

Efficacy of Rocuronium Pretreatment on Succinylcholine-induced Fasciculations and Myalgia: A Randomised Controlled Trial

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ABSTRACT

Introduction: Succinylcholine is a widely used muscle relaxant for its quick onset and short duration of action, however it is associated with fasciculations and myalgia. This may cause discomfort to the patient and can be avoided by using rocuronium as a pretreatment. This effect of rocuronium was evaluated during this study.

Aim: To establish the efficacy and safety of using rocuronium as a pretreatment to reduce succinylcholine-induced fasciculations and myalgia.

Materials and Methods: This is a double-blinded randomised controlled trial conducted at MM Institute of Medical Science and Research, Mullana, Ambala, Haryana, India between October 2022 and November 2023 and included 40 patients of the American Society of Anaesthesiologists (ASA), physical status I or II, posted for elective surgery under general anaesthesia, divided into two groups of 20 patients each. Group I patients were administered rocuronium 0.06 mg/kg, diluted up to 2 mL, and Group II patients were administered normal saline (2 mL). All patients received propofol induction 2 mg/kg and succinylcholine 1.5 mg/kg after 30 and 90 seconds of study drug respectively, and the intensity of fasciculations was assessed. Intensity of myalgia was assessed in the immediate postoperative period and after 24 hours. The statistical

significance was examined using the Chi Square test. p-value <0.05 was considered statistically significant.

Results: Baseline demographic data was comparable among both the groups (mean age in Group I was 42.95 years with 8 females and 12 males while in Group II age was 40.55 years, with 9 females and 11 males). The group that was administered rocuronium had 2 patients with mild fasciculations, 1 patient with mild myalgia and 1 patient with moderate myalgia. Group II had 9 patients with mild fasciculations, 6 with moderate fasciculations, 1 with severe fasciculations, 4 with mild myalgia, 2 with moderate myalgia, 1 with severe myalgia. There was a statistically significant reduction in the incidence and intensity of fasciculations (p-value 0.001). There was also a significantly lesser mean heart rate and mean arterial pressure in the rocuronium group compared to the saline group after intubation at 1 min, 3 min, and 5 min. There was a reduction in postoperative myalgia in the rocuronium group in the immediate postoperative period and after 24 h, but the difference was statistically non significant.

Conclusion: Rocuronium pretreatment is safe and effectively reduces succinylcholine-induced fasciculations and provides more stable haemodynamics at a dose of 0.06 mg/kg administered 30 sec before propofol induction. Therefore, rocuronium can be used safely and effectively as a precurarisation drug.

Keywords: Haemodynamics, Muscle relaxant, Propofol

INTRODUCTION

The non depolarising muscle relaxant succinylcholine is used for tracheal intubation because of its rapid onset and short duration of action. Muscle fasciculations and post operative myalgia are the most common side effects caused by succinylcholine [1]. Although succinylcholine's effectiveness is restricted because of these side effects, it is still the most frequently used depolarizing muscle relaxant in developing nations because of its faster onset and smaller duration of action [2]. Women and muscular adults have high prevalence of fasciculations and myalgia after succinylcholine injection. Precurarisation with a low dosage of a non depolarising muscle relaxant reduces the fasciculations [3]. Succinylcholine-induced side effects are prevented by using drugs like: d-tubocurarine, rocuronium, vecuronium, mivacurium, magnesium, gallamine, and atracurium [4].

Earlier d-Tubocurarine was the gold standard for defasciculation but due to several adverse effects like release of histamine, bronchoconstriction and hypotension, its use has declined [5]. Incidence of postoperative myalgia decreases with the use of lidocaine, diclofenac, aspirin, or phenytoin to some extent [6]. In clinical practice myalgia due to succinylcholine ranges from 5 to

85%. The use of pretreatment with non depolarising relaxants, benzodiazepines and local anaesthetics, reduces the incidence of myalgia around 30% [7].

