

# Effects of tracheal intubation without muscle relaxants on postoperative recovery conditions in patients with obstructive sleep apnea: A double-blind randomized controlled study

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## Abstract

**Aim:** We aimed to compare intubation with and without neuromuscular blocking agents with regard to intubation success, hemodynamic parameters, and postoperative recovery in Obstructive sleep apnea patients.

**Materials and Methods:** The study included 60 patients with a STOP-Bang (Snoring, Tiredness during daytime, Observed apnea, high blood Pressure, Body mass index, Age, Neck circumference, Gender) score of  $\geq 3$ . The patients were randomly divided into two groups: (I) rocuronium group (Group E) and (II) remifentanyl group (Group R). Group R received 4 mcg/kg remifentanyl and Group E received 0.6 mg/kg rocuronium and then the patients' intubation difficulty scale scores and their responses to train-of-four (TOF) nerve stimulation, and postoperative recovery were evaluated in both groups.

**Results:** The median time to recovery of the TOF ratio to 0 following anesthetic induction was significantly higher in Group R compared to Group E ( $p < 0.001$ ). The overall incidences of postoperative sore throat and hoarseness were remarkably high ( $p < 0.002$  and  $p < 0.001$ , respectively). The numbers of patients with relaxed vocal cords and complete jaw relaxation were significantly higher in Group E compared to Group R ( $p < 0.001$ ).

**Conclusion:** The results indicated that rocuronium provides better intubation conditions and leads to less peri- and post-operative complications compared to remifentanyl.

**Keywords:** Obstructive sleep apnea syndrome; intubation without muscle relaxants; postoperative recovery; stop bang tracheal intubation.

## INTRODUCTION

Obstructive sleep apnea (OSA) is a clinical condition characterized by multiple pauses in breathing, intermittent awakenings and snoring during sleep and continual sleepiness during the day, caused by upper airway narrowing or collapse (1,2). Patients with OSA undergoing surgical procedures have an increased risk for perioperative complications including arrhythmia, hypoxemia, hypercapnia, and delirium. Moreover, difficult intubation may be experienced in 22-45% of these patients due to upper airway collapse. Additionally, the analgesic and sedative-hypnotic agents administered for the induction of general anesthesia result in increased collapsibility of the upper airway in OSA patients compared to non-OSA individuals, and OSA patients have an increased risk for postoperative cardiovascular and

respiratory complications (3).

Polysomnography (PSG) is the golden-standard method for the diagnosis of OSA. However, PSG is difficult to implement due to a number of factors including its prolongation of the process of surgery, high cost of implementation, requirement of a specialist for implementation, and its non-availability in all centers (4). For these reasons, the diagnosis and anesthetic management of patients at high risk of OSA prior to surgery can be highly difficult. Nevertheless, a recently invented screening modality known as STOP-Bang (Snoring, Tiredness during daytime, Observed apnea, high blood Pressure, Body mass index, Age, Neck circumference, Gender) questionnaire has been used for the diagnosis of such patients, which is a concise, self-administered, and easy-to-use questionnaire consisting of 8 yes/no

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questions (2). Patients are considered to be at high risk of OSA if they answer yes to  $\geq 3$  items. In more than 90% of patients with OSA, OSA level is moderate and severe. (5).

Neuromuscular blockers (NMB) are commonly used to facilitate tracheal intubation, to provide a convenient setting for surgery, and to improve mechanical ventilation in patients with reduced lung capacity. However, NMB have been shown to have several side effects such as causing various respiratory symptoms including dysphagia, aspiration, and decreased inspiratory airflow and vital capacity by affecting upper airway muscles. Moreover, NMB have also been shown to cause increased collapsibility of the upper airway by inducing an impaired dilatation reflex, thereby leading to OSA (6). In addition to their respiratory side effects, NMB are also associated with postoperative residual curarization (PORC), which is a serious condition leading to neuromuscular insufficiency and increased morbidity and mortality (7). PORC has also been shown to contribute to upper airway dilator muscle dysfunction, to increase upper airway obstruction, and to cause serious postoperative respiratory problems in OSA patients compared to non-OSA individuals (8, 9).

