Original Article

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Anaesthesia Section

Intubating Conditions and Efficacy of Rocuronium versus Atracurium in Paediatric Patients undergoing Elective Surgeries under General Anaesthesia: A Randomised Clinical Trial

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ABSTRACT

Introduction: Atracurium and rocuronium are non depolarising Neuromuscular Blockers (NMBs) with an intermediate duration of action and are used safely in the short and intermediate duration of surgical procedures in paediatric population.

Aim: To compare the efficacy and safety of NMBs (rocuronium versus atracurium) at a dose 2 x (ED95) for elective surgeries under general anaesthesia in paediatric patients.

Materials and Methods: The present randomised, double-blinded, clinical trial study was conducted in the Department of Anaesthesiology and Intensive care, Adesh Institute of Medical Science and Research (AIMSR), Bathinda, Punjab, India, from October 2021 to April 2022. Seventy American Society of Anaesthesiologists (ASA) grade I-II patients of both sexes of 1-12 years age, undergoing elective surgeries under general anaesthesia were included in the study. These patients were randomly divided into two groups: patients receiving rocuronium (0.6 mg/kg) (group R, n=35) and patients receiving atracurium (0.5 mg/kg) (group A, n=35) for endotracheal intubation. Assessments were done for timing of intubation, intubation score, interpretation of relaxogram, haemodynamics, adverse events, extubation (normal or delayed) and recovery time. All the data was entered in Microsoft excel sheet and results were expressed as percentages and mean±Standard Deviation (SD), Chi-square test and unpaired t-test.

Results: Time of intubation was faster with rocuronium than atracurium (66±20.32 vs 100.29±21.76 seconds). Intubation score was significantly lower in group A (2.14±0.36) than group R (3.74±0.44). Heart Rate (HR) increased significantly after intubation with atracurium. Adverse effects like bronchospasm, hypotension, skin reaction and wheeze were found in patients receiving atracurium but not in rocuronium group. Faster onset and recovery with short clinical duration was found with rocuronium on relaxogram. Delayed extubation was found in 45.7% patients in atracurium group and 5.7% patients in rocuronium group.

Conclusion: Rocuronium gives excellent intubating conditions with faster induction time, shorter clinical duration, high recovery index, minimal side-effects and good haemodynamic stability than atracurium in paediatric patients.

Keywords: Clinical duration, Intubation score, Induction time, Recovery index

INTRODUCTION

Neuromuscular Blocker (NMB) is an essential part of general anaesthesia. They are used for endotracheal intubations and mechanical ventilation. They avoid patient movement, facilitate surgery, decrease anaesthetic requirement and oxygen consumption [1].

Atracurium and rocuronium are non depolarising NMBs with an intermediate duration of action and are used safely in the short and intermediate duration of surgical procedures in paediatric population [2]. Depolarising NMB like succinylcholine has early onset and short duration of action but it is not preferable in paediatric patients due to its side-effects like hyperkalemia, myoglobinaemia, rhabdomyolysis, cardiac arrhythmias, masseter spasm and malignant hyperthermia [2,3].

Rocuronium bromide is an aminosteroidal non depolarising NMB, monoquaternary analogue of vecuronium. It is primarily eliminated via hepatic reuptake and biliary excretion, and up to 20% is excreted unchanged in urine [4]. It has one metabolite 17-desacetyl rocuronium with 5-10% activity of the parent compound and no histamine release. ED95 is the amount of neuromuscular blocking drug required to reduce twitch height by 95%. Several multiples of the ED95 (e.g., two to three times ED95) are usually administered to ensure adequate neuromuscular blockade for intubation. Adult ED95 of rocuronium is 0.3 mg/kg [5].

Atracurium is benzylisoquinoline non depolarising NMB. It is eliminated mainly by Hofmann degradation resulting in metabolite laudanosine which has no neuromuscular blocking effect. Atracurium causes histamine release and may cause slight fall in arterial pressure. The adult ED95 is 0.5 mg/kg [6].

