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Comparison of 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

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Abstract: ***Background: The aim of this prospective, randomized, double blind study was to assess and compare the time of onset, duration of action and intubating conditions with three different doses of rocuronium bromide (0.3 mg/kg, 0.6 mg/kg, 0.9 mg/kg). Methods: The anaesthesia was induced with sleeping dose of thiopentone sodium (till eyelash reflex lost) I.V. After 30sec, non-depolarizing muscle relaxant rocuronium bromide was administrated intravenously. Patients were randomly allocated to three groups according to dose of Rocuronium (0.3 mg/kg, 0.6 mg/kg and 0.9 mg/kg). Jaw relaxation, cord relaxation, motor response to intubation and overall intubating conditions were assessed. Results: Excellent intubating conditions were seen in 0%, 60% and 85% of the patients after 0.3 mg/kg, 0.6 mg/kg, 0.9 mg/kg of Rocuronium respectively: P<0.001. Onset of action and duration of action were dose dependant. Conclusion: rocuronium bromide in a dose of 0.9 mg/kg IV has rapid onset of action, longer duration of action and excellent intubating conditions in comparison to 0.6 mg/kg and 0.3 mg/kg dose at 60 seconds. So it can be used in intubation for surgery longer than one hour duration. Rocuronium in a dose of 0.6 mg/kg IV having acceptable intubating conditions, onset time, and short duration of action than 0.9 mg/kg dose, can be used for intubation if duration of surgery is less than one hour. Rocuronium in a dose of 0.3 mg/kg cannot be accepted as intubating dose because of unfavorable intubating conditions and prolonged onset of action.***

Keywords: Anesthesia, Intubation conditions, onset of action, Duration of action, Rocuronium

1. Introduction

Modern use of neuromuscular blocking drugs dated from 1932, when purified fractions of d-Tubocurarine (dTc) were administered to control skeletal muscle spasm in patient with tetanus. In 1940 dTc was used as an adjuvant to drug induced electroshock therapy. The first use of dTc to produce muscle relaxation during general anaesthesia was reported in 1942 (Griffith and Johnson 1942).

The neuromuscular blocking effects of Suxamethonium were described by Bovet and co-workers in 1949. Suxamethonium is considered as a agent of choice for endotracheal intubation because of its unequalled speed of onset, short duration of action and profound relaxation, but it has some side effects like potassium release, elevated intraocular and intra gastric pressure, post anaesthesia myalgia, myoglobinuria and myotonic reaction.

For these and other reasons, the search for an alternative drug to Suxamethonium or an alternative method of using the non-depolarizing neuromuscular blocking agent for use in rapid sequence induction technique has been sought [1]-[3]

With the introduction of rocuronium in 1990s; a steroidal non-depolarizing agent with a quick onset and intermediate duration of action, almost all the disadvantages of suxamethonium and vecuronium are claimed to be eliminated. Rocuronium has 1/6th of potency of vecuronium and is extremely cardio stable and has a rapid onset of action; which would render it ideal for facilitation of both routine and crash induction[4].

ED95 of rocuronium is 0.3mg/kg. Traditionally doses used to facilitate tracheal intubation are 2 x ED95. Increasing the dose of rocuronium from 0.6 to 1.2mg/kg shortened the onset time of complete neuromuscular blockade, but significantly prolonged the clinical duration, when the dose of rocuronium reduced to 0.25 to 0.5 mg/kg, its onset time is still shortest (1.5 min) among all the non depolarizing neuromuscular blocking drugs presently available when used in equipotent doses.

The present study was undertaken to compare the onset, duration of action and intubating condition of three dosages 0.3mg/kg, 0.6mg/kg, 0.9mg/kg of Rocuronium bromide.

2. Method

This study was approved by the hospital ethics committee and written consent taken from all patients. 60 patients of either sex in the age group 18-50 years undergoing elective surgery under general anaesthesia and requiring at least 45-60 minutes for surgical procedure, were included in this study. Patient with serious, potentially life threatening disease, that are not optimally managed (ASA grade III & IV), Obvious anatomical contraindication to tracheal intubation (mallampati scoring III & IV), previous history of difficult intubation, those with irritable upper airway, patients having disorder of CVS, neuromuscular junction and myopathies and patients taking drugs which have interaction with rocuronium were excluded from study. Pre-

anaesthetic assessment included a detailed history taking, physical examination and necessary investigations like CBC, B. Urea and S. Creatinine, Liver Function Test, Chest X-ray and ECG. Patients were kept on overnight fasting.

