# Sugammadex versus neostigmine in reversal of rocuronium-induced neuromuscular block in obese patients

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***Background*** Obese patients are especially susceptible to critical respiratory events in the postoperative period, including airway obstruction, hypoventilation, hypercapnia, hypoxia, and postoperative residual curarization (PORC); hence, rapid and complete reversal of neuromuscular blockade (NMB) is desirable at the end of surgery.

***Objective*** This study aimed to compare between the effect of sugammadex and neostigmine on recovery time, PORC and estimate postoperative complications at the postanaesthetic care unit in obese patients.

***Patients and methods*** Seventy obese patients, BMI greater than 35 kg/m$^2$ American Society of Anaesthesiologist class I–II, scheduled for a surgical procedure under general anesthesia were included in this study. Patients received rocuronium for muscle relaxation, and, at the end of the surgery, patients were divided randomly into two groups: one group received sugammadex 2 mg/kg of ideal body weight (group S) and the other group received neostigmine 0.05 mg/kg plus atropine 0.01 mg/kg of ideal body weight (group N) to reverse the NMB. NMB was monitored using train-of-four (TOF). At reappearance of the second twitch (T2) of TOF, patients received the study drugs, and time to reach (TOF) greater than 0.9, was recorded. All patients were observed at the postanaesthetic care unit for one hour for PORC and haemodynamic value (heart rate, mean arterial pressure, and $SpO_2$) by a blinded investigator.

***Results*** At the end of surgery extubation was done when reached a train-of-four (TOF %) score of 2, patients at this percentage received the study drugs the neuromuscular function was recorded and time to achieve 90% of TOF (safe extubation) was measured. Train-of-four (TOF%) is the ratio of the fourth muscle response to the first one . It meaning median time to recovery of the T4:T1 ratio to 0.9.

***Conclusion*** Administration of sugammadex provides fast recovery of neuromuscular function than neostigmine following NMB by rocuronium and prevents PORC in obese patients.

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## Introduction

Obesity is associated with metabolic, respiratory, and cardiovascular complications [1]. General anesthesia of obese patients puts them at increased risk for postoperative anesthesia-related complications including hypoxemia, hypercarbia, airway obstruction, and respiratory failure [2–3].

In obese patients, pharmacological changes of most anesthetic drugs are observed. Doses of most drugs may be based on ideal body weight (IBW); however, such doses may result in delayed onset and peak of action because of the greater volume of distribution. Muscle relaxants are one of the most commonly used drugs in anesthesia practice. They are used to facilitate endotracheal intubation and decrease muscle tone during surgery, to facilitate controlled ventilation in general anesthesia and, to some extent, in ICUs [4]. The fast and total reversal of neuromuscular blockage (NMB) is necessary in order to avoid residual paralysis and related side effects. Postoperative residual curarization (PORC) is clinically not detected at the moment of extubation but only discovered at the postoperative care unit (PACU) using an objective measurement such as train-of-four (TOF) [5]. Extubating of a patient with PORC can cause acute respiratory failure and also the risk of aspiration of the lungs due to depressed reflexes from the larynx and pharynx, which is increased in these patients. PORC could be avoided if neuromuscular function is measured routinely during anesthesia by TOF [6].

TOF provides a convenient and reliable method of assessing the depth of muscle relaxation. As residual paralysis, with subsequent postoperative pulmonary complications, remains one of the major anesthetic complications (although reversal with cholinesterase inhibitors and routine neuromuscular monitoring diminish its incidence), the development of an alternative drug with excellent safety profile was a must [7].

Sugammadex is a very effective new NMB agent used to reverse NMB produced by the aminosteroid NMB drugs rocuronium, vecuronium and pancuronium and can reverse muscle relaxation in any stage of muscle

relaxation through encapsulation and inactivation of these muscle relaxants [7]. It is a γ-cyclodextrin consisting of oligosaccharides linked around a central cavity. The muscle relaxant becomes entrapped within this cavity in a short time after sugammadex administration, neutralizing the relaxants, decreasing their plasma level and creating a concentration gradient between the neuromuscular end plate and plasma [8]. It forms a complex with rocuronium, removes it from the circulation and terminates NMB [9]. Sugammadex is biologically inactive, does not bind to plasma proteins, and appears to be safe. In addition, it has no effect on acetylcholinesterase or any receptor system in the body [10]. Sugammadex is one of the most expensive drugs in anesthesia practice, which prevents it from being used as a standard neuromuscular reversal drug [11].

Neostigmine is a cholinesterase inhibitor and is a standard for the reversal of the effect of neuromuscular blockers, but side effects, such as bradycardia, increased secretion and bronchospasm, make its use more difficult [12]. These can be avoided by anticholinergic drugs, including atropine and glycopyrrolate, which are used for preventing these side effects but increase the frequency of arrhythmia and cause blurred vision and sedation. Cholinesterase inhibitors have difficulty in reversing deeper muscular paralysis [13].