Both atracurium and rocuronium have intermediate duration of action but rocuronium has rapid onset of action as compared to atracurium [3]. Apart from excellent intubating conditions due to rapid onset of action, rocuronium provides high recovery index, minimal side-effects and good haemodynamic stability than atracurium in paediatric patients. In spite of these advantages rocuronium is not used in daily practice so more studies are required to compare the intubating conditions, recovery profile, haemodynamic changes and complications between rocuronium and atracurium.

The study was conducted to compare the efficacy and safety of NMB rocuronium versus atracurium at a dose 2 x (ED95) for elective surgeries under general anaesthesia in paediatric patients. The primary objectives were to compare the onset of action, intubating conditions, recovery of the NMB between the two groups. Secondary objective was to compare the haemodynamic changes and complications between the two groups.

MATERIALS AND METHODS

This randomised, double-blinded, clinical trial study was conducted in the Department of Anaesthesiology and Intensive care, Adesh Institute of Medical Science and Research (AIMSR), Bathinda, Punjab, India, from October 2021 to April 2022. The approval from Institutional Ethical Committee was obtained (AU/EC/FM/2021/137) and the trial was registered at the Clinical Trial Registry of India (CTRI/2021/10/037489). Written informed consents were obtained from the parents during the preanaesthetic evaluation.

Inclusion criteria: A total of 70 American Society of Anaesthesiologists (ASA) grade I-II patients of both sexes, age between 1-12 years, Mallampati class I and II undergoing elective surgeries of average duration <1 hour, under general anaesthesia were included in the study.

Exclusion criteria: Parents refusing to give informed consent, history of major cardiovascular, pulmonary, hepatic, renal and neuromuscular diseases, allergic to any study drug, patients on medications which interfere with NMBs (calcium channel blockers, B-blockers, steroids, anticonvulsants, frusemide, polypeptide antibiotics or aminoglycosides), those with diseases affecting neuromuscular transmission (myopathies) or family history of neuromuscular disease, overweight patients, children coming for emergency operations were excluded from the study,

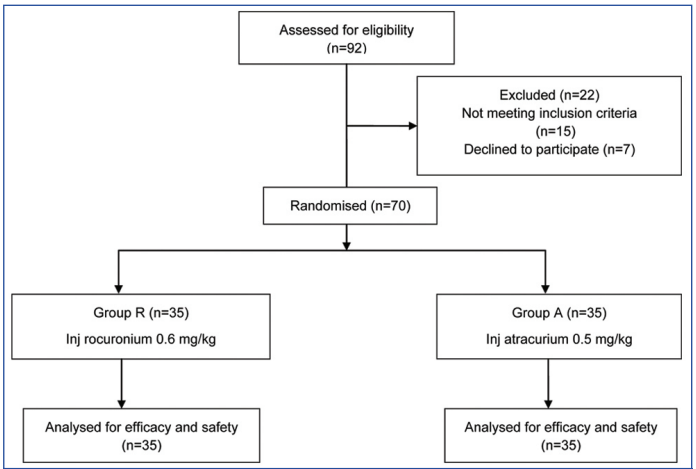
Sample size calculation: Sample size was calculated using sample size calculator method [7] with confidence level 95% and margin of error 5%. Sample size was found to be 60 (30 per group). In addition, for any cases which may be excluded after the start of the procedure 10% additional number of cases was added to the sample size. So the final sample size was set as 70 (35 per group).

Study Procedure

A detailed preanaesthetic check-up was done. Written informed consent was obtained during the preanaesthetic evaluation and explained to parents or child if he or she can understand the study procedure. The study procedure and drug's side-effects were explained to them in the language they understand.

