patients aged 18 and older. Participants were divided into two groups based on train-of-four (TOF) counts: Group A (2 mg/kg) for TOF counts more significant than two and Group B (4 mg/kg) for TOF counts of 1-2. Primary outcomes included recovery time from NMB.

**Results:** The extubation time was shorter in Group B ( $1.81 \pm 1.08$  min) compared to Group A ( $3.78 \pm 1.28$  min,  $p = 0.001$ ). Both groups showed improvements in oxygen saturation and respiratory parameters, although Group B had a transient increase in systolic blood pressure. Faster recovery of the faster-twitch response was observed in the 4 mg group.

**Conclusion:** A 4 mg/kg dose of Sugammadex leads to faster neuromuscular and respiratory recovery compared to a 2 mg/kg dose, indicating its advantages over traditional reversal agents. Further multicenter studies are needed to confirm these findings.

**Keywords:** Sugammadex, Reversal Agent, Laparoscopic Cholecystectomy.

## INTRODUCTION

Neuromuscular blocking agents (NMBAs), such as rocuronium, are frequently used to facilitate endotracheal intubation and optimize surgical conditions. However, the rapid and effective reversal of NMB is crucial to prevent postoperative complications associated with residual neuromuscular blockade, such as respiratory insufficiency and prolonged recovery times.<sup>[1-3]</sup> Sugammadex, a modified cyclodextrin, has emerged as a novel agent that encapsulates steroidal NMBAs, thereby facilitating their rapid elimination from the neuromuscular junction and allowing for swift

recovery from paralysis.<sup>[4-6]</sup> Sugammadex, a selective relaxant binding agent, offers a distinct mechanism of action compared to traditional reversal agents, such as neostigmine, allowing for a more predictable and rapid recovery from neuromuscular blockade (NMB) induced by rocuronium, which is commonly used in laparoscopic surgeries.<sup>[1-3]</sup>

The rationale for this study is further strengthened by evidence indicating that Sugammadex facilitates faster recovery from neuromuscular blockade (NMB) compared to traditional agents, such as neostigmine, and reduces the incidence of postoperative complications, including nausea and vomiting.<sup>[7-9]</sup>

The choice of laparoscopic cholecystectomy as the surgical procedure for this study is particularly pertinent, given that this minimally invasive technique often necessitates profound neuromuscular blockade to facilitate optimal surgical conditions. The ability of Sugammadex to provide rapid and effective reversal of NMB can significantly impact postoperative recovery, as evidenced by research demonstrating quicker return of gastrointestinal function and reduced time to first flatus and bowel movement in patients receiving Sugammadex.<sup>[1,14,15]</sup> Furthermore, investigating two different doses (2 mg/kg and 4 mg/kg) is critical, as existing literature suggests a dose-dependent effect of Sugammadex on recovery from NMB.<sup>[16-18]</sup>

Moreover, the potential implications of this study extend beyond immediate recovery metrics. This study aims to contribute to the existing body of knowledge by providing comparative data on the effectiveness and safety of two doses (2 mg/kg and 4 mg/kg) of Sugammadex, thereby informing clinical practice and enhancing patient care in the context of laparoscopic surgeries.

## **MATERIALS AND METHODS**

### **Study Objective**

To evaluate the effects of Sugammadex at two different doses (2 mg/kg and 4 mg/kg) as a neuromuscular blockade reversal agent in patients undergoing laparoscopic cholecystectomy under general anesthesia.

### **Study Design**

This prospective observational study is conducted to assess real-world outcomes in clinical practice. Observational data is collected prospectively in this design without altering the standard care provided to patients. The data focuses on comparing two predetermined doses of Sugammadex as per clinical protocols.

### **Study Setting**

The study was conducted at the Elective Operation Theatre Complex of Santosh Medical College and Hospital, Ghaziabad. This location ensures uniformity in patient management and access to necessary equipment for TOF monitoring. The study is conducted over 2 years, allowing sufficient time for participant recruitment, intervention, and follow-up. Before the commencement of the study, ethical clearance was obtained from the institute's ethical committee, and it was ensured that written consent was obtained after a detailed explanation of the study objectives, procedures, and potential risks. The study adhered to the principles outlined in the Declaration of Helsinki. The confidentiality of participant data was maintained through anonymization and restricted access.

