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Research Article

Assessing the efficacy of sugammadex based on ideal body weight for reversal of moderate neuromuscular blockade in obstetric patients across different BMI categories: A prospective study

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ABSTRACT

Background: This investigation aimed to evaluate the effectiveness of administering 2 mg/kg intravenous (IV) sugammadex, dosed according to the ideal body weight (IBW) of obstetric patients across three different BMI groups, for the reversal of neuromuscular blockade caused by rocuronium.

Materials and Method: A total of ninety female patients, who were categorized as American Society of Anesthesiologists (ASA) II and were 18 years or older, participated in this study. These patients were all scheduled to undergo elective cesarean sections under general anesthesia, providing a well-defined cohort for our investigation. Participants were separated into three groups according to their BMI: Group 1 (n=30) consisted of patients with a BMI less than 30 kg/m^2, Group 2 (n=30) included those with a BMI ranging from 30 to 39.9 kg/m^2, and Group 3 (n=30) comprised patients with a BMI over 40 kg/m^2. At the end of the surgery, each patient received intravenous sugammadex at 2 mg/kg based on ideal body weight, with additional doses as needed, while recording the total amount administered and the times for extubation, motor responses, and first breastfeeding.

Results: The total sugammadex dose was found to be notably higher in Group 3 (p=0.002). The time required to reach a Train of Four (TOF) ratio greater than 90% was similar across the groups (p=0.120). However, the recorded durations between sugammadex administration and extubation, accurate motor response, and the time to first breastfeeding significantly differed between the groups.

Conclusions: We found that IV sugammadex 2 mg/kg, administered according to the IBW of patients, was effective for reversing moderate neuromuscular blockade in patients of weight categories. However, administering a sugammadex dose of IBW+25% appears to be safer for class III obese patients.

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1. Introduction

Obesity is a globally expanding health problem, with a higher prevalence in women. A recent study reported that 34.9% of the adult population in the United States has a body mass index (BMI) over 30 kg kg/m^2 [1]. Additionally, 2–5% of the adult population in Western societies has a BMI over 40 kg/m^2 [2]. Obesity is known to have significant effects during pregnancy. Overweight and obese women are at a higher risk of developing hypertension, diabetes mellitus, and cardiovascular problems during pregnancy [3]. Several studies have shown that the incidence of cesarean section (CS) has increased by more than 30% in obese patients [4,5]. Moreover,

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obesity affects the pharmacokinetics of several drugs due to reductions in body fluids and muscle mass. It is known that rocuronium bromide and vecuronium bromide have an increased duration of action in obese patients compared to those with a normal BMI. Therefore, in clinical practice, neuromuscular blocking agents (NMBs) are recommended to be administered based on the ideal body weight (IBW) of patients [6]. Furthermore, obesity is a significant risk factor for respiratory complications in the recovery room. Consequently, the rapid, reliable, and complete reversal of NMB agents in obese patients is of vital importance [7].

Sugammadex is a well-known drug for effectively reversing neuromuscular blockade induced by both rocuronium and vecuronium bromide [8]. Although several studies have evaluated the optimal dose for patients with normal body weight and morbid obesity, the ideal dose for patients with a BMI between 30 kg/m^2 and 40 kg/m^2 (Obesity Class I and II) remains a controversial issue [9]. Furthermore, previous studies on dose adjustments of sugammadex for morbidly obese (Obesity Class III) patients have reported conflicting results [10–13].

In this study, we aimed to evaluate the efficacy of intravenous (IV) sugammadex at a dosage of 2 mg/kg, calculated according to the ideal body weight (IBW) of obstetric patients in three distinct BMI categories, in reversing moderate neuromuscular blockade induced by rocuronium. The primary objective was to identify the average sugammadex dose required in each BMI group for successful extubation, as determined by Train of Four (TOF) monitoring. Secondary objectives included assessing the time from the initial sugammadex dose to successful extubation, the time to motor response to verbal commands, and the interval between the end of surgery and the first breastfeeding session, evaluated across different BMI groups.

