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COMPARISON OF EFFICACY OF ATRACURIUM AND CISATRACURIUM IN PATIENTS UNDERGOING SURGERIES UNDER GENERAL ANAESTHESIA

Anaesthesiology

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ABSTRACT

Background: Neuromuscular blocking drugs (NMB) are very important adjuvant to general anaesthesia . Cisatracurium is a purified 1R cis-1'R cis isomer of atracurium introduced for clinical use in 1995 which is 3 to 5 times more potent and it provides faster onset, longer duration of action with good intubating conditions and is devoid of histamine release. The aim of the study was to compare the efficacy of Atracurium (0.5mg/kg) versus Cisatracurium (0.3mg/kg) as regard to onset of action, duration of action, intubating conditions, haemodynamic effects and signs of histamine release. **Material and Methods:** The study was designed as a prospective randomized single blinded study conducted in the Department of Anaesthesiology and Critical care, Silchar Medical College, Silchar, Assam after obtaining institutional ethical committee clearance. Only ASA I and II without any anticipated difficult airway (MPS-I) and who had given valid informed consent were included. 100 ASA I& II of age 18-60 years were divided into Group-A and Group-B of 50 in each group (n=50). Group-A received inj atracurium 0.5 mg/kg IV & group-B received inj cisatracurium 0.3 mg/ kg IV. Patients with cardiovascular or neuromuscular disease or on drugs known to interact with muscle relaxants, history of allergy to study drugs were excluded from the study. **Results:** Onset time, duration of action,intubating conditions, haemodynamic effects and signs of histamine release in both groups were recorded.In Group-A, mean onset time and duration of actions were 178.72±12.7 (sec) and 38.72±3.36(min), whereas in Group-B, it was 143.82±5.36(sec) and 56.78±1.93(min) respectively and statistically significant ($p<0.05$). In Group-A, 70%(35) had excellent and 30%(15) good intubation grade whereas 92% (46) had excellent and 8% (4) good in Group-B with better haemodynaemic stability & no histamine release. **Conclusion:** In this study,we concluded that cistracurium 0.3mg/kg provided rapid onset, longer duration of action with excellent intubating conditions, better haemodynamic stability and was devoid of histamine release as compared to atracurium 0.5mg/kg .

KEYWORDS

Atracurium, Cisatracurium, Histamine release

INTRODUCTION:

Neuromuscular blocking drugs (NMB) are used as an adjunct to general anaesthesia. They aid endotracheal intubation ,mechanical ventilation & facilitate excellent surgical conditions during general anesthesia. In 1935, D-tubocurarine, a NDMR was the first muscle relaxant isolated from South American vine called Chondrodendron Tomentosum but due to its ganglion blocking properties it resulted in hypotension and tachycardia.[4]

In 1952, Succinylcholine a depolarizing muscle relaxant was introduced which has a faster onset and ultrashort duration of action and is still the relaxant of choice today for rapid sequence induction technique but it has many unintended side effects as fasciculation, masseter spasm, myalgia, hyperkalamia, bradycardia ,increased intraocular, intragastric and intracranial pressure.[5,6] So there was continued research towards the development of new muscle relaxants of rapid onset with longer duration of action, optimal intubating conditions, stable haemodynaemics and devoid of histamine release. Atracurium is a non-depolarizing neuromuscular blocking agent of intermediate duration of action, a racemic mixture of 10 optical isomers of benzyl-isoquinolinium diester. It is eliminated by Hoffman degradation and nonspecific ester hydrolysis.But it triggers histamine release[2] Cisatracurium is a purified 1R cis-1'R cis isomer of atracurium, which is 3 to 5 times more potent than atracurium at higher doses with more haemodynaemic stability and devoid of histamine induced cardiovascular side effects. It is metabolished mainly by Hofmann elimination producing its one metabolite laudanosine which has no neuro-muscular blocking effect. ED95 of cisatracurium is 0.05 mg/kg[2]

AIMS AND OBJECTIVES :

In this study, we compared the efficacy of Atracurium (0.5mg/kg) versus Cisatracurium (0.3mg/kg) in patients undergoing surgeries under general anaesthesia as regard to:

- Onset of action,
- Duration of action ,
- Intubating conditions ,
- Haemdynamic effects (HR,MAP)
- Signs of histamine release.