On the other hand, due to the side effects of NMB mentioned above, rapid-acting opioids such as remifentanyl have recently emerged as popular agents for facilitating intubation in anesthetic practice. Remifentanyl, particularly when used in combination with propofol, has been shown to provide adequate relaxation in laryngeal muscles during intubation without using NMB. Additionally, remifentanyl also has significant advantages for anesthetic induction as it has no effect on hemodynamic parameters, allows early postoperative recovery of neurologic and cognitive functions, and leads to less postoperative complications compared to NMB (10).

In the present study, we aimed to compare intubation with and without neuromuscular blocking agents with regard to intubation success, hemodynamic parameters, and postoperative recovery in OSA patients.

## MATERIAL and METHODS

### Patients

After obtaining an approval from the local ethics committee (Approval date: December 19, 2018; No: 11), the study was registered in a public trial registry (ClinicalTrials.gov) (NTC 03824470). Preoperative anesthetic evaluation was performed in patients at high risk for OSA using the STOP-Bang questionnaire. Patients with a score of  $\geq 3$  were informed about the study protocol. A total of 68 patients aged 18-65 years with an ASA score of I-II and a Mallampati score of I-II were included in the study after obtaining a written and verbal consent from each of them. Of these, 8 patients that did not meet the inclusion criteria or declined to participate were excluded from the study and thus the remaining 60 patients were included in the study (Figure 1).

Patients that were postoperatively transferred to the intensive care unit (ICU) intubated, patients that were using

a Continuous Positive Airway Pressure (CPAP) device or receiving OSA therapy at home, patients with a history of head and neck surgery or who were planned for head and neck surgery, patients with central nervous system (CNS) injury, active smokers, patients with cardiovascular or pulmonary instability and neuromuscular comorbidities, patients who were allergic to anesthetic agents, patients that failed to provide a written and verbal consent, pregnant patients, and patients with ASA III and IV scores were excluded from the study.

### Study Protocol

The 60 patients included in the study were randomly divided into two groups using the sealed envelope method: (I) rocuronium group (Group E) and (II) remifentanyl group (Group R). The rocuronium and remifentanyl used in the study were purchased from Esmeron®, Abdi İbrahim, Istanbul, Turkey and Ultiva®, GlaxoSmithKline, Belgium, respectively. Demographic characteristics, physical examination findings and hematological parameters were recorded for each patient. Prior to surgery, the patient was transferred to the operating room and noninvasive monitoring including heart rate, mean arterial pressure, and oxygen saturation (SpO<sub>2</sub>) was performed in each patient by an anesthesiologist blinded to the study protocol. These measurements were accepted as baseline hemodynamic measurements. After inducing sedation with i.v. 2 mg/kg midazolam (Demizolam®, Dem, Turkey), the response of the patient to train-of-four (TOF) nerve stimulation was recorded. Anesthetic induction was achieved with i.v. 1 mg/kg lidocaine, 4 mcg/kg remifentanyl, and 2 mg/kg propofol (1% Propofol® Fresenius Kabi, Turkey) in Group R and with i.v. 1 mg/kg lidocaine, 2 mg/kg propofol, 1 mcg/kg remifentanyl, and 0.6 mg/kg rocuronium in Group E. In both groups, the patient was intubated and general anesthesia was induced when the recovery of TOF ratio to 0 was achieved. Difficulty of intubation was assessed using the intubation difficulty scale (IDS). Anesthetic induction was achieved with 8% desflurane in an air/O<sub>2</sub> mixture (60%/40%) and remifentanyl infused at 0.025 mcg/kg/min in both groups. Throughout the surgical procedure, hemodynamic parameters were recorded every 5 min within the first 20 min and every 10 min after the first 20 min. Immediately after the completion of the surgical procedure, intravenous infusions were stopped and the time from the onset of neuromuscular blockade to attaining a TOF ratio of 70% (TOFR70) or higher was recorded. When the TOF ratio reached 70%, i.v. 10 cc normal saline was administered in Group R, whereas 2/mg/kg sugammadex diluted in 10 cc saline was administered in Group E to reverse the effects of muscle relaxants. In both groups, the patient was extubated when the TOF ratio reached 90% (TOFR90). Time from TOFR70 to TOFR90, time for spontaneous eye opening, time to extubating, time to follow verbal commands, time to attain a modified Aldrete score of 10, the level of surgeon satisfaction (good, moderate, poor), and duration of surgery were recorded for each patient. Incidences of postoperative sore throat, laryngospasm, hoarseness, and desaturation and the

requirement of bag-valve-mask (BVM) ventilation were recorded for each patient.