2. Materials and Method

Following approval from the University Clinical Research Ethics Committee (Reference No: LUT–10/60, 06.03.2017), this study was registered with the Australian New Zealand Clinical Trials Registry, carrying the registration number ACTRN12618001633279. It was structured as a prospective, observational, controlled trial. Informed consent was secured from each participant prior to their inclusion in the study. Female patients over the age of 18, classified as American Society of Anesthesiologists (ASA) status II, who were scheduled for elective cesarean sections (CS) under general anesthesia, were recruited for the study between November 5, 2018, and December 20, 2018. Patients were excluded if they had pulmonary conditions such as asthma or chronic obstructive pulmonary disease, had known drug allergies to the medications used in the study, or were taking medications that could impact neuromuscular blockade, including magnesium sulfate, anticonvulsants, macrolides, or aminoglycosides. Individuals who declined participation were also excluded from the study.

The study participants were categorized into three groups based on their BMI: those with a BMI of less than 30 kg/m^2 (normal weight and pre-obesity) formed Group 1 (n=30), patients with a BMI between 30 and 39.9 kg/m^2 (Class I and II obesity) were assigned to Group 2 (n=30), and individuals with a BMI exceeding 40 kg/m^2 (Class III obesity) constituted Group 3 (n=30). In the operating room, all patients were subjected to standard monitoring, including electrocardiography (ECG), non-invasive blood pressure, pulse oximetry, end-tidal CO2, bispectral index (BIS), and Train of Four (TOF) monitoring. A 20-gauge intravenous line was inserted, and an infusion of isotonic saline (15 mL/kg/hour) was initiated. Following three minutes of preoxygenation with 100% O2, general anesthesia was induced with intravenous propofol (1.5–2 mg/kg) and rocuronium bromide (0.9 mg/kg). Anesthetic doses were calculated based on the ideal body weight (IBW) of each patient. Endotracheal intubation was performed when the BIS value fell below 60 and TOF reached less than 10%. Anesthesia maintenance involved 0.8–2.5% end-tidal sevoflurane in a mixture of 40% O2 and 60% N2O, with a target BIS range of 40 to 60. After delivery, fentanyl (1 mcg/kg) and ondansetron (4 mg) were administered intravenously, with dosages based on IBW. For postoperative analgesia, tramadol (2 mg/kg) was given intravenously at the end of surgery. Sugammadex 2 mg/kg was administered intravenously based on IBW when the TOF reached 25% to reverse the moderate neuromuscular blockade. TOF readings were taken every 20 seconds post-sugammadex administration, and if the TOF ratio (T4/T1) remained below 90% after two minutes, an additional dose of sugammadex (2 mg/kg) was given. Once the TOF ratio exceeded 90%, patients were extubated and transferred to the post-anesthesia care unit (PACU), where they were monitored for postoperative residual curarization (PORC) for one hour before being moved to the surgical ward. In the surgical ward, patients were observed for complications such as PORC, allergic reactions, bronchospasm, and postoperative nausea and vomiting (PONV) for 24 hours. For all patients, the total dose of sugammadex administered, the time between sugammadex administration and extubation, motor responses, and the time to first breastfeeding were recorded. Motor response was assessed by asking the patient to stick out her tongue or raise her head in response to verbal commands.

3. Sample Size and Statistical Analyses

The sample size was based on prior studies [13–15] evaluating a 2 mg/kg sugammadex dose according to ideal body weight (IBW) in Class III obese and normal-weight patients. To achieve an α error of 0.05 and a β error of 0.1, at least 27 participants per group were needed. Considering a 10% drop-out rate, each group included a minimum of 30 patients.

Statistical analysis was conducted using SPSS software version 22.0. Initially, descriptive statistics such as mean, median, minimum, maximum, standard deviation,

and ratio were calculated to summarize the data. To compare parametric variables that exhibited a normal distribution among the three groups, a one-way ANOVA was employed, followed by the Bonferroni test for post hoc pairwise comparisons. In cases where parametric variables did not conform to a normal distribution, the Kruskal-Wallis test was utilized to assess differences among the three groups, and the Mann-Whitney U test was applied for pairwise comparisons. For nonparametric variables, the analyses were conducted using Pearson's chi-square test and the Fisher-Freeman-Halton test. Additionally, the relationship between BMI and various intraoperative time periods, as well as the need for supplemental doses of sugammadex, was evaluated using Pearson's correlation test. A p-value of less than 0.05 was deemed statistically significant, indicating a meaningful difference in the results.

