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ORIGINAL ARTICLE

The Effect of Continuous Infusion of Rocuronium Versus Incremental Doses on Quality of Recovery in Patients Undergoing Abdominal Surgeries

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ABSTRACT

Background: Neuromuscular blocking agent (NMBA) are given for tracheal intubation and optimization of surgical conditions. The main goals of neuromuscular blockade are paralysis of the vocal cords and jaw muscles to allow endotracheal intubation in addition of respiratory muscles of the diaphragm to allow controlled ventilation. **Aim of work**: This study is to compare the effect of continuous infusion of rocuronium versus incremental doses on quality of recovery in patients undergoing abdominal surgeries. **Patients & Methods:** This prospective double blinded randomized controlled clinical study was carried out at the Anesthesia Department of Zagazig University Hospital within 8 months after approval of the research ethical committee of faculty of medicine, Zagazig University and written informed consent from each patient. Forty adult patients of both sexes between two groups, 20 in each group, were enrolled in the study. After induction of general anesthesia; one group was given incremental doses (0.15mg/kg) of rocuronium (group I) while the other one was given continuous infusion (0.5 mg/kg/h)of rocuronium (group C) for maintenance of anesthesia in patients scheduled for abdominal surgeries. Routine monitoring were applied for assessment of heart rate, mean arterial blood pressure and arterial oxygen saturation perioperatively and at specific intervals every 10 min. Also, nerve stimulater (Train-of-Four) TOF was used to assess muscle power recovery intraoperative and postoperatively. The quality of recovery (QoR-40) was assessed two times, before induction of anesthesia and 6h after recovery from anesthesia..

Results: The continuous infusion of rocuronium group (group C) was preferred in parameters of QoR-40 (physical independence, emotional state, physical comfort, pain, psychological support) and group C also preferred in hemodynamic parameters (heart rate and mean arterial blood pressure) and time of recovery.

Conclusions: The continuous infusion of rocuronium (0.5 mg/kg/h)is preferred on incremental doses of rocuronium (0.15mg/kg) on recovery status in patients scheduled for abdominal surgeries.

Keywords: Neuromuscular blocking agent (NMBA)**,** Rocuronium, Abdominal Surgeries, Quality of recovery (QoR).

INTRODUCTION

Neuromuscular blocking agent (NMBA) are given for tracheal intubation and optimization of surgical conditions**[1]**. The main goals of neuromuscular blockade are paralysis of the vocal cords and jaw muscles to allow endotracheal intubation in addition of respiratory muscles of the diaphragm to allow controlled ventilation**[2]**. The overall safety of anesthesia has well been established, but neuromuscular blockade induced by NMBA has the potential for significant adverse outcomes**[3].** Prolonged

recovery after surgery can lead to delayed hospital discharges and increased costs, which can impact resource utilization and mitigate patient satisfaction[4]. Complete return of neuromuscular function should be achieved at the end of surgery, unless mechanical ventilation is planned. Without reversal of paralysis, residual effects, including hypoxia, weakness, and respiratory complications, can occur, which increases the risks for morbidity and mortality**[5]**.

An aminosteroidal rapid acting neuromuscular blocking agent, rocuronium bromide, has been introduced into clinical practice. Its main advantage over other currently used drugs of this kind is its fast onset of action, which could render rocuronium the muscle relaxant of choice for rapid facilitation of tracheal intubation**[6]**.

It competes with acetylcholine and bind to cholinergic receptors at neuromuscular junctions. It is free of clinically significant cardiovascular side effects at effective blocking doses **[7].** Postoperative recovery is a key outcome in the perspective of anesthesiologists. It is defined as the patients return to the normal state after a surgery, and has traditionally been referred in terms of pain scores, duration of hospital stay, and return to normal activities. It involves several factors such as regain of physical, physiologic and social functions. Therefore, it is fundamental for the evaluation of health care and patient satisfaction after surgery **[8].** Number of patient-centered measurement tools have been developed as a means of assessing quality of recovery in the postoperative setting as quality of recovery (QoR-40) questionnaire and measurement**[9].**Previous studies reported that the incremental doses of rocuronium seems insufficient to cover neuromuscular blockade during the complete intra operative period **[10].** When appropriately titrated NMBA (rocuronium) administration to individual patient requirements, infusion techniques may potentially help avoid periods of both inadequate and excessive drug effects and may actually decrease the total drug requirement**[11]**.