MATERIALS AND METHODS :

The study was designed as a hospital based, prospective randomized single blinded study conducted in the Department of Anaesthesiology and Critical care, Silchar Medical College and Hospital, Silchar ,Assam. The study was done for one year w.e.f. 1st June 2021 to 31st May 2022 after obtaining Institutional Ethical Committee clearance and written informed consent from patients.100 patients of American Society of Anaesthesiologist (ASA) I & II, age of 18-60 years were divided into group-A and group-B of 50 in each group (n=50)

Inclusion criteria :

Only ASA I and II without any anticipated difficult airway (MPS-I) who had given valid informed consent & patients scheduled for elective surgical procedure under general anaesthesia were included.

Exclusion criteria:

- Patients refusal for general anaesthesia,
- Anticipated difficult airway.
- Patients with Cardiovascular or neuromuscular disorders.
- Drugs known to interact with muscle relaxants.
- History of allergy to study drugs.

Group-A: All the patients in group-A received inj atracurium 0.5 mg/kg body weight IV.

Group-B: All the patients in group-B received inj cisatracurium 0.3 mg/ kg body weight I.V.Pre anaesthethic evaluation was done one day prior to surgery. A detailed system wise clinical examination including airway was done. Basic laboratory investigations like complete blood count, urine analysis, blood sugar, kidney function test, chest x-ray, viral markers and ECG were done. Echocardiography, serum electrolytes, PT/INR were advised as required.

All patients were premedicated with tab alprazolam 0.25 mg orally and tab ranitidine 150 mg at bed time on the previous night of surgery and all patients were kept NPO for 8 hrs prior to surgery.

On the day of the surgery, on arrival in the operation theatre,body weight of all patients were recorded. Basic monitoring devices including ECG, NIBP, pulse oximeter were connected and baseline values of haemodynaemic variables like heart rate (HR) , mean arterial pressure (MAP) and peripheral oxygen saturation (SPO2) were recorded and IV line was secured with one 18 G IV cannula.

Anaesthetic Technique:
For stimulation of the ulnar nerve, 'Idmed ToFscan' neuromuscular transmission monitor was attached and ECG electrodes are applied at the volar aspect of the wrist . The distal electrode 'negative' (black) was placed about 1 cm proximal to proximal wrist crease The proximal electrode ' positive' (red) was placed 2 -5 cm proximal to the distal electrode along the path of the ulnar nerve.

Pre-medication:
Patients were pre-medicated with inj. Glycopyrolate 0.2mg IV, inj. Fentanyl 2 mcg/kg IV, inj. Ranitidine 50 mg IV& Ondansetron 4 mg IV.

Patients were preoxygenated with 100% oxygen by facemask for 3 minutes before tracheal intubation. Patients were induced with Propofol @ 2mg/ kg IV over 15 seconds.

Following loss of consciousness, the ulnar nerve was stimulated using 'Idmed ToFscan' neuromuscular transmission monitor.Calibration and control values were obtained by supramaximal stimulus of the ulnar nerve before administering the neuromuscular blocking agents.Vital parameters were recorded. A bolus dose of inj. atracurium 0.5 mg/kg body weight IV was given to the patients in the Group-A and inj. cisatracurium 0.3mg/kg body weight IV was given in the Group-B.

Patient was ventilated with 60% N2O and 40% O2 till the TOF reached 0 in the neuromuscular monitor. Supramaximal TOF stimuli were applied to ulnar nerve at every 15 seconds interval and attempted endotracheal intubation after disappearance of all four responses. The time interval between the administration of the dose of inj atracurium or inj cisatracurium and disappearance of all four twitches in TOF monitor (TOF score zero) was noted and taken as onset time of the study drugs.

Intubating conditions were graded by using four points score of Coopers' scoring system as

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

Scoring of 8-9 graded excellent, 6-7 good, 3-5 fair and 0-2 poor / inadequate. If intubating condition was excellent or good tracheal intubation was performed.

Maintenance:
Anaesthesia was maintained with 60% nitrous oxide in oxygen and isoflurane 0.8 to 1% using closed circuit system with controlled ventilation . Haemodynaemic variability were recorded.

Neuromuscular function was monitored using train of four stimuli every 15 minutes. The duration of action of the muscle relaxant was defined as time from disappearance of all four twitches in TOF stimulation till 25% recovery of T1 & was recorded as the duration of the action..Intraoperative monitoring for any sign of histamine release i.e skin changes like erythema, flush , wheals and complications like desaturation, laryngospasm and bronchospasm were recorded .