Rocuronium is preferred for preventing succinylcholine-induced fasciculations because of its quicker onset, which also shortens the time needed for pre-curarization [8]. An ideal time of 3 min is suggested [9] for Precurarisation, however this may be too lengthy and during this time patient may experience side effects of non depolarising muscle relaxant like difficulty breathing or diplopia. The present trial aimed to establish the efficacy of 0.06 mg/kg rocuronium given 30 seconds before succinylcholine as safe and effective precurarisation drug. The primary outcome was to evaluate the effectiveness of rocuronium for reducing succinylcholine-induced fasciculations and myalgia. The present trial also assessed the safety profile and adverse effects of rocuronium, the difference in haemodynamics, and the requirement of propofol and fentanyl as secondary outcomes.

MATERIALS AND METHODS

This double-blinded, randomised controlled trial was conducted in MM Institute of Medical Science and Research, Mullana, Ambala,

Haryana, India between October 2022 and November 2023 after ethical committee clearance (project number 2032) and registration with Clinical Trial Registry of India (CTRI/2022/10/046136) dated 03/10/2022 for 40 patients after taking informed consent.

Inclusion and Exclusion criteria: Patients between 18-60 years of age with ASA status 1 or 2 with Mallampati Grade (MPG) 1 or 2 scheduled under general anaesthesia for elective surgery were included in the study. Patients with ASA status 3 or above, MPG 3 or above, age less than 18 or more than 60 years or with any other known co-morbidity were excluded.

Sample size calculation: A post hoc power analysis was conducted using the software package, G*Power version 3.1.9.2 (Franz Faul, university kiel, Germany). The alpha level used for this analysis was $p < 0.05$ and beta was 0.20. Sample size was estimated from the results of previous study [8] using the incidence of fasciculations as the parameter, which was the primary outcome of the present trial. The sample size came out to be 20 subjects per group at power of 0.99 and with an effect size of 2.24 with 10% chance of error with $\alpha = 0.05$, $\beta = 0.20$ and confidence interval of 95%.

Using computerised randomisation, the patients were split into two groups of 20 each [Table/Fig-1]:

Group I: Patients received rocuronium 0.06 mg/kg diluted to 2 mL [7].

Group II: Patients received normal saline of 2 mL.

Study Procedure

In order to assure double blinding, an employee unrelated to study prepared envelopes based on random numbers generated and placed them in a locked box. An investigator removed a closed, numbered envelope from a locked box and presented it to another employee who prepared the medication to a standard volume of 2 mL away from the sight of the investigator.

Patients were informed about the study and evaluated for participation before the day of the procedure during pre-anaesthesia interviews. Informed consent was taken. Day before surgery patients were kept fasting for 8 hours and given Tab. pantoprazole 40 mg and Tab. alprazolam 0.25 mg at night and morning 6 a.m. Intravenous line was secured and preoperative vitals were recorded. Patients were then moved to the operation room, where they were monitored using non invasive blood pressure monitoring, pulse oximeter, an Electrocardiogram (ECG) and End-Tidal Carbon Dioxide (ETCO₂). Three minutes of 100% oxygen was given to the patients. The study medication was administered, followed 30 seconds later by induction with fentanyl 1.5 µg/kg and propofol titrated to effect (loss of verbal response) and succinylcholine 1.5 mg/kg. Additional doses of Fentanyl were given intraoperatively depending on requirement and haemodynamic parameters indicating pain.

An experienced anaesthesiologist not related to study used a four-point grading system [1] to gauge the severity of the fasciculation, and the laryngoscopy was done following succinylcholine delivery. Absent meant no fasciculations, mild meant fine fasciculation of the eyes, face, neck, finger without limb movement, moderate meant fasciculation of greater intensity than mild which occurred at more than 2 sites or that produced limb movement, and severe meant vigorous, sustained and widespread fasciculations possibly requiring forceful retention. Anaesthesia was maintained with isoflurane, nitrous oxide and oxygen. The end tidal carbon dioxide of the patients was kept between 31 and 36 mmHg by mechanical ventilation. Rocuronium was given as needed as a maintenance dose. Patients were given glycopyrrolate 0.01 mg/kg and neostigmine 0.05 mg/kg after surgery for reversal.