Using a computer generated sequence of random numbers and sealed envelop technique, patient allocated in three groups (0.3mg/kg in group I, 0.6mg/kg in group II and 0.9mg/kg in group III), which were opened by an investigator not involved with data collection.

After proper counselling and informed consent, the patient was taken for anaesthesia. Intravenous line was secured and infusion of 5% dextrose was started. Monitor for SPO2, ECG, NIBP was applied. Baseline heart rates, systolic/ diastolic BP, respiratory rate, SPO2 were noted. Pre medication was done by injection Glycopyrrolate 0.005mg/kg, injection tramadol 2mg/kg, injection midazolam 0.05mg/kg I.V. Then patient was pre oxygenated for 3min. The anaesthesia was induced with sleeping dose of thiopentone sodium (till eyelash reflex lost) I.V. After 30sec, non-depolarizing muscle relaxant (rocuronium bromide) calculated according to body weight (0.3mg/kg in group I, 0.6mg/kg in group II and 0.9mg/kg in group III) was administrated intravenously. Patient was ventilated with 100% Oxygen on Bain circuit. Time of onset of apnoea in seconds was recorded as onset time. Endotracheal intubation was done by a senior faculty member. Endotracheal intubation was attempted at 60sec. using cuffed endotracheal tube of appropriate size. Jaw relaxation, cord relaxation, motor response to intubation and overall intubting conditions were assessed according to scheme proposed by lund and stovner and was recorded in proforma at the same time. Endotracheal tube was secured in position after auscultation. The patients in which intubation was not possible at 60 seconds, were ventilated with bag and mask and intubated after full relaxation.

Details of three facets of intubation are:

1) **Jaw Relaxation: Good** : complete opening: **Fair** :Partial opening; **Poor** : No opening or very slight opening
2) **Cord Relaxation: Good** : wide abduction; **Fair** : gentle pressure required to pass the tube Slight: almost adducted; **Poor** : cords opposed, firm pressure required to pass the tube.
3) **Reaction to Intubation: Nil** : no movement or bucking; **Slight**: only slight bucking after insertion of tube; **Marked:** marked bucking and gross movement of the limbs.

Overall grading of intubation condition: Grade I: excellent-- Cords are abducted, not moving, easy passage of tube without bucking. **Grade II**: **satisfactory**-- Slight movements of the cords when touched, passage of the tube with coughing or bucking or both;. **Grade III: poor**-- Passage of the tube with moderate coughing or bucking or both. **Grade IV: Impossible**--Intubation not possible.

Anaesthesia was maintained with Oxygen and nitrous oxide in a ratio of 40:60 with halothane 0.6-0.8%. Supplementary doses of non-depolarizing muscle relaxant (rocuronium bromide) was given as and when required. Pre-induction, after induction, 5, 10, 15 minutes after intubation vitals were recorded. Then through out operation vitals were recorded every 15 minutes. Time of onset of respiration after neuromuscular blockade was considered as clinical duration of action and recorded.

At the completion of surgery the patients were reversed with neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg. A thorough endotracheal and oropharyngeal suction was done. After patients eye opening on verbal command and assessing patient's respiration, extubation was done. Adequacy of reversal was determined by head lifting test.

3. Statistics

Statistical t test is used to judge significance of difference between different values (time of onset, duration of action, changes in heart rate and B.P. etc.) due to change in dose of rocuronium. Following formula is used for computation of t:

$$t_{(x1-x2)} = X_1 - X_2 \Big/ \sqrt{\frac{(SD1)2}{n1} + \frac{(SD2)2}{n2}}$$

Where X = mean
S.D. = Standard deviation n = number of patients in each group
Critical values of t at 5% and 1% level of significance taken from statistical tables.
Comment on results: If computed value of t is greater than critical value of t at 5%, difference is considered to be significant(S) and if greater than critical value of t at 1%, difference is considered to be highly significant (H.S.). While if computed value of t is lesser than critical value of t at 5%, difference is considered to be non significant(N.S.) In our study number of patients in each group is 20(n=20) critical value of t at 5% is 2.093 and at 1% is 1.973.

