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A COMPARATIVE STUDY BETWEEN CISATRACURIUM AND ROCURONIUM FOR ONSET TIME, INTUBATING CONDITIONS AND DURATION OF ACTION IN ADULT PATIENT UNDERGOING SURGERY IN GENERAL ANAESTHESIA

Anaesthesiology

Dr. Vaibhav Singh — Assistant Professor, Department of Anaesthesiology and Critical Care, Moti Lal Nehru Medical College, Prayagraj, U.P.

Dr. Dharmendra Kumar Yadav — Associate Professor, Department of Anaesthesiology and Critical Care, Moti Lal Nehru Medical College, Prayagraj, U.P.

Dr. Bhawna* — Junior Resident, Department of Anaesthesiology and Critical Care, Moti Lal Nehru Medical College, Prayagraj, U.P. *Corresponding Author

ABSTRACT

Background : Muscle relaxants have made anaesthesia much safer and provide good operating conditions. An ideal muscle relaxant minimizes the time for intubation and reduces the hemodynamic stress response. The study was designed to compare the onset time, intubating conditions and duration of action between cisatracurium and rocuronium in adult patients undergoing surgery in general anaesthesia. **Materials And Methods :** In this prospective, comparative, randomized, double blinded study, 54 patients of ASA grade I/II of either sex between 20-60 years scheduled for elective surgery under general anaesthesia were randomly allocated into two groups of 27 each; Group-1: given Inj. Cisatracurium 0.1mg/kg and Group-2: given Inj. Rocuronium 0.6mg/kg. The onset time and duration of action were compared between both muscle relaxants using Train of Four (TOF) device after stimulating ulnar nerve. The intubating conditions and hemodynamic variables including systolic and diastolic blood pressure and heart rate were also compared between both of them. **Result :** There was no significant difference between the demographic characteristics between both groups. Group-2 showed significant shorter onset time (2.1±0.24 versus 3.5±0.34 min with $p<0.05$), significant shorter duration of action (30.37±3.37 versus 42.2±2.5 min with $p<0.05$) and significantly better intubating conditions (7.7±1.2 versus 6.7±1.3 with $p<0.05$) than Group-1. There was no significant difference between the hemodynamic variables between both the groups. **Conclusion** : We concluded that Rocuronium has shorter onset time, shorter duration of action and better intubating conditions than Cisatracurium.

KEYWORDS

Cisatracurium, Rocuronium, TOF

INTRODUCTION :

The use of neuromuscular blocking agents remains an essential part of general anaesthesia. With the use of muscle relaxation, endotracheal intubation is made easy and it also aids mechanical ventilation, prevents patient's movement during surgery, decreases anaesthetic requirements, decreases oxygen consumption and provide appropriate surgical conditions.

For many years, much effort has been made to develop neuromuscular blocking agents with rapid onset and short duration[1]. Two such drugs which provide similar conditions are cisatracurium and rocuronium. Cisatracurium and rocuronium are non-depolarizing neuromuscular blockers with an intermediate duration of action. They were introduced into clinical practice in 1992 (rocuronium) and 1995 (cisatracurium) respectively[2,3].

Cisatracurium is a kind of non-depolarising neuromuscular blocking agent with intermediate duration of action. Because cisatracurium is the isomer of atracurium, the neuromuscular blocking potency of cisatracurium is approximately three-fold that of atracurium and the time to maximum blocking is up to 2 minutes longer for equipotent doses of cisatracurium compared to atracurium[4]. A pharmacodynamic profile of cisatracurium is similar to that of atracurium, except for a slower onset[5]. Also, cisatracurium is metabolized by Hoffmann elimination to laudanosine and a monoquaternary acrylate such as atracurium[6]. Unlike atracurium, about five times less laudanosine is produced,and accumulation of this metabolite is not thought to be of any consequence in clinical practice[7].

Rocuronium is a widely used and representative neuromuscular blocking agent, due to possessing a relatively fast onset of peak effects and short duration of muscle relaxation[8]. Rocuronium is a steroid-based, intermediate acting relatively low-potency neuromuscular blocker, primarily eliminated via the liver. Its main advantage is the rapid onset of neuromuscular block.

Adequate control of the duration and quality of neuromuscular blockade during surgery is essential for safe and successful surgery. Incomplete recovery of neuromuscular blockade can endanger patients, decrease the sensitivity to hypoxia, augment the risk of lung complications, cause aspiration, upper airway obstruction, visual trouble, and dysphagia[9,10]. Thus, the proper use of neuromuscular blockers is important[11]. Neuromuscular monitoring is essential to prevent postoperative residual neuromuscular block[12].