### **Study Participants**

In the present study, patients classified as American Society of Anesthesiologists (ASA) I or II, indicating mild or no systemic disease, aged 18 years or older,

undergoing laparoscopic cholecystectomy under general anesthesia, were selected. Patients with diagnosed neuromuscular disorders (e.g., myasthenia gravis, Eaton-Lambert syndrome) were excluded from enrollment. Even obese patients with a body mass index (BMI) exceeding 30 kg/m<sup>2</sup> and patients with any contraindication to Sugammadex, such as hypersensitivity to the drug, were also excluded from the present study.

### **Sample Size Determination**

The sample size was determined based on a prior study by Shigeaki Otomo *et al.*, which evaluated the recovery rates for Sugammadex doses. Using a two-proportion formula with a 95% confidence level and 80% power, each group will include 45 patients, resulting in a total sample size of 90 aged 18 years or above.

### **Study Procedures**

#### **Preoperative Preparation**

All patients underwent a thorough evaluation to assess their fitness for anesthesia before the surgery. To ensure their safety, preoperative fasting guidelines were strictly adhered to. Patients were instructed to fast for 8 hours before the procedure for solids and to refrain from consuming clear liquids for at least 2 hours before surgery. These measures were implemented to minimize the risk of complications during the anesthesia process.

#### **Intraoperative Monitoring**

Upon arrival in the operating room, patients were immediately connected to essential monitoring devices to ensure continuous assessment of their vital parameters. A pulse oximeter was used to monitor oxygen saturation, while an electrocardiogram (ECG) provided a continuous evaluation of the cardiac rhythm. Non-invasive blood pressure (NIBP) monitoring was conducted to track hemodynamic stability throughout the procedure. Additionally, a train-of-four (TOF) monitor was utilized to evaluate neuromuscular function, ensuring appropriate management of muscle relaxation during anesthesia. These monitoring measures were implemented to enhance patient safety and optimize perioperative care.

#### **Interventions**

Patients were allocated into two groups based on their train-of-four (TOF) count. Group A included those who received Sugammadex at a dose of 2 mg/kg if their TOF count was greater than 2, while Group B consisted of patients who received 4 mg/kg of Sugammadex if their TOF count was between 1 and 2. The reversal agent was administered intravenously at the specified dose, based on TOF monitoring results, to ensure effective reversal of neuromuscular blockade and optimize patient recovery.

#### **Study Outcome**

The primary outcomes of the study included the time required for recovery from Vecuronium-induced neuromuscular blockade and the patterns of TOF ratio recovery within five minutes of Sugammadex administration. Secondary outcomes assessed the time to extubation following drug administration, the

duration until transfer to the recovery room, and the occurrence of adverse effects such as hypersensitivity or cardiovascular instability. Data collection was conducted using a standardized proforma, which captured patient demographics, baseline clinical parameters, intervention details, and outcome measures. To ensure accuracy and consistency, trained personnel utilized pretested forms for data recording and monitoring.

### Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (Armonk, NY: IBM Corp.). Continuous variables were summarized using mean  $\pm$  standard deviation (SD) and analyzed for normality. The independent t-test was applied to compare continuous variables between the two groups. To assess within-group variations over time, repeated measures analysis of variance (ANOVA) was used for time-dependent continuous variables. Categorical variables were expressed as frequency (N) and percentage (%). To compare the proportions between the two groups, Chi-square tests/ Fisher's exact test were performed. A p-value of less than 0.05 was considered statistically significant. The selected statistical methods ensured robust comparisons between groups and enabled time-dependent trend analyses within each group.

### Data Collection

To maintain accuracy and reliability in monitoring and data collection, all equipment, including TOF monitors and infusion pumps, was calibrated at regular intervals to ensure proper functioning and precise measurements. This calibration process was conducted according to standardized protocols to minimize technical errors and enhance the accuracy of recorded parameters. Additionally, data collection forms were pretested in a pilot phase and revised accordingly to eliminate potential ambiguities and reduce the likelihood of errors during data recording. To further ensure data integrity, all entries were independently verified by two researchers, enabling cross-checking and the prompt identification of any inconsistencies. This rigorous approach aimed to enhance the reliability of the study findings and maintain the highest standards of data accuracy.

