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Research Protocol

Anaesthesia Section

Comparison of Intubating Conditions of Two Doses of Rocuronium Bromide with Succinylcholine in Children-Protocol for a Randomised Control Trial

MAITRI PATEL[1], VIJAY CHANDAK[2]

ABSTRACT

Introduction: As a depolarising Neuromuscular Blocking Drug (NMBD), succinylcholine is a muscle relaxation of choice during intubation due to its fast onset effect and ultrashort duration of action. But, it is associated with complications like bradycardia, asystole, hyperkalaemia, myalgia, an increase in intraocular pressure and masseter spasm in children. Rocuronium bromide is an intermediate-acting non depolarising muscle relaxant with faster onset of action. So, it can be used as an alternative for intubation to avoid unwanted side-effects of succinylcholine.

Aim: To compare two doses of rocuronium bromide with succinylcholine in terms of intubating conditions, duration of action, haemodynamic variations and complications associated with muscle relaxant.

Materials and Methods: A randomised double blinded clinical trial will be planned after taking prior permission from ethical committee. A total 90 children of age between 1-10 years with American Society of Anaesthesiologists (ASA I) and ASA II would be equally divided into three groups. Group S would receive succinylcholine 1.5 mg/kg while Group R9 and R12 would receive rocuronium bromide 0.9 mg/kg and 1.2 mg/kg, respectively. Comparative evaluation of intubating conditions would be done around 60 seconds in all three groups. Also, the duration of action, haemodynamic parameters and complications would be observed.

Conclusion: At the end of study, one can compare the two doses of rocuronium bromide against succinylcholine which provides the same intubating conditions without haemodynamic variations and complications.

Keywords: Duration of action, Endotracheal intubation, Muscle relaxant, Neuromuscular blocking drug

INTRODUCTION

The NMBDs are used to provide muscle relaxant during intubation, which is most important process that involved in surgeries of children undergoing in general anaesthesia. The main goal of NMBDs is to provide paralysis of vocal cords and muscles of jaw during intubation. To achieve successful tracheal intubation with less laryngeal injuries, rapid onset of neuromuscular blockade is required. In 1952, Thesleff and Foldes and associates have introduced succinylcholine, which rapidly gained attention and changed anaesthesia practise because of the rapid onset of effect and ultrashort duration of neuromuscular blockade. Due to this, rapid endotracheal intubation and rapid recovery from neuromuscular blockade is possible. It is the only depolarising muscle relaxant in clinical use. As depolarising muscle relaxant succinylcholine, produces prolonged depolarisation of end plate region. The ultrashort action is due to its rapid hydrolysis by butyrylcholinesterase.

Although, being as a muscle relaxant of choice for intubation, succinylcholine has also received significant attention because of the severity of the possible complications. Cardiac arrythmia may follow intravenous (i.v.) administration. Cardiac sinus arrest may follow after first i.v. bolus but it is most commonly seen in children after second bolus administration. Cardiac arrest may occur in children at any age [1]. Therefore, a vagolytic drug should be administrated just before the first dose in all children unless a contraindication to tachycardia. The bradycardia may be prevented by administration of atropine, ganglion blocking agent and NMBDs [2]. The potential of rhabdomyolysis and hyperkalaemia as well as the risk of malignant hyperthermia, suggest that succinylcholine should not be routinely used in children [3]. To avoid these complications in normal healthy children, a routine administration of succinylcholine during intubation should be avoided.

Because of unwanted complications that are associated with administration of succinylcholine in normal healthy children, the use of succinylcholine in children only reserved for emergency airway management including of severe laryngospasm and as a part of a Rapid Sequence Induction (RSI) where the child has a full stomach. So, there is a need to find out alternative NMBD for intubation in healthy children undergoing elective surgeries which provides intubation conditions with fast onset of action like succinylcholine.

Many trials were done to replace succinylcholine with NMBDs like vecuronium and atracurium but because of slower onset of action these drugs are not suitable for emergency intubation and where the securing airway is the priority. Rocuronium bromide, as an intermediate acting non depolarising NMBD with faster onset of action and have low potency as compared to other NMBDs. When succinylcholine is contraindicated or its side-effects are undesired, RSI can be accomplished using high dose of rocuronium bromide, this provides adequate intubating condition in less than 90 seconds [4]. Although, the use of a large dose of rocuronium bromide can lead to long duration of action [5]. So, in the elective surgeries where return of spontaneous recovery is not needed, rocuronium bromide with its large intubating dose can be a good alternative option to achieve same intubating conditions like succinylcholine.