Neuromuscular monitoring has four patterns of electrical stimulation which are Single Twitch, Tetany, Double-burst stimulation and Train-of-Four, out of which we will compare our drugs here using Train-of-Four. We designed this study to compare the most recent neuromuscular blockers rocuronium and cis-atracurium for onset time, intubating conditions, and duration of action with the help of Train-of-Four monitor in patients undergoing surgery in general anaesthesia.

MATERIALS AND METHODS :

The present study was carried out in Moti Lal Nehru Medical College and associated hospitals (Swaroop Rani Nehru Hospital), Prayagraj over a period of one year after approval from Institutional Ethical Committee. Written and informed consent was obtained from all the patients/ guardian. A comparative, randomized, prospective, double blind study was carried out on 54 patients undergoing surgery under general anaesthesia aged between 20-60 years of either sex of ASA Grade I-II.

The study included the patients who confirm the following :

Inclusion Criteria:

1. Patients who gave informed and written consent.
2. Age between 20-60 years of either sex.
3. ASA grade I and II patients.
4. Mallampatti class I and II patients.
5. Patients scheduled for elective surgery under general anaesthesia.

Exclusion Criteria:

1. Patient refusal.
2. Patient having age < 20 or > 60 years.
3. ASA physical status III or > III.
4. Mallampatti Grading III or > III.
5. Patient having BMI > 35 kg/mt2.
6. Pregnant and lactating women.
7. Patients with neuromuscular weakness and diseases affecting neuromuscular transmission (myopathies).
8. Patients having major cardiovascular, pulmonary diseases.
9. Patients having prior history of allergy to any of the drugs used in this study.

Randomisation And Group Allocation:

Patients fulfilling the inclusion criteria were randomly allocated and

divided into two groups (27 patients in each group) using computer generated random number table.

GROUP-1 (CISATRACURIUM)	27 Patients	Each patient received Cisatracurium 0.1mg/kg
GROUP–2 (ROCURONIUM)	27 Patients	Each patient received Rocuronium 0.6mg/kg

Double blinding :

Double blinding was achieved by different anaesthesiologists – one for preparation of the study drug and administration of the drug and second for the data collection. Hence, the observer and patient both were unaware of the study.

Statistical Analysis:

The results were analysed using descriptive statistics and making comparisons among various groups. Categorical data were summarized as in proportions and percentages(%) while discrete as mean±SD. The Chi Square test is used for testing the association between variables. The Mann-Whitney U test is used to compare whether there is a difference in the dependent variable for two independent groups. It compares whether the distribution of the dependent variable is the same for the two groups and therefore from the same population. P-value < 0.05 will be considered as statistically significant.

METHODOLOGY :

A detailed Pre-Anaesthetic evaluation was done one day before surgery. After checking all vital parameters, doing systemic examination and evaluating routine investigations patient was given fitness for surgery. All patients received Tab. Alprazolam (0.25 mg) orally and Tab. Ranitidine (150 mg) orally night before surgery, and were advised Nil per oral (NPO) for 6-8 hours.

A standardized protocol for General anaesthesia was followed for all the patients. On the day of surgery, patient was shifted to the operation theatre and an iv line by 18G cannula was secured. The patients received Ringer Lactate i.v.fluid during anaesthesia. Standard parameters including Electrocardiography(ECG), Non Invasive Blood Pressure (NIBP), pulse rate (PR), oxygen Saturation (SpO2), Temperature probe, end-tidal CO2 were attached to the patient and was continuously monitored and recorded every 5 minutes.

Train-of-Four (TOF) monitor was attached to the patient to determine the onset time and duration of action of neuromuscular blocking drug given. For stimulation of ulnar nerve, two ECG electrodes were placed on the volar aspect of the wrist of the patient, one proximal and one distal electrode. Proximal electrode is the positive electrode and distal electrode is the negative electrode. The distal electrode was placed about 1 cm proximal to proximal flexion crease of the wrist. The proximal electrode was placed 2-6 cm proximal to the distal electrode. Electrical stimulation elicits thumb adduction. Placement of negative electrode distally elicits greatest neuromuscular response normally.

