ORIGINAL RESEARCH ARTICLE

Comparative Study of Different Doses of Rocuronium Bromide for Intubating Conditions & Haemodynamic Stability for General Anaesthesia in Paediatric Patients

Manisha Kapdi[1], Shivangi Patel[2]

[1]Associate Professor, Department of Anaesthesia, NHLM Medical College, Ahmedabad, [2]Resident, Department of Anaestheaia, NHLM Medical College, Ahmedabad, Gujarat, India

Corresponding author: Manisha Kapdi, Associate Professor, Department of Anaesthesia, NHLM Medical College, Ahmedabad, India

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A B S T R A C T

Introduction: Endotracheal intubation is necessary for General anaesthesia use of succinylcholine for intubation is since decades Burnes non depolarising agent Rocuroniumbromide provide early intubation with Haemodynamic stability. Study aimed to compare the intubating conditions & Haemodynamic responses of different doses (0.6, 0.9, 1.2 mg/kg) of Rocuronium bromide at 60 seconds in children.

Material and methods: This study was conducted to compare and evaluate effect of three different doses of Rocuronium bromide for endotracheal intubation in paediatric ASA I & II patients aged2-12 years of either sex.

Group A - 0.6 mg/kg of Rocuronium bromide
Group B - 0.9 mg/kg of Rocuronium bromide
Group C - 1.2 mg/kg of Rocuronium bromide

Results: Laryngoscopy and endotracheal intubation in each group were accessed by Cooper et al criteria. 60%, 85%, 100% patients showed Excellent intubating conditions in group A, B, C respectively. 25% and 15% patients showed Good intubating condition in group A and B respectively, while only group A showed poor intubating condition in 15% of patient. Rocuronium bromide has clinically unacceptable intubating condition at 60 seconds after bolus dose of 0.6 mg/kg (15%) as compared to 0.9 and 1.2 mg/kg (0%).

Conclusion: Rocuronium bromide is a hemodynamically stable neuromuscular blocking agent at dose 0.6.mg/kg, 0.9 mg/kg and 1.2 mg/kg as hemodynamic parameters like HR, SBP, DBP at 1 min, 3 min and 5 min after intubation were stable, within normal limits and comparable. (p>0.05)

Keywords: Doses of Rocuronium Bromide, Intubating Conditions, Haemodynamic Stability, General Anaesthesia, Paediatric Patients

INTRODUCTION

Endotracheal intubation is of paramount importance in general anesthesia requiring relaxation of laryngeal musculature leading to total inactivity of vocal cords. Ever since the advent of anesthesia, anesthesiologists have been in search of an ideal muscle relaxants which can provide ideal intubating conditions in ultrashort duration with minimal side effects.[1] Out of all the relaxants Succinylcholine has been the drug of choice for intubation since its introduction in 1952. Doses of 1-1.5mg/kg provide excellent intubating condition in 60-90 seconds with short duration of action. Considering the side effects and contraindications efforts were made to find out a newer neuromuscular blocking agent with a comparable fast onset and shorter duration of action but without associated side effects.[2,3,4] Thus considering the problems associated with succinylcholine for search for a new nondepolarizing neuromuscular blocking agent with rapid onset, brief duration of action and minimal side effect has led to discovery of Rocuroniumbromide which is a new aminosteroidal neuromuscular blocking agent related structurally to Vecuronium. Chemically it is, 1– [17β-acetyloxyl–3-α-hydroxy–2B (4Morpholinyl) 5α-androstan-16β-y1] –1– (2–propenyl) pyrolidinium bromide. The new NDMR drug Rocuronium bromide introduced in 1994 became the first competitor for Succinylcholine.[5,6] Rocuronium bromide when given in two to three times the ED95, is said to produce excellent to good intubating conditions in 60 seconds similar to those obtained with Succinylcholine but with excellent cardiovascular stability. Further Rocuronium bromide being a nondepolarizing agent is devoid of the adverse effects that are seen with Succinylcholine. Its main advantage over other currently used drugs of this kind is its fast onset of

action, which could render Rocuronium bromide the muscle relaxant of choice for rapid facilitation of tracheal intubation. Present study was done to compare the effect of different doses of Rocuronium bromide for endotracheal intubation at 60 seconds & to compare the effect of three doses 0.6 mg/kg, 0.9 mg/kg, 1.2 mg/kg of Rocuronium bromide in facilitating tracheal intubation in variou Surgeries in paediatric patients divided in three groups of 20 patients each.

