EAS Journal of Anaesthesiology and Critical Care
Abbreviated Key Title: EAS J Anesthesiol Crit Care
ISSN: 2663-094X (Print) & 2663-676X (Online) Open Access
Published By East African Scholars Publisher, Kenya

OPEN ACCESS

Volume-1 | Issue-1 | Jan-Feb-2019 |

Original Research Article

Comparative Study of Efficacy of 0.6mg/Kg and 0.9mg/Kg Rocuronium Bromide with 1.5mg/Kg Succinyl Choline for Optimal Intubating Conditions During Rapid Sequence Induction

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Abstract: Introduction: Muscle relaxants play an important role in rapid sequence induction (RSI) technique advocated to prevent aspiration of gastric contents into the bronchial tree in high risk patients. This prospective randomised study was carried out with the aim compare the efficacy of 0.6mg/kg and 0.9mg/kg of rocuronium bromide (roc) with 1.5mg/kg of succinyl choline (sch) in providing optimal intubating conditions during RSI. Methods: Total 90 patients were randomly allocated into 3 groups. Muscle relaxant given in group A is roc 0.6mg/kg, in group B roc 0.9mg/kg and in group C sch 1.5mg/kg. Intubating conditions, haemodynamic parameters and adverse effects were noted. Statistical analysis was performed with ANOVA/Kruskal Wallis test and Chi-Square test. Results: intubating conditions at 60s were poor with roc 0.6mg/kg when compared with roc 0.9mg/kg and sch 1.5mg/kg. Mean time of onset of action was (80.2 ± 4.74) secs in roc 0.6mg/kg, (57.33 ± 2.28) secs in roc 0.9mg/kg and (55.6 ± 2.22) secs in sch 1.5mg/kg. Statistically, changes in heart rate and mean blood pressure were significant ($p<0.0001$) immediately after and 5 min after intubation ($p<0.0001$) but not significant at 10 and 15 min after intubation ($p>0.05$) among the three groups Conclusion: rocuronium bromide in dose of 0.9mg/kg is good and safe alternative to succinylcholine for RSI.

Keywords: Rapid Sequence Induction, Rocuronium Bromide, Succinyl Choline.

INTRODUCTION:

Elective surgeries are ideal for Anaesthesiologist while emergency surgeries are the one frequently encountered. Emergency anaesthesia poses significant challenge to Anaesthesiologist due to increased risk of pulmonary aspiration of gastric contents than elective cases who are adequately fasted. The sequelae of aspiration varies depending upon the pH and volume of aspirated fluid into the bronchial tree.

Rapid sequence induction (RSI) is a technique performed to prevent aspiration of gastric contents in patients having high risk for aspiration. In 1961, Sellick described a manoeuvre to prevent regurgitation of gastric or oesophageal contents during intubation by appling pressure over cricoid cartilage against the cervical vertebrae to occlude the oesophagus against it.(Sellick BA, 1967) Since then, cricoid pressure has been routinely applied during RSI.

RSI involves loss of consiousness during criocoid pressure (at 20–40 N) followed by intubation without face mask ventilation with the aim to intubate the trachea as quickly and as safely as possible. For a long time thiopentone and succinylcholine had been employed as induction agent and muscle relaxant respectively for RSI. Nowadays several induction agents and several alternatives to succinylcholine are being used by Anaesthesiologist. Succinyl choline is a depolarising muscle relaxant which has faster onset and shorter duration of action which is very desirable in this setting. It is considered as an agent of choice but has some side effects like potassium release, elevated intraocular and intragastic pressure, post anaesthesia myalgia, myoglobinuria and myotonic reaction. Hence an alternative drug to succinyl choline has always been sought.

