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Clinical Evaluation of Intubating Conditions and Hemodynamic Effects Using Two Doses of Rocuronium Bromide: A Prospective Comparative Study

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ABSTRACT

To assess the ease of intubation by comparing two doses of Rocuronium bromide for endotracheal intubation. Eighty four patients were selected for the study and the patients were randomized into two groups using chit and box method: Group I: Patients received intravenous Rocuronium: 0.6 mg kg^{-1} b.wt., intubated at 60 sec and Group II: Patients received intravenous Rocuronium -0.9 mg kg^{-1} b.wt., intubated at 60 sec. Hemodynamic variables: HR, Systolic Diastolic BP and Mean Arterial Pressure were recorded. The intubating circumstances and hemodynamic outcomes of two dosages of Rocuronium bromide were examined in this prospective clinical research. Rocuronium Bromide 0.60 mg per kilogram; 0.90 mg per kilogram were given intravenously. The mean age was among group I and II was 37.86±11.70 and 38.52±7.40 years respectively with 52.4% males and 47.6% females among study population. The mean heart rate before intubation, following intubation, 1, 2, 5 and 10 min post intubation was relevant more in group-I than group-II. The mean Systolic blood pressure 1 min post-intubation and 2 min post-intubation was more among group I compared to group II. The mean Diastolic blood pressure at 1, 2, 5 and 10 min post-intubation was more relevant in group II than group I. The mean MAP at 1, 2, 5 and 10 min post-intubation was more relevant in group II than group1. The mean percentage change in HR, SBP, DBP, MAP and SpO2 among group I was 8.66, 2.59, 7.04, 3.59 and 0.65%, respectively and group II was 2.62, 0.44, 0.13, 1.16 and 0.55%, respectively. Cooper Score 9 was more among group II compared to group I. Cooper Score 6 and 7 was significantly more among group I in comparison to group II. 0.90 mg per kg dose of. Rocuronium 0.90 mg kg^{-1} is well suited in RSI. 0.60 mg per kg and 0.90 mg per kg rocuronium provide reasonably good intubating situations, although 0.90 mg per kilo provides superior conditions than 0.60 mg per kg.

INTRODUCTION

Endotracheal intubation is very important for administering the general anesthesia for relaxing the muscles of the larynx that helps in achieving vocal cords inactivity[1]. Maintaining a patent airway is an essential part of General Anaesthesia, regardless of the whatever method is used. Endotracheal intubation is the "Gold Standard" for securing the airway[2]. The most dangerous time of anesthesia is the interval between suppressing the protective reflexes while induction of the anaesthesia and achievement of satisfactory intubating conditions. Regurgitation of the stomach contents and aspiration of the stomach contents into the lungs can be most frequent at this time. It is therefore most desirable to shorten the time interval between the onset and intubation as much as possible[3]. During emergency procedure, Rapid sequence intubation is preferred with faster onset of induction and relaxation, with securing airway in a smooth-way and less chance of gastric regurgitation leading to aspiration. An ideal NMB used in RSI must have quick onset-time, short lasting, enough paralysis, without any haemodynamic changes[4]. Since the development of the anesthesia, anaesthesiologists have been searching for ideal muscle relaxants, that helps in providing the ideal intubating conditions for the ultra-short time period with minimum of the side effects[5,6]. Therefore, we need a drug which is safer, with an onset of time which is comparable with Succinylcholine and with least side effects. Rocuronium-bromide is a low potency NDMR drug which has a fast onset time period[7-13]. It recovers quickly, maintains cardiovascular stability and produces no substantial histamine release. The minor side effects include muscular pain, tightness in chest, difficulty with breathing, hives, itching or skin rash, cough, dysrhythmia, dizziness. There is difference in succinylcholine and rocuronium with respect to the ability for providing the suitable intubation conditions, with Rocuronium having more superiority for this property[14]. Rocuronium-Bromide in the dosage more than 2-3 times ED95, produces excellent intubating conditions within 60 secs which resembles that of the Succinylcholine with the advantage of the excellent stability of the cardiovascular system. Rocuronium may not deliver enough muscular relaxation in low doses, which is essential for a safe and successful intubation. Rocuronium bromide allows for fast tracheal intubation, however, a higher dose can extend the duration of action[15,16]. Therefore, this study had the purpose of evaluating the suitable drug dosage of Rocuronium-Bromide required for ET-intubation; comparison of intubating conditions. Our study compares the hemodynamic effects of 2 doses of 0.60 mg kg^{-1} 0.90 mg kg^{-1} Rocuronium-Bromide.