Aim of this study is to compare the effect of continuous infusion of rocuronium versus incremental doses on quality of recovery in patients undergoing abdominal surgeries.

PATIENTS AND METHODS

This prospective double blinded randomized controlled clinical study was carried out at the Anesthesia Department of Zagazig University Hospital within 8 months after approval of the research ethical committee of faculty of medicine, Zagazig University and written informed consent from each patient. Forty adult patients of both sexes between two groups, 20 in each group, were enrolled in the study. After induction of general anesthesia; one group was given incremental doses (0.15mg/kg) of rocuronium (group I) while the other one was given continuous infusion (0.5 mg/kg/h)of rocuronium (group C) for maintenance of anesthesia in patients scheduled for abdominal surgeries. Routine monitoring were applied for assessment of heart rate, mean arterial blood pressure and arterial oxygen saturation perioperatively and at specific intervals every 10 min. Also, nerve stimulater (Train-of-Four) TOF was used to assess muscle power recovery intraoperative and postoperatively. The quality of recovery (QoR-40) was assessed two times, before induction of anesthesia and 6h after recovery from anesthesia..

The work has been carried out in accordance with the code of ethics of the world medical association (Decleration of Helsinki) for studies involving humans.

Inclusion criteria: Patients aged between 21 and 60 years old with an ASA physical status I–II of both sex on abdominal surgeries. Body mass index (BMI) of less than 35kg m-2 and the duration of surgery within 2 hours.

Exclusion criteria: Patients who having hepatic, renal or neuromuscular diseases. Patients who were taking any sedative, opioid, or sleep aid drugs. Patients who have an allergic history of any study drug. Patients receiving drugs known to interact with neuromuscular blocking agents such as aminoglycoside antibiotics, diuretics metronidazole, calcium antagonists, alpha and beta adrenergic antagonists, antiarrhythmic drugs, protamine were excluded.

Operational Design:

Study design: Prospective randomized comparative clinical study were conducted between two groups, incremental doses group versus continuous infusion of rocuronium group during general anesthesia for patients undergoing abdominal surgeries.

Field work: Patient demographic data were collected. Routine monitoring including: electrocardiograph, non-invasive arterial blood pressure, peripheral pulse oximeter, were applied for assessment of heart rate, mean arterial blood pressure and arterial oxygen saturation perioperatively at specific intervals every 10 min before and after intubation. The nerve stimulater (Train-of-Four) TOF (Fisher and Paykel Electronics Ltd, NewZeland) was used to assess muscle power recovery intraoperative and postoperatively.

In both groups the induction was done by propofol (1-2 mg/kg), fentanyl (1-2 µg/kg) with rocuronium (0.9mg/kg), tracheal intubation with mechanical ventilation TV (7-10 ml/kg), RR (10-14 breath/min), O2: AIR (50%:50%) and the general anesthesia was maintained by isoflurane inhalational gas (1-1.2 mac).

In (group I) rocuronium was adminsitrated in separate incremental doses (0.15mg/kg) with 25% of (TOF), while in (group C) rocuronium was administrated via continuous infusion that was prepared as 30mg of rocuronium bromide in 60ml of 5% dextrose, which yields a concentration of 0.5mg/ml . The infusion was started by(0.5 mg/kg/h) at 5 min following the intubating dose of rocuronium and stopped at the beginning of skin suture and the reversed by neostigmine (0.05-0.07 mg/kg with atropine 0.01-0.02mg/kg) was given to return of TOF to 75% and then awake extubation was done.

The following data were collected of interest:

Recovery time of block (time from stoppage inhalational anesthetic at the end of abdominal surgery to time of tracheal extubation), peripheral oxygen saturation, hemodynamic parameters (heart rate and mean arterial blood pressure). The quality of recovery after general anesthesia and surgery was measured by the quality of recovery questionnaire (QoR-40).

The quality of recovery (QoR-40) was assessed two times, before induction of anesthesia and 6h after recovery anesthesia. This questionnaire assesses five dimensions of recovery: physical comfort, emotional state, physical independence, psychological support, and pain. Analgesia was given postoperatively for all patients as (Diclofenac sodium75 mg/IM every 8hours) and (Paracetamol 1 gram I/V infusion every 6hours).