## RESULTS

The study analyzed the age and gender distribution, extubation time, oxygen saturation, respiratory rate, tidal volume, hemodynamic parameters, and

neuromuscular recovery in patients receiving either 2 mg/kg or 4 mg/kg of Sugammadex. Participants were categorized into three age groups (21–40, 41–60, and 61–80 years), with the 2 mg group having a broader age range (24–80 years) than the 4 mg group (20–65 years). However, the mean age did not differ significantly between groups ( $p = 0.889$ ). Both groups exhibited a female predominance, with 78% in the 2 mg group and 74% in the 4 mg group, respectively. There was no significant gender difference ( $p = 0.640$ ) (Table 1). Extubation time was significantly shorter in the 4 mg group ( $1.81 \pm 1.08$  min) compared to the 2 mg group ( $3.78 \pm 1.28$  min), indicating a highly significant difference ( $p = 0.001$ ) and suggesting a faster recovery with a higher dose. Oxygen saturation increased over time in both groups, with no significant difference observed at any time point ( $p = 0.065$ – $0.175$ ); however, within-group improvements over a five-minute period were significant ( $p = 0.001$ ). The respiratory rate was initially higher in the 4 mg group but stabilized by five minutes, showing significant within-group improvements ( $p = 0.001$ ). Similarly, tidal volume increased more rapidly in the 4 mg group but showed no significant difference at five minutes ( $p = 0.604$ ), despite within-group significance ( $p = 0.001$ ). Hemodynamic parameters revealed transiently higher systolic blood pressure in the 4 mg group, but both groups exhibited significant decreases over time ( $p = 0.001$ ). Diastolic blood pressure differences were insignificant, except at five minutes ( $p = 0.043$ ). The pulse rate was initially higher in the 2 mg group but stabilized at a higher level in the 4 mg group, with significant changes over time ( $p = 0.001$ ) (Table 2). Neuromuscular recovery findings demonstrated that the 4 mg group achieved faster twitch response recovery, with full recovery by three minutes and significant differences at one and two minutes ( $p = 0.001$ ). Swallow reflex recovery was quicker in the 2 mg group, with all participants regaining it by two minutes. Verbal response, cough reflex, and upper limb movement recovery occurred earlier in the 4 mg group, with significant differences at multiple time points ( $p < 0.05$ ). Overall, the study findings suggest that a 4 mg/kg dose of Sugammadex results in significantly faster neuromuscular and respiratory recovery compared to the 2 mg/kg dose. Faster extubation, improved tidal volume, and quicker reflex recovery support the use of a higher dose for accelerated neuromuscular blockade reversal in surgical patients. The results are presented in Table 3.

**Table 1: Demographic Details**

Parameters		Group I	Group II	P value
Age (Mean $\pm$ SD)		42.36 $\pm$ 12.38	42.68 $\pm$ 10.50	0.889
Gender	Male	11(22)	13(26)	0.640
	Female	39(78)	37(74)	

**Table 2: Clinical Parameters**

Parameters		Group I	Group II	P value
Extubation time		3.78 $\pm$ 1.28	1.81 $\pm$ 1.08	0.001*
SPO2	1 min	95.60 $\pm$ 1.49	94.80 $\pm$ 3.02	0.097
	2 min	96.88 $\pm$ 1.21	96.34 $\pm$ 2.09	0.118

	3 min	97.44±0.84	97.74±1.30	0.175
	4 min	98.16±0.82	98.40±0.49	0.079
	5 min	98.63±0.73	98.40±0.49	0.065
	P Value	0.001*	0.001*	---
Respiratory rate	1 min	10.22±2.15	12.32±1.95	0.001*
	2 min	12.40±1.89	14.84±1.46	0.001*
	3 min	14.30±1.44	16.08±0.69	0.001*
	4 min	16.04±1.64	16.80±1.06	0.007*
	P value	0.001*	0.001*	
Tidal Volume	1 min	203.22±94.83	267.66±148.23	0.011*
	2 min	295.10±105.36	361.44±97.69	0.002*
	3 min	379.06±109.57	463.92±108.71	0.001*
	4 min	435.24±89.57	500.50±96.04	0.001*
	5 min	527.84±69.81	518.52±105.65	0.604
	P value	0.001*	0.001*	
Systolic Blood pressure	3 min	136.02±5.58	158.28±26.41	0.001*
	4 min	132.98±8.36	137.68±10.02	0.012*
	P value	0.001*	0.001*	
Diastolic blood pressure	5 min	79.32±9.07	82.44±5.73	0.043*
	P value	0.001*	0.001*	
Pulse Rate	1 min	103.06±10.54	92.14±5.51	0.001*
	3 min	90.16±9.63	93.76±7.35	0.038*
	4 min	88.26±6.39	90.48±6.93	0.099
	5 min	83.62±7.16	89.16±7.99	0.001*
	P value	0.001*	0.001*	