### Statistical analysis

Data were analyzed using SPSS 25.0 (IBM Corporation, Armonk, New York, USA) and Paleontological Statistics Software Package (PAST) 3.12 (Hammer, Ø. Harper, D.A.T., Ryan, P.D. 2001. Paleontological statistics). Normal distribution of univariate data was assessed using Shapiro-Wilk test and the homogeneity of variance was assessed using Levene's test. Normal distribution of multivariate data was assessed using Mardia's Multivariate Normality Test and Doornik and Hansen's omnibus test and the homogeneity of variance was assessed using Box's M test. The means of two independent groups were compared using Independent-samples t-test with bootstrapping and by using Mann-Whitney U test with Monte Carlo simulation. Dependent quantitative variables and repeated measurements were compared with each other using Wilcoxon Signed-Rank Test with Monte Carlo simulation. Categorical variables were compared using Pearson's Chi-Square and Fisher's Exact Test with the Fisher-Freeman-Halton extension and Monte Carlo simulation and were expressed with a Benjamini-Hochberg adjusted p value after the comparison of column

proportions. The odds ratio was used for weighing the risk posed by each categorized variable, with a confidence interval (CI) of 95%. Quantitative variables were expressed as mean±standard deviation (SD) and median (minimum-maximum) and categorical variables were expressed as frequencies and percentages. A p value of <0.05 was considered significant.

### RESULTS

Demographic characteristics and the STOP-Bang scores of the two groups were similar (Table 1). The median time to recovery of the TOF ratio to 0 following anesthetic induction was significantly higher in Group R compared to Group E ( $p<0.001$ ). The median time from TOFR70 to TOFR90 after anesthetic induction was significantly higher in Group E compared to Group R ( $p<0.001$ ). The median time from TOFR70 to TOFR90 and the median time to attain a modified Aldrete score of 10 following the reversal of neuromuscular blockade were significantly higher in Group E compared to Group R ( $p<0.05$ ). However, no significant difference was found between the groups with regard to the time for spontaneous eye opening, time for extubating, and the time to follow verbal commands ( $p>0.05$ ) (Table 2).