4. Results

60 patients were enrolled in study, 20 in each group. There was no significant difference in patient characteristics in three groups. Jaw relaxation was good in only 5% in group I while all 100% patients showed good relaxation in group II and III (Table 1). Cord relaxation was good in none of the group I pts, while group II showed good in 55% cases and in group III, good in 85% cases.(Table 1). Reaction to intubation was marked in 100% cases in group I, in group II nil in 55% and group III, nil in 85% cases(Table 1).

Table 1: Jaw and cord relaxation and reaction to intubation in three groups

S. No.			Group I (0.3 mg/kg)	Group II (0.6 mg/kg)	Group III (0.9 mg/kg)
1	Jaw relaxation	Good	1(5%)	20(100%)	20(100%)
		Fair	5(25%)	-	-
		Poor	14(70%)	-	-
2	Cord relaxation	Good	-	11(55%)	17(85%)
		Fair	1(5%)	9(45%)	3(15%)
		Slight	4(20%)	-	-
		Poor	15(75%)	-	-
3	Reaction to intubation	Nil	-	11(55%)	17(85%)
		Slight	-	9(45%)	3(15%)
		Poor	20(100%)	-	-

In group I intubating conditions at 60 seconds were poor in 65% patients and intubation was impossible in 35%. In group II intubating conditions were excellent in 60%, and satisfactory in 40%. In group III intubating conditions were excellent in 85% and satisfactory in 15% (Table 2). In our study there is no significant differences in intubating condition in males and females in all three groups.

Table 2: Distribution of overall grading of intubation conditions according to the group.

S. No.	*Grading of Intubation condition*	*Groups*		
		I (0.3mg/kg)	*II (0.6mg/kg)*	*III (0.9mg/kg)*
1	I Excellent	-	12 (60%)	17 (85%)
2	II Satisfactory	-	08 (40%)	03 (15%)
3	III Poor	13 (65%)	-	-
4	IV Impossiable	07 (35%)	-	-
5	Total	20	20	20

In our study onset of apnoea is considered as onset of action of rocuronium. Time of onset of action was 125±19.9, 65.8±10.24 and 49.4±6.9 seconds in group I,II and III respectively(Table 8). In our study there was no significant difference (p>0.05)in onset of action between male and female in all three groups.

In our study clinical duration of action was 16±2.6 minutes, 30.55±4.32 minutes and 40.45±5.08 minutes with 0.3 mg/kg, 0.6 mg/kg and 0.9 mg/kg rocuronium respectively (Table 3),

Table 3A: Time of onset and duration of action in three groups

S.No.	Group	No. of pts.	Times of onset of action (Mean±SD) in seconds	Duration of action (Mean±SD) in seconds
1	I (0.3 mg/kg)	20	125±19.9	16±2.6
2	II (0.6 mg/kg)	20	65.8±10.24	30.55±4.32
3	III (0.9 mg/kg)	20	49.4±6.9	40.45±5.08

Table 3B: Statistcal significance for time of onset and duration of action between three groups

Comparison between groups	Critical t at 5%	Computed t for time of onset	Significance for time of onset	Computed t for duration of action	Significance for duration of action
Group I & II	2.093	7.006	**S**	12.91	**S**
I & III	2.093	16.08	**S**	19.16	**S**
II & III	2.093	5.94	**S**	6.64	**S**

In our study there was no significant difference (p>0.05) in duration of action between male and female in all three groups.

In the present study the hemodynamic parameters compared were heart rate, mean arterial blood pressure (MAP) after intubation. Vital parameters were recorded preoperatively, after induction, after intubation and 5min, 10min, 15min after intubation. (Table 4).