## Patients and methods

This study was carried out from March 2017 to August 2018 at Al-Zhraa University Hospital. After approval from our hospital ethical committee and after written informed consent was obtained, 70 patients of both sexes, aged between 21 and 60 years, American Society of Anaesthesiologist I–II, with a BMI greater than 35 kg/$m^2$ scheduled for general anesthesia were included in the study. The patients were randomly assigned into two groups, neostigmine group (Neostigmine methylsulphate 0.5 mg/ml, amriva pharm.IND, El-Amriya Pharm Industries, Alexandria, Egypt) and sugammadex group (Bridion 100 mg/ml; MSD, Oss, The Netherlands), by computer-generated random numbers. Exclusion criteria were history of hypersensitivity to study drugs, coexisting muscular diseases, chronic alcoholism or drug abuse, liver or renal dysfunction and pregnancy; lactating patients were excluded and so were patients with obstructive sleep apnea.

In this study, on arrival of the patients to the operating room, an intravenous cannula was inserted, and all patients were monitored by noninvasive blood pressure, ECG and peripheral oxygen saturation (pulse oximetry). Anesthesia was started with fentanyl (1–2 μg/kg) as analgesia, propofol (1–2 mg/kg) before rocuronium administration (Rocuronium Bromide 50 mg/5 ml vial; N.V. Organon, Oss, The Netherlands) and neuromuscular monitoring was carried out by TOF-watch SX (Organon, Dublin, Ireland) through stimulation of the ulnar nerve and activity of the adductor pollicis muscle. Two electrodes were positioned at the opposite side to the infusion line and the blood pressure monitoring device. One electrode was placed about 1 cm proximal to the wrist skin crease. The other electrode was placed 3–4 cm proximally. This causes stimulation of the flexor carpiulnaris muscle and also augments thumb adduction. After calibration and baseline responses were obtained of the TOF-Watch SX, rocuronium (0.6 mg/kg) intravenous bolus was administered in both groups.

When neuromuscular transmission showed 0 score TOF, tracheal intubation was facilitated, and controlled ventilation was started; the ventilation parameters were adjusted to maintain a normocapnia. Maintenance of anesthesia was achieved with a mixture of oxygen, air (1 : 1) and sevoflurane at 1–2% minimum alveolar anesthetic concentration, and rocuronium was administered at 0.1 mg/kg when TOF reached a score of 2. At the end of surgery and reappearance of T2, sevoflurane was switched off, and the study drugs were administered; group S received sugammadex 2 mg/kg (diluted and administered at a slow rate) on the basis of IBW calculated from Broca's formula (Ideal body weight = height -(cm) -100), and the other group received neostigmine 0.05 mg/kg plus atropine 0.01 mg/kg on the basis of IBW (group N). All patients were extubated fully awake in the operating room when a TOF ratio greater than 0.9 was achieved, and patients were awake and orientated, arousable with minimal stimulation. The duration of the operation, the dose of fentanyl and total dose of rocuronium (mg) used were recorded for both groups. Extubation time also was recorded in two groups (time from switch of the vaporizer until the patient fulfilled global and respiratory criteria for safe extubation).

Neuromuscular monitoring was discontinued; thereafter the patients were transferred to the PACU. In the recovery room, vital parameters were recorded every 15 min for 1 h and Aldrete score was also recorded. All patients were treated and if need to reintubation recorded and not excluded from the study. The patients were also observed for presence of PORC in the form of appearance of any sign of reoccurrence of muscle weakness, such as difficulty swallowing, blurred vision,

and respiratory difficulties, and all patients were treated with need to reintubation. Moreover, postoperative adverse events were recorded, as postoperative nausea and vomiting (PONV), shivering and dry mouth. Thereafter, patients were transferred to their regular surgery wards after fulfilling criteria of modified Aldrete's scoring system of discharging from PACU. We used for postoperative analgesia, a nonsteroidal anti-inflammatory drug (Ketorolac 60 mg intramuscularly) and Paracetamol 1000 mg/IV (every 6 h) in both groups.

The primary end point in this study was to evaluate the recovery times to 4/1 of 0.9 after the administration of the sugammadex or neostigmine on the basis of IBW in obese patients and incidence of PORC.

### Statistical analysis

Data were collected, revised, coded, and entered into the statistical package for the social sciences (IBM SPSS) Version 10.1 (SPSS Inc., Chicago, IL, USA). The quantitative data were presented as mean, SD, and ranges when their distribution was found to be parametric. Moreover, qualitative data were presented as number and percentages. The comparison between two independent groups with qualitative data was carried out by using $\chi^2$-test and/or Fisher exact test only when the expected count in any cell was found to be less than 5. The comparison between two independent groups with quantitative data and parametric distribution was performed by using independent *t*-test. The confidence interval was set to 95%, and the margin of error accepted was set to 5%. Thus, the *P* value was considered significant at the level of less than 0.05.