4. Results

A total of 96 patients were screened for inclusion in the study, and 90 patients were recruited, all of whom completed the study. Age, height, and IBW were similar across the groups; however, there were significant differences among the groups in terms of weight, BMI, and operation time. The demographic data of the patients are summarized in Table 1.

Table 1. Demographic data of the groups.

	Group I (n:30) (BMI < 30)	Group II (n:30) (30 < BMI < 40)	Group III (n:30) (BMI ≥ 40)	p
Age (years)	28.9±5.2	30.4±4.7	29.2±4.3	0.379
Weight (kg)	66.9±7.3	84.4±6.9	109.5±11.6	0.000**
Height (cm)	150±0.6	160±0.6	158±0.6	0.606
BMI (kg/m^2)	26.0±2.2	32.9±1.9	43.4±2.6	0.000
IBW (kg/m^2)	53.40±4.09	53.67±4.41	52.5±4.44	0.597
Systemic disease (yes/no)	4/26	5/25	1/29	0.294
Smoking (yes/no)	3/27	7/2	3/27	0.279

BMI: Body mass index; IBW: Ideal body weight

Mean rocronium bromide doses applied were similar in all groups (p=0.653), however, total sugammadex dose was found notably high in class III obese group (group 3) compared to other groups (p=0,.05). Eight patients (26.7%) in Group 3, 1 patient (3.3%) in Group 2 needed additional sugammadex dose while none of the patients needed additional sugammedex dose in group 1 (p=0.002) (Table 2).

Table 2. Mean rocuronium bromide and sugammadex doses administered amoung groups.

		Group I (n:30) (BMI < 30)	Group II (n:30) (30 < BMI < 40)	Group III (n:30) (BMI ≥ 40)	p
Rocuronium (mg)		47.46±53.91	47.76±4.19	46.83±3.85	0.653
Sugammadex (mg)		106.46±8.37	110.66±25.92	133.20±50.03	0.005**
Add Sug (n)(%)	No	30 (100)	22 (73.3)	30 (100)	0.002*
	Yes	0 (0)	8 (26.7)	0 (0)	

Add Sug: Additional sugammadex dose

The time needed to reach a TOF value over 90% was 62.2 ± 16.5 seconds in Group 1, 57.7 ± 2 seconds in Group 2, and 79.1 ± 64 seconds in Group 3. The difference among the groups was not statistically significant (p=0.120). The recorded durations between the administration of sugammadex and extubation were 76.1 ± 26 seconds in Group 1, 72.7 ± 28 seconds in Group 2, and 107.1 ± 63 seconds in Group 3. This difference was statistically significant (p=0.012). Additionally, the durations for accurate motor response and the time to first breastfeeding significantly differed between the groups and are summarized in Table 3.

Table 3. The distribution of perioperative durations across the groups.

	Group I (n=30)	Group II (n:30)	Group III (n:30)	p
TOF 0.9	62.2±16.5	57.7±20.9	79.1±63.7	0.120
Sug-extubation (sec)	76.1±25.9	72.7±28.1	107.1±63.0	0.012*
Sug-tongue stick (sec)	177.8±38.6	178.6±47.1	212.0±63.2	0.015*
Sug-breast feeding (h)	3.2±0.8	3.6±1.1	5.7±1.3	0.000**

TOF 0.9: Time needed for Train of Four 0.9; Sug-extubation: Time needed from application of Sugammadex to extubation; Sug-tongue stick: Time needed from application of Sugammadex to sticking out the tongue; Sug-breast feeding: Time needed from application of Sugammadex to first breast feeding

According to Pearson correlation analysis, BMI was positively correlated with the need for an additional sugammadex dose, time to reach a TOF value over 90% (TOF 0.9), extubation time, motor response time, and time to first breastfeeding. These correlations were statistically significant and are summarized in Table 4.

Table 4. Pearson correlation between Body Mass Index and other parameters.