All patients were pre-medicated just before induction of anaesthesia with i.v Inj. Midazolam (0.01mg/kg), i.v. Inj. Glycopyrrolate (0.01mg/kg) and i.v. Inj. Fentanyl (2 micrograms/kg). All patients were pre-oxygenated for 3 minutes with 100% oxygen. The patients were induced with i.v. Inj. Propofol (2mg/kg). Following loss of consciousness, the ulnar nerve was stimulated using the neuromuscular monitor. The current strength was progressively increased, and single twitch noted, Current strength for maximal thumb adduction was noted and 25% above that strength which is supramaximal stimulus was used for train of four stimulation. Vitals parameters were recorded. A bolus of i.v. Inj. Cis-atracurium (0.1mg/kg) or i.v. Inj. Rocuronium Bromide (0.6mg/kg) depending on the group was given over a period of 5 to 10 seconds. Patient was ventilated with 66.7% Nitrous oxide and 33.3% Oxygen, Train of four was elicited every 10 seconds and intubation was attempted after disappearance of all 4 responses (onset time- Interval from end of muscle relaxation injection and disappearance of all 4 responses). Intubation was done with appropriate sized cuffed endotracheal tube under direct laryngoscopy. Position of the tube was confirmed with auscultation of bilateral equal air entry with bilateral equal chest expansion and capnography, then the tube was fixed with adhesive. The conditions of intubation were evaluated and scored according to the scoring system described by Cooper et al[13] and ease of laryngoscopy was observed by modified Cormack Lehane grading[14].

After confirmation of position of tube, intermittent positive pressure ventilation (IPPV) was started. Anaesthesia was maintained with Oxygen and Nitrous Oxide mixture (33.3%:66.7%) and inhalational anaesthetic agent Isoflurane at 0.8-1% MAC using closed circuit system with controlled ventilation. Ventilation parameters were tidal volume of 6-8ml/kg, respiratory rate of 12-14/min, and peak inspiratory pressure of 30 cmH2O. End-tidal CO2 was maintained between 35-45 mm Hg. Blood pressure and pulse rate were noted at baseline, induction, intubation, and 5, 10, 15, 30, 45, 60 minutes after intubation. Neuromuscular function monitored using TOF stimuli every 5 minutes, The interval between injection of bolus dose to reappearance of 2 responses to TOF was taken as the duration of action. Reversal of neuromuscular blockade of cis-atracurium and rocuronium was done with i.v. Inj. Neostigmine (0.05mg/kg) and i.v. Inj. Glycopyrrolate (0.01mg/kg). Extubation was done when the TOF ratio is 0.9 and the patient became awake, with regular respiration and clinically adequate tidal volume, after thorough suctioning of oral cavity. The post-operative analgesia was provided with i.v. Inj. Diclofenac sodium (75 mg).

OBSERVATIONS :

Table 1 : Comparison of Demographic Profile

Variable	Total	Group 1	Group 2	p-value
Gender Male/Female	25(46.3%)/ 29(53.7%)	14(51.9%)/ 13(48.1%)	11(40.7%)/ 16(59.3%)	p>0.05
Age in years (Mean+SD)	39.2+14.3	37.2+12.2	39.11+16.2	p>0.05
Weight in Kg (Mean+SD)	60+7.4	61.03+7.3	58.9+7.47	p>0.05

Demographic profile (Age,Weight,Gender) were comparable between with no significant differences between both groups (p>0.05).

Table 2: Comparison of outcome variables among the two groups

	Group-1	Group-2	p-value
Onset Time(min) (Mean±SD)	3.5+0.34	2.1+0.24	P<0.05
Duration of Action(min) (Mean±SD)	42.2+2.5	30.37+3.37	P<0.05
CL Grade 1 Grade 2a Grade 2b Grade 3	14(51.9%) 7(25.9%) 3(11.1%) 3(11.1%)	15(55.6%) 5(18.5%) 4(14.8%) 3(11.1%)	P>0.05

Onset time and duration of action were significantly shorter in Group-2 than in Group-1 (p<0.05). There was no significant difference in CL grading between both the groups (p>0.05).

Table 3: Comparison of Jaw Relaxation, Response to Intubation and Vocal Cord of Group-1 vs Group-2

	Score 1	Score 2	Score 3	Mean+SD	p-value
Jaw Relaxation					P<0.05
Group-1	10(37%)	16(59.3%)	1(3.7%)	1.6+0.5	
Group-2	1(3.7%)	3(11.1%)	23(85.2%)	2.8+0.48	
Response to Intubation					P>0.05
Group-1	9(33.3%)	4(14.8%)	14(51.9%)	2.2±0.64	
Group-2	15(55.6%)	3(11.1%)	9(33.3%)	2.4±0.63	
Vocal Cord					P>0.05
Group-1	0	14(51.9%)	13(48.1%)	2.4+0.5	
Group-2	0	9(33.3%)	18(66.7%)	2.6+0.48	

There was significant difference in mean jaw relaxation between both groups (p<0.05) but the mean scores of response to intubation and vocal cord position were comparable between both groups (p>0.05).