MATERIAL AND METHODS

The study was conducted by taking 60 randomly selected paediatric patients for various surgeries of moderate duration. Patients belonged to ASA Grade I/II aged 2-12 years were divided into 3 groups of 20 patients each.

Group allocation was done by Randomization table, execution of randomised opaque sealed envelopes were opened at the time of giving general anaesthesia.

Group-A: Rocuronium bromide 0.6 mg/kg I.V. (2x ED_{95})
Group-B: Rocuronium bromide 0.9 mg/kg I.V. (3 x ED_{95})
Group-C: Rocuronium bromide 1.2 mg/kg I.V. (4 x ED_{95})

Exclusion Criteria

Pattients Known or anticipated difficult airway, with neuromuscular disease, on drugs known to interact with neuromuscular blocking agents

Renal or Hepatic disorder, Known allergy to drugs

Preoperative Evaluation

Written informed consent was obtained from parents of all the children. All the patients were evaluated preoperatively for any past or present medical and surgical illness, any history of previous anesthetic exposures, drug treatment or drug-allergy. Patients were thoroughly examined generally and systemicaly and investigations like complete blood count, blood Sugar, renal function test, serum electrolytes, serum bilirubin and chest X-Ray, ECG were reviewed. patients were Nil by mouth as per standard starvation protocol.

Monitoring

In the operation theatre, I.V. line of appropriate size was secured after applying EMLA cream20 min before taking patient for operation. I.V. Ringers Lactate solution started. Noninvasive BP cuff, ECG monitor, pulse oximeter, peripheral nerve stimulator were applied to patient.

Group Allocation

Randomised group allocation was done by computerised Randomisation table.

Execution of Randomisation at the time of giving general anaesthesia.

Premedication

Inj. Glycopyrrolate 0.004 mg/kg I.V. and inj.mildazolam 0.02 mg/kg & Inj. Fentanyl 1 µg/kg I.V. 5 minutes before induction of anaesthesia.

Induction

All Patients were preoxygenated with 100% O_2 and were induced with Injection thiopentone5 mg/kg I.V. slowly and Injection Rocuronium Bromide according to group allocation and the time of Injection of Rocuronium bromide noted.

In Group A - 0.6 mg/kg
In Group B - 0.9 mg/kg
In Group C - 1.2 mg/kg

Patients were ventilated with 100% oxygen with facemask. At 60 seconds after completion of Rocuronium bromide injection, laryngoscopy was done and patients intubated with well lubricated cuffed endotracheal tube of appropriate size. Bilateral breath sounds checked for equality $EtCO_2$ monitor applied after fixing the tube.

Laryngoscopy and endotracheal intubation were accessed and graded according to Cooper et al criteria.[8]

Score	Jaw relaxation	Vocal cords positions	Response to Intubation
0	Poor (Impossible)	Closed	Severe bucking or coughing
1	Minimal (Difficult)	Closing	Mild coughing
2	Moderate (Fair)	Moving	Slight diaphragmatic movement
3	Good (Early)	Open	None

Score interpretation

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

Clinical acceptable: 6-9

Clinical unacceptable 0-5 The vital parameters like pulse rate, systolic and diastolic blood pressure were recorded at fixed time intervals i.e. Before Induction, After Induction, 1 min after Intubation 3 min after Intubation, 5 min after Intubation

Maintainance

Anaesthesia was maintained with Oxygen, Nitrous oxide, Sevoflurane (1%) and Inj.Rocuronium.

Peroperatively patients heart rate, blood pressure, ECG, SpO_2 and $EtCO_2$ were monitored. Patients were also watched for any adverse reactions like anaphylactic reaction, rash, exanthema, urticaria and bronchospasm.

Reversal: At the end of surgery patients were reversed with Injection Glycopyrrolate 0.01 mg/kg and Injection Neostigmine 0.05 mg/kg after recovery of spontaneous respiration. Oropharyngeal suction was done and patient was extubated when fully awake and after recovery of adequate muscle tone& power with, cough reflex.

STATISTICAL ANALYSIS

The results were expressed as mean±SD and percentages. All recorded data were entered using MS Excel software and analysed using SPSS software IBM Armonk NY 2016 for determining the one-way statistical significance Analysis of Variance (ANOVA) with Kruskal Wallis test was used to study the significance of mean of various study parameters among the three groups.

