A Randomized, Comparative Study of Intubating Conditions and Duration of Action of Three Different Doses of Rocuronium Bromide 0.6, 0.9 And 1.2 Mg/Kg Body Weight

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Abstract

Background: Rocuronium is a monoquaternary amino steroid nondepolarizing neuromuscular blocking drug with rapid onset, intermediate duration of action and widely used when succinylcholine is considered undesirable or contraindicated for rapid sequence intubation.

The current study aims to compare three multiples of ED95 doses of rocuronium 2xED95(0.6mg/kg), 3x ED95(0.9 mg/kg) and 4x ED95 (1.2mg/kg) in terms of their intubating conditions at the end of 60 sec and their duration of action in patients undergoing elective surgeries under general anaesthesia. **Methodology:** After our Hospital Research and Ethics Committee approval and obtaining informed written consent, 90 ASA physical status I or II patients scheduled for elective surgeries under general anesthesia were included in this prospective, randomized, comparative study. The patients were randomly assigned into three groups of 30 patients each, to receive one of the three doses 0.6 mg/kg, 0.9 mg/kg or 1.2 mg/kg of rocuronium. Intubation was performed 60 sec later and intubating conditions were assessed using coopers scoring system including the parameters jaw relaxation, vocal cord condition and response to intubation. In addition vocal cord position and movement of limbs during intubation were also assessed. Continuous TOF monitoring is initiated after induction and the time to recovery of 25% of first twitch of TOF is determined to be the duration of action of the induction dose of rocuronium. Patients were monitored throughout the procedure for any adverse effects. **Results:** The three groups had similar demographics in terms of age, gender, weight, ASA grade and MMP grade .The intubating conditions in group A (0.6 mg/kg) were excellent in 63.3%,good in 30 %, unacceptable in 6.7 %.The intubating conditions in group B (0.9 mg/kg) were excellent in 86.7%,good in 13.3 %.The intubating conditions in group C (1.2mg/kg) were excellent in 93.3 % and good in 6.7 %.Jaw Relaxation was similar in group B (90 % excellent, 10 % good) and C (93.3% excellent ,6.7% good) with no statistically significant difference. Group A showed 63.3 % excellent, 33.3%good and 3.3% fair relaxation .Vocal cord position observed was similar in Group B and C with

93.3% in abducted position and 6.7% in intermediate position .In Group A cords were in intermediate position in 13.3% and abducted in the rest. Movement of limbs : 90 % in group A had no movement where as 10 % showed slight movement of limbs. In group B, 93.3% had no movement and 6.7 % had slight movement. Group C showed no movement of limbs. Group B and Group C showed no significant difference with respect to vocal cord position and movement of limbs. These finding correlated as well with findings of coopers criteria. There is no statistically significant difference observed with respect to movement of limbs among group A and B as well. The duration of action determined in the study was Group A : 32.97±4.57 min,Group B : 45.27±8.57 min,Group C : 63.27±7.01 min **Conclusion:** Rocuronium 0.9 mg/ kg and 1.2 mg/kg provided acceptable intubating conditions at the end of 60 sec in all cases.Duration of action increases significantly as the dose increases .1.2 mg/kg achieved best intubating conditions compared to 0.6 mg/kg and 0.9 mg/kg .Increasing the dose of rocuronium to 1.2 mg/kg did not produce any adverse effects

Introduction: Endotracheal intubation has become an integral part of balanced anaesthesia since its introduction by Ivan. W. Magill and Rowbotham in 1921 during the World War I [(1)]. Patients requiring emergency endotracheal intubation are at risk of regurgitation and aspiration and hence often require a rapid sequence induction (RSI) intubation technique. This necessitates the use of an induction agent and rapidly acting neuromuscular blocker given in rapid succession. The ideal neuromuscular blocking agent for rapid sequence induction should have a faster onset of action, brief duration of action, provide profound relaxation and be free from haemodynamic changes.[2,3] Historically succinylcholine is the relaxant of choice[3)].Rocuronium bromide provides clinically acceptable intubating conditions within 60-90 s in dose range of 0.6-1.2 mg/kg[4] but large doses unduly prolong its duration of action, making it unsuitable for short surgical procedures. Some studies have shown that 3x ED 95 dose provides excellent intubating conditions at 60 seconds[5].