Table 4: Comparison of Intubation score and Intubation Grade of Group-1 vs Group-2

Intubation Score	Group-1	Group-2	p-value
	6.2+1.15	8.07+1.10	P<0.05
Intubation Grad Excelle Good Fair	5(18.5%) 16(59.3%) 6(22.2%)	22(81.5%) 3(11.1%) 2(7.4%)	P<0.05

The mean intubation score was significantly more in Group-2 (8.07+1.10) than Group-1 (6.2+1.15) (p-value<0.05). There was statistical significant difference in intubating conditions between both groups (p<0.05).

Table 5: Group wise comparison of Mean Heart Rate, Systolic BP and Diastolic BP at different time interval

	HR (Mean ±SD)			SBP (Mean±SD)			DBP (Mean ±SD)		
	Group-1	Group-2	p-value	Group-1	Group-2	p-value	Group-1	Group-2	p-value
Baseline	80.1+9.34	77.9+9.6	p>0.05	118.1+8.2	116.7+8.6	p>0.05	74.7+6.1	74.07+6.13	p>0.05
Induction	76.1+7.5	76.03+8.3	p>0.05	122.2+5.2	121.9+7.4	p>0.05	78.3+6.2	79.3+6.1	p>0.05
Intubation	87.14+6.7	88.37+7.6	p>0.05	128.2+4.9	127.3+5.4	p>0.05	83.6+4.8	83.6+4.7	p>0.05
Post 5 min	80.6+5.7	81.8+6.7	p>0.05	119.18+4.08	118.37+4.18	p>0.05	76.5+4.8	77.25+4.3	p>0.05
10 min	78.03+4.3	80.8+4.7	p>0.05	119.25+5.11	118.44+6.75	p>0.05	73.3+5.7	73.1+5.9	p>0.05
15 min	75.3+6.8	76.7+4.2	p>0.05	120+5.29	118.4+5.7	p>0.05	74.4+6.5	74.5+5.5	p>0.05
30 min	77.5+5.65	77.3+4.8	p>0.05	118.14+4.5	115.8+5.6	p>0.05	73.7+5.04	75.2+5.8	p>0.05
45 min	76.5+6.4	77.4+5.05	p>0.05	119.8+5.5	117.7+6.13	p>0.05	76.4+5.35	75.77+6.42	p>0.05
60 min	78.7+6.27	80.8+4.99	p>0.05	120.88+4.4	120.74+6.02	p>0.05	80.5+5.2	79.5+5.03	p>0.05

The hemodynamic variables (HR,SBP,DBP) were comparable between both the groups at all periods of observation.

RESULT :

The demographic data was comparable between both the groups in respect of age, gender, weight (p >0.05).(Table 1)

Statistical analysis showed that the mean onset time of Group-2 (2.1±0.24 min) was significantly shorter than Group-1 (3.5±0.34 min) **(p<0.05)** and the mean duration of action of group-2 (30.37±3.37 min) was significantly shorter than group-1 (42.2±2.5 min)(p<0.05). With regard to CL grading for ease of laryngoscopy, there was no statistical significant difference between both the groups (p>0.05). (Table 2)

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On analysing the jaw relaxation, there was difficulty in opening the jaw in 10(37%) cases in group-1 and 1(3.7%) case in group-2. Fair opening of jaw was seen in 16(59.3%) cases in group-1 and 3(11.1%) cases in group-2. Easy opening of jaw was seen in 1(3.7%) cases in group-1 and 23(85.2%) cases in group-2. Statistical difference was seen in mean jaw relaxation between both the groups (p<0.05).(Table 3)

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Regarding response to intubation, 9(33%) and 15(55.6%) cases in group-1 and group-2 respectively had mild coughing. Slight diaphragmatic response was seen in 4(14.8%) cases in group-1 and 3(11.1%) cases in group-2. There was no response in 14(51.9%) cases in group-1 and 9(33.3%) cases in group-2. Mean score of response to intubation was not statistically significant between both groups (p>0.05). With regard to vocal cord position, vocal cords were moving in 14(51.9%) cases in group-1 and 9(33.3%) cases in group-2. Vocal cords were open in 13(48.1%) cases in group-1 and 18(66.7%) cases in group-2. Mean score for vocal cord position was statistically insignificant between both groups (p>0.05).(Table 3)