## Result

Seventy patients were enrolled in our study, there were 35 patient participants in the sugammadex group and another 35 patient participants in the neostigmine group. The demographical characteristics (age, height, weight, BMI, American Society of Anaesthesiologist, and surgical duration) were comparable in both groups, and there was no significant difference between two groups in the total dose of rocuronium or fentanyl during surgery (Table 1). Recovery time of the TOF ratio to 0.9 was significantly faster ($P<0.001$) with the sugammadex group compared with the neostigmine group (Table 2, Fig. 1). The incidence of PORC was significantly lower (no patients) in the sugammadex group compared with the neostigmine group (four patients) (Table 3). The mean time to obtain an Aldrete score of 10 was significantly longer ($P=0.014$) in group N (10.50±3.6 min) than in group S (8.45 ±3.25 min) (Table 4, Fig. 2). There were no significant differences between the two groups in $SpO_2$, heart rate, and MAB at PACU for 1 h postoperatively (Figs 3–5). Adverse effects of study drugs were assessed; it was mainly PONV that showed significant elevation in the neostigmine group ($P=0.024$) compared with the sugammadex group. Other complications showed a nonsignificant difference in both groups (Table 5).

**Table 1 Demographic data in both groups (mean±SD)**

| | Group S (*n*=35) [*n* (%)] | Group N (*n*=35) [*n* (%)] | *P* value |
|---|---|---|---|
| Age (years) | | | |
| Mean±SD | 39.1±12.15 | 37.95±9.65 | 0.662 |
| ASA | | | |
| I | 23 (80.0) | 21 (70.0) | 0.620 |
| II | 12 (20.0) | 14 (30.0) | |
| Sex | | | |
| Females | 22 (35.0) | 20 (55.0) | 0.625 |
| Males | 13 (65.0) | 15 (45.0) | |
| Weight (kg) | | | |
| Mean±SD | 103±10.22 | 95±23.21 | 0.066 |
| Height (cm) | | | |
| Mean±SD | 161.10±10.13 | 164±4.72 | 0.129 |
| BMI (kg/m$^2$) | | | |
| Mean±SD | 39.26±3.91 | 40.16±2.84 | 0.274 |
| Surgical duration (min) | | | |
| Mean±SD | 79±37.33 | 65.00±27.63 | 0.079 |
| Total rocuronium (mg) dose | | | |
| Mean±SD | 87.25±18.45 | 86.28±17.90 | 0.824 |
| Total fentanyl (μg) dose | | | |
| Mean±SD | 173±16.5 | 175.75±21.16 | 0.546 |

ASA, American Society of Anesthesiologists; group N, neostigmine group; group S, sugammadex group. $P>0.05$ is considered insignificant.

## Discussion

The results of the current study had shown that sugammadex was superior to neostigmine with atropine for reversal of NMB in obese patients as evidenced by the shorter recovery and extubation times, prevention of PORC, and lower incidence of adverse effects due to its beneficial pharmacological profile.

In this study, the recovery time was statistically shorter in the sugammadex group (2.2±0.746 min) than in the neostigmine group (10.8±5.98 min). This in agreement with Alsaeed *et al.* [14] who compared sugammadex versus two doses of neostigmine for reversal of rocuronium in gastric sleeve surgery. At the end of surgery, (group A) Sugammadex 2 mg/kg of calculated body weight (CBW), neostigmine 2.5 mg (group B), and neostigmine 5 mg (group C) were administered. They found that the time in seconds for the three groups to reach TOF 90% was significantly shorter with group A versus groups B and C ($P<0.05$) and was 210, 610, and 654 s, respectively.

**Table 2 Recovery time of train-of-four to 0.9 in min (mean ±SD)**

| | Recovery time of TOF to 0.9 in min | | *P* value |
|---|---|---|---|
| | Group S (*n*=35) | Group N (*n*=35) | |
| Mean±SD | 2.2±0.746 | 10.8±5.98 | <0.001 |

Group N, neostigmine group; group S, sugammadex group; TOF, train-of-four. $P<0.001$ is considered highly significant.

Similar to our findings, Hristovska *et al.* [15] compared sugammadex 2 mg/kg and neostigmine 0.05 mg/kg for reversal of rocuronium-induced moderate NMB and found that sugammadex 2 mg/kg was 10.22 min (6.6 times) faster than neostigmine 0.05 mg/kg (1.96 vs. 12.87 min) in reversing moderate NMB but Sugammadex 4 mg/kg was 45.78 min (16.8 times) faster than neostigmine 0.07 mg/kg (2.9 vs. 48.8 min) in reversing deep induced paralysis.