In this context, three multiples of ED 95% dose of rocuronium were studied and intubating conditions of each dose were observed to determine the dose that provides optimum intubating conditions and its duration of action determined.

Methods

Ninety patients after obtaining institutional ethical committe both male and female belonging to ASA I and II, aged between 18-60 years with no anticipated difficult intubation will be divided into three groups randomly according to randomized table. Group A would receive 0.6 mg/kg (n=30), group B would receive 0.9mg/kg(n=30) and group C would receive 1.2 mg/kg (n=30) of rocuronium bromide. All patients will be visited on the day prior to surgery and explained in detail regarding anesthetic procedure. An informed and written consent is obtained. A detailed pre-anesthetic evaluation will be done including history and general examination. All patients will receive Tab. Alprazolam 0.5mg and Tab. Ranitidine 150mg on the previous night and will be kept nil per oral from 10pm onwards. Patient will be shifted to OT. An IV line will be secured with 18 gauge vasofix; a slow infusion of lactated Ringer's solution will be started. Airway cart will be kept ready. The patients will be connected to the monitors and the pre-induction systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR) and oxygen saturation (SpO_2) are recorded. All patients will be given Inj. Glycopyrolate 0.01mg/kg, Inj. Midazolam 0.02mg/kg, and Inj. Fentanyl 1- 2 mcg/kg. After preoxygenation of the patient for three minutes; anesthesia will be induced with InjPropofol 2 mg/kg. On loss of verbal contact, assuring facemask ventilation was possible, the patient will be given intravenous rocuronium in a dose of 0.6,0.9 or 1.2mg/kg (in group A, group B and group C respectively), diluted in normal saline solution to a total volume of 10 ml. Thirty patients would receive each dose of rocuronium. At 60s

after i.v. administration of rocuronium, laryngoscopy is initiated. Anesthesia was then maintained with N2O andO2 with Isoflurane depending upon the need and depth of anesthesia for surgery. Neuromuscular monitoring is done using a peripheral nerve stimulator by stimulating the ulnar nerve at the wrist via surface electrodes placed along the course of the nerve. Before induction of anesthesia, surface electrodes will be placed over the ulnar nerve at the wrist. When the patient lost consciousness, train of four (TOF) stimulation (at 2 Hz and repeated every 12s) will be recorded. Continuous TOF monitoring is done until 25 % recovery of first twitch of TOF. Intubating conditions will be graded excellent, good, or poor according to coopers scoring system criteria. The duration of action of rocuronium will be defined as the time from the end of injection of rocuronium until 25 % recovery of first twitch of TOF.

Statistical Analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients, and Post-hoc test (Pair wise significance) by Tukey test.Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Suggestive significance (P value: $0.05<P<0.10$), Moderately significant (P value:$0.01<P \leq 0.05$), Strongly significant (P value: $P \leq 0.01$). The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Study design: A Prospective, randomized, Comparative three group observational clinical study

Results

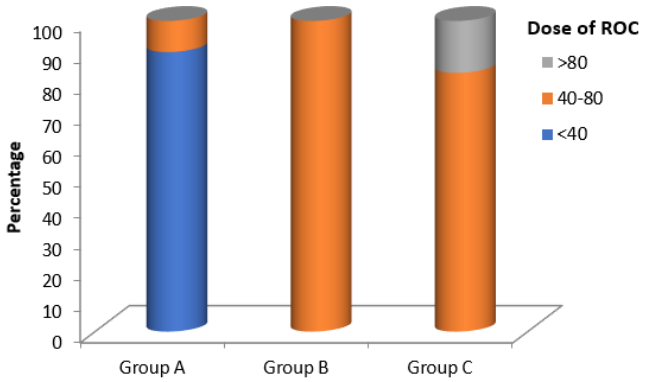
The demographic profile of patients was comparable in all the groups.