In the Post Anaesthesia Care Unit (PACU) 24 hours after surgery, the occurrence and magnitude of myalgia were graded using a scale [1]. Absent meant no myalgia, mild meant muscle stiffness or pain when specifically asked about in the nape of neck- oriented shoulder and

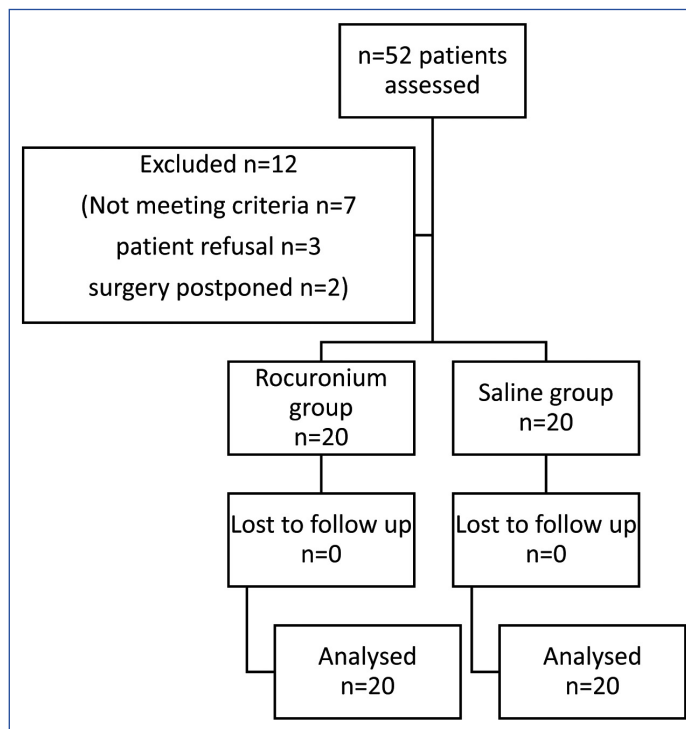
lower chest on deep breathing, moderate meant muscle stiffness and pain spontaneously complained of by the patient that require analgesics, and severe meant incapacitating generalised muscle stiffness or pain. Rescue analgesia with Inj. Tramadol was given in case of moderate and severe myalgia. The incidence and severity of fasciculations and postoperative myalgia immediately and after 24 hours were recorded. Haemodynamic parameters like heart rate and mean arterial pressures were recorded prior to intubation, and post intubation at 1 minute, 3 minutes, and 5 minutes. Any adverse events both in preoperative and postoperative period were recorded. Intensity of fasciculations and myalgia was rated as per 4 points rating scale [1].

STATISTICAL ANALYSIS

For quantitative variables, the mean and standard deviation were used in the descriptive analysis, while frequency and proportion were used for categorical variables. By contrasting the mean values, the relationship between categorical explanatory variables and the quantitative outcome was evaluated. The mean difference and its 95% confidence interval were seen. The t-test on an independent sample was performed to evaluate statistical significance. Cross tabulation and percentage comparison were used to determine the relationship between the explanatory variables and the category outcome. The statistical significance was examined using the chi-square test. p-value < 0.05 was considered statistically significant.

RESULTS

A total of 52 patients requiring surgery under general anaesthesia with tracheal intubation were interviewed for participation in the study, out of which 12 got excluded (7 were outside inclusion criteria, 3 refused to participate, and 2 patients had their surgery postponed). The remaining 40 patients were randomised and distributed among the two groups [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) Diagram.