In the study by Güleç *et al.* [16], patients having lower abdominal and urological surgery under general

**Table 3 Postoperative residual curarization**

| | Group S (*n*=35) [*n* (%)] | Group N (*n*=35) [*n* (%)] | *P* value |
|---|---|---|---|
| PORC | 0 (0.0) | 4 (11.4) | 0.039 |

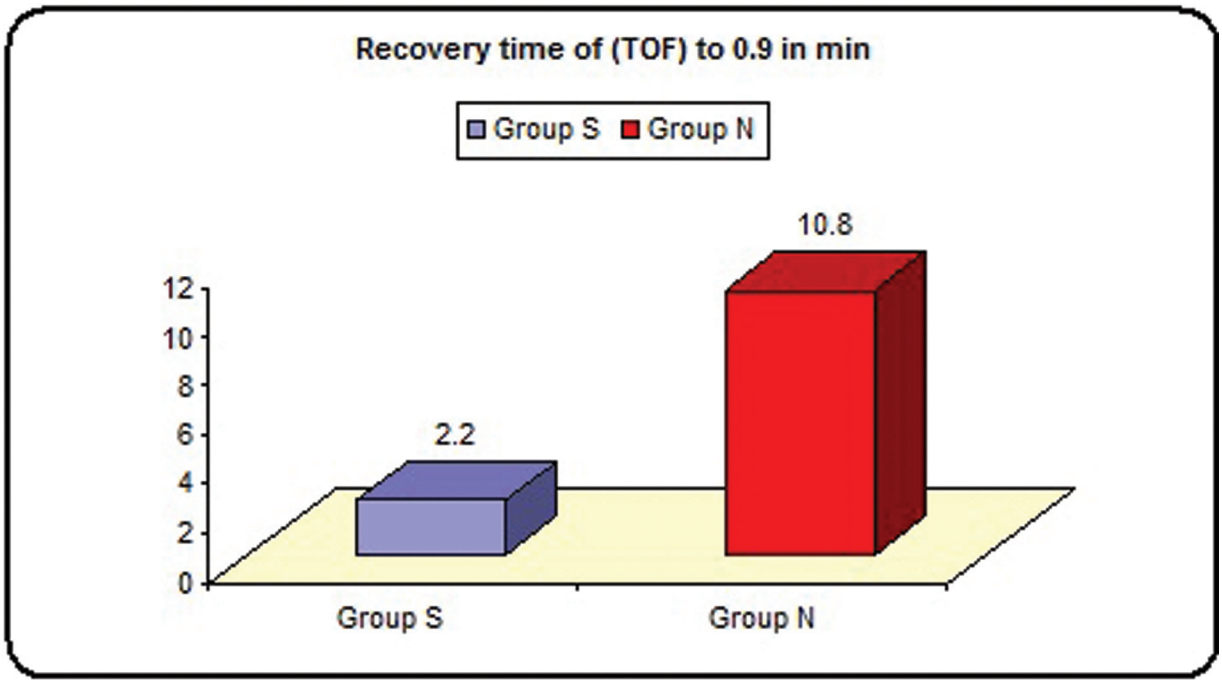
Group N, neostigmine group; group S, sugammadex group; PORC, postoperative residual curarization. $P<0.05$ is considered significant.

**Table 4 Mean time to obtain an Aldrete score of 10 min (mean ±SD)**

| | Mean time to obtain an aldrete score of 10 in min | | *P* value |
|---|---|---|---|
| Mean±SD | Group S (*n*=35) | Group N (*n*=35) | |
| | 8.45±3.25 | 10.50±3.6 | 0.014 |

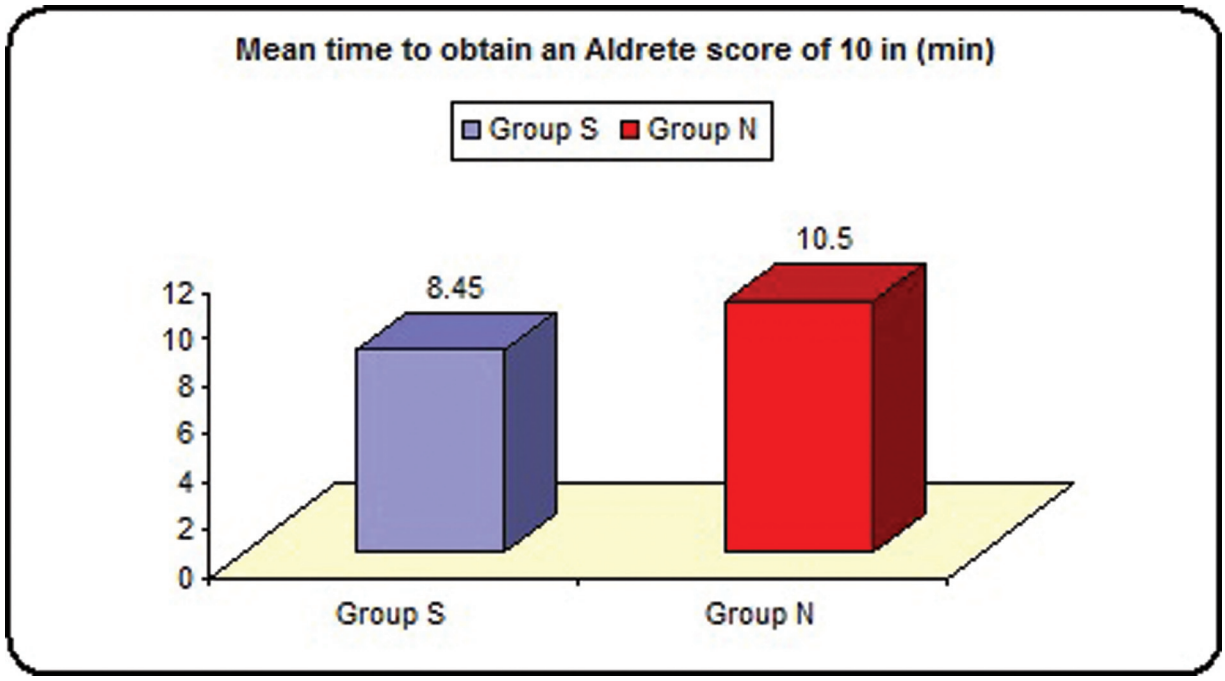
Group N, neostigmine group; group S, sugammadex group. $P<0.05$ is considered significant. $P<0.001$ is considered highly significant.