Samples are age matched with P=0.252. As the P value is greater than 0.05, there is no significant gender difference among the three groups. There is no significant weight difference among the three groups as the p 0.09. There is no significant difference in terms of ASA grade distribution among the three groups as the p value 0.679. MPG distribution in three groups of patients studied was not significant with p value of 0.873

Table 1: Dose of Rocuronium(ROC) distribution in three groups of patients studied

Dose of ROC	Group A	Group B	Group C	Total
<40	27(90%)	0(0%)	0(0%)	27(30%)
40-80	3(10%)	30(100%)	25(83.3%)	58(64.4%)
>80	0(0%)	0(0%)	5(16.7%)	5(5.6%)
Total	30(100%)	30(100%)	30(100%)	90(100%)

P<0.001*, significant, Fisher Exact test



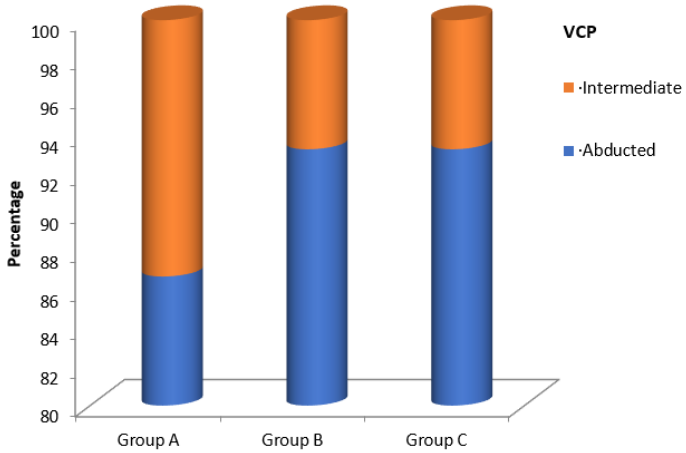
Graph 1: Dose of ROC distribution in three groups of patients studied

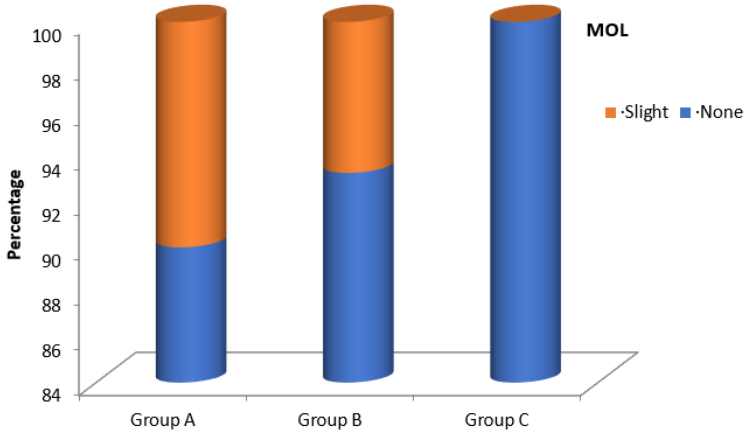
Table 2: VCP/MOL distribution in three groups of patients studied

	Group A (n=30)	**Group B (n=30)**	**Group C (n=30)**	**Total (n=90)**	**P value**
Vocal cord position(VCL)					
• Abducted	19(86.7%)	28(93.3%)	28(93.3%)	82(91.1%)	0.002**
• Intermediate	11(13.3%)	2(6.7%)	2(6.7%)	8(8.9%)	
Movement of limbs(MOL)					
• None	24(90%)	28(93.3%)	30(100%)	85(94.4%)	0.021*
• Slight	6(10%)	2(6.7%)	0(0%)	5(5.6%)	

Chi-Square test/Fisher Exact test
Vocal cord position: A vs B- P=0.005**; A vs C-P=0.005** and B vs C-P=1.000
Movement of limbs::A vs B- P=0.129; A vs C-P=0.010** and B vs C-P=0.150

There is no significant difference between group B and C with respect to VCP and MOL as the p value is 1 and.15 respectively.
Group A and B showed no significant difference regarding MOL.