The mean intubation score of group-2 was significantly higher than group-1 (8.07±1.10 vs 6.2±1.15) (p<0.05). Acceptable intubating conditions were seen in 5(18.5%) and 16(59.3%) patients for excellent and good scores in group-1 respectively and 22(81.5%) and 3(11.1%) in group-2 respectively. 6(22.2%) patients in group-1 and 2(7.4%) patients in group-2 had fair intubating conditions. Group-2 had significantly better intubating conditions than group-1 (p<0.05). (Table 4)

There was no significant difference in the mean heart rate, systolic blood pressure and diastolic blood pressure between both the groups at all periods of observation (p>0.05).(Table 5)

DISCUSSION :

Muscle relaxants have made anaesthesia much safer and provide good operating conditions. Muscle relaxation is required for tracheal intubation and to facilitate surgical procedures as part of balanced anaesthesia[15]. An ideal muscle relaxant minimizes the time for intubation and reduces the hemodynamic stress response. The ED95 of rocuronium is 0.3mg/kg and cisatracurium is 0.05mg/kg and 2XED95 is the intubating dose of neuromuscular blocking agent. In our study, the intubating dose of both the muscle relaxants Rocuronium and Cisatracurium i.e. 0.6mg/kg and 0.1mg/kg respectively were taken in adult patients under general anaesthesia and we compared the onset time, intubating conditions, duration of action and hemodynamic variables between both the groups. In previous literature, there were limited comparative studies between Rocuronium and Cisatracurium regarding their onset time, intubating conditions and duration of action, therefore, we decided to use these two drugs in our study in two groups of 27 patients each.

We observed that Group-2 was having significantly shorter onset time as compared to Group-1 and also the duration of action of Group-2 was significantly shorter than Group-1. The intubating conditions were significantly better in Group-2 than in Group-1.

Omera M et al[16] compared both Rocuronium and Cisatracurium at a dose 2xED95 evaluating their onset of action in 40 patients and found that Rocuronium -0.6mg/kg had a significant shorter onset time(70.6±18.2 sec) than Cisatracurium –0.1 mg/kg(160.4±14.3 sec) with p<0.001 and significant shorter duration of action (30.3±5.2 min) than Cisatracurium(45.7±7.5 min) with p<0.001. He also found that clinically acceptable intubating conditions were achieved after 60 seconds more frequently after rocuronium (80%) than after cisatracurium (p<0.05).

As per study done **by Naguib M et al**[17] in comparing the time course of 1xED50, 1,1.5 and 2xED95 doses of both cisatracurium and rocuronium, rocuronium had a faster onset as compared with equipotent doses of cisatracurium (p<0.001).

Adamus M et al[18] compared between Cisatracurium and Rocuronium in 120 patients randomized into 4 groups receiving different Cisatracurium (0.1or 0.15mg/kg) and Rocuronium (0.6 or 0.9mg/kg) doses and concluded that rocuronium had a significant shorter clinical duration than cisatracurium for lower doses (p<0.05) and this result is similar to our study.

In study of Wierda J.M.K.H et al[19] the average onset times of 2XED90 dose of Rocuronium(172±71sec) and Vecuronium(192±49 sec) were significantly shorter than that of Mivacurium (229±60 sec) with p<0.05 and the intubating conditions at 90sec after rocuronium were significantly better than those after vecuronium and mivacurium (p<0.05).

The difference of CL grading between both the groups was statistically insignificant (p>0.05). The hemodynamic variables like HR, SBP and DBP were comparable at all periods of observation and there was no statistical difference between both the groups.

Li G et al[20] compared Rocuronium (1.2mg/kg) and Succinylcholine (1mg/kg) for rapid sequence induction in the emergency department of a hospital and orotracheal intubation was performed by direct laryngoscopy which was graded by modified CL grading. They found that there was no statistically significant difference between both the groups (p=0.528).

CONCLUSION

From our study, we concluded that Rocuronium 0.6mg/kg provides faster onset time, better intubating conditions and shorter duration of action as compared to Cisatracurium 0.1mg/kg when 2xED95 doses are used in patients undergoing surgery in general anaesthesia.

Limitations In Our Study

There were few limitations in our study:

1. The sample size used was relatively small.
2. As our study was a single centre study, it is possible that differences in the reported outcomes still exists but could have been influenced by the small sample size.

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