**Figure 1**



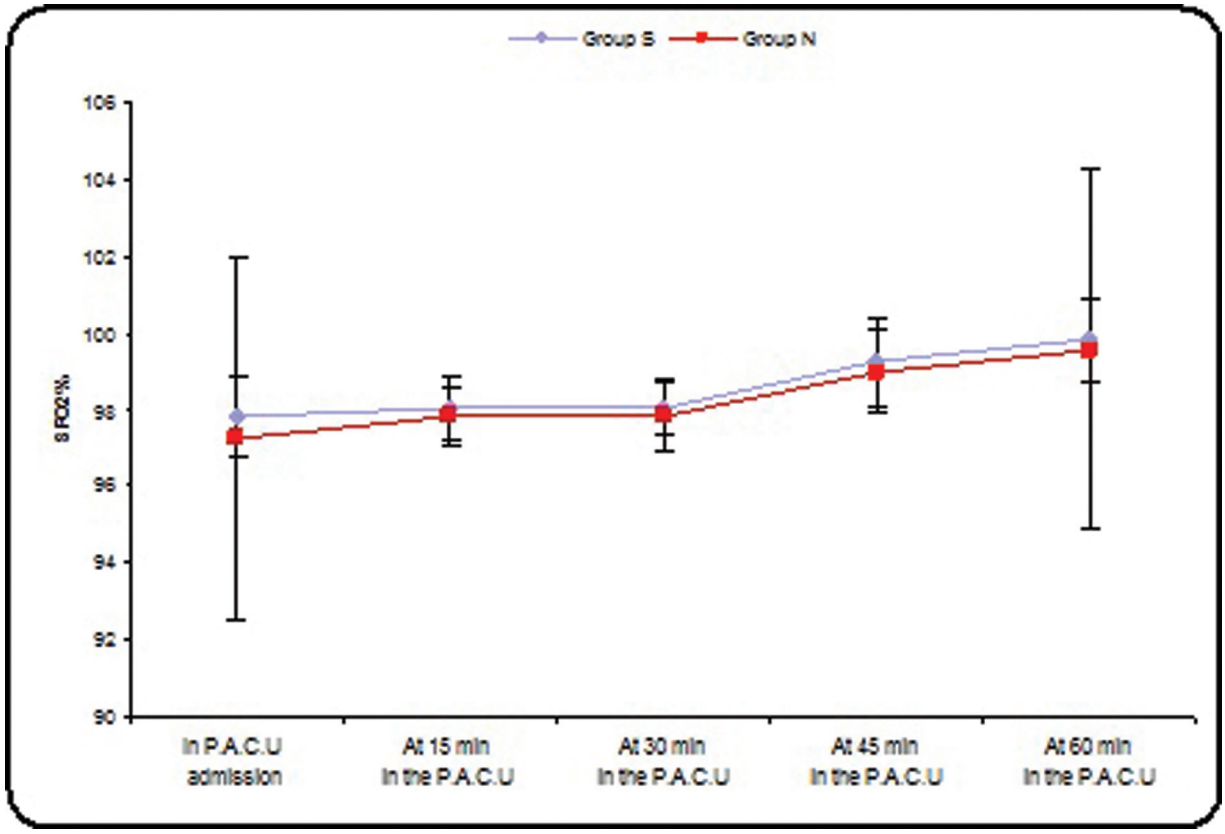

Recovery time of train-of-four to 0.9 in min.

**Figure 2**




Mean time to obtain an aldrete score of 10 min.