Graph 2: VCP/MOL distribution in three groups of patients studied

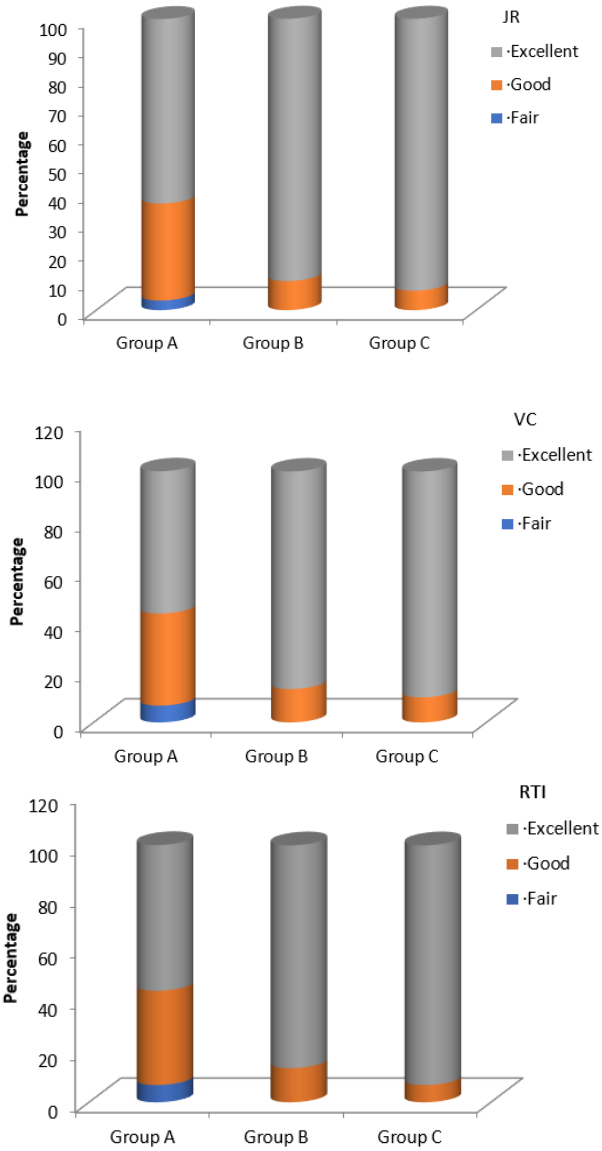
Table 3: Cooper's criteria distribution in three groups of patients studied

Cooper`s criteria	Group A (n=30)	Group B (n=30)	Group C (n=30)	Total (n=90)	P value
Jaw relaxation(JR)					
• Fair	1(3.3%)	0(0%)	0(0%)	1(1.1%)	0.010**
• Good	10(33.3%)	3(10%)	2(6.7%)	15(16.7%)	
• Excellent	19(63.3%)	27(90%)	28(93.3%)	74(82.2%)	
Vocal cords(VC)					
• Fair	2(6.7%)	0(0%)	0(0%)	2(2.2%)	0.011*
• Good	11(36.7%)	4(13.3%)	3(10%)	18(20%)	
• Excellent	17(56.7%)	26(86.7%)	27(90%)	70(77.8%)	
Response to intubation(RTI)					
• Fair	2(6.7%)	0(0%)	0(0%)	1(1.1%)	0.155
• Good	11(36.7%)	4(13.3%)	2(6.7%)	13(14.4%)	
• Excellent	17(56.7%)	26(86.7%)	28(93.3%)	76(84.4%)	

Chi-Square test/Fisher Exact test

JR	VS	RTI
A-B:P=0.030*	A-B:P=0.025*	A-B:P=0.025*
A-C:P=0.010**	A-C:P=0.009**	A-C:P=0.003**
B-C:P=1.000	B-C:P=1.000	B-C:P=0.671

There is significant statistical difference between groups A and B, and groups A and C, whereas groups B and C did not show any significant statistical difference according to the p value.

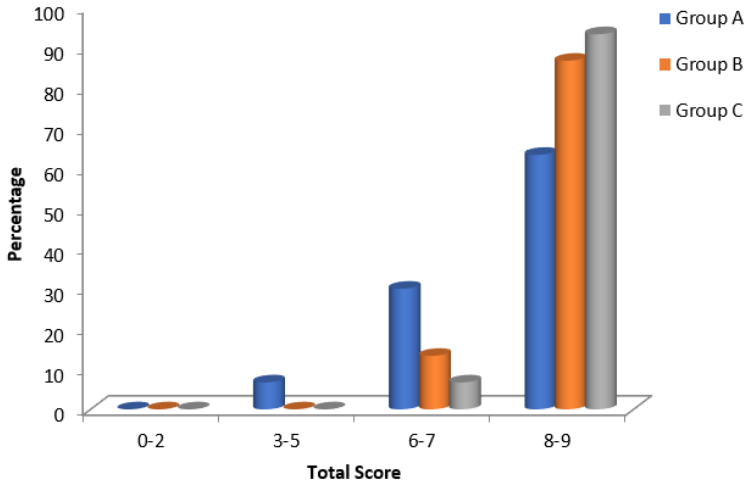


Graph 3: Cooper's criteria distribution in three groups of patients studied

Table 4: Total Score for COOPERS CRITERIA

Total Score	Group A	Group B	Group C	Total
0-2	0(0%)	0(0%)	0(0%)	0(0%)
3-5	2(6.7%)	0(0%)	0(0%)	2(2.2%)
6-7	9(30%)	4(13.3%)	2(6.7%)	15(16.7%)
8-9	19(63.3%)	26(86.7%)	28(93.3%)	73(81.1%)
Total	30(100%)	30(100%)	30(100%)	90(100%)