**Table 3: Clinical parameters: Swallow; Cough Relexs and movements**

Parameters	Time	Response (A/P)	Group I	Group II	P value
Swallow	1 min	Absent	23(46)	40(80)	0.001*
		Present	27(54)	10(20)	
	2 min	Absent	0	30(60)	0.001*
		Present	50 (100)	20(40)	
	2 min	Absent	39(78)	25(50)	0.006*
		Present	11(22)	25(50)	
	3 min	Absent	1(2)	29(58)	0.001*
		Present	49(98)	21(42)	
Cough Reflex	1 min	Absent	50(100)	30(60)	0.001*
		Present	0	30(60)	
	2 min	Absent	45(90)	20(40)	0.001*
		Present	5(10)	30(60)	
	3 min	Absent	33(66)	20(40)	0.016*
		Present	17(34)	30(60)	
Upper limb movement	1 min	Absent	50(100)	38(76)	0.001*
		Present	0	12(24)	
	2 min	Absent	50(100)	18(36)	0.001*
		Present	0	32(64)	
	3 min	Absent	33(66)	18(36)	0.003*
		Present	17(34)	32(64)	
Lower limb movements	3 min	Absent	35(70)	50(100)	0.001*
		Present	15(30)	0	

## DISCUSSION

Sugammadex is a selective relaxant binding agent that has demonstrated rapid and effective reversal of neuromuscular blockade caused by rocuronium and vecuronium. A critical area of research in anesthesiology is the comparison of extubation times associated with two different doses of sugammadex. Several studies have demonstrated that a higher dose of sugammadex (4 mg/kg) yields significantly shorter extubation times compared to a lower dose (2 mg/kg). A study by Güleç et al. found that extubation with 4 mg/kg of sugammadex took about 2.9 minutes, compared to 50.4 minutes with neostigmine.<sup>[19]</sup> This highlights the significant advantage of sugammadex for quick recovery from anesthesia in surgical settings. Hakimoğlu et al. found that 2 mg/kg of sugammadex provided a faster reversal of

neuromuscular functions compared to 50 µg/kg of neostigmine, leading to reduced extubation times.<sup>[20]</sup> This aligns with other research indicating that sugammadex accelerates recovery and lowers the risk of residual curarization. Additionally, Karwacki et al. noted that sugammadex significantly shortened the time to optimal extubation conditions, achieving complete neuromuscular recovery in about 2.7 minutes, contrasting with longer recovery times for traditional agents.<sup>[21]</sup>

Research indicates that the dosage of sugammadex has a significant impact on postoperative respiratory function. Kheterpal et al. (2020) found that lower rates of postoperative pulmonary complications were associated with better respiratory outcomes.<sup>[22]</sup> Farahat and Mousa (2022) noted that a stable cerebral metabolic rate of oxygen (eCMRO2) in the sugammadex group helps balance cerebral blood



flow and metabolic needs, enhancing brain oxygen delivery.<sup>[23,24]</sup>

Brueckmann et al. (2015) and Ji et al. (2020) highlighted the significance of optimizing respiratory recovery in postoperative care with pre-existing respiratory conditions compared to neostigmine.<sup>[25,26]</sup> Kashiwai et al. (2012) warn that residual neuromuscular block may still occur, potentially leading to respiratory insufficiency, underscoring the importance of careful sugammadex dosing.<sup>[27]</sup> Finally, Gu et al. (2021) observed no significant difference in pneumonia and atelectasis rates between patients receiving sugammadex and those who did not.<sup>[28]</sup>

Research indicates that adequate neuromuscular function can enhance respiratory mechanics, thereby improving tidal volume and ventilation efficiency, particularly in patients with pre-existing lung conditions.<sup>[29]</sup> Maintaining lower tidal volumes is crucial to prevent further lung injury. The positive end-expiratory pressure, is also significant, as inappropriate tidal volumes can exacerbate lung injury. Therefore, the dosing of sugammadex should consider ventilatory settings and patient-specific factors.