MATERIALS AND METHODS

All patients were chosen based on inclusion and exclusion criteria after receiving consent from IEC. Every individual received a thorough medical history, a thorough physical examination and standard and relevant investigations with written and informed consent. Pre-anaesthetic evaluation was done in all the subjects before surgery. Each subject was explained the entire procedure in his/her language. Written informed consent for the procedure was taken from all the patients and participation sheet were filled out. On receiving approval from the institute's Ethical Committee, 84 subjects were chosen to be a part of this conducted research. On entering the operation theatre, all ASA standard monitors which includes Non-Invasive B.P monitor, Plethysmograph and ECG leads attached to the subject. I.V Fluids like crystalloid was begun after securing an IV line. Baseline hemodynamic variables were noted that included-Systolic and Diastolic BP, PR and Mean MAP.

Subjects pre-medicated with the following:

- Injection glycopyrrolate (0.20 mg kg^{-1}) intravenously
- Injection Ondansetron (4.0 mg kg^{-1}) intravenously
- Injection Fentanyl (2.0 mg kg^{-1}) intravenously
- Injection Midazolam (1.00 mg kg^{-1}) intravenously

Every individual was preoxygenated using 100% Oxygen for 3 min. Injection Propofol iv in the dose 2 mg kg^{-1} was given for inducing the patient under general anaesthesia.

The intubating person was not aware of the drug concentration they'll be giving to the patient. The person who conducted endotracheal intubation was unaware of the muscle relaxant utilised.

Following the administration of the relaxant according to the group in which the subject was allocated, the laryngoscopy was done by a consultant in Anaesthesiology after 60s. Laryngoscopy and endotracheal intubation's duration was limited to not more than 60 sec each. If there is diaphragmatic activity or any activity during intubation, it will be documented. Propofol 1.0 mg kg^{-1} will be given as a rescuing agent.

Endotracheal intubation was done using an ET tube of an accurate size. Following successful intubation, tracheal cuff was inflated, controlled ventilation initiated. EtCO2 monitor attached. Anaesthesia was maintained with Isoflurane, N_2O, O_2, Propofol with supplementation of relaxant doses as and when needed.

Cooper *et al*.[7] and LeVasseur and Desai[8] scoring system of endotracheal intubating circumstances were used to evaluate and assess intubating situations (Table 1 and 2).

If the intubating value was <6, no intubation was attempted and the individual was ventilated for the next 30 sec. If the intubation score stayed less than six after 90 sec of NMB drug, the subject was ventilated again and the score was reviewed every 30 sec until a good intubating score had been attained intubation was done then. Hemodynamic variables: Heart rate, systolic and diastolic BP and Mean

Arterial pressure were recorded:

- Prior to intubation and after intubation
- Approximately 1 min following intubation
- Approximately 2 min following intubation
- Approximately 5 min following intubation
- Approximately 10 min following intubation

Effects of muscle-relaxant blockage reversed using Neostigmine 0.040 mg kg^{-1} IV and Glycopyrrolate 0.01 mg kg^{-1} iv, respectively at end of operation. The patient would be reversed and sent to the postoperative recovery unit after careful oral suctioning and confirmation of airway reflexes.

Any serious adverse effects were documented. Mean values compared by using the "student t test" and frequencies compared by using chi-squared test amongst the 2 groups. When p value was 0.05, it was reported to be clinically relevant.

RESULTS

Group I and II's mean ages were compared using unpaired student t test. Mean age difference b.wt., groups I and II wasn't really significant. Group I and II had a mean-age of 37.8611.70 and 38.527.10 years, respectively (Table 3).

Gender distribution in groups I and II was compared using Chi-square test. Between groups I and II, there wassn't a discernible change in the allocation of males and females. There were 52.4% males and 47.6% females among study population (Table 4).

The chi-square tests were used to compare the distribution of ASA grade among groups I and II. There was no apparent variation in ASA grade distribution among group I and II (Table 5).

The mean heart rate at baseline, before intubation, immediately after intubation, 1 min post-intubation, 2 min post-intubation, 5 min post-intubation and 10 min post-intubation was compared between groups I and II using the unpaired t-test. The mean heart rate before intubation, immediately after intubation, 1 min post-intubation, 2 min post-intubation, 5 min post-intubation and 10 min post-intubation was significantly more among group I compared to group II (Table 6).

Comparison of mean Systolic blood pressure at baseline, before intubation, immediately following intubation, 1, 2, 5 and 10 min post-intubation, respectively, by unpaired t-test. Mean Systolic blood pressure1 min and 2 mins post-intubation was more relevant in group I than group II (Table 7).