Demographic characteristics such as age, gender, ASA grade, MPG, weight, and height were similar in both the groups (p-value > 0.05) [see Table/Fig-2]. The baseline haemodynamic parameters (Heart rate and mean arterial pressure) were recorded and were similar in both the groups. The mean dose of propofol and fentanyl used was lesser in Group 1 and the difference was statistically significant [Table/Fig-3]. There was a statistically significant difference in the mean heart rates of the two groups at one, three, and five minutes

Parameters		Group I (Mean±SD)	Group II (Mean±SD)	p-value
Age (years)		42.95±11.50	40.55±10.02	0.17
Gender	F	8 (40%)	9 (45%)	0.74
	M	12 (60%)	11 (55%)	
ASA	1	3 (15%)	2 (10%)	1.00
	2	17 (85%)	18 (90%)	
MPG	1	5 (25%)	6 (30%)	1.00
	2	15 (75%)	14 (70%)	
Weight (kilograms)		62.05±7.96	61.90±7.06	0.95
Height (centimeters)		158.00±7.37	157.00±7.33	0.67
Time to injection of succinylcholine (seconds)		90.25±7.11	90.35±5.71	0.961

[Table/Fig-2]: Demographic and baseline parameters .

Parameters		Group I (Mean±SD)	Group II (Mean±SD)	p-value
Propofol (mg)		111.00±7.18	133.00±4.70	<0.001
Fentanyl (micrograms)		116.50±4.89	145.50±5.10	<0.001

[Table/Fig-3]: Dose of propofol and fentanyl used in the study groups.

following intubation [Table/Fig-4]. The difference in Mean Arterial Pressure (MAP) in both the groups after intubation was found to be statistically significant (71.45±2.44 at 1 min, 71.20±2.61 at 3 min, 70.95±2.42 at 5 min in Group I vs 81.00±5.14 at 1 min, 78.45±4.29 at 3 min, 75.80±3.72 at 5 in in Group II) [Table/Fig-5]. Among the patients of Group I, only 2 patients had fasciculation which were mild in intensity. In Group II, mild fasciculations occurred in 9 patients (45%), moderate fasciculations occurred in 6 patients (30%), and severe fasciculations occurred in 1 patient (5%). With a p-value of 0.001, the difference in fasciculation incidence was statistically significant [Table/Fig-6]. Among the patients of Group I, mild postoperative myalgia occurred in 1 patient (5%), moderate myalgia occurred in 1 patient (5%), and there was no incidence of severe myalgia. In Group II, mild myalgia occurred in 4 patients (20%), moderate myalgia occurred in 2 patients (20%), and severe myalgia occurred in 1 patient (5%). A p-value of 0.268 indicated that the difference in incidence of postoperative myalgia was not

Heart rate in beats/minute	Group I (Mean±SD)	Group II (Mean±SD)	p-value
Hr_pre-intubation	73.15±3.33	73.35±3.03	0.844
Hr_1 min	74.65±3.50	85.30±5.16	<0.001
Hr_3 min	74.30±3.26	82.20±3.78	<0.001
Hr_5 min	73.50±3.14	79.15±3.90	<0.001

[Table/Fig-4]: Comparison of heart rate among the study groups.

MAP (mmHg)	Group I (Mean±SD)	Group II (Mean±SD)	p-value
MAP_pre-intubation	70.90±2.36	70.95±2.21	0.945
MAP_1 min	71.45±2.44	81.00±5.14	<0.001
MAP_3 min	71.20±2.61	78.45±4.29	<0.001
MAP_5 min	70.95±2.42	75.80±3.72	<0.001

[Table/Fig-5]: Comparison of mean arterial pressure (MAP) among the study groups.

Variables		Group I n (%)	Group II n (%)	Total	p-value
Fasci- culation	Mild	2 (10)	9 (45)	11	0.001
	Moderate	0	6 (30)	6	
	Severe	0	1 (5)	1	
	NIL	18 (90)	4 (20)	22	
Total		20 (100)	20 (100)	40	

[Table/Fig-6]: Comparison of incidence of fasciculations among the study groups.

statistically significant between the two groups. Among the patients of Group I, there was no incidence of postoperative myalgia after 24 hours. In Group II, mild myalgia occurred in 1 patient (5%), moderate myalgia occurred in 1 patient (5%), and there was no incidence of severe myalgia. With a p-value of 0.349, the difference in incidence of postoperative myalgia in the two groups was not determined to be statistically significant [Table/Fig-7]. No subject in present trial reported experiencing any negative effects after receiving the rocuronium pretreatment dose.