These patients were equally randomly divided into two groups (Group R and Group A, 35 patients in each group) with the help of computer generated randomisation [Table/Fig-1]:

- Group R: Patients receiving rocuronium (0.6 mg/kg) for endotracheal intubation
- Group A: Patients receiving atracurium (0.5 mg/kg) for endotracheal intubation



[Table/Fig-1]: CONSORT diagram.

The concerned anaesthetist was kept blind about the type of study group. Patients were kept Nil By Mouth (NBM) for six hours prior to surgery. In the operating room intravenous Isolyte-P drip was started. Standard ASA monitors were attached. Baseline Heart Rate (HR), blood pressure and Oxygen Saturation (SpO_2) were recorded. Before start of procedure paracetamol suppository (20-30 mg/kg) was administered for postoperative analgesia.

Preparation of constant current peripheral nerve stimulator for monitoring of action potential of the first dorsal interosseous muscle as a result of percutaneous stimulation of the ulnar nerve at the wrist of the left forearm was done by cleaning the forearm and hand with alcohol, then the five surface electrodes of the device was fixed. Two were placed for the stimulation of ulnar nerve, two were placed for recording Electromyography (EMG) response of that muscle, while the fifth was placed for grounding, and then the hand was carefully fixed with adhesive plaster.

All patients were premedicated with Intravenous (i.v) glycopyrolate (0.004 mg/kg) and fentanyl (2 µgm/kg) 10 minutes prior to induction. All patients were preoxygenated with 100% oxygen for three minutes via mask gently placed over the face. For induction of anaesthesia 6% sevoflurane with simultaneous mask ventilation with 50% Oxygen (O_2) and 50% Nitrous Oxide (N_2O), 6 L/min flow rate via Jackson Rees circuit was given.

Calibration of the relaxogram was performed using supramaximal stimulation delivered in Train-Of-Four (TOF) every 20 seconds and when twitch height was stable, it was considered as a control and then the intubating dose of NBM was injected. Endotracheal intubation was facilitated with rocuronium (0.6 mg/kg) i.v. in group R and atracurium (0.5 mg/kg) i.v in group A with suitable sized cuffed endotracheal tube.

The anaesthetist who was blind to the given NBM did the endotracheal intubation after 60 seconds of NBM injection and at the same time intubating conditions were assessed with intubation score by using a four point scale:

- **Excellent (score-4):** relaxed jaw, abducted immobile vocal cords, and no diaphragmatic movement.
- **Good (score-3):** relaxed jaw, abducted immobile vocal cords, and some diaphragmatic movement (bucking).
- **Poor (score-2):** relaxed jaw, moving vocal cords, coughing on intubation.
- **Inadequate (score-1):** jaw is not relaxed, adducted vocal cords, and impossible intubation.

If the intubating condition was excellent or good, tracheal intubation was performed, and if it was poor or inadequate, intubation was postponed and it was reattempted every 30 seconds. Anaesthesia was maintained with 50% N_2O and 50% O_2 and sevoflurane to total MAC of 2-3%. Mechanical ventilation was adjusted to maintain End Tidal CO_2 ($EtCO_2$) between 35-40 mmHg.

Interpretation of the relaxogram chart was done to determine the following parameters:

- **Onset time:** Time from NMB injection to 95% suppression of height of first twitch (T) of TOF (sec).
- **Clinical duration:** Time from NMB injection to 25% recovery of twitch height (T_1) (min).
- **75% recovery:** Time from NMB injection to 75% recovery of twitch height (T_1) (min).
- **90% recovery:** Time from NMB injection to 90% recovery of twitch height (T_1) (min).
- **The recovery index:** Time from 25% to 75% recovery of twitch height (T_1) (min).
- **Recovery time:** Time interval between completion of NMB injection and return to TOF 70%.

Haemodynamic variables like HR, Mean Arterial blood Pressure (MAP) were recorded at the following intervals:

- **A0:** before induction (baseline).
- **A1:** after induction and before injection of NMB.
- **A2:** after injection of NMB and before endotracheal intubation.