Sugammadex can influence blood pressure, with moderate hypotension observed in a patient receiving 2 mg and lower arterial pressure in another receiving 4 mg, suggesting a dose-dependent effect.<sup>[30]</sup> Tsai et al. (2023) found patient required additional antihypertensive medication indicating better hemodynamic stability during emergence from anesthesia.<sup>[31]</sup> Sugammadex is primarily excreted unchanged by the kidneys, which may help restore baseline hemodynamic parameters quickly after administration, potentially reducing the duration of hypotensive or hypertensive episodes. Hakimoğlu et al. (2016) reported no significant effects on blood pressure or heart rate with sugammadex, indicating a stable hemodynamic profile. However, higher doses may increase the risk of bleeding and affect blood pressure dynamics in the perioperative setting. Additionally, its interaction with vasopressors and anesthetic agents complicates hemodynamic effects, necessitating a comprehensive understanding of a patient's medication regimen.

The pulse rate is a critical indicator of hemodynamic stability and autonomic function during and after anesthesia. Sugammadex promotes a dose-dependent recovery of TOF ratios, achieving levels greater than 0.9 more rapidly at higher doses.<sup>[1]</sup> The drug is rapidly cleared through renal excretion. However, the optimal dosage should be tailored to each patient's specific context to achieve the best outcomes.

The use of Sugammadex has been associated with improved long-term outcomes, including reduced morbidity related to prolonged NMB, which can lead to complications such as respiratory issues and delayed recovery of muscle function.<sup>[19-21]</sup> The choice of dosage impacts patient safety and satisfaction, especially in outpatient settings. A systematic review highlighted that Sugammadex is associated with a

significant reduction in the occurrence of postoperative nausea and vomiting (PONV) compared to neostigmine, which is particularly relevant in the context of laparoscopic surgeries where PONV is a common concern.<sup>[10,11]</sup> Additionally, studies have shown that Sugammadex can lead to shorter lengths of stay in the post-anesthesia care unit (PACU), thereby enhancing overall surgical efficiency and patient throughput.<sup>[12,13]</sup> This is important due to surgical factors and opioid use increasing PONV risk.

Sugammadex's mechanism not only reverses NMB but may also alleviate emetic effects associated with neostigmine. In pediatric patients, higher doses of sugammadex have been shown to reduce PONV and contribute to significantly quicker recovery times. A higher doses of sugammadex correlate with a reduced need for additional antiemetic therapy postoperatively, enhancing patient satisfaction and recovery outcomes. Evidence shows that a dose of 4 mg is more effective than 2 mg in reducing postoperative nausea and vomiting (PONV), particularly in high-risk surgical settings. Sugammadex's rapid action and lack of muscarinic side effects make it a valuable option for managing neuromuscular blockade.

Sugammadex offers significant advantages over neostigmine, particularly in terms of clinical efficacy and economic implications. Although it is generally more expensive, its ability to reduce extubation times and accelerate recovery can result in shorter hospital stays and lower overall costs. Cost-effectiveness analyses indicate that the quicker recovery may offset its higher initial price. Additionally, sugammadex has a lower incidence of postoperative complications, such as residual neuromuscular blockade, which can further enhance patient safety and satisfaction. This makes sugammadex a valuable option in anesthetic practice, particularly for procedures that require rapid recovery and reversal.

The study's strengths included a prospective design that minimized bias and standardized protocols for patient management, leading to reliable results. However, the single-center study design limits the generalizability of its findings, as patient demographics and clinical protocols may vary across different settings. Additionally, the observational nature of the study restricts the ability to establish direct causality between interventions and outcomes. Despite these limitations, the study offers valuable insights into the effectiveness of sugammadex and underscores the need for further multicenter research.

## CONCLUSION

Sugammadex is a novel selective relaxant binding agent used to reverse neuromuscular blockade induced by aminosteroid non-depolarizing muscle relaxants. Its rapid and effective action is particularly beneficial in anesthesia practice, ensuring faster recovery of neuromuscular function and reducing

postoperative respiratory complications. The present study evaluates the comparative effectiveness of 2 mg/kg and 4 mg/kg doses of Sugammadex in terms of extubation time, respiratory parameters, hemodynamic changes, and neuromuscular recovery in surgical patients.

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