Reversal and Extubation :
Neostigmine (0.05 mg/kg) and glycopyrolate (0.01kg/kg) IV and extubation was performed when respiration was adequate and patient was able to obey verbal commands.

Statistical Analysis:
All recorded data were entered using MS Excel software and analyzed using SPSS version-21 software for determining the statistical significance. All data were presented in terms of Mean ± SD and in percentage. The tests employed were unpaired t test and chi-square test. P value taken is for significance is 0.05.
$p>0.05$ – Statistically Not Significant (NS)
$p<0.05$ – Statistically Significant (S)

RESULTS AND OBSERVATIONS :
Demographic variables including age, sex ,height , weight ,ASA physical status, mean duration of surgery, type of surgery were comparable in both groups and were statistically not significant ($p>0.05$). (TABLE -1)

Mean Onset time, Mean duration of action, intubating conditions, haemodynamic effects and signs of histamine release in both groups were assessed and recorded during the study

Table-1: Demographic Profiles Of Study Population

CATEGORY	GROUP –A (n=50)	GROUP –B (n=50)	p-Value
Age(years) Mean± SD	36.58 ± 10.42	34.9 ± 9.65	0.405(NS)
Sex Male Female	 18(36%) 32 (64%)	 16(32%) 34(68%)	0.446(NS)
ASA Physical Status I II	 43(86%) 7(14%)	 42(84%) 8(16%)	0.779(NS)
Weight(kg) Mean± SD	59.28±8.24	47.72±9.27	0.376(NS)
Height(cm) Mean± SD	166.44±2.45	166.52±2.17	0.863(NS)
Duration of surgery (min)	71.46±7.67	72.47±8.60	0.559(NS)

The demographic variables were compared between Group-A and Group–B and was found that there were no significant differences between the two groups with respect to age, sex ,height , weight , ASA physical status and duration of surgery.

Table-2: Shows The Comparison Of Mean Onset Time Between The Two Groups.

DURATION (SEC)	GROUP-A		GROUP-B		P VALUE
	NUMBER	%	NUMBER	%	<0.001
110-150	6	12	49	98	
160-200	44	88	1	2	
TOTAL	50	100	50	100	
MEAN ±SD	178.72±12.7		143.82±5.36		<0.001

Mean onset time in Group-B (cisatracurium 0.3 mg/kg) was 140.82±19.49 (second) and it was 178.72 ±12.7(second) in group–A(cisatracurium)**.** This difference was statistically significant (p value=<0.001). Cisatracurium with dose of 6x ED95 (0.3 mg/kg) was found to be statistically more rapid onset of action as compared to 2x ED 95 dose of atracurium (0.5mg/kg).

Table -3 Shows The Mean Duration Of Action Between The Two Groups

DURATION(MINUTE)	GROUP-A		GROUP-B		P VALUE
	Number	%	Number	%	<0.001
35-40	35	70	0	0	
41-50	15	30	0	0	
51-60	0	0	50	100	
TOTAL	50	100	50	100	
MEAN±SD	38.72±3.36		56.78±1.93		<0.001

Mean duration of action after the first dose of atracurium(0.5 mg/kg) was 38.72± 3.36 min(group-A) and cisatracurium (0.3 mg/kg) was 56.78± 1.93 min(group-B) which was more statistically significant as compared to atracurium.(p value<0.001). 6x ED 95 dose of cisatracurium (higher dose) showed significantly longer duration of action than 2x ED 95 dose of atracurium.

Table -4: Shows Comparison Of Mean Intubating Conditions Between The Two Groups

INTUBATION GRADE	GROUP-A		GROUP-B		P VALUE
	NUMBER	%	NUMBER	%	0.0095
POOR	0	0	0	0	
GOOD	15	30	4	8	
EXCELLENT	35	70	46	92	
TOTAL	50	100	50	100	

Table- 5: Showing The Distribution Of Intubation Scoring

INTUBATION SCORING	GROUP-A (ATRA)	GROUP-B (CISATRA)	P VALUE
	MEAN±SD	MEAN±SD	
JAW RELAXATION	2.52±0.51	2.68±0.47	0.014
VOCAL CORDS	2.6±0.5	3±0	<0.001
INTUBATION RESPONSE	2.68±0.47	2.76±0.43	0.375
INTUBATION SCORE	7.8±0.97	8.44±0.64	0.001

In Group-A, 70%(35) had excellent and 30%(15) good intubation grade whereas 92%(46) had excellent and 8%(4) good in Group-B(Table-4). Regarding intubation score, the mean intubating score for group-A was 7.8±0.97, whearas for group-B it was 8.44±0.64(Table-5) . Cisatracurium in the dose of 0.3mg/kg were significantly better intubating condition than dose of atracurium 0.5 mg/kg.