Variables	Group I n (%)	Group II n (%)	p-value
Myalgia			
Mild	1 (5)	4 (20)	0.268
Moderate	1 (5)	2 (10)	
Severe	0	1 (5)	
NIL	18 (90)	13 (65)	
Myalgia 24 hours			
Mild	0	1 (5)	0.349
Moderate	0	1 (5)	
Severe	0	0	
NIL	20 (100)	18 (90)	

[Table/Fig-7]: Comparison of incidence of myalgia among the two groups.

DISCUSSION

Because of its quick onset, superior muscular relaxation, suitability for intubation, and quick recovery profile, succinylcholine is one of the most often utilised muscle relaxants in clinical practice. Muscle fasciculation, hyperkalaemia, post-operative myalgia, elevated intraocular pressure, and elevated intracranial pressure are among the side effects of succinylcholine usage [10,11]. The goal of present study was to employ rocuronium to prevent or reduce the muscular fasciculations and postoperative myalgia brought on by succinylcholine.

In present trial, it was discovered that the group that received rocuronium prior to succinylcholine saw a significant decrease in both the occurrence and severity of fasciculations. The results of this investigation confirmed that rocuronium is effective at avoiding or decreasing succinyl choline-induced muscular fasciculations. In a study done by Senapati LK et al., [12], they compared the efficacy of 0.06 mg/kg rocuronium with 0.01 mg/kg vecuronium given 90 seconds prior to induction with propofol. They found that the group that received rocuronium saw a considerably lower incidence and intensity of fasciculations, making it a better agent than vecuronium for precurarisation. They also stated that due to its faster onset, rocuronium is able to produce good intubating conditions within 60 seconds. Similarly, Farhat K et al., [10] also reported lesser incidence and intensity of fasciculations after rocuronium pretreatment which supports these findings. This difference occurred because rocuronium inhibits the presynaptic nicotinic acetylcholine receptors, thereby preventing fasciculations. Rocuronium is efficacious as a precurarizing agent due to its short onset of action which makes it suitable for routine use. In contrast to present trial, Kim KN et al., [4] concluded that 0.04 mg/kg was optimal precurarisation dose of rocuronium which could be due to the reason that defasciculating dose of rocuronium was given after induction with propofol.

Although most of the studies had used 0.1 mg/kg dose of rocuronium [3,9,10,13] as precurarizing dose, precurarisation with 0.06 mg/kg rocuronium lowered the incidence of postoperative myalgia, however, the difference in myalgia between the two groups was not statistically significant in the present study (p-value >0.05). It could be due to the fact that patients might be under the effects of perioperative analgesics and were unable to differentiate myalgia separately.

The efficacy of this strategy depends on the dosage and the interval between the pretreatment and succinylcholine administration. There

should be no adverse effects like breathing difficulty, difficulty in swallowing, etc, and the pretreatment dosage should be effective. After a defasciculating dosage that is greater than 20% of the 95% effective dose, these possible adverse effects are typically seen. As a result, 10% of ED95 has been suggested as a safe and efficient pretreatment dosage [14], which was used in present study.

For many frequently used substances including atracurium and d-tubocurarine, an ideal pretreatment time of three minutes has been suggested [15]. However, such a lengthy wait is not only impractical due to the hectic operating room schedule, but it also exposes the awake patient to the potentially uncomfortable symptoms of breathing difficulty, muscular weakness, and difficulty swallowing. Rocuronium was administered 30 seconds before beginning propofol induction in the present trial in order to prevent these risks. In this study the mean time to administration of succinylcholine after study drug in Group I was 90.25 ± 7.11 seconds and in Group II it was 90.35 ± 5.71 seconds with a p-value of 0.961 and the difference was not significant.