P=0.023*, significant, Fisher Exact test
A-B:P=0.087+
A-C:P=0.012*
B-C:P=0.671
Group B and C did not show any significant statistical difference as the p value is 0.671.. Comparision between A and B might suggest significance.

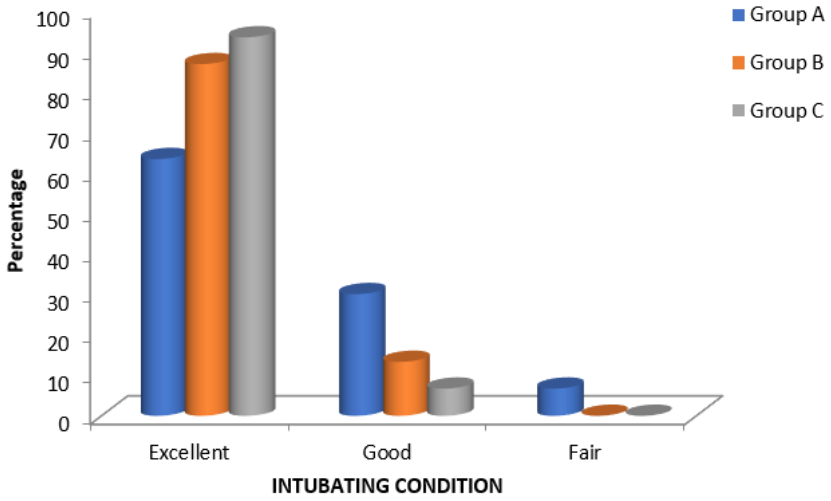


Graph 5: Total Score for COOPERS CRITERIA

Table 6: INTUBATING CONDITION distribution in three groups of patients studied

INTUBATING CONDITION	Group A	Group B	Group C	Total
Excellent	19(63.3%)	26(86.7%)	28(93.3%)	73(81.1%)
Good	9(30%)	4(13.3%)	2(6.7%)	15(16.7%)
Fair	2(6.7%)	0(0%)	0(0%)	2(2.2%)
Total	30(100%)	30(100%)	30(100%)	90(100%)

P=0.023*, significant, Fisher Exact test
A vs B-P=0.087+
A vs C-P=0.012* and
B vs C-P=0.671
Group B and C did not show any significant statistical difference as the p value is 0.671. Comparision between A and B might suggest significance.



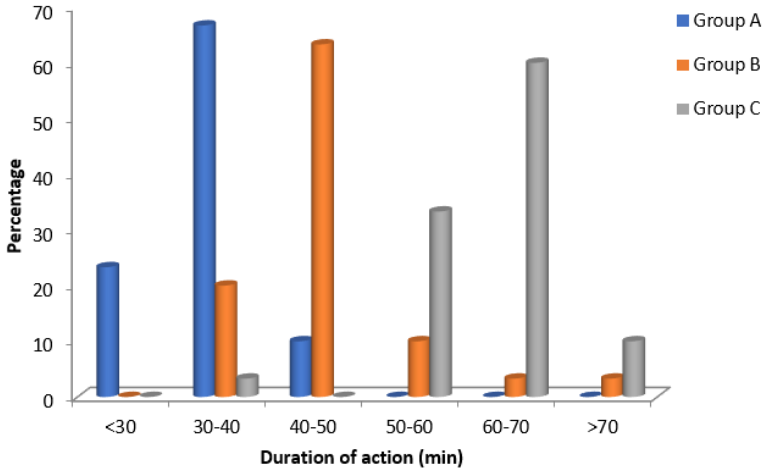
Graph 6: INTUBATING CONDITION distribution in three groups of patients studied

Table 7: duration of action (min) distribution in three groups of patients studied