Quick Response Code

Journal homepage:
http://www.easpublisher.com/easjacc/

Article History
Received: 10.02.2019
Accepted: 18.02.2019
Published: 25.02.2019

DOI: 10.36349/easjacc.2019.v01i01.004

In 1990's Rocuronium; a steroidal non-depolarising muscle relaxant was introduced in market. It has rapid onset and intermediate duration of action. Rapid onset of action render it ideal for facilitation of both routine and rapid sequence induction. Doses used to facilitate tracheal intubation are twice of ED95 i.e. 0.6mg/kg for rocuronium. Increasing the dose of rocuronium from 0.6mg/kg to 0.9mg/kg shortened the onset time of complete neuromuscular blockade, but at the expense of prolonging the clinical duration of action.

The present study was undertaken with the aim to compare onset of action and intubating conditions during rapid sequence induction of anaesthesia following two doses i.e. 0.6mg/kg and 0.9mg/kg of rocuronium bromide and 1.5mg/kg succinyl choline. The secondary endpoints were to assess the Success rate of tracheal intubation in grade I and II of Mallampati and haemodynamic parameters i.e. pulse rate (HR), mean blood pressure (MBP), peripheral saturation of oxygen (SPO_2) before induction, after induction, immediately after intubation, 5min ,10 min and 15 min after intubation and incidence of side effects, if any.

METHODS

After obtaining Institutional Ethical Committe (IEC) approval and taking informed written consent from the patient and his or her guardian, this prospective clinical study was conducted in 90 adult patients of age group 18-50 years of either gender and of American Society of Anaesthesiologist physical status I and II posted for surgery under general anaesthesia. Patient with Mallampati scoring III & IV, previous history of difficult intubation, those with upper airway pathology, having any systemic disorder including myopathies or are allergic to study drugs were excluded from the study.

Sample size was calculated considering power of study 80% and α error 0.05. Time period of study extended from november 2016 to may 2018. The patients were systematically allocated into three groups of thirty each by a computer generated sealed chits. After thorough pre anaesthetic evaluation patient was shifted to operation theatre. After proper counselling and informed written consent, intravenous line was secured and infusion of ringer lactate was started. Monitor for SpO_2, ECG, NIBP, $EtCO_2$ were applied and baseline heart rates, systolic/ diastolic and mean BP, respiratory rate, SpO_2 were noted. Pre medication was done with Glycopyrrolate 0.2mg IV, Nalbuphine 0.2mg/kg I.V., Midazolam 0.05mg/kg I.V. Then patient was pre oxygenated for 3min followed by induction with thiopentone sodium (4-6mg/kg) I.V. (till eyelash reflex lost) and cricoid pressure was applied by the assistant. Muscle relaxant calculated according to body weight (i.e. Rocuronium 0.6mg/kg in group A and 0.9mg/kg in group B and Succinyl choline 1.5mg/kg in group C) was administered intravenously. Time of onset of apnoea was recorded as onset time. Endotracheal intubation was attempted at 60seconds using cuffed endotracheal tube of appropriate size and following parameters recorded: Intubating conditions (table 1) and Intubation Score (table 2), haemodynamic parameters (i.e. pulse rate and mean arterial pressure before induction, after induction, after intubation, at the interval of 5 min, 10 min, and 15 min**)** and adverse effects eg. signs of histamine release such as wheal, flushing, bronchospasm, tachycardia or hypotension.

The patients in whom intubation was not possible at 60 seconds, were ventilated with bag and mask and intubated after full relaxation. After intubation, endotracheal tube was secured in position. Anaesthesia was maintained with Oxygen and Nitrous oxide (40:60), Halothane 0.6-0.8% and supplementary doses of Rocuronium bromide 0.1 - 0.2mg/kg as and when required. Vitals were recorded pre-induction, after induction, 5, 10 and 15 minutes after intubation. At the completion of surgery patients were reversed with Glycopyrrolate 0.01mg/kg and Neostigmine 0.05mg/kg. After patient eye opening on verbal command, assessing patient's respiration and thorough oropharyngeal suction, extubation was done. Adequacy of reversal was determined by head lifting test.

