A COMPARATIVE STUDY OF HAEMODYNAMIC EFFECTS AND INTUBATION CONDITIONS OF ROCURONIUM BROMIDE VERSUS SUXAMETHONIUM

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ABSTRACT

BACKGROUND

Suxamethonium chloride was a time-tested depolarising muscle relaxant with quick onset of action and produced excellent intubating conditions, but it is contraindicated and hazardous in certain situations. Rocuronium bromide had the most rapid onset, intermediate duration of action, minimal cardiovascular side effects and with no histamine release, emerged as a good alternative.

The present study was undertaken to evaluate the efficacy of rocuronium bromide in comparison to succinylcholine for use during rapid sequence induction of anaesthesia. Fifty patients posted for elective surgeries were divided into two groups of 25 each randomly. Group S received succinylcholine 1.5 mg/kg and Group R received rocuronium bromide of 0.9 mg/kg. Laryngoscopy and intubation was done at 60 seconds after assessing the relaxation of jaw, vocal cords status and response to intubation using a standard intubation scoring system by a double-blind assessor. Results were tabulated and analysed using appropriate statistical methods. Excellent intubating conditions were seen in 100% of Group S and 90% in Group R respectively. Haemodynamic changes returned to pre-induction baseline values by the end of 5 minutes in both groups. Hence, we concluded that rocuronium bromide was a safer and a good alternative to succinylcholine for rapid sequence intubation of anaesthesia in adult patients where succinylcholine was contraindicated provided that there was no anticipated difficulty in intubation.

MATERIALS AND METHODS

The present study was undertaken to evaluate the efficacy of rocuronium bromide in comparison to succinylcholine for use during rapid sequence induction of anaesthesia. Fifty patients posted for elective surgeries were divided into two groups of 25 each randomly. Group S received succinylcholine 1.5 mg/kg and Group R received rocuronium bromide 0.9 mg/kg. Laryngoscopy and intubation was done at 60 seconds after assessing the relaxation of jaw, vocal cords status and response to intubation using a standard intubation scoring system by a double-blind assessor.

RESULTS

Results were tabulated and analysed using appropriate statistical methods. Statistical analysis was done using the software Statistical Package of Social Science version 20. Excellent intubating conditions were seen in 100% of Group S and 90% of Group R respectively.^{1,2,3} Haemodynamic changes returned to pre-induction baseline values by the end of 5 minutes in both groups.

CONCLUSION

Hence, we concluded that rocuronium bromide was a safer and a good alternative to succinylcholine for rapid sequence intubation of anaesthesia in adult patients, where succinylcholine was contraindicated provided that there was no anticipated difficulty in intubation.

KEY WORDS

Intubating Conditions, Rocuronium Bromide, Succinylcholine.

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BACKGROUND

Maintenance of patient's airway is a basic and essential component of general anaesthesia. Endotracheal intubation is one of the available means of doing so in common day-to-day practice.

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Muscle relaxants and enable laryngoscopy and intubation. Rapid sequence induction and orotracheal intubation is an established technique to secure a patent airway in patients considered to be at risk for aspiration of gastric contents.

The goal of rapid sequence induction is to secure the patient airway smoothly and quickly minimising the chances of regurgitation and aspiration of gastric contents. Its use is indicated in the presence of full stomach in emergency situations and other situations where there is an increased risk of aspiration. Traditionally, suxamethonium has been the neuromuscular blocking drug of choice in rapid sequence induction and intubation technique. Yet its use is associated with a number of undesirable side effects like fasciculations, myalgia, hyperkalaemia, bradyarrhythmias, raised intraocular pressure, intracranial pressure, intragastric pressure, anaphylaxis, malignant hyperthermia and masseter

spasm.^{4,5} Hence, it is not suitable in situations when patients have neuromuscular disorders, burns, head injury, intracranial bleeding, open eye injury and cerebrovascular accidents. The potential problems associated with suxamethonium have prompted the search for alternative methods, the use of non-depolarising muscle relaxants.

Rocuronium is a relatively newer non-depolarising muscle relaxant. It is expected to have an onset time, possibly as ratio as that of suxamethonium without its adverse side effects. But unlike suxamethonium, rocuronium has little or no cardiovascular side effects and does not cause histamine release. Thus, it is ideal for rapid sequence induction of anaesthesia and may be preferable to suxamethonium in compromised patients in whom cardiovascular effects are to be avoided. Also Rocuronium has intermediate duration of action, similar to that of vecuronium and atracurium and does not depend extensively on renal elimination, hepatic-biliary mechanisms primarily accounting for elimination.^{6,7}

Rocuronium in a dose of > 0.9 mg/kg has been reported to offer intubating conditions at 60 secs that are similar to those observed with suxamethonium. The present study was designed to compare the endotracheal intubating conditions and haemodynamic responses of Rocuronium vs Suxamethonium.