Comparison of mean systolic blood pressure at baseline, before intubation, immediately following intubation, 1, 2, 5 and 10 min post-intubation,

Table 1: Response to intubation

Rate	Jaw relaxation	Vocal cords	Response to intubation
1	Poor (Impossible)	Closed	Severe coughing or bucking
2	Minimal (difficult)	Closing	Mild coughing
3	Moderate (fair)	Moving	Slight diaphragmatic movement
4	Good (easy)	Open	None

Table 2: Scoring of intubating conditions

No	Scores	Intubating score
1	8-9	Excellent
2	6-7	Good
3	3-5	Fair
4	0-2	Poor

Table 3: Comparison of mean age between groups I and II

	Age		
Groups	Mean	Standard deviation	p-value
Group I	37.86	11.70	0.748
Group II	38.52	7.40	

Unpaired t-test #Non-significant difference

Table 4: Comparison of Gender between group I and II

	Gender					
	Male		Female		Total	
Groups	No.	Percentage	No.	Percentage	No.	Percentage
Group 1	22	52.4	22	52.4	44	52.4
Group 2	20	47.6	20	47.6	40	47.6
Total	42	100.0	42	100.0	84	100.0

χ^2: 0.000, p = 1.000, Chi-square test #Non-significant difference

Table 5: Comparison of ASA grade between group I and II

	ASA					
	Grade I		Grade II		Total	
Groups	No.	Percentage	No.	Percentage	No.	Percentage
Group I	29	69.0	13	31.0	42	100.0
Group II	24	57.1	18	42.9	42	100.0
Total	53	63.1	31	36.9	84	100.0

χ^2 value: 0.001*, p = 1.000, Chi-square test and #Non-significant difference

Table 6: Mean heart rate comparsion between group I and 11

	Group I		Group II				
Heart rate	Mean	Std. deviation	Mean	Std. deviation	Mean difference	T-test value	p-value
Baseline	72.86	11.70	73.52	7.40	-0.67	-0.312	0.756
Before intubation	79.00	5.29	73.21	5.82	5.79	4.770	0.001*
Immediately after intubation	78.86	5.56	73.17	5.21	5.69	4.841	0.001*
1 min post-intubation	83.02	4.74	75.50	7.39	7.52	5.553	0.001*
2 min post-intubation	83.50	7.37	77.52	4.32	5.98	4.535	0.001*
5 min post-intubation	81.69	8.41	76.83	2.87	4.86	3.544	0.001*
10 min post-intubation	79.17	7.89	75.45	3.85	3.71	2.744	0.007*

Unpaired t-test and *Significant difference

Table 7: Mean SBP comparison between group I and II

	Group I		Group II				
SBP	Mean	Std. deviation	Mean	Std. deviation	Mean difference	t-test value	p-value
Baseline	126.00	7.82	125.81	6.04	0.19	0.404	0.500
Before intubation	128.14	6.28	126.88	4.55	1.26	1.054	0.295
Immediately after intubation	123.71	9.66	123.10	7.01	0.62	0.336	0.738
1 min post-intubation	130.57	8.31	126.57	7.38	4.00	2.332	0.022*
2 min post-intubation	128.26	6.89	123.55	4.47	4.71	3.719	0.001*
5 min post-intubation	122.83	6.25	123.74	4.25	-0.90	-0.775	0.440
10 min post-intubation	122.74	3.74	121.45	2.60	1.29	1.829	0.071

Unpaired t-test and *Significant difference

Table 8: Mean SBP comparison between groups I and II

	Group I		Group II				
SBP	Mean	Std. deviation	Mean	Std. deviation	Mean difference	t-test value	p-value
Baseline	126.00	7.82	125.81	6.04	0.19	0.404	0.500
Before intubation	128.14	6.28	126.88	4.55	1.26	1.054	0.295
Immediately after intubation	123.71	9.66	123.10	7.01	0.62	0.336	0.738
1 min post-intubation	130.57	8.31	126.57	7.38	4.00	2.332	0.022*
2 min post-intubation	128.26	6.89	123.55	4.47	4.71	3.719	0.001*
5 min post-intubation	122.83	6.25	123.74	4.25	-0.90	-0.775	0.440
10 min post-intubation	122.74	3.74	121.45	2.60	1.29	1.829	0.071