Pearson correlation	r	p
BMI-add sug dose	+0.438	0.000**
BMI-TOF 0.9	+0.243	0.021*
BMI-extubation	+0.338	0.001*
BMI-tongue stick	+0.243	0.021*
BMI-breast feeding	+0.614	0.000**

BMI: Body mass index; add sug dose: Additional sugammadex dose; TOF 0.9: Time needed for Train of Four 0.9; Tongue stick: Time needed from application of sugammadex to sticking out the tongue

The postoperative complications were similar between the groups: PORC; none of the patients experienced PORC in group 1 and 2, but 2 patients (6.7%) in group 3 required an oxygen support in PACU (p=0.326). PONV; two patients (6.7%) in group 1, 4 patients (13.3%) in group 3 had PONV, but none of the patients in group 2 had PONV (p=0.159). Bronchospasm: One patient (3.3%) in group 2 and 4 patients (13.3%) in group 3 had bronchospasm. No patients experienced bonchospasm in group 1 (p=0.122).

5. Discussion

In the current study, we investigated the effectiveness of a standard sugammadex dose administered according to IBW in patients with different BMIs after cesarean section (CS). We found that Class III obese patients required significantly more additional sugammadex doses compared to normal BMI, pre-obese, Class I, and Class II obese patients. Additionally, the extubation time, motor response time, and time to first breastfeeding after sugammadex administration were significantly longer in severely obese patients than in the other groups. Although the time needed to reach a TOF value over 0.9 tended to be longer in severely obese patients, the differences between the groups were not statistically significant.

In pregnancy, the insidence of obesity increases over time and has become the most frequently observed morbidity in obstetric practice [5]. Maternal obesity plays a significant role in the occurrence of chronic hypertension, preeclampsia, and pregestational and gestational diabetes. Previous studies have reported that the rate of CS increases by 30% in obese women [4,5]. Unfortunatelly, the risk of postoperative respiratory complications is known to be higher in obese patients [16]; even when the TOF value reaches 0.9, obese patients remain at a higher risk of developing repiratory disfunctions such as partial airway obstruction [17]. In a multi-center observational study [18], the incidence of postoperative residual curarization (PORC) was found to be as high as 63.5%, even in the general population in Canada, and PORC has been shown to lead to respiratory insufficiency and hypoxia [19]. Given these risks, applying the most appropriate sugammadex dose based on BMI in obese patients is crucial. However, calculating the optimal dose is challenging in obese patients, as obesity reduces total body fluids and muscle mass, which affects the pharmacokinetics of drugs [20]. It is well established that administering the recommended dose of sugammadex can be insufficient for reversing neuromuscular blockade in Class III obese patients who received rocuronium bromide based on their actual body weight [21,22]. However, even when these drugs are administered according to IBW, their duration of action can be prolonged in Class III obese patients [6]. Specifically in Class III obesity, changes in the pharmacokinetic properties of drugs like sugammadex may necessitate the use of different dosing regimens [23]. Our findings align with this literature: the mean sugammadex dose administered per patient was 2.53 mg/kg, which is approximately 125% of the induction dose in the Class III obese group.

In the current literature, there are many strudies investigating the ideal sugammadex dose for class III obese patients. In a meta-analysis by Liao et al [24], administering sugammadex based on IBW was found to cause a delay in the reversal of neuromuscular blockade induced by rocuronium/vecuronium bromide. Similarly, Horrow et al. [25] conducted a multicenter study to compare the effects of sugammadex doses based on actual body weight (ABW) versus IBW in Class III obese patients and reported that doses based on ABW provided faster recovery. On the other hand, Li et al. [26] ompared sugammadex doses calculated using IBW versus corrected body weight (CBW) and found that dosing based on CBW was effective for the reversal of deep neuromuscular blockade (NMB) after continuous infusion of rocuronium in Class III obese patients. Although several studies have evaluated different sugammadex dosing strategies in Class III obese patients, and the results have been conflicting, there is limited data evaluating the efficacy of sugammadex specifically in Class I and II obese patients with a BMI between 30 and 40 kg/m^2. Therefore, we aimed to assess the realiablity and efficiency of a 2 mg/kg sugammadex dose calculated using IBW in normal-weight, pre-obese, Class I & II obese, and Class III obese patients. We found the mean extubation times to be 76.2 seconds, 72.7 seconds, and 107.1 seconds, respectively. Additionally, 8 patients in the Class III obese group required additional sugammadex doses, resulting in a final dose that was 25% higher than the initial dose in this group. These findings are consistent with previous studies in the literature. Van Lancker et al. [12] evaluated the effects of different suggammadex doses in obese patients undergoing laparoscopic bariatric surgery. They administered sugammadex 2 mg/kg based on IBW in Group 1, IBW+20% in group 2 and IBW+40% in Group 3, and based on ABW in group 4. They reported that none of the patients experienced PORC; however, the time to extubation significantly decresaed as sugammadex doses increased.