Suxamethonium

It is a depolarising neuromuscular blocker with rapid onset of effect and ultra-short duration of action. Suxamethonium is composed of 2 molecules of acetylcholine linked back to back through the acetyl methyl groups. Dosage: The ED₉₅ of suxamethonium is 0.51 - 0.63 mg/kg. Administration of 1 mg/kg results in complete suppression of response of neuromuscular stimulation in approximately 60 seconds. The short duration of action is due to its rapid hydrolysis by the Butyrylcholinesterase to succinylmonocholine and choline.

Rocuronium

This is a monoquaternary amino steroidal non-depolarising neuromuscular blocking agent with shorter onset of action under intermediate duration of action. Rocuronium lacks the acetyl ester that is found in the steroidal nucleus of pancuronium and vecuronium in the A ring. The introduction of cyclic substitutes other than piperidine at the 2 and 16 positions resulted in fast-onset compound. The methyl group attached to the quaternary nitrogen of vecuronium and pancuronium is replaced by an allyl group in rocuronium, as the result of rocuronium at about 6 and 10 times was less potent than vecuronium.

Rocuronium act by combining with nicotinic acetyl choline (ACh) receptors without causing any activation of ion receptor channels. It undergoes minimal or no metabolism and is eliminated primarily by the liver and small fraction (=10%) eliminated in urine. The initial dosage is determined by the purpose of administration.

Dose of intubation 0.6 - 1.0 mg/kg, supplemental dose after intubation 0.1 mg/kg. increasing the dose of Rocuronium from 0.6 (2× ED₉₅) to 1.2 (4× ED₉₅) mg /kg shortened the onset time of complete neuromuscular blockade from 89 ± 33 seconds (mean ± SD) to 55 ± 14 seconds, but significantly prolonged the clinical duration (recovery of T₁ to 25% of baseline) from 37 ± 15 to 73 ± 32 minutes respectively.

Sugammadex

Is (Org 25969) a novel agent for reversal of neuromuscular blockade by the agent Rocuronium in general anaesthesia. It is the first selective relaxant binding agent. Sugammadex is a modified (placing eight carboxyl into ether group at the 6th carbon positions) γ -cyclodextrin with a lipophilic core and a hydrophilic periphery.

Factors Affecting the Speed of Onset of Neuromuscular Block

Speed of onset of neuromuscular block is one of the requirements to rapidly secure the airway, and it is affected by several factors including the rate of delivery of the drug to the neuromuscular junction, receptor affinity, plasma clearance and the mechanism of neuromuscular blockade. The speed of onset is inversely proportional to the potency of non-depolarising neuromuscular blockers. A high ED₉₅ (low potency) is predictive of rapid onset and vice versa.

The differences in assessment of the quality of intubating conditions make comparison among studies difficult and sometimes impossible. So, the "Copenhagen Consensus in 1994" established a set of internationally acceptable guidelines for good clinical research practice in studies of neuromuscular blocking agents including intubation conditions.

Variable	Clinically Acceptable		Clinically Unacceptable
	Excellent	Good	Poor
Laryngoscopy	Easy	Fair	Difficult
Vocal cords position	Abducted	Intermediate	Closed
movement	None	Moving	Closed
Reaction to ETT insertion and/or cuff inflation:			
Movements of Limbs	None	Slight	Vigorous
Coughing	None	slight	Sustained

A) Intubating Conditions:

- Excellent: All qualities are excellent.
- Good: All qualities are either good or excellent.
- Poor: The presence of a single quality listed under "poor."

B) Laryngoscopy:

- Easy: Jaw relaxed, no resistance to blade in the course of laryngoscopy.
- Fair: Jaw not fully relaxed, slight resistance to blade.
- Difficult: Poor jaw relaxation, active resistance by the patient to laryngoscopy.

Objectives

The purpose of present study was to compare the onset time, intubating conditions of rocuronium and succinylcholine and to evaluate haemodynamic responses to these agents.^{8,9}

MATERIALS AND METHODS

The clinical study was carried out after obtaining approval from the ethical committee, laryngoscopy and intubation and haemodynamic changes were compared in 50 patients of ASA Grade 1 and Mallampati Grade 1 between 18 - 60 years of age group, either sex undergoing elective surgical procedures under general anaesthesia requiring endotracheal intubation. Patients with morbid obesity, anticipated difficult airway

(Mallampati grade 3 and 4), pregnancy, neuromuscular disorders, known allergy to study drugs were excluded from the study.