The aim of the present study was to compare two doses of rocuronium bromide with succinylcholine to get better alternative dose of rocuronium bromide which provides the same intubating conditions like succinylcholine in the children undergoing elective surgeries. The primary objective of the study is to compare intubating conditions at 60 seconds while the duration of action, haemodynamic variations and complications are the secondary objectives of this study.

MATERIALS AND METHODS

A randomised control trial, during period of 2020-2023, would be carried out in the Department of Anaesthesia at Jawaharlal Nehru Medical College, Sawangi, Wardha, Maharashtra, India. The permission from ethical committee has been obtained (DMIMS(DU/IEC/2020-21/9360).

Inclusion criteria: Ninety children aged between 1-10 years would be selected of ASA I and ASA II for elective surgeries under general anaesthesia.

Exclusion criteria: Children undergoing emergency surgeries, with history of hyperkalaemia, neurological disorder, burn, family history of malignant hyperthermia and those with known/anticipated difficult intubation.

Ninety children will be divided randomly into three groups as below:

- Group S- Succinylcholine 1.5 mg/kg would be given.
- Group R9- Rocuronium bromide 0.9 mg/kg would be given.
- Group R12- Rocuronium bromide 1.2 mg/kg would be given.

A table of random number will be generated in the computer by allotting equal number of children in each group. Three junior resident of anaesthesia will be assisted by an expert anaesthesiologist during the procedure. Intubation will be performed by one of the junior resident. Blinding at three levels will be done in the form of the drug loader, the drug administrator and anaesthesia resident performing the intubation.

Study Procedure

Thorough preanaesthetic check-up will be done prior to surgery. Nil per oral will be confirmed prior to surgery. After taking informed, verbal and written consent from parents/guardian children would shift to operative room. Monitors will be attached and baseline haemodynamic parameters will be noted. The patients will be induced with sevoflurane and i.v. access will be secured. Inj. Glycopyrrolate 0.004 mg/kg and Inj. Midazolam 0.5 mg/kg will be given. Inj. propofol will be given as 1 mg/kg. For analgesia, Inj. fentanyl 2 mcg/kg will be given. Check for ventilation will be done. The drug of choice of muscle relaxant will be administered as per the group allocation. After giving muscle relaxant intubation will be performed around 60 seconds and following parameters will be noted:

- Intubation conditions around 60 seconds in each group.
- Haemodynamic variables like Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP) (at 0, 5, 10 min).
- Duration of neuromuscular blockade.

After above observation, child will be maintained on oxygen+ N20+sevoflurane and supplementation of muscle relaxant doses as per requirement till end of surgery. At the end of surgery, the child would be received either myopyrolate 0.05 mg/kg and extubated after checking adequate respiratory efforts.The intubating conditions will be assessed according to the following scoring system [Table/Fig-1] [6].

Score	Jaw relaxation	Vocal cords	Response to intubation
0	Impossible to open	Closed (adducted)	Severe coughing or bucking
1	Opens with difficulty	Closing	Mild coughing
2	Moderate opening	Moving	Slight diaphragmatic movement
3	Easy opening	Open (relaxed)	No movement

[Table/Fig-1]: Scoring of intubating conditions.
Scores would be graded as follows: 8-9=excellent, 6-7=good, 3-5=fair, 0-2=poor

STATISTICAL ANALYSIS

Statistical analysis will be done using software SPSS-11. Quantitive data like haemodynamic variables, age, weight, duration of action in all three study group would be expressed as mean±SD and compared among group using ANOVA. Qualitative data like sex, ASA category and intubating condition would be compared in all three groups using Chi-square test. The difference should be statistically significant if p-value <0.005 for all above analysis.