Unpaired t-test and *Significant difference

Table 9: Mean diastolic blood pressurecompared between group I and II

	Group I		Group II				
Diastolic blood pressure	Mean	Std. deviation	Mean	Std. deviation	Mean difference	t-test value	p-value
Baseline	77.40	9.00	75.29	5.31	2.12	1.417	0.104
Before intubation	75.10	8.76	74.60	4.28	0.50	0.333	0.740
Immediately after intubation	76.31	8.65	76.05	7.39	0.26	0.149	0.882
1 min post-intubation	74.26	6.92	79.43	5.28	-5.17	-3.847	0.001*
2 min post-intubation	71.79	5.73	75.00	3.51	-3.21	-3.100	0.003*
5 min post-intubation	71.86	4.52	74.81	6.35	-2.95	-2.454	0.016*
10 min post-intubation	71.95	5.22	75.38	5.92	-3.43	-2.814	0.006*

Unpaired t-test and *Significant difference

Table 10: Mean map compared between group I and II

	Group I		Group II				
MAP	Mean	Std. deviation	Mean	Std. deviation	Mean difference	t-test value	p-value
Baseline	117.07	5.28	117.22	6.00	8.85	0.488	0.289
Before intubation	117.81	9.10	116.89	4.25	0.92	0.594	0.554
Immediately after intubation	117.55	10.98	117.08	8.90	0.47	0.215	0.831
1 min post-intubation	117.79	8.49	121.62	6.39	-3.83	-2.338	0.022*
2 min post-intubation	114.54	7.27	116.18	2.56	-1.64	-2.038	0.047*
5 min post-intubation	112.80	6.37	116.06	6.92	-3.25	-2.242	0.028*
10 min post-intubation	112.87	6.20	115.87	6.41	-3.00	-2.180	0.032*

Unpaired t-test and *Significant difference

Table 11: meanSPO_2 compared between group I and II

	Group I		Group II				
SpO_2	Mean	Std. deviation	Mean	Std. deviation	Mean difference	t-test value	p-value
Baseline	99.02	0.81	99.29	0.86	-0.26	-1.433	0.156
Before intubation	99.10	1.01	99.24	0.98	-0.14	-0.658	0.513
Immediately after intubation	98.81	0.83	99.76	0.43	-0.95	-6.578	0.001*
1 min post-intubation	99.10	0.85	99.24	0.98	-0.14	-0.712	0.478
2 min post-intubation	99.38	0.94	99.48	0.74	-0.10	-0.517	0.606
5 min post-intubation	100.00	0.00	100.00	0.00	0.00	0.000	1.000
10 min post-intubation	99.67	0.75	99.83	0.38	-0.17	-1.281	0.204

Unpaired t-test [and #]Non-significant difference

Table 12: Distribution of side effects between group I and II

	Bradycardia		Dysrhythmia		Sore throat	
Groups	No.	Percentage	No.	Percentage	No.	Percentage
Group I	0	0.0	0	0.0	0	0.0
Group II	0	0.0	0	0.0	0	0.0
Total	0	0.0	0	0.0	0	0.0

#Non-significant difference

Table 13: Distribution of Cooper's Score between group I and II

	Cooper's score									
	6		7		8		9		Total	
Groups	No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage
Group I	7	16.7	16	38.1	19	45.2	0	0.0	42	100
Group II	0	0.0	0	0.0	7	16.7	35	83.3	42	100
Total	7	8.3	16	19.0	26	31.0	35	41.7	84	100

χ^2 value = 63.538, p<0.001* and *Significant differenc

respectively, by unpaired t-test. Mean Systolic blood pressure1 min and 2 min post-intubation was more relevant in group I than group II (Table 8).

The unpaired t-tests used for comparison of mean Diastolic blood pressure between groups I and II at baseline, before intubation, immediately following intubation, 1, 2, 5 and 10 min post intubation, respectively. When comparing group II to I, the mean DBP was considerably higher at 1, 2, 5 and 10 min post-intubation (Table 9).

The unpaired t-test used for Comparison of mean MAP at baseline, prior intubation, immediately following intubation, 1, 2, 5 and 10 min post-intubation, respectively was compared between groups I and II. When comparing groupII to I, the mean MAP at 1, 2, 5 and 10 min post-intubation, was considerably higher (Table 10).

The unpaired t-test used for Comparison of mean Spo2 at baseline, prior intubation, immediately following intubation, 1, 2, 5 and 10 min post-intubation, respectively between groups I and II. Between groups I and II, mean SpO_2 was not considerably different at baseline, before intubation, immediately after intubation, at 1, 2, 5 and 10 min (Table 11).