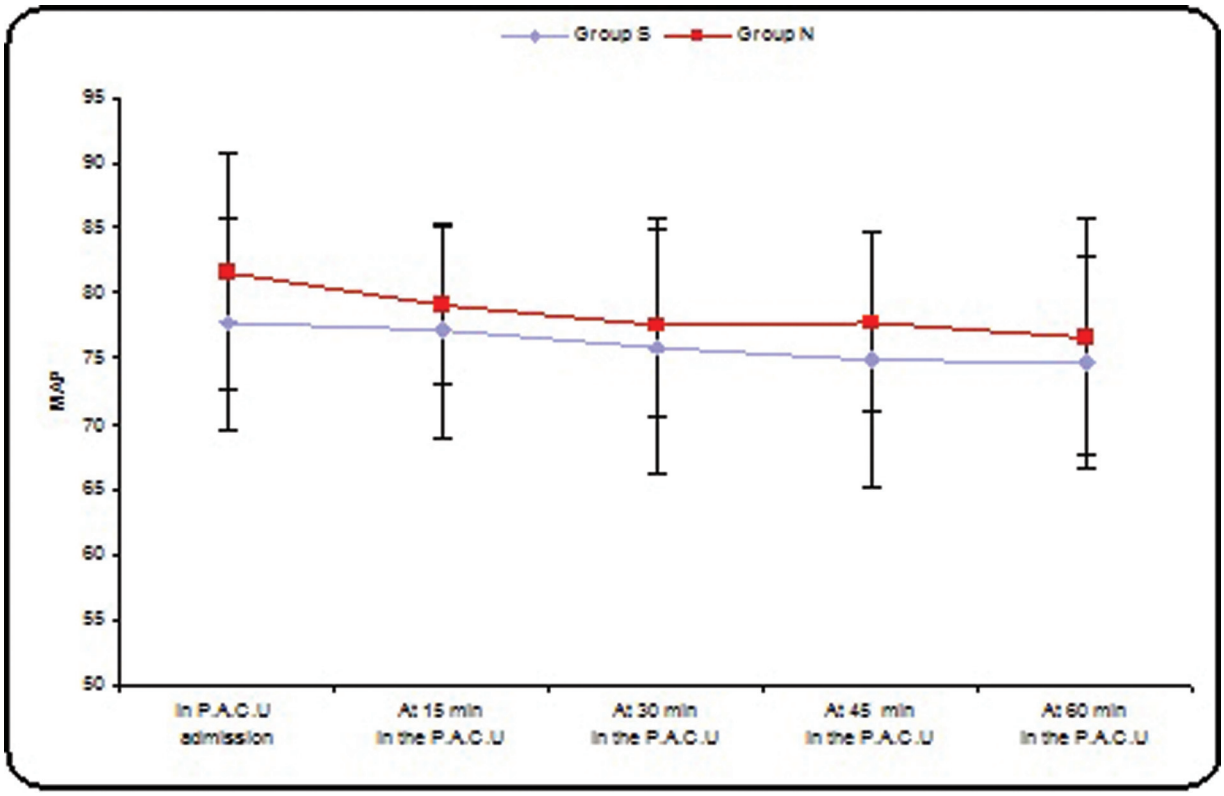
**Figure 3**




Comparison between the two groups with regard to $SpO_2$%. $SpO_2$% at each time interval is presented as mean±SD.

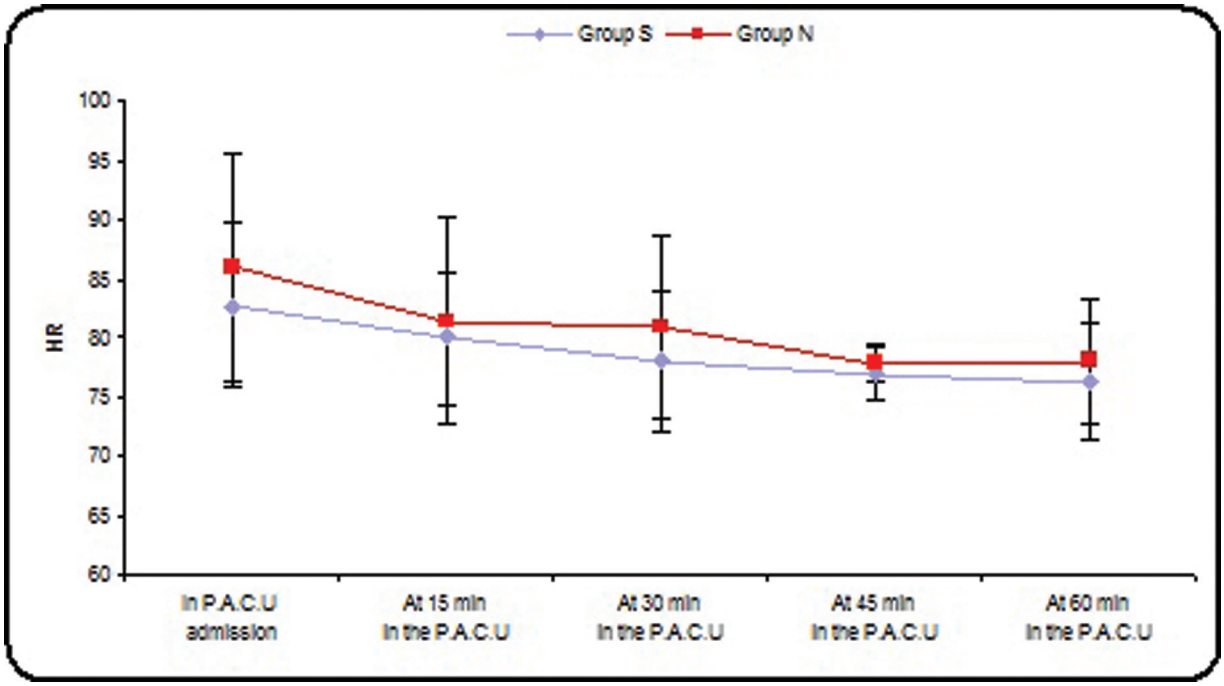
anesthesia were included. Extubation time was recorded in seconds and took 130.37±167.29 s after 2 mg/kg sugammadex administration. However, following 0.03 mg/kg neostigmine and atropine 0.01 mg/kg, extubation took a significantly longer time, 269.1±135.21 s.