P value	
>0.05	Non Significant(NS)
<0.05	Significant(S)
<0.001	Highly Significant(HS)

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Parameter	Group A	Group B	Group C	Group D	Inference
Age	6.2±1.2	7.4±1.5	6.3±1.9	6.1±1.7	0.96(NS)
Weight	24.2±4.3	22.5±8.6	23.5±7.5	21.6±7.2	0.97(NS)
Sex(M/F)	12/8	12/8	11/9	11/9	-
ASA Grade(I/II)	15/5	14/6	15/5	14/6	-
Duration of surgery	49+/-5	50 ±6	53±3	52±4	0.7(NS)

Table–1: Demographic data

Jaw relaxation	Group A	Group B	Group C
Good (early)	13(65%)	17(85%)	20(100%)
Moderate (fair)	4(20%)	3(15%)	0
Minimal (difficult)	3(15%)	0	0
Poor (impossible)	0	0	0

Table–2: Jaw relaxation

Vocal cords	Group A	Group B	Group C
Open	12(60%)	17(85%)	20(100%)
Moving	6(30%)	3(15%)	0
Closing	2(10%)	0	0
Closed	0	0	0

Table-3: Vocal cord position

	Group A	Group B	Group C
None	10(50%)	16(80%)	20(100%)
Slight diaphragm movement	7(35%)	4(20%)	0
Mild coughing	3(15%)	0	0
Severe bucking or coughing	0	0	0

Table–4: Response to intubation

Intubation conditions	Group A	Group B	Group C
Excellent (8-9)	12 (60%)	17 (85%)	20 (100%)
Good (6-7)	5 (25%)	3 (15%)	0
Poor (3-5)	3 (15%)	0	0
Bad (0-2)	0	0	0

Table–5: Intubating Conditions

Parameter	Group A	Group B	Group C
Clinically acceptable	17(85%)	20(100%)	20(100%)
Clinically unacceptable	3(15%)	0	0

Table-6: clinical acceptable conditions

RESULTS

Sixty elective paediatric patients of either sex of 2-12 years and belonging to ASA I and II were included in the study. In each group 20 patients were included. Patients were divided into 3 groups.

Group A: Rocuronium bromide 0.6 mg/kg I.V.

Group B: Rocuronium bromide 0.9 mg/kg I.V.

Group C: Rocuronium bromide 1.2 mg/kg I.V.

Table-1 shows demographic data are comparable in all the three groups.Patient belonging to ASA Grade I and II were included in this study.

Table-2 shows that jaw relaxation was most difficult in group A (15%) as compared to group B (0%) and group C (0%) During laryngoscopy, in group A 60% of patient had open vocal cord position, while in group B 85% and group C (100%) patient showed open vocal cord position (table-3).

Slight diaphragmatic movement was noticed 35%, 20% and 0% in group A, B, C respectively. Mild coughing was seen in group A (15%). No patient in any group had severe bucking or coughing (table-4).

60%, 85%, 100% patients showed excellent intubating conditions in group A, B, C respectively. 25% and 15% patients showed Good intubating condition in group A and B respectively, while only group A showed poor intubating condition in 15% of patient (table-5).

85% patient in group A had clinically acceptable intubating conditions, while in group B and C all (100%) patients had clinically acceptable intubating condition (table-6).

DISCUSSION

Neuromuscular blocking agents are required for smooth endotracheal intubation during general anesthesia. There are maximum chances of hypoxia, regurgitation and aspiration after induction of anaesthesia and before tracheal intubation with cuffed endotracheal tube. So, muscle relaxant should be such that it facilitates early intubation to decrease the chances of hypoxia and regurgitation.

The provision of muscle relaxation during endotracheal intubation demands a drug that can provide good to excellent intubating conditions, as early as possible, with minimal side effects and stable hemodynamic profile.

Succinylcholine is a depolarizing neuromuscular blocking agent which has been gold standard since its introduction in 1952 for endotracheal intubation. Dose of Succinylcholine 1-1.5 mg/kg provide excellent intubating condition in 60-90 seconds with short duration of action. Unfortunately it has many side effects because of which it has fallen in disrepute.Other nondepolarising muscle relaxant such as Atracurium and Vecuronium have adverse effects like histamine release and slower onset of action respectively. In search of alternatives, Nondepolarising muscle relaxant Rocuronium bromide has emerged which has rapid onset (60-90 seconds) intermediate duration of action depending on dose. Rocuronium bromide is a derivative of Vecuronium bromide and is 5-7 times less potent than Vecuronium.The present study was conducted by taking 60 randomly selected patients for various surgeries belonging to ASA Grade I/II aged 18 to 60 years of either sex and MPG grade I/II.