Study Design and Setting

All patients were randomly divided into two groups of 25 patients each using computer generated random number table and allocation concealment was done with closed sealed envelope technique. The patients were divided into two groups in randomised double-blind fashion. The intubating person was not aware of type of muscle relaxant used and waiting period from administration of muscle relaxant to intubation attempt. Group S (N= 25) patients received suxamethonium 1.5 mg/kg and Group R (N= 25) patients received Rocuronium 0.9 mg/kg. Informed written consent was obtained.^{10,11}

On arrival all the patients were pre-medicated with Inj. Glycopyrrolate 0.2 mg IV 5 mins before surgery. Induction was achieved with Inj. Propofol 2 mg/kg IV followed by muscle relaxant, Inj. suxamethonium 1.5 mg/kg IV in Group S and Inj. Rocuronium 0.9 mg/kg IV in Group R. Sixty seconds after the relaxant administration, intubation was done and intubation condition were assessed as per the intubation scoring system of consensus conference on good clinical research practice in pharmacodynamic studies of neuromuscular blocking agents, Copenhagen consensus.

The haemodynamic variables (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, oxygen saturation) were monitored continuously and recorded at time interval as below for analysis-

- T1= Baseline.
- T2= After induction and just before intubation.
- T3= One minute after intubation.
- T4= Two minutes after intubation.
- T5= Three minutes after intubation.
- T6= Four minutes after intubation.
- T7= Five minutes after intubation.

Duration of laryngoscopy and response of the patient during endotracheal intubation was observed at the time of intubation. Any changes in haemodynamic variables by 30% from the baseline value was considered as significant and managed accordingly. Anaesthesia was maintained, and no noxious stimulus was allowed during the study period of 5 minutes after intubation.^{12,13}

At the end of surgery, the neuromuscular block was reversed by using Inj. atropine 0.02 mg/kg and Inj. neostigmine 0.04 mg/kg titrated according to response. Oropharyngeal suction was done, and patient was extubated when fully awake and when T1 had returned to 90% of the control.

Statistical Analysis

Statistical analysis was done using the software Statistical Package of Social Science version 20. Quantitative data viz. Haemodynamic parameters, age, weight, duration of laryngoscopy of the study groups were expressed in terms of mean $\pm$ SD and conduct an unpaired 't' test and one-way repeated measure (ANOVA) in SPSS. This includes both between subjects' factors and within subject factors.

Qualitative data viz. sex, weight and intubating conditions were compared across the group using chi-square test. Differences were considered statistically significant if $p < 0.01$ for all the above statistical analysis.

RESULTS

Sl. No.	Suxamethonium (n=25)	Rocuronium (n=25)	Total (n=50)	Statistical Significance
1	Age Group (yrs.)			
(a)	Less than 30	6 (16.0)	4 (24.0)	$\chi^2=0.50@$ ($p=0.479$) df= 1
(b)	More than 30 yrs.	19 (84.0)	21 (94.0)	
	Total	25 (100.0)	25 (100.0)	
2	Mean Age and SD (yrs.)			$t=1.14@$; $p=0.26$
3	Mean Wt. SD			$t=0.36@$; $p=0.71$
4	Sex			
(a)	Male (1%)	12 (48.0)	13 (52.0)	$\chi^2=0.08@$ ($p=0.777$) df= 1
(b)	Female (1%)	13 (52.0)	12 (48.0)	
	Total	25 (100.0)	25 (100.0)	

Table 1. Age, Weight, Sex Distribution

@ Not significant.

Sl. No.	Group	Duration of Laryngoscopy (Sec) (Mean $\pm$ SD)
1	Suxamethonium	18.68 $\pm$ 6.97
2	Rocuronium	19.72 $\pm$ 7.94
	Total	19.20$\pm$ 7.33
Statistical significance		t= 0.492@; p= 0.625
Table 2. Duration of Laryngoscopy		

Table 2. Duration of Laryngoscopy

@ Not significant.

Intubation Score	Suxamethonium Group (n= 25)	Rocuronium Group (n= 25)	Total (n= 50)	Chi-Square
Excellent	20 (80.0)	11 (44.0)	31 (62.0)	$\chi^2=7.168^*$ ($p=0.028$) df= 2
Good	5 (20.0)	13 (52.0)	18 (36.0)	
Poor	0 (0.0)	1 (4.0)	1 (2.0)	
Total	25 (100.0)	25 (100.0)	50 (100.0)	

Table 3. Intubation Score

*Significant at 0.05 level ($p < 0.05$).