In present trial, the group that received rocuronium experienced a lower incidence and severity of postoperative myalgia both immediately after surgery and 24 hours later; nevertheless, this difference was not statistically significant (p-values are 0.349 and 0.268). There is ongoing debate on the effectiveness of pretreatment in lowering postoperative myalgia. Some studies [5,9] demonstrated a pretreatment-related decrease in the incidence of postoperative myalgia, whilst other research did not demonstrate any relationship between pretreatment and the incidence of myalgia [16-18]. When compared to atracurium, Tsui BC et al [3] found that rocuronium pretreatment at a dosage of 0.1 mg/kg before propofol induction of anaesthesia more successfully reduces fasciculations and succinylcholine-induced myalgias. Findlay GP et al [9] compared rocuronium 6 mg and vecuronium 1 mg given 60 seconds before administration of succinylcholine and found that occurrence of post operative myalgia after rocuronium was significantly less than vecuronium on day 1 and day 4. In a similar study, Kim KN [4] evaluated the precurarizing dose of rocuronium. Doses of rocuronium used were 0.02, 0.03, 0.04, 0.05 and 0.06 mg/kg and patients received succinylcholine 1.5 mg/kg after 2 minutes of precurarisation. Severity and incidence of fasciculation was decreased with increasing rocuronium dose whereas myalgia did not change significantly. According to the study 0.04 mg/kg of rocuronium was optimal for precurarisation to reduce severity and incidence of fasciculation and myalgia.

The mean dose of propofol and fentanyl used was lesser in Group 1 and the difference was statistically significant. This could be attributed to the fact that we tend to give more of induction agents in case of patient showing moderate to severe fasciculation. At one, three, and five minutes, the mean heart rate increased to a greater extent in saline group than in rocuronium group, which was statistically significant. The mean arterial pressure in Group II was significantly higher at 1 minute, 3 minutes, and 5 minutes after intubation. In our study, patients of Group I had more stable haemodynamics. Gupta et al [19], found no significant change in MAP post intubation at 5 minutes as compared to pre-intubation MAP using rocuronium 0.06 mg/kg as pretreatment drug, although there was significant increase in mean heart rate at 5 minutes post intubation. They attributed this to vagolytic property of rocuronium.

The use of succinylcholine for muscle relaxation is associated with various adverse effects. Precurarizing doses of non depolarising muscle relaxants are used to reduce these side effects, however, these drugs are not free of side effects themselves. Non depolarising muscle relaxants can be associated with side effects like anaphylaxis, residual paralysis, increased pulmonary vascular resistance, difficulties swallowing, breathing, and muscle weakness [20]. Other adverse effects include sore throat, hoarseness, heavy eyelids, diplopia, allergy, and laryngospasm.

No subject in present trial reported experiencing any negative effects after receiving the rocuronium pretreatment dose. Contrary to present results, Martin R et al [7] reported ocular adverse effects in 90% of patients undergoing pretreatment. This might be because of the lengthy (4-minute) gap between the succinylcholine and rocuronium defasciculating dosage. Other researchers like Findlay GP and Spittal MJ [9] Kim KN et al., [4] Farhat K et al., [2] and Senapati LK et al., [12] who used rocuronium 0.06 mg/kg in their studies, did not report side effects.

Limitation(s)

Precurarisation with rocuronium can be done by using various doses like 0.02 mg/kg, 0.03 mg/kg, 0.04 mg/kg, 0.05 mg/kg however the present trial was limited to use of single dose of 0.06 mg/kg. Various time intervals between administration of rocuronium and succinylcholine have been described, but in the present trial succinylcholine was administered around 30 seconds after pretreatment with rocuronium. Since, present trial was a single centre study, there was limited generalisability of the results.

CONCLUSION(S)

When rocuronium was administered at a dosage of 0.06 mg/kg 30 seconds before propofol induction, fasciculations caused by succinylcholine were avoided with more stable haemodynamics. Side effects associated with precurarisation were avoided by using adequate dose and a shorter interval between rocuronium and propofol (30 seconds). Hence, rocuronium 0.06 mg/kg could be used effectively and safely as a precurarisation drug 30 seconds before induction.

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