STATISTICAL ANALYSIS

The sample size:

Assuming that mean ± SD of recovery durations status at 15 minutes postoperative in patients who received continuous infusion (group C) and patients who received incremental doses of rocuronium (group I) were (5.46 ± 0.63 VS 6.3±0.62) .The sample was calculated to be 40 patients (20 in each group) using open Epi with power of test 80% and confidence interval 95%**. [11]**

Method of analysis:

The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 18.0. Qualitative data were represented as frequencies and relative percentages. Chi square test was used to calculate difference between qualitative variables.

RESULTS

Our results show that regarding age, sex and weight of the patients and durations of surgeries there was no statistically significant difference between two groups (group I) and (group C). Table (1)

Our results show that regarding the mean arterial blood pressure recorded intraoperatively for both incremental group (group I) and continuous infusion group (group C), it was statistically significant higher in (group I) compared to(group C) ($p \leq 0.05$) at 30, 40, 50 and 60 min (it was 85.1±7.3 versus 80.3±6.3, 89.4±8.5 versus 83.1±8.9, 86.2±6.9 versus 81.2±7.6, 87.2±9.3 versus 82±5.8 respectively). While at other times of measures, there were no statistically significant difference. Table (2)

Our results show that regarding the heart rate recorded intraoperatively for both incremental group (group I) and continuous infusion group (group C), it was statistically significant higher in (group I) compared to(group C) ($p \leq 0.05$) at 30, 40 and 50 min (it was77.4±5.1 versus74.2±4.2, 77.5±3.8 versus 75.1±3.4, 81.7±6.2 versus 77.4±7.1 respectively). While at other times of measures, there were no statistically significant difference. . Table (3)

Our results show that regarding the time of recovery recorded for both incremental group (group I) and continuous infusion group (group C).The group C was significantly shorter time of recovery in comparison to group I (it was 9.7 min versus15.5 min respectively), as shown in Figure (1)

Our results show that regarding the peripheral oxygen saturation (spo^2) recorded intraoperatively and postoperatively anesthesia for both incremental group (group I) and continuous infusion group (group C), there was no significant difference in both studied groups (group I). Table (4)

our results regarding quality of recovery; there were no statistically significant differences between the two studied groups ($p > 0.05$) in all items (physical comfort, emotional state, physical independence, psychological support, and pain) recorded before anesthesia.

Also, our results regarding quality of recovery recorded 6hrs postoperatively showing no statistically significant differences between the two studied groups ($p > 0.05$) in emotional state, physical comfort, psychological support and physical independence (Tables5,6,7 and 8).

While our results regarding pain sensation recorded 6hrs postoperatively in as an item in quality of recovery assessment showing no statistically significant differences in all parameters between the two studied groups except in backache which was significantly higher in group I than in group C ($p < 0.05$) (Table9).

Table 1: Demographic characteristics of the two studied groups

Variable	Group I n=(20)	Group C n=(20)	t- test	p-value
Age(years)	35.3±4.8	36.7±5.4	0.7	0.8
Sex **Male (19)** **Female (21)**	 12 (60.0%) 8 (40.0%)	 9 (45.0%) 11 (55.0%)	2.5	0.1
Weight (kg)	72.5±2.5	73.8±3.1	1.15	> 0.05
Durations of surgeries (minutes)	81.2±13.4	80.4±12.6	1.23	> 0.05

Age was expressed as mean ± SD**.**
Sex was expressed as number and percentage**.**

Table 2: Mean arterial blood pressure (mmHg) at different time intervals of the studied groups

Mean arterial blood pressure (mmHg)	Group I n= (20)	Group C n=(20)	t-test	p-value
Before anesthesia	79.1±9.7	78±8.3	0.38	0.7
10 minutes	82.1±11.7	81.3±8	0.25	0.8
20 minutes	83±6.9	79±7.6	1.7	0.1
30 minutes	85.1±7.3	80.3±6.3	2.1	**0.04***
40 minutes	89.4±8.5	83.1±8.9	2.3	**0.03***
50 minutes	86.2±6.9	81.2±7.6	2.1	**0.04***
60 minutes	87.2±9.3	82±5.8	2	**0.048***
70 minutes	78±2.3	75.5±9.8	1.1	0.27
80 minutes	75±1.9	74.9±1.75	0.17	0.86
90 minutes	71.3±1.5	70.8±1.4	1.08	0.28