Haemodynaemic variables (HR & MAP) were recorded at following intervals:

- Baseline(T0),
- Before induction(T),
- Before intubation(T1) ,
- Then, 1st (T2), 2nd (T3), 5th (T4), 10th (T5), 15th (T6), 30th (T7), 45th (T8) and 60th (T9) minutes after intubation.

There was a significant increase in MAP and HR from the baseline values immediately after attempt of tracheal intubation in the both groups and continued till 10-15 min post intubation, followed by return to the baseline without intergroup differences.(Table- 6,7) But relatively more haemodynaemic stability and lesser variability of all the haemodynaemic variables from the baseline were observed in group-B (cisatracurium) as compared to group-A (atracurium).

Table-6 : Shows The Changes In Mean Mean Arterial Pressure (map) At Different Time Intervals In Group-a And Group-b (in Mmhg)

STUDY PERIOD	Mean Arterial Pressure (mmHg)		P VALUE
	GROUP-A	GROUP-B	
T0	92.50±4.97	90.87±4.45	0.087
T	91.72±4.03	90.03±4.63	0.053
T1	92.90±3.91	91.34±4.08	0.053
T2	100.47±2.65	99.2±3.07	0.029
T3	98.29±1.97	96.47±4.47	0.010
T4	93.59±1.80	90.44±3.46	<0.001
T5	92.89±2.48	92.21±2.88	0.208
T6	92.59±2.42	91.51±2.74	0.039
T7	92.42±2.42	91.56±0.087	0.087
T8	91.69±2.48	91.02±3.08	0.235
T9	92.27±2.05	91.85±2.76	0.397

Table-7 : Changes In Mean Heart Rate (hr) At Different Time Intervals In Group-a And Group-b (beats Per Minute)

Study period	HEART RATE(BEATS/MINUTE)				p value
	Group A (ATRA)		Group B(CIS)		
	Mean	SD	Mean	SD	
T0	89.12	7.76	87.98	7.60	0.46
T	87.86	7.74	85.90	5.82	0.155
T1	90.18	7.98	87.54	9.77	0.142
T2	91.58	8.12	88.6	6.82	0.049
T3	96.78	8.016	91.4	8.58	0.002
T4	99.82	10.11	95.18	10.46	0.026
T5	102.7	8.30	95.72	7.025	<0.0001
T6	92.38	5.11	90.68	9.41	0.264
T7	90.00	4.82	88.26	6.51	0.132
T8	87.92	8.71	85.90	6.51	0.192
T9	89.38	7.12	87.54	9.38	0.272

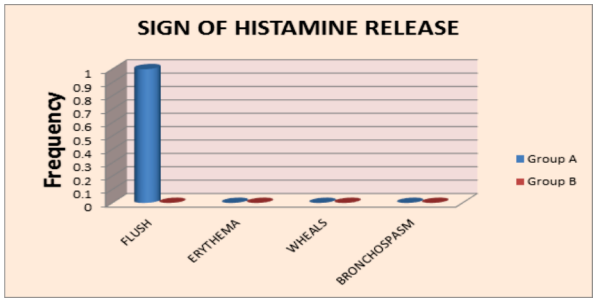

Fig -1: showing the adverse events observed during the study: We noticed one patient with sign of histamine release in the form of transient facial flushing after the administration of atracurium in Group-A. No sign of histamine release were noted in Group-B (cisatracurium). None of the cases had any erythema wheals or bronchospasm in both groups .