- **A3:** just after intubation.
- Then every five minutes for 30 minutes after intubation, then every 15 minutes afterwards till extubation and complete recovery.

Any adverse events like histamine release in the form of skin reaction, bronchospasm, wheeze, increased airway pressure, O_2 desaturation, or hypotension were recorded. Any postoperative pain at the site of injection of NMB was recorded.

Isolyte P was infused at rate 4 mL/kg/hour. Surface warming was applied to maintain oesophageal temperature between 36-37°C. No top-up doses of NMB were given. At the end of operation sevoflurane was discontinued and 100% oxygen was given at flow rate of 6 L/min, neuromuscular blockade was reversed by using neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg after return of spontaneous breathing. Extubation was done once patient was awake, with adequate spontaneous breathing, maintaining normal SpO_2 and $EtCO_2$, normal vital signs and no significant bleeding from the surgical site. If extubation was within expected time (<15 minutes) it was noted as normal extubation. If extubation took more than expected time (>15 min) it was noted as delayed extubation. After extubation patient was shifted to recovery room for standard recovery room care. Recovery was assessed with the Modified Aldrete score at 5, 15 and 30 minutes following extubation of patient [8,9].

STATISTICAL ANALYSIS

All the data was recorded and analysed using Microsoft excel software. Results were expressed as percentage or mean±Standard Deviation (SD). The discrete and categorical variables were analysed using Chi-square test. Continuous variables were analysed using unpaired t-test. The p-value less than 0.05 was considered to be statistically significant.

RESULTS

Total 70 patients (group R and group A, 35 patients in each group) were enrolled and finally analysed. Patients of the study groups were comparable with respect to demographic data. Statistical analysis revealed non significant differences between the two study groups regard to age, weight, sex and ASA grading [Table/Fig-2].

Parameters	Group A (n=35)	Group R (n=35)	p-value
Age (years), Mean±SD	6.51±3.12	6.34±3.14	0.82
Weight (Kg), Mean±SD	20.71±8.72	19.94±8.02	0.701
Gender (M:F)	23:12	17:18	0.147
ASA grading I:II	24:11	27:8	0.420

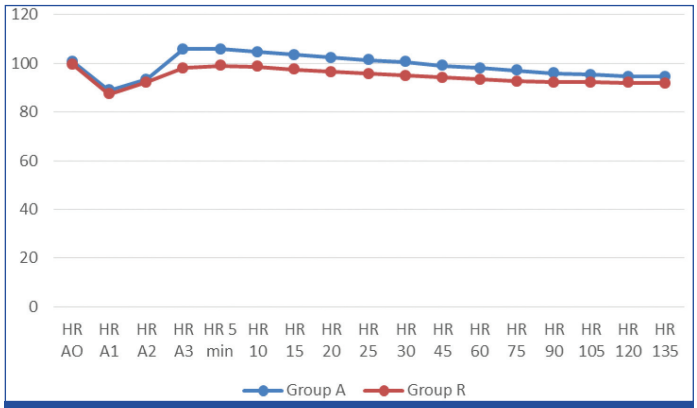
[Table/Fig-2]: Comparison of demographic data between two groups.
SD: Standard deviation; M: Males; F: Females; ASA: American society of anaesthesiologists

After induction of anaesthesia endotracheal intubation was facilitated with rocuronium (0.6 mg/kg) i.v. in group R and atracurium (0.5 mg/kg) i.v. in group A. Intubation score was significantly lower in group A than group R. Modified Aldrete score (at 5, 15, 30 minutes) were similar in both groups [Table/Fig-3].