Continuous variables were presented as mean ± SD and median and categorical variables were presented in number and percentage (%). Normality of data was tested by Kolmogorov-Smirnov test and if normality was rejected then non parametric test was used. Quantitative variables were compared using ANOVA/Kruskal Wallis test (when the data sets were not normally distributed) between three groups. A (p value) of <0.05 was considered statistically significant. Qualitative variables were correlated using Chi-Square test. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Table - 1: Scoring of intubating conditions

score	**0**	**1**	**2**	**3**
JAW RELAXATION	poor	minimal	moderate	good
VOCAL CORD POSITION	Closed	closing	moving	open
RESPONSE TO INTUBATION	Severe coughing or bucking	Mild coughing	Light diaphragmatic movement	None

Table - 2: Total score

Intubating Conditon	Score
Excellent	8-9
Good	6-7
Poor	3-5
Bad	0-2

RESULTS:

Total 90 patients were enrolled in this study, 30 in each group. There was no significant difference (i.e. p>0.05) in patient demographic characteristics among three groups. Jaw relaxation was adequate in all patients in all 3 groups with no significant difference (p=1) among three groups. Vocal Cords were fully open in 60% of the group A (roc 0.6mg/kg) pts, while group B (roc 0.9mg/kg) and group C (sch 1.5mg/kg) showed fully open vocal cords in 83.33% and 96.67% cases respectively. Response to intubation was none in 40% cases in group A, 73% cases in group B and 97% cases in group C (Table 3).

Table - 3: Comparison of intubating conditions among the three groups

S.No.			Group A	Group B	Group C
1.	Jaw relaxation	Good	30	30	30
		Moderate	-	-	-
		minimal	-	-	-
		poor	-	-	-
2.	Vocal cords	open	18	25	29
		Moving	12	5	1
		Closing	-	-	-
		Closed	-	-	-
3.	Reaction to intubation	None	12	22	29
		Light diaphragmatic movements	15	8	1
		Mild coughing	3	-	-
		Severe coughing	-	-	-

Intubation score was found to be significantly lower with groupA (mean = 7.9 ± 1.06) when compared with group B (mean = 8.57 ± 0.77) and group C (mean = 8.93 ± 0.37) ($P < 0.0001$). No significant difference was found between roc 0.9mg/kg and sch 1.5mg/kg. Overall grading of intubating conditions at 60 seconds with group A is excellent in 60% cases and satisfactory in 40% cases, with group B excellent in 83.33% and satisfactory in 16.67% cases and with group C excellent in 93.33% and satisfactory in 6.67% cases (Table 4). Thus intubating conditions provided by roc 0.6mg/kg were poorer when compared with the other two i.e roc 0.9mg/kg and sch 1.5mg/kg.

Table - 4: Comparison of grading of intubating conditions among the three groups

GRADING OF INTUBATING CONDITIONS	GROUPS			χ^2	P value
	Roc (0.6mg/kg)	Roc (0.9mg/kg)	Sch (1.5mg/kg)		
EXCELLENT	18	25	28	10.541	P = 0.005 (SIGNIFICANT)
SATISFACTORY	12	5	2		
POOR	0	0	0		
IMPOSSIBLE	0	0	0		

In this study onset of apnoea was considered as onset of action. While comparing time of onset of action, mean time of onset was (80.2 ± 4.74) secs in group A, (57.33 ± 2.28) secs in group B and (55.6 ± 2.22) secs in group C. P<0.0001 which is highly significant. There was no significant difference (p>0.05) in onset of action between male and female in all three group

In our study haemodynamic parameters compared were heart rate, mean arterial blood pressure (MAP). Vital parameters were recorded preoperatively, after induction, after intubation and 5min, 10min, 15min after intubation. Statistically changes in heart rate were significant (p<0.0001) immediately after intubation and 5 min after intubation (p<0.0001) but not significant at 10 and 15 min after intubation (p>0.05) among the three groups (Table 5).