Table 4: Hemodynamic parameters in three groups with time

S.No	**Time**	**Heart Rate**			**MAP**		
		Gp I	**Gp II**	**Gp III**	**Gp I**	**Gp II**	**Gp III**
1	**Pre-induction**	81.9±7.45	82.1±8.24	82±8	96.6±7.38	96.83±9.61	97.64±10.54
2	**After induction**	87.4±4.99	86.3±7.24	84.5±7.43	95.46±6.05	95.33±8.47	96.4±9.02
3	**After intubation**	91.9±5.41	90±6.58	87±6.67	108.8±4.42	97.76±7.23	101.63±9.04
4	**5min After intubation**	87±3.75	85.7±5.92	85.7±7.9	99.2±6.76	96.29±8.33	100.05±9.13
5	**10 min After intubation**	85±5.82	84.1±6.97	83.8±8.08	101.1±4.84	94.2±8.37	97.4±9.31
6	**15 min After intubation**	84.496	83±5.94	82.2±7.05	97.26±6.39	88.4±9.32	96.79±9.57

Statistically in group I changes in heart rate are significant after induction (p<0.05), highly significant (p<0.01) after intubation and significant 5 min after intubation. In group I and II changes in heart rate are significant after induction and intubation (p<0.05) but not significant 5, 10 and 15 min after intubation (p>0.05) (Table 5).

Table 5: T and P values for heart rate in three groups at different times

Statistical value	After induction			After intubation			5min After intubation			10 min After intubation			15 min After intubation		
	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III
T	2.78	2.70	2.12	6.91	3.42	2.22	3.16	1.58	1.46	1.48	0.82	0.706	1.190	0.61	0.082
P	<0.05	<0.05	<0.05	<0.01	<0.05	<0.05	<0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05
Significance	S	S	S	HS	S	S	S	NS	NS	NS	NS	NS	NS	NS	NS

Statistically MAP changes in group I are highly significant after intubation (p<0.01), significant 5 min after intubation (p<0.05) but not significant 10, 15 min after intubation (p>0.05). In group II and III MAP changes are significant

after intubation (p<0.05) but not significant 5, 10 and 15 min after intubation (p>0.05) (Table 6).

Table 6: T and P values for MAP in three groups at different times

Statistical value	After induction			After intubation			5min After intubation			10 min After intubation			15 min After intubation		
	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III	Gp I	Gp II	Gp III
T	5.22	5.21	2.398	7.32	3.44	2.180	2.17	0.187	0.769	2.07	0.913	0.076	0.301	0.280	0.266
P	<0.05	<0.05	<0.05	<0.01	<0.05	<0.05	<0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05
Significance	S	S	S	HS	S	S	S	NS	NS	NS	NS	NS	NS	NS	NS

No untoward or adverse reaction and complication was noted in this study.

5. Discussion

The present study was to assess and compare the time of onset, duration of action and intubating conditions with three different doses of rocuronium bromide (0.3 mg/kg, 0.6 mg/kg, 0.9 mg/kg).

In the study, 60 patients of either sex within age group of 18 to 55 years were chosen.. The demographic profile of patients, their ASA grade were similar to studies done by De May JC, Debrock, Sonboonviboon et al [5] (2000) Bunburaphang P (2001).

The grouping of 60 patients were quite similar to previous studies by Sonboonviboon et al (2000) [6] and Bunburaphang P (2001).

In this study all patients were premedicated with 0.005mg/kg glycopyrrolate, 2 mg/kg tramadol and 0.05 mg/kg midazolam, given intravenously. After preoxygenation for 3 minutes, induction was done with sleeping dose of 2.5% thiopentone sodium. This technique of induction was quite similar to the previous study by Bunburaphang et al (2001) (fentanyl, thiopentone), Sonboonviboon et al (2000)(6)(fentanyl, thiopentone), Zhang X et al [7] (1997) (fentanyl, thiopentone)

After induction, rocuronium in a dose of 0.3 mg/kg, 0.6 mg/kg and 0.9 mg/kg to respective groups. At 60 seconds intubation was performed and intubating conditions were assessed and scored. Bunburaphang et al evaluated intubating conditions at 60 seconds, Cooper R et al (1), Zhang X et al (0.6 mg/kg) assessed intubating conditions at 60 and 90 seconds [7].

Intubating conditions were scored according to Lund and Stovner criteria. In the previous studies by Puhringer et al [8] and Sparr et al [9] evaluated intubating conditions according to Coopers criteria. Both Lund and Stovner and Coopers criteria takes into consideration the jaw relaxation, cord relaxation and reaction to intubation.