DISCUSSION

In this study, the comparison of two doses of rocuronium bromide with succinylcholine in children will be done to evaluate which dose of rocuronium bromide could provide acceptable alternative to succinylcholine with regards to intubating conditions and haemodynamic variables. The dosage of rocuronium bromide would be 0.9 mg/kg and 1.2 mg/kg while succinylcholine 1.5 mg/kg for the study. Haemodynamic parameters like HR, SBP, DBP and MAP. Complications due to muscle relaxant will be noted in the present study.

Naguib A et al., found that rocuronium bromide 0.9 mg/kg provided acceptable intubating conditions for rapid tracheal intubation in children when compared with succinylcholine [7]. Sardhara NV et al., compared the effect of different doses (0.6 mg/kg, 0.9 mg/kg, 1.2 mg/kg) of rocuronium bromide for endotracheal intubation at 60 seconds [8]. The study showed that rocuronium bromide in the dose of 0.9 mg/kg and 1.2 mg/kg provides better clinically acceptable intubating conditions at 60 seconds than 0.6 mg/kg. Rocuronium bromide is a haemodynamically stable neuromuscular blocking agent with all the three doses 0.6 mg/kg, 0.9 mg/kg and 1.2 mg/kg.

A study comparing three different doses of rocuronium bromide (0.6 mg/kg, 0.9 mg/kg, 1.2 mg/kg) at 60 seconds in paediatric ASA I and ASA II patients concluded that all three doses are providing stable haemodynamic conditions in the form of heart rate, systolic and diastolic blood pressures at one minute, three minutes and five minutes after intubation [9]. Raizada N et al., compared three same above-mentioned doses of rocuronium bromide [10]. They reported that with 1.2 mg/kg i.v. dose a rapid onset of action, longer duration and excellent intubating conditions is achieved as compared to other two doses of rocuronium bromide. So, the large dose can be used for intubation where succinylcholine is contraindicated. Narasimha Gnani BC and Uma BR compared rocuronium bromide (0.9 mg/kg and 1.2 mg/kg) with succinylcholine for paediatric intubation and concluded that duration of action is slightly different in two doses of rocuronium bromide although suitable intubating conditions can be achieved with two doses of rocuronium bromide [5].

Chavan SG et al., also studied 0.6 mg/kg and 0.9 mg/kg rocuronium bromide with succinylcholine for endotracheal intubation and concluded that though succinylcholine provide superior intubating conditions with propofol and fentanyl [11]. A large dose of rocuronium bromide give perfect intubating conditions when succinylcholine is contraindicated. Apart from above mentioned studies, rocuronium bromide 0.6, 0.9 and 1.2 mg/kg doses were compared in various aspects and with various agents to find out excellent intubating conditions like succinylcholine. In these studies, rocuronium bromide 0.9 and 1.2 mg/kg can provide excellent or good intubating condition like succinylcholine while 0.6 mg/kg dose is not. So, high dose of rocuronium bromide can be used as better alternative to succinylcholine to avoid its unwanted complications in normal healthy children in the terms of intubating conditions and stable haemodynamics.

Limitation(s)

The limitation of high dose of rocuronium bromide is the long duration of neuromuscular blockade as compared to succinylcholine. So, its use can be limited to elective surgeries in which spontaneous recovery of respiration is not needed. Although, with the availability of sugammadex, as a rapid onset selective binding agent for rocuronium, rapid return of spontaneous ventilation can be possible during intubation and RSI with high dose of rocuronium bromide.

CONCLUSION(S)

Being a muscle relaxant of choice during intubation, succinylcholine is associated with unwanted side-effects. To avoid these side-effects rocuronium bromide can be a good alternative to succinylcholine for intubation because of its fast onset of action. To achieve similar intubating conditions like succinylcholine (stable haemodynamics and without complications) the study will compare two doses of rocuronium bromide with succinylcholine to find out which dose of rocuronium bromide is more suitable as an alternative to succinylcholine for intubation in children undergoing elective surgeries.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College, Sawangi, Wardha, Maharashtra, India.
2. Associate Professor, Department of Anaesthesia, Jawaharlal Nehru Medical College, Sawangi, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Maitri Patel,
Postgraduate Resident, Department of Anaesthesia, Jawaharlal Nehru Medical College, Sawangi, Wardha, Maharashtra, India.
E-mail: patelmaitrii26@gmail.com

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