**Figure 4**




Comparison between the two groups with regard to mean arterial pressure. Mean arterial pressure at each time interval is presented as mean ±SD.

**Figure 5**




Comparison between the two groups with regard to heart rate. Heart rates at each time interval are presented as mean±SD.

Moreover, extubation time in the neostigmine group was statistically higher than that in the sugammadex group in the study carried out by Fathi and Ezz [17] in morbidly obese patients during ophthalmic surgery under general anesthesia.

**Table 5 Postoperative adverse effects of both studied drugs**

| | Group S ($n$=35) [$n$ (%)] | Group N ($n$=35) [$n$ (%)] | $P$ value |
|---|---|---|---|
| PONV | 1 (2.9) | 7 (20.0) | 0.024 |
| Shivering | 4 (11.4) | 2 (5.7) | 0.393 |
| Dry mouth | 1 (2.9) | 3 (8.6) | 0.302 |

Group N, neostigmine group; group S, sugammadex group; PONV, postoperative nausea and vomiting. $P<0.05$ is considered significant.

This study was close to that of Gaszynski *et al.* [18] who reported that, in morbidly obese patients, at the end of surgery, sugammadex 2 mg/kg CBW or neostigmine 0.05 mg/kg CBW with atropine 0.02 mg/kg CBW was administered randomly. The time to achieve 90% of TOF was 3.5 times shorter in the SUG group ($P<0.05$). The study by Carron *et al.* [19] agrees with our study result, although they used sugammadex 4 mg/kg total body weight (deep NMB) and neostigmine (70 μg/kg lean body weight) plus atropine, and they found time to recovery of the TOF ratio of 0.9 after sugammadex administration compared with neostigmine administration was significantly shorter ($P<0.001$).

In agreement with the current study, Flockton *et al.* [20] who found time from the start of administration of reversal agent to recovery of the TOF ratio to 0.9 was 4.7 times faster with sugammadex than with neostigmine with a $P$ value of less than 0.0001, which was a significant difference. In addition, Jones *et al.* [21] reported that sugammadex was 17 times shorter in recovery time than neostigmine in routine reversal of deep NMB.

In this study, use of sugammadex reduced the risk of PORC. The number of patients with PORC was four in the neostigmine group and they were treated with another dose of neostigmine with mask oxygen, but no patient developed PORC in the sugammadex group.

These results were in agreement with Abd El Aziz and El Metainy [22], who used TOF % ratio at 15 min at PACU and found that, in group S, As regard incidence of postoperative residual curarisation (PORC) AT (PACU) no patients (0.0%) developed recurrence in group S, while in group N there were 4 patients (25.0%) developed residual curarisation and treated with oxygen face mask and another dose of neostigmine. Assessment of any signs of muscle weakness and respiratory depression or ventilator failure was carried out by spirometry lung function tests; forced expiratory volume in 1 s and forced vital capacity and were registered and compared with other tests carried out after one day after bronchoscopy surgery. Signs of respiratory distress or impending ventilator failure were significantly higher in the group N, but no patients needed reintubation.

In consistence with our result, Gaszynski *et al.* [18] examined the patients directly after arrival to PACU by a blinded investigator for the presence of PORC using TOF stimulation in PACU and found that, in most patients, administration of sugammadex prevented PORC in morbidly obese patients. Similar to the present study, Wu *et al.* [23] obtained considerable data in a multicentre study performed on 230 Chinese participants and demonstrated that residual NMB was significantly higher in neostigmine group. Furthermore, Carron *et al.* [24] have shown that sugammadex decreases PORC in the morbidly obese.