Patient were divided into 3 groups of 20 patients each.

Group A received - 0.6 mg/kg of Rocuronium bromide

Group B received - 0.9 mg/kg of Rocuronium bromide

Group C received - 1.2 mg/kg of Rocuronium bromide

Demographic Data
In our study, Table 1 shows Age, Weight, Sex, ASA Grading, Duration of surgery were comparable in each group (p>0.05). Jamshid Ali et al (2008)[18] have comparable demographic data. (p>0.05)

Premedication
In our study, all the patients were premedicated with Injection Glycopyrrolate 0.004 mg/kg 1.V. and Injection Fentanyl 1 μg/kg 1.V. 5 minutes before induction of anaesthesia. Cooper et al (1992)[8] used Fentanyl as premedication.
Kirkegaard Mielsen H et al (1999)[19] premedicated patient with Midazolam 2 mg and Fentanyl 2 μg/kg. Glycopyrolate is used as antisecretory agent. By giving Fentanyl as premedication so that mask placement for induction would be easy for induction. In this study, induction was done with injection thiopentone 5 mg/kg I.V. and Injection Rocuronium bromide (0.6, 0.9, 1.2 mg/kg). Cooper et al (1992)[8] anaesthetised patients with Thiopentone sodium. Cheng et al (2002)[7] did a study with Thiopentone sodium and alfentanyl induction. Jamshid Ali et al (2008)[18] induced patients with Thiopentone sodium.

Dose of Rocuronium Bromide
In our study, we compared intubating conditions with three different doses of Rocuronium bromide 0.6, 0.9 and 1.2 mg/kg in fascilitating tracheal intubation. Magorian et al (1993)[24] compared the effects of one of the three doses of Rocuronium bromide (0.6, 0.9, 1.2 mg/kg) with Vecuronium (0.1 mg/kg), or Succinylcholine (1.0 mg/kg).
Dr Chanda Khatri et al (2016)[14] compared three different doses 0.3, 0.6 and 0.9 mg/kg Rocuronium bromide for endotracheal intubation.
Raghavan L et al (2016)[30] compared three different doses of Rocuronium bromide 0.6, 0.9, 1.2 mg/kg for intubating conditions.
Raizada et al (2018)[26] compared three different doses 0.6, 0.9, 1.2 mg/kg Rocuronium bromide.
Kumar A et al (2018)[20] evaluated the intubating conditions with Rocuronium bromide at 0.6 and 0.9 mg/kg at 60 seconds.

Time of intubation
In our study we aimed to achieve tracheal intubation at 60 seconds after Rocuronium bromide injection. We have taken 60 seconds because this is within the time range (60-90 seconds) recommended for tracheal intubation so as to avoid aspiration and hypoxia and within the range used in previous studies.
Copper et al (1992)[8] assessed intubating conditions after administration of Rocuronium bromide 0.6 mg/kg at 60 or 90 seconds in groups of 20 patients.
Alvarez-Gomez JA et al (1994)[3] used 0.6 mg/kg Rocuronium bromide for endotracheal intubation within 60 second.
Curl JF etal[9] have used to Rocuronium,with alfentanyl, propofol & access for intubation at 45 sec after Rocuronium.
Kusuma Parikh et (2014)[21] compared intubating conditions after succinylcholine 1.5 mg/kg at 60 seconds, Rocuronium bromide 0.6 mg/kg at 60 seconds and 90 seconds.
Kumar A et al (2018)[20] evaluated the intubating conditions with Rocuronium bromide at 0.6 and 0.9 mg/kg at 60 seconds.

Criteria for assesment of intubating conditions
In our study we used Cooper et al criteria for grading intubating condition.Cooper et al (1992)[8] used Cooper et al criteria for comparision. Jamshed et al (2008)[18] used Cooper et al criteria for comparing intubating condition.

Intubating conditions
In this study, patients were divided in 3 groups according to dose of Rocuronium bromide given as
Group A - 0.6 mg/kg
Group B - 0.9 mg/kg
Group C - 1.2 mg/kg
After 60 seconds of giving Rocuronium bromide intubating conditions were assessed and patients were intubated.Table no 2, 3, 4 showed jaw relaxation, vocal cord position, response to intubation in three groups. Table no 5, 6 showed intubating conditions according to Cooper et al criteria in three groups. The intubating conditions achieved in this study are as under:

ln Group A (0.6 mg/kg) - 60% patients had excellent, 25% patients had good, 15% patients had poor intubating condition.i.e. 85% patients had clinically acceptable and 15% patients had clinicallyunacceptable intubating condition.