Table - 5: Comparison of pulse rate (pre induction, after induction, after intubation, and 5min, 10min, and 15min after intubation) among the three groups

PARAMETER (PULSE RATE)	Roc (0.6mg/kg)	Roc (0.9mg/kg)	Sch (1.5mg/kg)	p value
Pre – Induction	77 ± 6.45	74.13 ± 4.45	74.8 ± 4.89	P= 0.09 (NOT SIGNIFICANT)
After induction	88.93 ± 5.22	88.27 ± 3.14	88 ± 3.79	P=0.669 (NOT SIGNIFICANT)
After – Intubation	107.33 ± 5.66	97.6 ± 3.21	93 ± 6.76	P<0.0001 SIGNIFICANT
5 min	95.6 ± 5.16	90.73 ± 2.7	87.13 ± 5.3	P<0.0001 SIGNIFICANT
10 min	79.8 ± 5.26	81 ± 3.39	79.67 ± 3.64	P=0.391 NOT SIGNIFICANT
15 min	76.13 ± 5.2	77.73 ± 3.81	76.53 ± 3.44	P=0.311 NOT SIGNIFICANT

Statistically MAP changes were significant immediately after intubation ($p<0.0001$) and 5 min after intubation ($p<0.0001$) but not significant at 10, 15 min after intubation ($p>0.05$) among the three groups (Table 6).

Table - 6: Comparison of mean blood pressure (before induction, after induction, after intubation, and 5min, 10min, and 15min after intubation) among the three groups

PARAMETER MEAN BP (mmhg)	Roc (0.6mg/kg)	Roc (0.9mg/kg)	Sch (1.5mg/kg)	p value
Pre induction	79.6 ± 4.34	79.4 ± 3.68	80.4 ± 4.74	P=0.36 NOT SIGNIFICANT
AFTER – Induction	86.07 ± 3.91	85.2 ± 3.26	86.4 ± 2.8	P=0.287 NOT SIGNIFICANT
After – Intubation	109.07 ± 5.87	97.87 ± 4.17	98.2 ± 4.68	P<0.0001 SIGNIFICANT
5min	95.4 ± 4.76	91.33 ± 3.91	91.17 ± 3.26	P=0.0005 SIGNIFICANT
10min	80.93 ± 4.06	79.13 ± 4.16	79.33 ± 5.36	P=0.421 NOT SIGNIFICANT
15min	77.2 ± 4.02	76.6 ± 3.24	75.67 ± 4.33	P= 0.441 NOT SIGNIFICANT

There was no difference among the groups with regard to intubate the trachea successfully in each group, with 100% successful intubation rate (P = 1). No significant adverse event or complication noted during this study.

DISCUSSION:

The present study was undertaken to assess and compare the intubating conditions, time of onset, and haemodynamic parameters with two different doses of rocuronium bromide (0.6 mg/kg, 0.9 mg/kg) and succinylcholine 1.5mg/kg for rapid sequence induction.

Total 90 patients of either sex within age group of 18 to 50 years were chosen. The demographic profile of patients, their ASA grade were comparable and were similar to studies done by De May JC Debrock et al. (De JM et al., 1994), Weiss et al. (Weiss JH et al., 1997), Sonboonviboon, Bunburaphang P et al. (Somboonviboon W et al, 2000) and Chandra khatri et al. (Khatri C et al., 2016)

In this study all patients were premedicated with inj Glycopyrrolate 0.2mg IV, Nalbuphine 0.2mg/kg I.V., Midazolam 0.05mg/kg I.V. followed by pre oxygenation for 3mins. Induction is done with inj thiopentone sodium (4-6mg/kg) I.V. (till eyelash reflex lost) and cricoid pressure was applied by the assistant. Muscle relaxant calculated according to body weight (i.e. Rocuronium 0.6mg/kg in group A and 0.9mg/kg in group B and Succinyl choline 1.5mg/kg in group C) was administered intravenously. Time of onset of apnoea was recorded as onset time. At 60 seconds intubation was performed and intubating conditions were assessed and scored taking into consideration the jaw relaxation, cord relaxation and reaction to intubation. In the previous studies by Puhringer et al. (Pühringer FK et al., 1992) and Sparr et al. (Sparr HJ et al., 1996) intubating conditions were assesed according to Cooper's criteria (Cooper R et al., 1992) while Chandra khatri et al. (Khatri C et al., 2016) evaluated

intubating conditions via Lund and Stovner criteria. (Lund I et al., 1962)