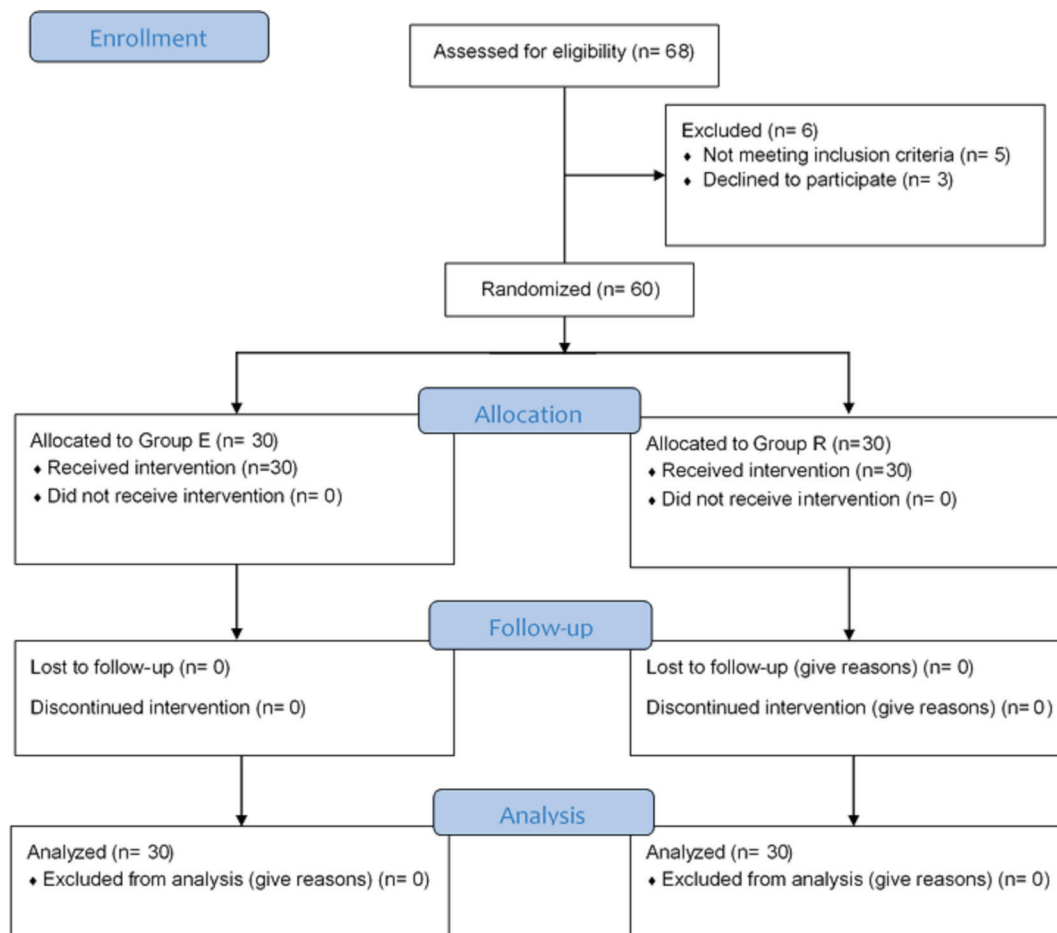


Figure 1. Flowchart of the study patients

The incidences of postoperative sore throat and hoarseness were higher in Group R compared to Group E ( $p < 0.002$  and  $p < 0.001$ , respectively). However, no significant difference was found between the groups with regard to the incidences of postoperative laryngospasm and desaturation and the requirement of BVM ventilation (Table 3).

The numbers of patients with relaxed vocal cords and complete jaw relaxation were significantly higher in Group E compared to Group R ( $p < 0.001$ ). The number of patients that did not experience cough during intubation

was significantly higher in Group E compared to Group R ( $p < 0.05$ ). Nevertheless, no significant difference was found between the groups with regard to laryngoscopy difficulty ( $p > 0.05$ ) (Table 4).

Similarly, no significant difference was found between the two groups with regard to median heart rate, median baseline SpO<sub>2</sub>, median SpO<sub>2</sub> between 5-30 min, and the median change in SpO<sub>2</sub> between 5-30 min ( $p > 0.05$ ). However, the median change in blood pressure (BP) was significantly higher in Group E compared to Group R ( $p < 0.05$ ).

**Table 1. Demographic and surgical characteristics**

	Total (n=60)	Rocuronium (n=30)	Remifentanyl (n=30)	P
Age	42.55±13.08 (18-65) n (%)	41.10±13.06 (18-64) n (%)	44.00±13.16 (19-65) n (%)	0.417 1
Gender				
Female	37 (61.7)	21 (70.0)	16 (63.3)	0.288 2
Male	23 (38.3)	9 (30.0)	14 (46.7)	
ASA				
I	15 (25.0)	7 (23.3)	8 (26.7)	0.999 2
II	45 (75.0)	23 (76.7)	22 (73.3)	
	Median (min-max)	Median (min-max)	Median (min-max)	
Height (cm)	161 (150-190)	160 (155-190)	163.5 (150-190)	0.784 3
Weight (kg)	78 (60-110)	78 (60-110)	76.5 (60-110)	0.825 3
BMI	28.04 (19.59-39.06)	27.69 (23.15-39.06)	28.04 (19.59-36.79)	0.796 3
STOP-Bang score	3 (3-6)	3 (3-5)	3 (3-6)	0.870 3
Duration of surgery (min)	60 (30-120)	60 (30-120)	60 (30-100)	0.196 3