In the present study, it was observed that the duration from the administration of sugammadex to the onset of motor response was significantly prolonged in the Class III obese group when compared to patients with normal BMI, as well as those classified as Class I and II obese. This prolonged interval is likely attributed to the extended time required for these patients to achieve a Train of Four (TOF) value of 0.9, which in turn results in a delay in the extubation process for individuals with severe obesity.

Furthermore, it is important to consider the implications of anesthesia maintenance on recovery times. The use of sevoflurane, a commonly administered anesthetic agent, may have contributed to a more extended recovery period, hindering the ability of severely obese patients to execute voluntary movements postoperatively. This assertion is supported by findings from Zeidan et al., who reported that the end-tidal concentration of sevoflurane necessary to attain a Bispectral Index (BIS) score below 50 (the effective dose for 95% of the population, ED95) was 1.8% in severely obese patients after receiving propofol induction. In contrast, the average concentration required in the normal population was found to be 1.6% [27].

These findings suggest that Class III obese patients may have been subjected to higher doses of sevoflurane during their anesthetic management. Consequently, this increased exposure could have played a significant role in prolonging their recovery times, ultimately affecting their ability to regain normal function and responsiveness following surgery. Therefore, understanding the specific anesthetic requirements and recovery challenges faced by severely obese patients is crucial for optimizing their perioperative care and improving outcomes.In our investigation, we observed that the time to the first breastfeeding was significantly prolonged in Group 3. This finding aligns with existing literature. Prior studies [28,29] have reported that obese patients experienced delays in initiating breastfeeding and exhibited poorer lactation performance. Furthermore, Buonfiglio et al. [30] noted in their experimental research that obese rats displayed elevated leptin levels, which may contribute to both peripheral and central prolactin resistance. Supporting the literature, our analysis revealed a positive correlation between the time to first breastfeeding and increased BMI, as confirmed by Pearson correlation analysis.

Our study has some limitations. First, we combined patients with normal body weight (BMI between 18.5 and 24.9 kg/m^2) and pre-obese patients (BMI between 24.9 and 29.9 kg/m^2) patients in the same group (Group 1). Similarly, we grouped patients with Class I and Class II obesity together (Group 2). Although we could have divided the patients into five distinct groups, we believed this approach would not have been efficient. Secondly, after the initial dose of 2 mg/kg sugammadex, if the TOF value remained below 90% (T4/T1) at the end of the 2-minute interval, we administered an additional dose of 2 mg/kg sugammadex. We could have used a smaller dose (such as 0.5 or 1 mg/kg) to detect a more significant difference, but we chose to apply the standard dose recommended by the manufacturer.

6. Conclusions

In conclusion, we found that IV sugammadex 2 mg/kg, administered according to the IBW of patients, was effective for reversing moderate muscle blockade in normal body weight, pre-obese, and Class I, II, and III obese patients. However, applying a sugammadex dose of IBW+25% appears to provide a safer reversal in Class III obese patients based on the results of our study.

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Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

Author Contributions

All of the authors made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; were involved in drafting the manuscript or revising it critically for important intellectual content; and gave final approval of the version to be published.

Data Availability

The datasets created and/or analyzed during the current study are not publicly available, but are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee of Muğla Sıtkı Koçman University Clinical Research Ethics Committee (Reference No: LUT–10/60, 06.03.2017). Written informed consent was obtained from the participants. All methods were performed in accordance with relevant guidelines and regulations.

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