Duration of action (min)	Group A	Group B	Group C	Total
<30	7(23.3%)	0(0%)	0(0%)	7(7.8%)
30-40	20(66.7%)	6(20%)	1(3.3%)	27(30%)

40-50	3(10%)	19(63.3%)	0(0%)	22(24.4%)
50-60	0(0%)	3(10%)	10(33.3%)	13(14.4%)
60-70	0(0%)	1(3.3%)	18(60%)	19(21.1%)
>70	0(0%)	1(3.3%)	3(10%)	4(4.4%)
Total	30(100%)	30(100%)	30(100%)	90(100%)

P<0.001**, significant, Fisher Exact test

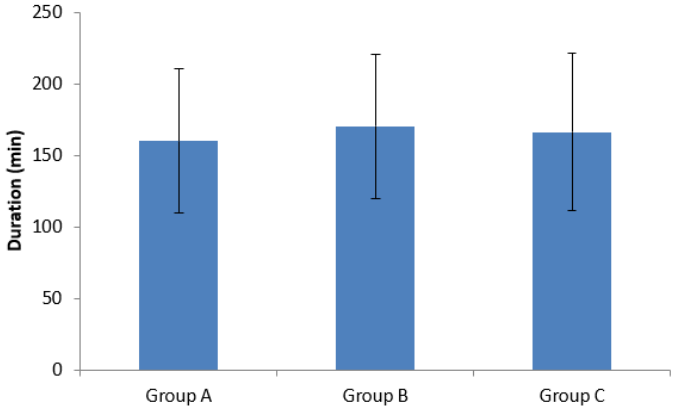


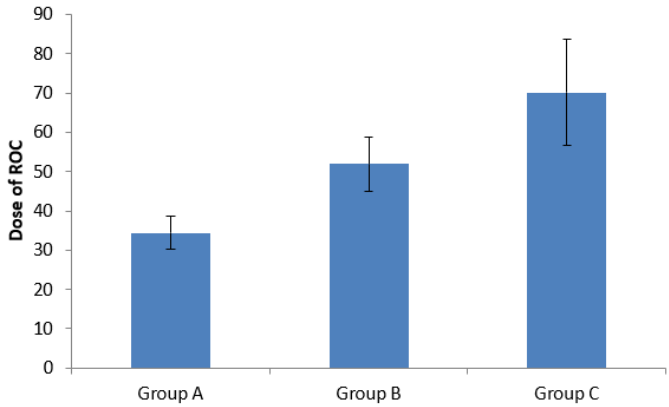
Graph 7: duration of action (min) distribution in three groups of patients studied

Table 8: Comparison of study variables in three groups studied

variables	Group A	Group B	Group C	Total	P value
Duration (min)	160.33±50.80	170.50±50.45	166.33±55.15	165.72±51.76	0.751
Dose of ROC	34.44±4.13	51.90±6.84	70.07±13.54	52.14±17.16	<0.001**

ANOVA test





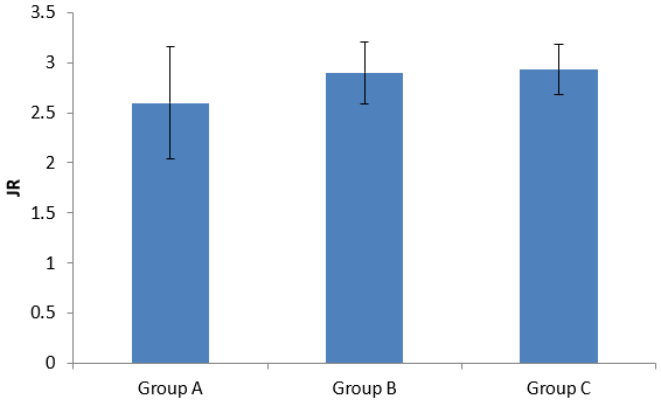
Graph 8: Comparison of study variables in three groups studied