Figure 1. Comparison of the Overall Intubation Conditions

The intubation conditions were graded as excellent in 20(80%) and 11(44%) patients of Group S and Group R respectively. The difference was statistically significant between Group S and Group R ($p < 0.05$). In Group S (suxamethonium) ($n = 25$) 20 patients had excellent intubating conditions, 5 patients had good intubating conditions and none of the patients had poor intubating conditions. In Group R (rocuronium) ($n = 25$) 11 patients had excellent intubating conditions, 13 patients had good intubating conditions and one patient had poor intubating condition.

Descriptive Statistics				
Time	Groups	Mean	Std. Deviation	N
T1	Group R	83.00	10.583	25
	Group S	79.40	11.053	25
	Total	81.20	10.863	50
T2	Group R	85.04	9.973	25
	Group S	85.08	10.704	25
	Total	85.06	10.239	50
T3	Group R	95.36	12.659	25
	Group S	92.12	13.430	25
	Total	93.74	13.019	50
T4	Group R	93.32	12.110	25
	Group S	86.08	15.223	25
	Total	89.70	14.096	50
T5	Group R	90.80	11.772	25
	Group S	83.84	15.448	25
	Total	87.32	14.040	50
T6	Group R	85.20	10.332	25
	Group S	79.12	12.804	25
	Total	82.16	11.917	50
T7	Group R	83.60	10.575	25
	Group S	79.00	11.083	25
	Total	81.30	10.970	50

Table 4. Changes in the Mean Heart Rate

Note: Group S: Suxamethonium; Group R: Rocuronium;

1. Mauchly's test of sphericity value 116.278; significant at $p < 0.001$ level (within time intervals).
2. Within-subjects' effects time * groups were not significant.

Figure 2. Comparison of Heart Rate Variations

Heart rate was comparable ($p > 0.05$) between both groups, (Group S and R) at baseline after induction and during the study period of 5 mins after intubation. However, in both the groups (Group S and R), patient's heart rate increased significantly at 0.001 level from the baseline up to 3 mins after intubation and came to below the baseline value during fourth and fifth minute after intubation.

Descriptive Statistics				
Time	Groups	Mean	Std. Deviation	N
T1	Group R	114.00	11.619	25
	Group S	115.52	11.095	25
	Total	114.76	11.270	50
T2	Group R	106.24	9.597	25
	Group S	107.84	10.180	25
	Total	107.04	9.825	50
T3	Group R	122.32	12.938	25
	Group S	125.36	12.526	25
	Total	123.84	12.696	50
T4	Group R	120.48	14.917	25
	Group S	122.80	10.677	25
	Total	121.64	12.892	50
T5	Group R	117.08	15.349	25
	Group S	116.92	9.823	25
	Total	117.00	12.754	50
T6	Group R	112.20	10.817	25
	Group S	113.52	9.010	25
	Total	112.86	9.875	50
T7	Group R	111.48	10.763	25
	Group S	111.88	8.964	25
	Total	111.68	9.805	50

Table 5. Changes in the Mean Systolic Blood Pressure

Note: Group S: Suxamethonium; Group R: Rocuronium;

1. Mauchly's test of sphericity value 190.979; significant at $p < 0.001$ level (within time intervals).
2. Within-subjects' effects time * groups were not significant.

Figure 3. Comparison of Mean Systolic Blood Pressure

Comparison of mean systolic blood pressure was not significant ($p > 0.05$) between both groups at baseline, after induction and during the study period of 5 mins after intubation. However, in both the groups (Group S and R), patient's systolic blood pressure increased significantly at 0.001 level from the baseline up to 3 mins after intubation and came to below the baseline value during 4th and 5th minute after intubation. When compared clinically, SBP values were within 30% from the baseline value in both groups.¹⁴

Sl. No.	Time	Suxamethonium Group (n=25)	Rocuronium Group (n=25)	Statistical Significance
1	T1	72.96±11.10	70.24±10.34	P>0.05;
2	T2	60.92±10.73	62.92±11.79	P>0.05;
3	T3	81.72±9.27	78.24±8.17	P>0.05;
4	T4	75.44±9.30	72.52±8.57	P>0.05;
5	T5	71.76±10.38	70.60±9.36	P>0.05;
6	T6	69.84±10.45	68.48±9.92	P>0.05;
7	T7	69.12±10.63	67.92±9.74	P>0.05;
Statistical Significance		F ratio= 9.541**; P = 0.000;	F ratio = 5.742 P < 0.000;	

Table 6. Changes in Mean Diastolic Blood Pressure

@- Not significant; **significant at 0.01 level (p < 0.01).