The side effects were compared between groups I and II using the “chi-square” test. There wasn’t a significant difference of effects between group I and II (Table 12).

The Chi- square test was used for comparison of distribution of Cooper's Score amongst groups I and II. Group II had a considerably higher Cooper's Score 9 than group I. When comparing groups I and II, Cooper's score 6 and 7 was significantly more in group I (Table 13).

DISCUSSIONS

Even though succinylcholine is the holy-grail for RSI, Rocuronium is said to have almost all of the attributes of an optimum muscle relaxant, including a non-depolarizing action, rapid time of onset, short-lived treatment, faster recovery, independent of CVS adverse effects, no histaminic release and biologically inert metabolic products[17-22].

Bhandari *et al*.[23] found that the mean action time of rocuronium of 0.6 mg kg^{-1} dose was 77.40±5.32 sec same with Kumar and Suchetha[4], Stoelting and Peterson[6], Heier and Caldwell[15], Bernar[24], Bunburaphong *et al*.[25], Patel and Kacha[26] and Hunter[27] but LeVasseur and Desai[8], Barve and Sharma[12], Bhandari *et al*.[23] and Mishra *et al*.[28] found that the mean action time of rocuronium bromide 0.90 mg kg^{-1} was 58.37±4.82 sec.

In present study, cooper's score 9 was significantly more among 0.90 mg kg^{-1} Rocuronium group-II (83.3%) compared to 0.60 mg k^{-1} Rocuronium group-I. Cooper's Score 6 and 7 was significantly more among group I (16.7 and 38.1%, respectively). The excellent intubating conditions (Cooper's score 8-9) was significantly more among 0.90 mg kg^{-1} of Rocuronium group-II (100.0%) compared to 60 mg k^{-1} Rocuronium group I (45.2%).

Bhandari *et al*.[23] observed outstanding to superb intubating parameters with 0.90 mg kg^{-1} dose in 93.33% of the participants at 1 min. Saikia *et al*.[3], Belekar and Khamankar[9] and Kopman *et al*.[29] conducted research. Only 58.2% of participants in the study of Hunter[27] had acceptable intubating state. It's conceivable that the relaxation of the laryngeal muscles commences well before adductor pollicis of the thumb, which might account for differences in intubating events.

In their study, Wood and Slater[30] discovered that when compared to conventional RSI with succinylcholine, the revised RSI with rocuronium had a shortened intubation phase, satisfactory intubation characteristics and a similar degree of issues. Throughout their investigation, Bartkowski *et al*.[13] found that Rocuronium induction dose of 0.80 mg kg^{-1} for establishing excellent intubating situations.

Hunter[27] When comparing 2 different NDMR, Rocuronium bromide 0.60 mg k^{-1} and vecuronium 0.10 mg kg^{-1} in procedures in heavy i.v sedation, researchers discovered that Rocuronium had a faster onset and enabled quicker intubation. Using the "timing concept," Belekar and Khamankar[9] and Mishra *et al*.[28] compared intubation parameters in Rocuronium bromide and vecuronium with Sch and discovered, Rocuronium 0.60 mg kg^{-1} delivers excellent intubation situations that are close to succinylcholine following anaesthesia.

Sardhara *et al*.[1] found that the changes of SBP, DBP and MAP in Group 0.6 mg kg^{-1} were more than 0.90 mg kg^{-1} and 1.20 mg kg^{-1}, groups but there was no statistically substantial change in any of the three groups. Our results are similar to Stevenson and Birch[31], who agreed that there was no significant difference in these haemodynamic with Rocuronium-bromide 0.60, 0.90, and 01.20 mg $kilo^{-1}$, Cooper *et al*.[7], who discovered no measurable difference in mean pulse rate and arterial blood pressure all through intubation and Raizada who encountered no significant difference in heart beat and pulse pressure during intubation.

Following induction, both groups experienced a decline in Mean arterial pressures and it wasn't clinically meaningful, which corresponded to the data of Heier and Caldwell[15] Mean arterial pressures (MAP) rose after intubation and held steady in both categories. Rocuronium can be utilised in cardiac/haemodynamically unstable individuals, as per research done by Patel and Kacha[26] and Kopman *et al.*[29]. According to Kumar and Suchetha[4], MAP reduced dramatically from 96.89-88.73 in the rocuronium group and this notable decline in mean BP stayed 5-10 min following intubation.

CONCLUSION

Both 0.60 and 0.90 mg kg^{-1} rocuronium provide reasonably good intubating situations, although 0.90 mg k^{-1} provides superior conditions than 0.60 mg k^{-1}.

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