In Group B (0.9 mg/kg) - 85% had excellent,15% had good intubating condition.
i.e. 100% patients had clinically acceptable intubating condition.

ln Group C (1.2 mg/kg)- 100% patients had excellent
i.e. clinically acceptable intubating condition.
So, Rocuronium bromide in the dose of 0.9 and 1.2 mg/kg seems to be adequate for tracheal intubation at 60 seconds and 0.6 mg/kg of Rocuronium may be inadequate in adult patient for intubation at 60 seconds. As all the patients in 0.9 and 1.2 mg/kg group had clinically acceptable intubating conditions, there seems to be no further advantage for intubating conditions in increasing the dose from 0.9 to 1.2 mg/kg.

Cooper et al (1992)[8] assessed intubating conditions by using Cooper et al criteria and found to be clinically acceptable (good and excellent) in 95% of patients at 60 seconds and in 100% of patients at 90 seconds in Rocuronium group.

Magorian et al (1993)[24] concluded that onset times for patients receiving 0.9 mg/kg and 1.2 mg/kg of Rocuronium bromide and Succinylcholine were similar. Onset times for groups given 0.6 mg/kg of Rocuronium and Vecuronium were significantly longer. So, dose dependent decrease in onset time with Rocuronium. Intubating conditions did not differ significantly in the five groups. Clinical duration of action was longest with 1.2 mg/kg Rocuronium, similar with 0.6 mg/kg and 0.9 mg/kg Rocuronium and Vecuronium and least with Succinylcholine.

Jamshid Ali et al (2008)[18] concluded that in unpremedicated patients intubating conditions after 0.6 mg/kg Rocuronium bromide at 60 seconds are unsatisfactory in a significant number of cases. So they suggested that higher doses of

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Rocuronium bromide (0.9-1.2 mg/kg) should be used for rapid sequence induction of anaesthesia especially if the anticipated surgical times is long.

Dr Chanda Khatri et al (2016)[14] found that in group 0.3 mg/kg intubating conditions at 60 seconds were poor in 65% and intubation was impossible in 35%. In group 0.6 mg/kg intubating conditions were excellent in 60% and satisfactory in 40%. In group 0.9 mg/kg intubating conditions were excellent in 85% and satisfactory in 15%.

Raghavan L et al (2016)[30] concluded that patients receiving 0.6 mg/kg were more likely to experience moderate coughing and bucking after tracheal tube insertion. Both 0.9 mg/kg and 1.2 mg/kg produce similar onset time and intubating conditions with no statistically significant difference between the two groups. Rocuronium in doses of 1.2 mg/kg produces similar intubating conditions as 0.9 mg/kg, but the duration of action is very much prolonged. No further improvement in intubation conditions were achieved by increasing the dose of Rocuronium from 0.9 mg/kg to 1.2 mg/kg.

Hemodynamic parameters

Changes in heart rate and systolic & Diastolic blood pressure following intubation with Rocuronium bromide with all three doses is minima & statistically Non significant. ($p>0.05$)

Maddineni et al (1994)[23] found no significant changes in both heart rate and mean arterial pressure while using 0.6 or 0.9 mg/kg of Rocuronium.

Levy et al (1994)[22] concluded that between three dose groups, there was no significant difference with respect to these hemodynamic parameters with Rocuronium bromide 0.6, 0.9 and 1.2 mg/kg.

Raghavan L et al (2016)[30] observed that there was no statistically significant difference with regard to mean heart rate and mean arterial pressure during intubation.

Raizada et al (2018)[26] observed no significant difference in pulse rate and MAP among three groups of 0.6, 0.9 and 1.2 mg/kg Rocuronium bromide.

From the above studies it is evident that Rocuronium bromide does not cause any significant changes in heart rate and blood pressure following intubation in clinically administered doses.

Adverse effects

In present study no adverse side effect had been reported in the doses used in terms of stable SpO_2, ECG, $ETCO_2$ & Hemodynamic parameters.

CONCLUSION

In nutshell 0.9 mg/ kg & 1.2 mg/ kg of Rocuronium provide clinical açceptable good Intubation conditions In comparison of 0.6 mg/kg in Paediatric patients.

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