In group I intubating conditions at 60 seconds were poor in 65% (13 patients) and intubation was impossible in 35% (7 cases). In group II intubating conditions were excellent in 60% (12 cases) and satisfactory in 40% (8 cases). In group III intubating conditions were excellent in 85% (17 cases) and satisfactory in 15% (3 cases) (Table 2). In a similar study by Bunburaphang et al, good intubating conditions were observed in 50% with rocuronium 0.3 mg/kg, in comparison to 85% and 95% with 0.6 mg/kg and 0.9 mg/kg rocuronium respectively, but excellent conditions were 5%, 30% and 45% with each dose of rocuronium respectively which is lesser than ours study. Cooper R et al(6)(0.6 mg/kg) found clinically acceptable (good or excellent) in 95% of patients at 60 seconds and in all patients at 90 seconds. These observations are similar to that of our study.

There was no significant differences in intubating condition in males and females in all three groups. In the study by Mencke T et al in(0.45 mg/kg rocuronium) observed better intubating conditions in females.

In our study onset of apnoea is considered as onset of action of rocuronium. Dubois et al [10], Schlaich N et al [11], found longer onset of action in their studies. De May JC, Debrock et al [5] observed that onset time in 0.6 mg/kg group was longer in comparison to that of 0.9 mg/kg group, which is similar to observations of our study.

In our study there was no significant difference (p>0.05)in onset of action between male and female in all three groups. In the study by Mencke T et al observed shorter onset of action in females.

Duration of action with different doses of rocuronium were similar to studies by Schlaich N et al [11] , and Hofmockel et al [12]. In the study by Fuch-Buder T et al [13] duration of action was 21±4 min. in 0.6 mg/kg group and 34±11 min. in 0.9 mg/kg group. As this study was carried out in children having shorter duration of action than of our study.

In our study there was no significant difference (p>0.05) in duration of action between male and female in all three groups. In the study by Mencke T et al observed shorter duration of action in females.

Many studies have been undertaken regarding cardiovascular stability of rocuronium. In the present study the hemodynamic parameters compared were heart rate, mean arterial blood pressure (MAP) after intubation with different doses of rocuronium. Vital parameters were recorded preoperatively, after induction, after intubation and 5min, 10min, 15min after intubation. The observations of all three groups were compared statistically. Statistically in group I changes in heart rate are significant after induction (p<0.05), highly significant (p<0.01) after intubation and significant 5 min after intubation. In group I and II changes in heart rate are significant after induction and intubation (p<0.05) but not significant 5, 10 and 15 min after intubation (p>0.05) (Table 5).

Statistically MAP changes in group I are highly significant after intubation (p<0.01), significant 5 min after intubation (p<0.05) but not significant 10, 15 min after intubation (p>0.05). In group II and III MAP changes are significant

after intubation ($p<0.05$) but not significant 5, 10 and 15 min after intubation ($p>0.05$) (Table 6). Lambalk et al [14] , Cooper et al [15] (0.6 mg/kg, o.9 mg/kg), Khuenl-Brady KS et al [16], Cornet et al, Maddineni et al [17] (0.6 mg/kg, o.9 mg/kg) also stated that rocuronium did not show changes in heart rate and MAP of clinical significance.

If we compare the variation in heart rate and MAP with pre-operative value, appreciable and statistically significant changes were observed just after induction (due to IV thiopentone administration) and just after intubation (specially highly significant in group I). The later increase was normal hemodynamic response to intubation due to increased sympathetic stimulation, which was marked in group I because intubation was not smooth. These results were in agreement with previous study by Apouleish et al(18), in which statistically significant increase in heart rate and MAP were observed 2min after administration of rocuronium, coinciding with completion of intubation and skin incision.

6. Conclusion

Rocuronium bromide in a dose of 0.9 mg/kg IV has rapid onset of action, longer duration of action and excellent intubating conditions in comparison to 0.6 mg/kg and 0.3 mg/kg dose at 60 seconds. So it can be used in intubation for surgery longer than one hour duration. Rocuronium in a dose of 0.6 mg/kg IV also has acceptable intubating conditions, onset time, and short duration of action than 0.9 mg/kg dose. So it can be used for intubation if duration of surgery is less than one hour. Rocuronium in a dose of 0.3 mg/kg cannot be accepted as intubating dose because of unfavorable intubating conditions and prolonged onset of action.

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