In contrast, the study of Bellod *et al.* [25] reported a case of delayed recurarisation after sugammadex reversal. The authors explained that event through either capturing or displacement reaction. In contrast, Le Corre *et al.* [26] reported a case of PORC in the sugammadex group shortly after extubation; the patient developed respiratory failure, requiring reintubation and an additional dose of sugammadex.

In this study, with regard to the mean time to obtain an alderet score of 10 (in min), the time was significantly prolonged in the neostigmine group than in the sugammadex group. This is in agreement with De Robertis *et al.* [27] who found the mean time to obtain an Aldrete score of 10 (indicating that these patients were ready to be discharged from PACU) was 16 min in group S and 21.8 min in group N ($P<0.05$).

In disagreement with this study, Ammar *et al.* [28] compared the effect of sugammadex and neostigmine in pediatric patients scheduled for lower abdominal surgeries; PACU discharge time showed no significant difference between both groups using the modified Aldrete scale; it was 42.0±11.8 min in group S and 46.6±14.1 min in group N. This study differs from our study, as it was carried out on pediatric patients who need a dose of neuromuscular blockers that is larger than that in adults, as children have a larger extracellular space volume with consequent lower plasma levels of neuromuscular blocker.

In the study by Hakimoglu *et al.* [29] who compared the effect of sugammadex and neostigmine-atropine on intraocular pressure and postoperative effects, it was found that the time to reach modified Aldrete recovery score was greater than 8, which was shorter in the sugammadex group, but the difference was not statistically significant.

In this study, postoperative $SpO_2$%, heart rate, and mean arterial pressure at PACU were higher at all times in patients given neostigmine with no statistically significant difference compared with group S. Most paper records haemodynamic immediately after given the study drug in surgical room but in our study we started recording haemodynamic in PACU for detection of late changes. We only study assessed this time but many studies assessed hemodynamics after tracheal extubation up to 30 min in operative room like study of Isik *et al.* [30] who compared the effect of sugammadex and neostigmine on renal biomarkers, and Kizilay *et al.* [31] who examined the effect of neostigmine and sugammadex for haemodynamic parameters in cardiac patients undergoing non cardiac surgery. However, our study finding was close to de Robertis *et al.* [27] who found no significant differences in $SpO_2$ at PACU admissions or discharge. In agreement with Ezri *et al.* [32], they did not find a statistically significant difference in $SpO_2$ at PACU. Moreover, in the study by Carron *et al.* [19], they reported that there was a significant decrease in $SpO_2$% in the neostigmine group at PACU admission.

In the present study, the incidence of drug-related adverse events was generally low in the sugammadex compared with the neostigmine group. The incidence of PONV was significantly higher in the neostigmine group compared with the sugammadex group; moreover, the incidence of dry mouth was slightly higher in the neostigmine group but with no statistical difference. Postoperative shivering was more in the sugammadex group than in the neostigmine group, with no statistical difference.

These findings are in consistence with the study by Yagana *et al.* [33] They compared the effects of 50 mg/kg neostigmine plus 0.2 mg/kg atropine and 2 mg/kg sugammadex on PONV. Furthermore, the results of our study are similar to the study by Ammar *et al.* [28] who found that the incidence of PONV and dry mouth was significantly lower in the sugammadex group, but postoperative shivering was comparable in both groups; the study was carried out on pediatric patients.The current study matched the study by Woo *et al.* [34] who compared Sugammadex versus neostigmine for reversal of moderate rocuronium-induced NMB in 128 Korean patients; they found that PONV was reported in three patients in the sugammadex group and six patients in the neostigmine group. It was also in agreement with the study by Koyuncu *et al.* [35] who found that nausea and vomiting scores were lower in the sugammadex-administered patients upon arrival in the PACU than in the neostigmine-administered patients. However, there were subsequently no significant differences during the remaining initial 24 postoperative hours.

In contrast to our study, Paech *et al.* [36] who compared the recovery characteristics of 304 patients receiving either sugammadex or neostigmine plus glycopyrrolate for reversal of neuromuscular found that the incidence of PONV, until 6 h after surgery, did not significantly differ between groups. This may be due to uses of dexamethasone 4 mg for antiemesis in all patients and may be because they observed the incidence of PONV for 6 h after surgery and we observed it in the PACU only. Moreover, Khuenl-Brady *et al.* [37] reported that the incidence of drug-related adverse events was slightly higher in the neostigmine group compared with the sugammadex group (22.2 vs. 14.6% of patients), with a higher incidence of dry mouth in the neostigmine group, but the incidence of vomiting was higher in the sugammadex group.

### Limitations

The limitation of the present study was that it did not record TOF ratio at PACU, but we considered the Aldrete score as a clinical index of full recovery from NMB. Furthermore, the number of clinical trials of sugammadex were not sufficiently powered to estimate the rates of significant adverse events due to cost value.

## Conclusion

Sugammadex provided more rapid reversal of neuromuscular functions, reduced PORC in obese patients and lowered the incidence of PONV when compared with the traditional reversal of neostigmine plus atropine.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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