1 Independent-Samples t-test (Bootstrap), 2 Pearson's Chi-Square Test (Exact), 3 Mann-Whitney U Test (Monte Carlo), SD: Standard deviation, Min: Minimum, Max: Maximum, BMI: Body mass index

**Table 2. TOF changes and postoperative recovery**

	Total (n=60) Median (min-max)	Rocuronium (n=30) Median (min-max)	Remifentanyl (n=30) Median (min-max)	p
Time to recovery of TOF ratio to 0 following anesthetic induction (min)	4 (1-8)	2 (1-4)	6 (4-8)	<0.001
Time from the onset of neuromuscular blockade to attaining a TOF ratio of 70% (min)	6 (2-16)	10 (2-16)	4 (2-10)	<0.001
Time from TOF 70% to 90% following decurarization (min)	3 (1-10)	3 (1-6)	2 (1-10)	0.040
Time to extubation (min)	6 (2-16)	6 (3-12)	5 (2-16)	0.088
Time to spontaneous eye opening (min)	8 (3-24)	8 (3-16)	7.5 (5-24)	0.247
Time to follow verbal commands (min)	12 (5-26)	13 (5-24)	12 (6-26)	0.077
Time to attain a modified Aldrete score of 10 (min)	16 (7-30)	18.5 (7-30)	15 (8-30)	0.030

Mann-Whitney U Test (Monte Carlo), Min: Minimum, Max: Maximum, TOF: train-of-four nerve stimulation

**Table 3. Postoperative complications and surgeon satisfaction**

	Total (n=60) n (%)	Rocuronium (n=30) n (%)	Remifentaniil (n=30) n (%)	P
<b>Postop sore throat</b>				
No	45 (75.0)	28 (93.3)	17 (56.7)	0.002 1
Yes	15 (25.0)	2 (6.7)	13 (43.3)	10.7 (2.1-53.3)*
<b>Laryngospasm</b>				
No	52 (86.7)	27 (90.0)	25 (83.3)	0.706 2
Yes	8 (13.3)	3 (10.0)	5 (16.7)	
<b>Desaturation</b>				
No	50 (83.3)	24 (80.0)	26 (86.7)	0.731 1
Yes	10 (16.7)	6 (20.0)	4 (13.3)	
<b>Requirement of bag-valve-maskventilation</b>				
No	45 (75.0)	23 (76.7)	22 (73.3)	0.999 1
Yes	15 (25.0)	7 (23.3)	8 (26.7)	
<b>Hoarseness</b>				
No	50 (83.3)	30 (100.0)	20 (66.7)	0.001 1
Yes	10 (16.7)	0 (0.0)	10 (33.3)	14.5 (1.7-122.4)*
<b>Surgeon satisfaction</b>				
Good	30 (50.0)	17 (56.7)	13 (43.3)	0.665 3
Poor	7 (11.7)	3 (10.0)	4 (13.3)	
Moderate	23 (38.3)	10 (33.3)	13 (43.3)	

1 Pearson's Chi-Square Test (Exact), 2 Fisher's Exact Test (Exact), 3 Fisher-Freeman-Halton Extension (Monte Carlo), \*Odds Ratio (95% CI)

**Table 4. Intubation difficulty scale**

	Total (n=60) n (%)	Rocuronium (n=30) n (%)	Remifentaniil (n=30) n (%)	p
<b>Laryngoscopy</b>				
Easy	22 (36.7)	14 (46.7)	8 (26.7)	0.258
Moderate	30 (50.0)	13 (43.3)	17 (56.7)	
Difficult	8 (13.3)	3 (10.0)	5 (16.7)	
<b>Vocal cords</b>				
Open	34 (56.7)	25 (83.3) B	9 (30.0)	<0.001
Mobile	9 (15.0)	1 (3.3)	8 (26.7) A	
Limited mobility	17 (28.3)	4 (13.3)	13 (43.3) A	
<b>Cough</b>				
Yok	36 (60.0)	24 (80.0) B	12 (40.0)	0.007
Mild	17 (28.3)	4 (13.3)	13 (43.3) A	
Moderate	7 (11.7)	2 (6.7)	5 (16.7)	
<b>Jaw relaxation</b>				
Complete	34 (56.7)	24 (80.0) B	10 (33.3)	<0.001
Soft	13 (21.7)	4 (13.3)	9 (30.0)	
Stiff	10 (16.7)	0 (0.0)	10 (33.3) A	
Rigid	3 (5.0)	2 (6.7)	1 (3.3)	