Parameters	Group A (n=35) (Mean±SD)	Group R (n=35) (Mean±SD)	t	p-value
Intubation score	2.14±0.36	3.74±0.44	-16.663	<0.001*
Modified aldrete score 5 minutes	8.6±0.5	8.77±0.43	-1.549	0.126
Modified Aldrete Sc score 15 minutes	9±0.49	9.17±0.38	-1.642	0.105
Modified Aldrete score 30 minutes	9.89±0.32	9.91±0.28	-0.393	0.695

[Table/Fig-3]: Comparison of intubation score and Modified Aldrete score in both groups.
SD: Standard deviation. *p-value <0.05 was considered statistically significant

The HR decreased from baseline in both groups at A0, A1 and A2 interval (before intubation). It increased significantly after intubation A3 and thereafter in group A as compared to group R (p-value <0.001) [Table/Fig-4]. It returned to baseline at the end of procedure in both groups. There was no significant difference in mean arterial pressure, SpO_2 and $EtCO_2$ in both the groups.



[Table/Fig-4]: Comparison of Heart Rate (HR) in both groups at different intervals.

In group A bronchospasm was observed in 2 (5.7%), hypotension in 1 (2.9%), skin reaction in 1 (2.9%), wheeze in 2 (5.7%) patients. No adverse effects were found in group R patients [Table/Fig-5].

Variables	Group A n (%)	Group R n (%)	p-value
Bronchospasm	2 (5.7%)	0	0.161
Hypotension	1 (2.9%)	0	
Skin reaction	1 (2.9%)	0	
Wheeze	2 (5.7%)	0	
Nil	29 (82.9%)	35 (100.0%)	

[Table/Fig-5]: Comparison of adverse effects in both groups.

Interpretation of the relaxogram chart was done. It showed that onset time was significantly higher in group A than group R. Recovery index was significantly higher in group A than group R. Recovery time was higher in group A than group R [Table/Fig-6].

Parameters	Group A (n=35) (Mean±SD)	Group R (n=35) (Mean±SD)	t	p-value
Onset time (seconds)	100.29±21.76	66±20.32	6.813	<0.001*
Clinical duration- 25% recovery of t_1 (minutes)	32.6±1.97	26.14±6.07	5.982	<0.001*
75% recovery of t_1 (minutes)	43.91±2.78	33.51±3.08	14.827	<0.001*
90% recovery of t_1 (minutes)	45.51±2.83	33.97±2.67	17.534	<0.001*
Recovery index (minutes)	9.89±1.49	8.89±1.59	2.718	0.008*
Recovery time (minutes)	47.28±7.26	35.86±4.2		0.02*

[Table/Fig-6]: Interpretation of relaxogram.
SD: Standard deviation. *p-value <0.05 was considered statistically significant

Extubation was delayed in 16 (45.7%) patients in group A as compared to 2 (5.7%) in group R, and it was normal in 19 (54.3%) patients in group A as compared to 33 (94.3%) in group R (p-value <0.001) [Table/Fig-7].

Extubation	Group A (n=35) n (%)	Group R (n=35) n (%)	p-value
Delayed	16 (45.7%)	2 (5.7%)	<0.001*
Normal	19 (54.3%)	33 (94.3%)	

[Table/Fig-7]: Comparison of time to extubation in both groups.
Normal extubation: <15 min, Delayed extubation: >15 minutes. *p-value <0.05 was considered statistically significant

DISCUSSION

Succinylcholine is the drug of choice for rapid and successful endotracheal intubation. Due to its adverse effects, an alternative like atracurium or rocuronium are considered [10]. Atracurium and rocuronium are the intermediate acting non depolarising

neuromuscular agents which can be used in paediatric patients for endotracheal intubation [2,11,12]. Atracurium is preferable especially in short and intermediate duration surgical procedures due to its prompt recovery but it causes side-effects like skin rash, erythema, hypotension, tachycardia or bronchospasm [10,13]. Rocuronium has early onset of action and shorter duration of action. Rocuronium (0.6 mg/kg) has good intubating conditions which results intubation within 60 seconds of intravenous administration [2,3,14,15]. Therefore, the aim of the present study was to compare the efficacy and safety of rocuronium versus atracurium. It was found that rocuronium provides excellent intubating conditions with faster induction time and high recovery index than atracurium in paediatric patients.