Data was represented as mean ±SD
Statistically significant difference ($p<0.05$)

Table 3: Heart rate at different time intervals of the both studied groups

Heart rate	Group I (n=20)	Group C (n=20)	t-test	p-value
Before anasthesia	75.5±4.7	73.8±6.6	0.8	0.3
10 minutes	77.6±3.5	78.1±7.6	0.2	0.7
20 minutes	77.4±6.5	73.9±5.1	1.8	0.07
30 minutes	77.4±5.1	74.2±4.2	2.18	**0.037***
40 minutes	77.5±3.8	75.1±3.4	2.1	**0.04***
50 minutes	81.7±6.2	77.4±7.1	2	**0.048***
60 minutes	78±6	79.9±7.2	0.4	0.7
70 minutes	80±3.4	81.2±8.4	0.3	0.8
80 minutes	81±2.5	82.3±2.2	1.7	0.1
90 minutes	83±2.4	84.1±2.3	1.47	0.15

Data was represented as mean ±SD
Statistically significant difference ($p<0.05$)

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Table 4: Peripheral Oxygen Saturation between groups I and C at different time intervals

Mean oxygen saturation	Group I n=(20)	Group C n=(20)	t-test	p-value
Before anesthesia	98.59±0.61	98.7±0.59	0.52	0.6
10 minutes	98.6±0.6	98.4±0.58	1.1	0.39
20 minutes	98.8±0.34	98.6±0.42	1.62	0.1
30 minutes	98.2±0.46	97.9±0.7	1.6	0.11
40 minutes	97. 9±1	98.2±0.6	1.6	0.11
50 minutes	98.6±0.73	98.75±0.43	0.79	0..43
60 minutes	97.9±0.9	98.3±0.46	1.7	0.09
70 minutes	98.9±0.67	99±0.48	0.54	0.59
80 minutes	98.7±0.63	98.3±0.83	1.7	0.09
90 minutes	98.7±0.1	98.8±0.43	1	0.32

Data was represented as mean ±S

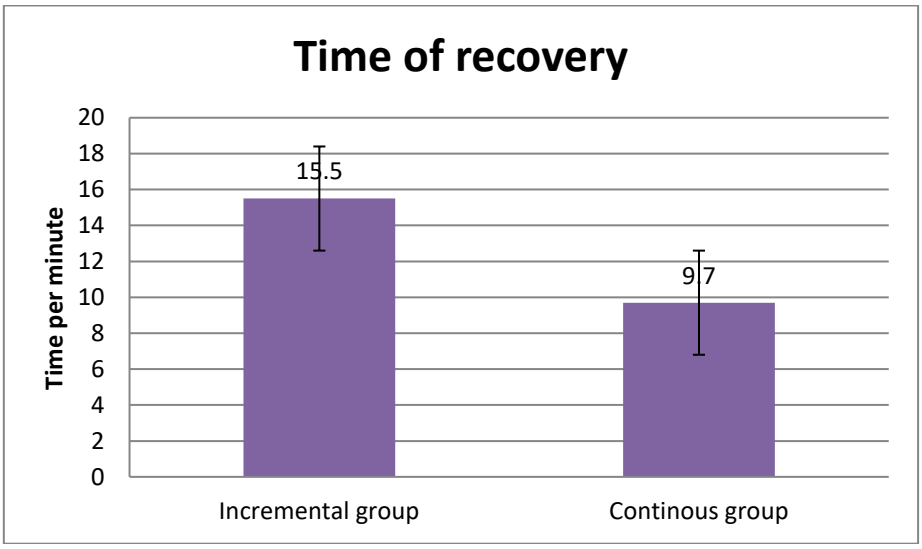

Figure 1: Data was expressed as bar chart for comparing time of recovery per minute between the two studied groups.

DISCUSSION

The our study was prospective randomized comparative clinical study included forty patients (20 incremental group and 20 continuous infusion group) aged between 21 and 60 years old with an ASA physical status I–II of both sex, body mass index (BMI) of less than 35kg m-2 and the duration of surgery within 2hours. The duration of the study had been 8 months.

In our study there was no statistically significant difference between the studied groups (group I) and (group C) regarding age, sex and durations of surgeries.

Our results agree with finding reported by **Ko et al., [12]** as they reported that there was no statistically significant difference between the studied groups in age and sex.