Descriptive Statistics				
Time	Groups	Mean	Std. Deviation	N
T1	Group R	70.24	10.349	25
	Group S	72.96	11.107	25
	Total	71.60	10.713	50
T2	Group R	62.92	11.797	25
	Group S	60.92	10.731	25
	Total	61.92	11.206	50
T3	Group R	78.24	7.666	25
	Group S	81.72	9.271	25
	Total	79.98	8.601	50
T4	Group R	72.52	8.579	25
	Group S	75.44	9.301	25
	Total	73.98	8.977	50
T5	Group R	70.60	9.363	25
	Group S	71.76	10.381	25
	Total	71.18	9.801	50
T6	Group R	68.48	9.921	25
	Group S	69.84	10.455	25
	Total	69.16	10.110	50
T7	Group R	67.92	9.738	25
	Group S	69.12	10.631	25
	Total	68.52	10.108	50

Note: Group S: Suxamethonium; Group R: Rocuronium;

1. Mauchly's test of sphericity value 145.551; significant at p < 0.001 level (within time intervals).
2. Within-subjects' effects time * groups were not significant.

Figure 4. Comparison of Mean Diastolic Blood Pressures

Diastolic blood pressure was comparable (p > 0.05) between both groups, (Group S and R) at baseline, after induction and during the study period of 5 mins after intubation. However, in both the groups patient's diastolic blood pressure increased significantly at 0.001 level from the baseline up to 3 mins after intubation and came to below the baseline value during the 4th and 5th minute after intubation. When compared clinically, DBP values were within 30% from the baseline value in both groups.¹⁵

Sl. No.	Time	Suxamethonium Group (n=25)	Rocuronium Group (n=25)	Statistical Significance
1	T1	87.16±10.56	84.84±8.83	P>0.05;
2	T2	76.64±9.70	77.40±8.489	P>0.05;
3	T3	96.40±8.03	92.64±6.75	P>0.05;
4	T4	91.24±8.51	88.36±6.94	P>0.05;
5	T5	86.84±8.83	84.52±6.52	P>0.05;
6	T6	84.40±8.90	82.80±7.39	P>0.05;
7	T7	84.32±8.90	82.36±7.71	P>0.05;
Statistical Significance		F ratio= 11.442; p < 0.001;	F ratio= 10.117; P < 0.001;	

Table 7. Changes in the Mean Arterial Pressure

Descriptive Statistics				
Time	Groups	Mean	Std. Deviation	N
T1	Group R	84.84	8.83	25
	Group S	87.16	10.56	25
T2	Group R	77.40	8.49	25
	Group S	76.64	9.70	25
T3	Group R	92.64	6.75	25
	Group S	96.40	8.51	25
T4	Group R	88.36	6.94	25
	Group S	91.24	8.51	25
T5	Group R	84.52	6.52	25
	Group S	86.84	8.83	25
T6	Group R	82.80	7.39	25
	Group S	84.40	8.90	25
T7	Group R	82.36	7.71	25
	Group S	84.32	8.90	25

Note: Group S: Suxamethonium; Group R: Rocuronium;

1. Mauchly's test of sphericity value 151.021; significant at p < 0.001 level (within time intervals).
2. Within-subjects' effects time * groups were not significant.

Figure 5. Comparison of Mean Arterial Pressure Variation

Mean arterial pressure was comparable ($p > 0.05$) between both groups, (Group S and R) at baseline, after induction and during the study period of 5 mins after intubation. However, in both the groups, patient's mean arterial pressure increased significantly $p < 0.001$ from the baseline up to 3 mins after intubation and came to below the baseline value during 4th and 5th minute after intubation. When compared clinically, MAP values were within 30% from the baseline value in both groups.

DISCUSSION

An ideal muscle relaxant should therefore have non-depolarising mechanism of action, rapid onset, short duration, rapid recovery, non-cumulative, no histamine release, no cardiovascular side effects, high potency and prompt reversibility by cholinesterase inhibitors and pharmacologically inactive metabolites.¹⁶

CONCLUSION

The following conclusions can be drawn from the above study. Both groups were comparable haemodynamically and had comparable clinically acceptable intubating conditions, although suxamethonium group had better intubation scores indicating the quality of intubation with suxamethonium is better than rocuronium. This proves that suxamethonium is still the "gold standard" for tracheal intubation. However, in conditions where suxamethonium is contraindicated, Rocuronium in a dose of 0.9 mg/kg can be used to intubate the trachea at 60 seconds.

It establishes the usefulness of Rocuronium in 0.9 mg/kg as a safer and better alternative to succinylcholine in conditions where the latter is contraindicated or hazardous.

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