Similar to the present study, Miguel RV et al., observed that rocuronium (0.45 mg/kg) had better intubation scores at 60 seconds than atracurium (0.5 mg/kg) [16]. Khan AK et al., in their 60 paediatric patients observed that with rocuronium (0.6 mg/kg) had better intubation score at 60 seconds than atracurium (0.46 mg/kg) (p-value <0.001) which was again similar to present study [3].

Elbaradie S conducted study on 60 patients undergoing general surgical operations. They reported rapid, successful intubation with rocuronium 0.6 mg/kg than with atracurium 0.5 mg/kg group [10]. Intubation within 90 seconds of the injection of the muscle relaxant in all 30 patients in the rocuronium group and in only 20 out of the 30 patients in the atracurium group (p-value=0.005).

Chetty MS et al., in day care dental procedures reported that percentage of good and excellent intubating conditions at 60 seconds was 80% for rocuronium (0.45 mg/kg) and 12.5% for atracurium (0.35 mg/kg) [17].

Scheiber G et al., conducted study on 60 children reported excellent or good intubating conditions with rocuronium 0.6 mg/kg than vecuronium 0.1 mg/kg and atracurium 0.5 mg/kg (intubation within 60 sec, 120 sec and 180 sec, respectively) [18]. They reported excellent intubation in 12 children in the rocuronium group, 5 children in vecuronium group and the 2 children in atracurium groups.

Whalley DG et al., conducted study on patients undergoing laparoscopic gynaecological surgery reported similar intubating conditions in both rocuronium 0.6 mg/kg and atracurium 0.5 mg/kg [19]. Khan MA et al., conducted study on 80 paediatric patients undergoing adenotonsillectomies observed that quality of intubation was good and same in majority of patients [2]. In contrast to present study, they used low doses of the both atracurium (0.3 mg/kg) and rocuronium (0.3 mg/kg) for intubation.

In the present study, HR was decreased from baseline in both groups at A0, A1 and A2 interval (before intubation). It was increased significantly after intubation A3 and thereafter in group A as compared to group R. This shows poor intubating conditions with atracurium which gives rise to increase in HR. HR returns to baseline at the end of procedure in both groups. There was no significant difference in mean arterial pressure, SpO_2 and $EtCO_2$ in both the groups.

Khan AK et al., reported that before induction and intubation there was no significant difference between rocuronium and atracurium group in HR and mean arterial pressure [3]. But significant rise of HR and fall of mean arterial pressure with atracurium and slight rise of HR, almost no change in mean arterial pressure with rocuronium was observed just after intubation (p-value <0.001). Atracurium increases HR due to poor intubation condition and decreases blood pressure due to histamine release when it is given rapidly. Elbaradie S also reported that atracurium resulted in significant decrease in mean arterial pressure and increase in HR whereas rocuronium did not produce any significant changes in MAP and HR (p-value <0.015) [10].

The adverse effects like macular rash or erythema along the course of the vein of injection, hypotension, tachycardia and bronchospasm are mainly due to histamine release after atracurium injection [13]. It results in positive inotropic and chronotropic effects on myocardial H_2 receptors. Other substances liberated by mast cell degranulation, such as tryptase or prostaglandins may also play a role [10].

In present study in group A bronchospasm, hypotension, skin reaction wheeze were observed. No adverse effects were found in group R patients. Elbaradie S also reported mild to moderate erythema over trunk and face with decrease in MAP and increase in HR due to histamine release in patients receiving atracurium [10]. In the present study, interpretation of relaxogram showed that onset time (from NMB injection to 95% suppression of T1) was faster with rocuronium than atracurium.