Our results show that regarding the mean arterial blood pressure recorded intraoperatively for both incremental group (group I) and continuous infusion group (group C), it was statistically significant higher in (group I) compared to(group C) .

This is in contrary of finding reported by **Marinal et al., [11]** as they reported that mean arterial pressure at different time intervals after intubation with rocuronium were not significantly different (P>0.05) between the groups.

Wang et al., [13] reported there was no significant difference regarding mean arterial blood pressure between both groups.

Our results show that regarding the heart rate recorded intraoperatively for both incremental group (group I) and continuous infusion group (group C), it was statistically significant higher in (group I) compared to(group C) .

This is in contrary of finding reported **Wang et al., [13] as they** reported that there was no significant difference regarding heart rates between both groups.

Marinal et al. [11] reported that the heart rate at different time intervals after intubation

with rocuronium were not significantly different between the two groups.

Our results agree with finding reported by **Diefenbach et al., [14] Mayer et al.,[15] Maddineni et al.,[16] Levy et al., [17] Booth et al., [18].**there were

insignificant difference steady-state variations in heart rate and mean arterial pressure at different time intervals after intubation with rocuronium in both groups.

Our results show that regarding the time of recovery (time of stopped inhalation to time of tracheal extubation) recorded for both incremental group (group I) and continuous infusion group (group C).The group C was significantly shorter time of recovery in comparison to group I .That's mean prolonged recovery time in (group I) more than (group C). TOF was checked every 10 minutes in both groups.

These findings were supported by **Ko et al., [12]** as they reported that's mean TOF counts checked every 10 min in both groups. The TOF counts were significantly higher in (groupI) from 30 min, that's mean prolonged recovery in (group I) than other group.

Marinal et al.[11] reported that recovery status in two groups was compared. On assessing the recovery status 5 min after administered neostigmine till 20 min, it was found that the continuous infusion group showed significantly better quality of recovery status. Complete recovery was attained within 20 min of administering neostigmine in the two groups, with a better score in infusion group.

Wang et al.,[13] reported that changes in the duration of neuromuscular blockade between the two groups. The laparoscopic surgery group, the several times of rocuronium injection until the end of surgery were cause significantly prolonged recovery compared with those in the open procedure group.

Sparr et al.[19] and McCoy et al.[20] in these previous studies when rocuronium was administered in repeated dosages, its serum profiles show a saw tooth pattern. So, when the plasma concentration of rocuronium was high, the patient movement were suppressed, but when tha plasma concentration is low, the patient movement occur and enough to interfere the surgery. On the other hand, the plasma concentration was kept constant by continuous infusion of rocuronium. So, the repeated incremental doses cause accumulation of rocuronium and leads to prolongation of recovery time.

Wang et al. [13] reported neuromuscular blockade may be prolonged following a single incremental dose of rocuronium given during laparoscopic procedures, and assess neuromuscular function to ensure safe recovery.

our results regarding quality of recovery; there were no statistically significant differences between the two studied groups in all items (physical comfort, emotional state, physical independence, psychological support, and pain) recorded before anesthesia.Also, our results regarding quality of recovery recorded 6hrs postoperatively showing no statistically significant differences between the two studied groups in physical comfort, emotional state, physical independence and psychological support .While our results regarding pain sensation recorded 6hrs postoperatively in as an item in quality of recovery assessment showing no statistically significant differences in all parameters between the two studied groups except in backache which was significantly higher in group I than in group C .

Martina MB et al., [10] reported the results of the (QoR-40) questionnaire, there was no difference between two groups (continuous infusion group) and (incremental dose group) in emotional state, physical comfort, pscychological support but there was found pain in the back after anaesthesia and surgery.

Veelo et al., [21] reported there was no differences in pain sensation between groups and there was no significant difference in other measures.

Finally, our study confirms the duration of clinical neuromuscular blockade following a single incremental dose of rocuronium was significantly prolonged during abdominal surgery compared with continuous infusion of rocuronium.

CONCLUSION

In (group I) rocuronium was adminsitrated in separate incremental doses (0.15mg/kg), while in (group C) rocuronium was administrated via continuous infusion of(0.5mg/kg/h). The infusion was started at 5 min following an intubating incremental dose of rocuronium**.**That by the statistical results; the continuous infusion of rocuronium is preferred on incremental doses of rocuronium group in recovery status in patients with abdominal surgeries within 2 hours**.**

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