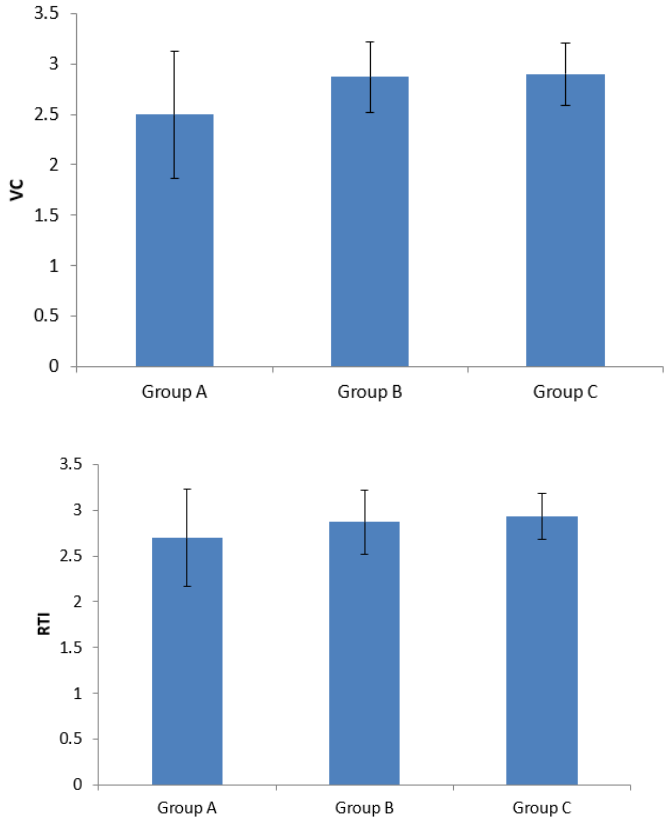
Table 9: Comparison of study variables in three groups studied

variables	Results				Overall P value	Pair wise significance		
	Group A	Group B	Group C	Total		A vs B	A vs C	B vs C
JR	2.60±0.56	2.90±0.31	2.93±0.25	2.81±0.42	0.003**	0.012*	0.005**	0.944
VC	2.50±0.63	2.87±0.35	2.90±0.31	2.76±0.48	0.001**	0.006**	0.003**	0.956
RTI	2.70±0.53	2.87±0.35	2.93±0.25	2.83±0.40	0.068+	0.238	0.064+	0.792
Total Score	7.77±1.41	8.60±0.81	8.77±0.68	8.38±1.10	<0.001**	0.006**	0.001**	0.801
Duration of action	32.97±4.57	45.27±8.57	63.27±7.01	47.17±14.26	<0.001**	<0.001**	<0.001**	<0.001**

ANOVA test, Pair wise significance by Post-Hoc Tukey test

Groups B and C did not show significant statistical difference. RTI is also not statistically significant among A-B and B-C.There is significant difference in duration of action among the three groups.





Graph 9: Comparison of study variables in three groups studied

Discussion

Anesthesiologists are in quest for NDMRs having ideal neuromuscular blocking properties with rapid onset of action and offering good to excellent intubation conditions without any significant adverse effects. Rocuronium has got intermediate duration of action with a rapid onset of action and is devoid of clinically significant cardiovascular side effects at effective neuromuscular blocking doses. Previous studies determined that Rocuronium 0.6 mg/kg (2 *ED 95) was found to have an onset of action of 60-90 s at the adductor pollicis muscle. At this dose, the block produced by rocuronium was not quite as predictable as succinyl choline. The range of effect was greater if the dose is doubled to 1.2 mg/kg, intubating conditions were very similar to those produced by succinyl choline 1mg/kg but large doses unduly prolong its duration of action, making it unsuitable for short surgical procedures[6].Larger doses of rocuronium (> or = 1 mg/kg) seem to be suitable for rapid-sequence induction under relatively light anaesthesia[7,8]. However, it is still a matter of controversy whether, in the case of an unanticipated difficult intubation, the long duration of rocuronium administered in such large doses outweighs the many adverse effects of succinylcholine. In view of diverse conclusions obtained from the previous studies, present study aim was to observe the difference in intubating conditions at the end of 60 sec using the three multiples of ED 95 dose of rocuronium 0.6 mg/kg (2 times ED), 0.9 mg/kg of rocuronium (3 times ED 95) and 1.2 mg / kg rocuronium (4 times ED 95). 0.6 mg/kg dose is widely used in numerous studies and was found to produce acceptable intubating conditions in most of the patients and onset of action was determined to be between 60-90 sec **The choice and doses of the induction agents used also influences the onset of neuromuscular blockade and the ease of intubation[9]. Propofol was used for induction in the studies performed by Andrews JI et al [11] and Woolf RL et al[12]**.