DISCUSSION:

Non depolarizing neuromuscular blocking drugs have made anaesthesia much safer and provide good operating conditions. They are used for endotracheal intubation and for surgical relaxation. An ideal muscle relaxant minimizes the time for intubation and reduces the untoward haemodynamic stress response. Cisatracurium, a derivative of atracurium besilate , is one such drug which has the properties of an ideal muscle relaxant. It is similar in chemical structure to Atracurium but has an added advantage of rapid onset of action, devoid of histamine release and less Laudanosine production.

In our study ,mean onset of action in Group-B (cisatracurium 0.3 mg/kg) was 140.82±19.49 (sec) and in group–A (atracurium 0.5 mg/kg) it was 178.72 ±12.7 (sec). Cisatracurium was found to be statistically more rapid in onset of action with longer duration of action as compared to atracurium (0.5mg/kg) with p value <0.001

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In the other study done by Subha P.D et al[7], where they compared the efficacy of the two drugs in the cisatracurium group mean onset time was 165.95±17.92 (sec) with dose of 0.3 mg/kg and in atracurium group with dose of 0.5 mg/kg body weight was 196.95±13.05 (second) which was statistically significant (p value<0.05) .. In a similar study by EL Kesaby et al[5] where they compared the different doses of cisatracurium with atracurium and it was found that mean onset time was significantly faster with higher doses of cisatracurium as compared to atracurium.. In another study conducted by Bluestein L.S et al[2]. and Carrol M.T et al[19] also had similar observation in their study.

In our study, mean duration of action after the first dose of atracurium was 38.72± 3.36 (min) and with cisatracurium with a dose 0.3mg/kg was 56.78± 1.93 (min) which was statistically significant . In another study done by El kasaby et al[5] it was found that the mean duration of action in atracurium group was 44.4±4.23 min and 78.4±8.6 min in cisatracurium group.This result was similar to our study. Similar observartions were found in the studies conducted by Niranajan S et al[9] , Subha PD et al[7] and Bluestein et al[2] where they observed that higher doses of cisatracurium provided significantly longer duration of action as compared to atracurium.

In this study intubation score for tracheal intubating conditions were assessed on the basis of degree of jaw relaxation , vocal cord movement and intubation response. In this study ,intubating conditions with Atracurium (Group-A) were found excellent in 70% of the patients and good in 30 % of the patients. In Cisatracurium (Group-B) intubating conditions were found excellent in 92 % of the patients and good in 8% of the patients. Mean Intubation score was 8.44±0.64 in group-B and it was 7.8±0.97 in Group-A which were statistically significant.

Cisatracurium in higher doses gives better intubating conditions than atracurium. In the study done by Niranjana S et al[9] they observed excellent intubating conditions in 46.7% and good in 50% of patients in group-A and in group-C they found excellent in 83% and good in 16.7% which was similar to our results .In the study done by Subha PD et al[7] they observed Cisatracurium with dose of 0.3 mg/kg provides better intubating conditions as compared to atracurium 0.5 mg/kg .

In this study, there was a statistically significant rise in MAP and HR in the both Group–A and Group- B from the baseline one minute after tracheal intubation.The increase continued till 5-10 minutes after intubation which were statistically significant.Thereafter these haemodynaemic parameters came near to the baseline values and statistically insignificant. but the group–B (cisatracurium) showed relatively more haemodynaemic stability and lesser variability of all the parameters from the baseline as compared to group-A (atracurium). In the other studies conducted by El Kasaby et al[5] and Jammar –P et al[6] found that there were statistically significant increased in HR and MAP after intubation in the atracurium group as compared to cisatracurium group. But these changes were not statistically significant after 5-20 minutes with the dose of 6x ED95 (cisatracurium).Ranjan P , et al[10] and Jammar- P et al[6] also observed statistically significant between two groups . But these changes were not statistically significant 10 minutes after intubation.

In this study we observed one patients with sign of histamine release in the form of transient facial flushing after the administration of atracurium; however, this patient did experience neither bronchospasm nor erythema or swelling .No signs of histamine release were noticed in Group-B (cisatracurium). In study done by EL Kesaby et al[5], no signs of histamine release were noted in any doses of cisatracurium and two cases were noted with atracurium. In study done by Subha P.D et al[7], did not notice any signs of histamine release in in both groups.

CONCLUSION:

In this study , we concluded that cistracurium 0.3mg/kg (Group-B) provided more rapid onset, longer duration of action with excellent intubating conditions, better haemodynamic stability and was devoid of histamine release as compared to atracurium 0.5mg/kg (Group-A).

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