MFisher-Freeman-Halton Extension (Monte Carlo), A: significant compared to the rocuronium group, B: significant compared to the Remifentaniil group

Table 5. Hemodynamic parameters

	Total (n=60) Median (min-max)	Rocuronium (n=30) Median (min-max)	Remifentanil (n=30) Median (min-max)	p1
Heart rate (beats/min)				
Baseline (A)	81.5 (56 / 116)	86 (56 / 104)	78 (60 / 116)	0.221
Mean (B) (5-30 min)	77 (60.2 / 215)	79.7 (60.2 / 215)	73.7 (61.6 / 105.2)	0.668
Change (B-A)	-4.2 (-22.8 / 133)	-5.4 (-22.8 / 133)	-4 (-14.4 / 10.2)	0.611
p2	<0.001	0.032	0.001	
TA				
Baseline (A)	91.5 (76 / 136)	92.5 (76 / 130)	90 (76 / 136)	0.836
Mean (B) (5-30 min)	82.9 (69 / 109.8)	79.9 (69 / 109.8)	87.4 (71.4 / 109.4)	0.087
Change (B-A)	-7.4 (-28 / 4.8)	-8.7 (-28 / 4.8)	-5.3 (-26.6 / 4.8)	0.032
p2	<0.001	<0.001	<0.001	
SpO <sub>2</sub>				
Baseline (A)	97 (90 / 99)	97 (90 / 99)	96 (91 / 99)	0.419
Mean (B) (5-30 min)	98.8 (95.6 / 99.8)	98.8 (95.6 / 99.8)	98.7 (95.8 / 99.4)	0.609
Change (B-A)	1.9 (-0.8 / 8.2)	1.8 (-0.2 / 8.2)	2.3 (-0.8 / 6.6)	0.316
p2	<0.001	<0.001	<0.001	

1 Mann-Whitney U Test (Monte Carlo), 2 Wilcoxon Signed-Rank Test (Monte Carlo), Min: Minimum, Max: Maximum

## DISCUSSION

In the present study, rocuronium was used for muscle relaxation and sugammadex was used for reversal and the results indicated that the group that underwent intubation after the administration of NMB had better intubation conditions and better hemodynamic stability along with lower complication rates compared to the group that underwent intubation after the administration of remifentanil. Additionally, a small number of patients underwent decurarization with neostigmine; however, these patients were not included in the study due to their small number. This could be accepted as a limitation of our study and could be a research topic for further studies.

Literature indicates that most of the OSA patients undergoing surgery cannot be diagnosed and even high-risk OSA patients cannot be evaluated prior to surgery. A previous study that was conducted in a university hospital in USA revealed that OSA is commonly seen in patients undergoing surgery and almost 81% of these patients remain undiagnosed prior to surgery. The same study also noted that approximately 5,000 OSA patients receive surgical treatment in their hospital without the knowledge of the surgeons and the anesthesiologists (11). On the other hand, OSA patients also have an increased risk for peri-, intra-, and post-operative complications compared to non-OSA individuals. Therefore, OSA patients represent a specific patient group that requires utmost care during anesthetic management. Previous studies indicated that OSA patients with a STOP-Bang score of  $\geq 3$  commonly have various complications including pulmonary complications such as perioperative respiratory distress, pneumonia, and bronchospasm, cardiac complications such as

arrhythmia, myocardial infarction, atrial fibrillation, and hypotension, repeated intubation, and CNS complications such as encephalopathy (2,3,12,13). Interestingly, the critical risk factor associated with all these complications is upper airway collapse in OSA patients. Moreover, the respiratory complications in OSA patients are associated with difficult intubation and repeated intubation and can lead to serious problems including anoxic brain injury and even death (14). In our study, we obtained similar findings and the overall incidences of postoperative sore throat, hoarseness, and requirement of BVM ventilation were remarkably high (25%, 16.7%, 25%, respectively). Similarly, the incidences of intraoperative complications such as laryngospasm, desaturation, and surgeon dissatisfaction (13.3%, 16.7%, 50%, respectively), as well as the incidences of laryngoscopy difficulty, vocal cord mobility, cough, jaw rigidity, and jaw stiffness were also considerably high (13%, 15%, 40%, 5%, 16%, respectively).