The choice of induction agent may influence the rate of onset of satisfactory intubating conditions as determined by Fuchs-Buder T[9], Sparr HJ[5,6]. Propofol is known to depress laryngeal reflexes and may therefore be a more appropriate induction agent[13]...Excellent intubating conditions with excellent jaw relaxation, open vocal cords and no response to intubation were observed in 63.3 % patients in Group A (0.6mg/kg).Good intubating conditions with moderate jaw relaxation, moving vocal cords, and slight diaphragmatic movement in response to intubation were observed in 30 % of the patients in 0.6 mg/kg group. 6.7 % patients had unacceptable intubating conditions with difficult jaw relaxation, closing vocal cords and mild coughing in response to intubation, which are not considered to be acceptable intubating conditions. no cases of poor intubating conditions or failed intubation were observed. In group B (0.9 mg/kg) excellent intubating conditions were observed in 86.7 % of patients studied and good intubating conditions which are considered acceptable for intubation were observed in 13.3 % of patients. There were no cases of fair, poor or failed intubation observed with this dosage. Group C (1.2 mg / kg) showed 93.3 % of excellent intubating conditions and 6.7 % of good intubating conditions. There were no cases of fair, poor or failed intubation observed with this dosage. Overall acceptable intubating conditions (excellent and good) were observed in 93.3% patients in group A, 100% in group B and 100 % in group C, with group B and group C showing no statistically significant difference among the two.The duration of action defined as the return of 25% of the height of the first twitch determined by continuous TOF monitoring was found to be 32.97 ± 4.57 in group a, 45.27 ± 8.57 in group b and 63.27 ± 7.01 in group c which showed highly significant statistical difference.

Dr Chanda Khatri et al (2016)[14], compared Onset, Duration of Action and Intubating Conditions of Three Dosages 0.3 mg/kg, 0.6 mg/kg, 0.9 mg/kg of Rocuronium Bromide in 60 patients. Jaw Relaxation, Cord Relaxation, Reaction to Intubation were considered for evaluating intubating conditions, which are similar in the present study. they have observed that jaw relaxation was 100 % in 0.6 mg/kg group and 0.9 mg/kg group. cord relaxation was excellent in 55% of patients in 0.6 mg/kg group and 85% in 0.9 mg/kg group.

.A study was conducted by Heggeri VM et al[15], (2015) aiming at comparing intubating conditions with 0.6 mg/kg and 0.9 mg/kg of rocuronium, using clinical criteria by cooper's score; assisted with adductor pollicis T.O.F response. They observed that 3XED95 [0.9mg/kg] dose of Rocuronium achieves more intense neuro muscular blockade, more smooth and acceptable intubating conditions at 60 seconds than 2XED95 [0.6mg/kg]dose. Kirkegaard – Nielsen et al (1999)[16] studied rapid tracheal intubation with rocuronium bromide aimed to predict the dose of the drug giving90% and 95% probability of intubation within 60 s and to estimate their durations of actions. The doses employed were 0.0, 0.4, 0.8, 1.2mg (n=20/dose) and they concluded that the D90 and D95 doses were 0.83 and 1.04 respectively and estimated time until first tactile train of four responses were 32 and 46 min respectively.

In a study conducted by Pino and M. Richard et al[17], it was determined Intubation conditions were good or excellent for both mivacurium and rocuronium at 0.9 mg/kg dose and at 1.2mg/kg dose (100%). They concluded that mivacurium in a 0.25 mg/kg divided dose and rocuronium at 0.9 mg/kg and 1.2mg/kg provide good or excellent intubation conditions at 90 s in most patients. Rocuronium was faster in onset at higher doses (0.9 and 1.2 mg/kg but had more prolonged recovery times to 25% single twitch height(6)

Conclusion

- -*Rocuronium 0.6 mg/kg did not produce acceptable intubating conditions in all the cases.

- Both rocuronium 0.9 mg/ kg and 1.2 mg/kg provided acceptable intubating conditions at the end of 60 sec in all cases.
- Duration of action increases significantly as the dose increases.
- If excellent intubating conditions are considered, 1.2 mg/kg achieved best intubating conditions compared to 0.6 mg/kg and 0.9 mg/kg.
- Increasing the dose of rocuronium to 1.2 mg/kg did not produce any adverse effects.

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