In the present study, 25%, 75% and 90% recovery in Group A was 32.6±1.97 min, 43.91±2.78 minutes and 45.51±2.83 minutes, respectively and in group R, it was 26.14±6.07 minutes, 33.51±3.08 minutes and 33.97±2.67 minutes, respectively. Recovery index was higher in Group A than Group R. Recovery time (from NMB injection to return of TOF to 70%) was significantly longer in group A than group R. This showed significantly faster onset and shorter clinical duration of the intubating dose of rocuronium than atracurium. There is large variability of neuromuscular response to non depolarising muscle relaxants in small children [19].

Similar to the present study, Elbaradie S also reported shorter onset time, clinical duration of intubating dose of muscle relaxant and time to spontaneous recovery of rocuronium 0.6 mg/kg than with atracurium 0.5 mg/kg group ((54±22 seconds, 34±6.9 minutes and 53±6.2 minutes, respectively) and the clinical duration of the intubating dose of the muscle relaxant was significantly shorter with rocuronium than atracurium (94±26 seconds, 45±7.1 minutes and 58.9±7.56 minutes, respectively) [10].

Similar to present study, Khan AK et al., reported that TOF ratio at 60 seconds was higher with atracurium than rocuronium (78.90±0.72 vs 60.43±0.87) [3]. This proved that neuromuscular blockade at 60 seconds at the adductor pollicis muscle was greater after rocuronium than that of atracurium.

Ribeiro FC et al., also proved that rocuronium is better option than atracurium for short surgical procedures in paediatric patients [20]. They reported significantly faster onset of action with rocuronium 0.6 mg/kg (86±44.9 seconds) than atracurium 0.5 mg/kg (126.3±61.0 seconds). They observed statistically significant difference between rocuronium and atracurium for recovery of T1 to 50%, 75% and 90% as well as for the time taken to a TOF ratio of 70%. But recovery index for rocuronium (9.2±3.43 minutes) and atracurium (10.9±2.65 minutes) was not significantly different. They reported significantly shorter clinical duration with rocuronium than atracurium (22.8±5.31 vs 31.5±6.01 minutes).

Scheiber G et al., did frequent interval intubation attempts to assess development of optimum laryngeal conditions [18]. They observed that 95% or more neuromuscular blockade with rocuronium or vecuronium and only one patient in atracurium group had less than 94% neuromuscular blockade. Peripheral neuromuscular block was not complete at the time of successful intubation in most patients in all groups. They proved that there was similar difference in onset at the laryngeal muscles compared with the adductor pollicis muscle in children.

Whalley DG et al., observed that onset time was shorter with rocuronium 0.6 mg/kg than atracurium 0.5 mg/kg (59.0±22.0 vs 98.6±41.4 sec) (p-value <0.001) [19]. But they reported slower recovery rate index and spontaneous recovery to 70% TOF with rocuronium which is not similar to present study.

Miguel RV et al., also observed that rocuronium (0.45 mg/kg) was better in onset than atracurium (0.5 mg/kg) [16]. Chetty MS et al., reported that rocuronium 0.45 mg/kg had fastest onset of block than atracurium 0.35 mg/kg (mean 313 vs mean 391.9 seconds) [17].

In the present study, extubation was delayed in 45.7% patients in group A as compared to 5.7% in group R. Khan MA et al., reported that extubation was normal and same in both rocuronium and atracurium groups which is not similar to present study [2]. It means recovery was same in both the groups and patients were smoothly discharged from the recovery room.

Limitation(s)

Limitation of this study is that only frequent-interval intubation attempts begun sufficiently early can reveal development of optimum laryngeal conditions because peripherially assessed onset of neuromuscular block can give no exact indication of the moment when optimum laryngeal relaxation has first been achieved.

CONCLUSION(S)

In the present study rocuronium had excellent intubating conditions with faster induction time, shorter clinical duration, high recovery index, early extubation, minimal side-effects and good haemodynamic stability than atracurium in paediatric patients. Due to these advantages rocuronium is preferable to atracurium in paediatric patients for short duration surgical procedures under general anaesthesia.

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