Neuromuscular blockers (NMB) such as rocuronium are frequently used to achieve adequate muscle relaxation in anesthetic practice. Additionally, NMB have been shown to facilitate intubation and anesthetic induction and also to reduce the incidence of postoperative laryngeal symptoms and tissue trauma during tracheal intubation (15). A previous study compared patients that did and did not receive rocuronium and revealed that the administration of rocuronium facilitated intubation, resulted in better tracheal intubation conditions, and reduced the rate of adverse hemodynamic events (16). Another study indicated that the administration of 2  $\mu\text{g kg}^{-1}$  remifentanil and 2  $\mu\text{g kg}^{-1}$  propofol provided the same level of muscle relaxation as that provided by the administration of

0.20 µg kg<sup>-1</sup> rocuronium as well as that provided by the administration of rocuronium at a dose of 0.20 µg kg<sup>-1</sup> for 60 sec (17). Similarly, another study reported that the administration of 2 or 3 µg kg<sup>-1</sup> remifentanyl and 5 µg kg<sup>-1</sup> thiopental provided suitable intubation conditions without the use of NMB (18). In contrast, another study compared the effectivity of atracurium and remifentanyl and reported that atracurium had no superiority over remifentanyl in terms of intubation conditions and postoperative laryngeal injury (15). One of our previous studies investigated the effects of remifentanyl and succinylcholine on intubation conditions and concluded that remifentanyl provides similar intubating conditions as those provided by NMB and remifentanyl is superior to succinylcholine in terms of hemodynamic stability and recovery duration (10). On the other hand, the effects of remifentanyl on anesthesia conditions in patients with OSA have been investigated in numerous studies. Remifentanyl-propofol or remifentanyl-sevoflurane complex has not been shown to cause postoperative respiratory complications and has been shown to be a safe anesthetic agent (19). Nevertheless, there are some studies reporting that opioid analgesics lead to respiratory depression and also noting that the incidence of respiratory depression is 5 in 1,000 in non-OSA patients and is higher in OSA patients (20, 21).

In the present study, we evaluated the peri-, intra-, and post-operative effects of NMB and remifentanyl in OSA patients and we obtained different findings from those reported in the literature. The median time to recovery of the TOF ratio to 0 was significantly lower in the rocuronium group compared to the remifentanyl group. However, in spite of the literature data suggesting that opioids are safe agents and NMB such as rocuronium are likely to have adverse effects on hemodynamic parameters, we found no significant difference between the two groups with regard to hemodynamic parameters such as BP, heart rate, and SpO<sub>2</sub>. Moreover, in contrast to other studies, the median change in BP was significantly higher in the remifentanyl group compared to the rocuronium group. The differences between our findings and those reported in the literature could be attributed to the characteristics of the rocuronium used in our study and to the administration of decurarization with sugammadex which has been shown to be superior to neostigmine in terms of postoperative recovery in some previous studies (22). Additionally, these differences could also be ascribed to the variability of the effects of anesthetic agents associated with the higher incidence of upper airway obstruction and comorbidities (e.g. cardiac and respiratory conditions) in OSA patients compared to non-OSA patients. Meaningfully, further studies are needed to investigate the effects of rocuronium and remifentanyl on postoperative recovery in OSA patients.

## CONCLUSION

In conclusion, patients at high risk of OSA should be meticulously evaluated for OSA perioperatively. Our results indicated that rocuronium provided better intubation

conditions and led to less peri- and post-operative complications compared to remifentanyl. Further studies with larger patient series are needed to substantiate our findings.

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