In our study overall all three study groups had clinically acceptable (good or excellent) intubating conditions, at 60 seconds. However the incidence of excellent grade of intubations was significantly higher with Succinylcholine i.e. 93%, while 83% with Rocuronium 0.9 mg/kg and 60% with Rocuronium 0.6 mg/kg at 60 seconds. In a similar study by Cooper Mirakhur R.K., et al. (Cooper R et al., 1992) intubating conditions after Rocuronium 0.6 mg/kg were found to be clinically acceptable (good or excellent) in 95% of patients at 60 seconds and in all patients after Succinylcholine. These observations are similar to that of our study. In a study conducted by Chanda Khatri et. al.[5] the incidence 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. These findings are also comparable to our study. There was no significant differences in intubating condition in males and females in all three groups.

In our study onset of apnoea is considered as onset of action. The (mean ± SD) onset of action time was (80.2 ± 4.74) seconds with Rocuronium 0.6 mg/kg, with Rocuronium 0.9 mg/kg and (55.6 ± 2.22) seconds with Succinylcholine 1.5 mg/kg. Comparing with other studies Cooper et al.,[8] Bhatia Pradeep kumar et al. (Bhatia Pradeep et al., 2004) observed that onset time with 0.6mg/kg of rocuronium is longer than for succinyl choline. Similarly De May JC et al. (De JM et al., 1994), Chandra khatri et al. (Khatri C et al., 2016) observed that onset time in 0.6 mg/kg group was longer in comparison to that of 0.9 mg/kg group, which is also 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 present study the haemodynamic parameters compared were heart rate, mean arterial blood pressure (MAP) after intubation with different doses of rocuronium. We observed variation in mean pulse rate and mean blood pressure just after intubation, and 5 minutes after intubation which was statistically significant ($p<0.0001$). This response was the normal hemodynamic response to intubation due to sympathetic stimulation. It was significantly higher with Rocuronium 0.6mg/kg group than with other two groups. These results were in agreement with previous study by Dr. Chanda khatri et al. (Khatri C et al., 2016), Dr. Aparna Shukla et.al. (Shukla A et al., 2004) in which variation in heart rate and MAP with preoperative value, appreciable and statistically significant just after induction and just after intubation (specially highly significant in rocuronium 0.3mg/kg and 0.6mg/kg group) because intubation was not smooth. But studies by Puhringer FK, Khuenl-Brady KS et al (Pühringer FK et al., 1992), Cooper et al (Cooper R et al., 1992), Mc Coy EP, Maddineni et al. (McCoy EP et al., 1993) stated that Rocuronium did not show changes in heart rate and MAP of clinical significance.

In our study the Success rate of intubation was 100% with either doses of Rocuronium (i.e. 0.6mg/kg and 0.9mg/kg) and Succinylcholine 1.5mg/kg. Marsch et al (Marsch SC et al., 2011) also found no difference between succinylcholine and rocuronium in terms of failed intubation attempts. Patanwala et al (Patanwala AE et al., 2011) also reported no difference in first-attempt intubation success between succinylcholine and rocuronium at a median dose of 1.19 mg/kg.

CONCLUSION:

In this study we conclude that Succinylcholine is an ideal agent for intubation in all surgical procedures (elective as well as emergency). It has both faster onset of action and higher incidence of excellent intubating conditions in comparison to Rocuronium. Intubating conditions of Rocuronium bromide at a dose of 0.9mg/kg (3xED95) is comparable to Succinylcholine 1.5mg/kg. Also Rocuronium is cardiostable with no known major side-effects. Therefore it can be used safely in patients where Succinylcholine is contraindicated.

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