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Original Research Article

A COMPARATIVE CLINICAL STUDY TO ASSESS THE INTUBATING CONDITIONS WITH TWO DIFFERENT DOSES OF CISATRACURIUM USING TRAIN OF FOUR FADE AND CLINICAL ASSESSMENT IN PATIENTS UNDERGOING SUGERY UNDER GENERAL ANAESTHESIA

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ABSTRACT
INTRODUCTION: Cisatracurium besylate is a potentially useful new nondepolarizing neuromuscular blocking drug. Cisatracurium is one of the ten isomers which constitute atracurium and constitute nearly 15% of the atracurium mixture**. AIM & OBJECTIVE:** compare between two different doses of Cisatracurium 0.15 mg/kg and 0.20 mg/kg regarding Onset time, Intubating Conditions, Untoward effects and Hemodynamic Response.
MATERIAL AND METHODS: Sixty patients between 20 to 65 years of age with ASA grade 1 and ASA grade 2 physical status posted for elective surgeries under general anaesthesia, randomly devided in two groups(30 each). Group A: Cisatracurium of 0.15mg/kg & Group B:Cisatracurium of 0.2mg/kg 30 patients and compare intubating condition,
RESULT & CONCLUSION: in our study we found that intubating condition and mean timefron intubating dosee to first maintenance dose were better in group B .

KEYWORDS: cis-atracurium, intubating condition

1. INTRODUCTION

The advent of neuromuscular blocking medications revolutionised the practice of anaesthesia. Before the discovery of muscle relaxants, anaesthesia was induced and maintained by intravenous or inhalation agents. Tracheal intubation was not very common, and muscle relaxation if required was achieved by deep inhalation anaesthesia with its potential risks of respiratory or cardiac depression, Following the introduction of muscle relaxants, anaesthesia went through a conceptual change.(1)

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Non-depolarizing NMBDs antagonize prejunctional receptors, which results in failure of mobilization of Acetyl choline to keep up with the demands of the stimulation frequency. Clinically, this is manifest as tetanic fade and Train of four (TOF) fade, in which there is a reduction in twitch height with successive stimuli. (2)

Cisatracurium besylate is a potentially useful new nondepolarizing neuromuscular blocking drug. Cisatracurium is one of the ten isomers which constitute atracurium and constitute nearly 15% of the atracurium mixture. Cisatracurium is nearly three times as potent as atracurium and have an ED95 of 0.05 mg/kg during balanced anaesthesia. Cisatracurium is an intermediateacting neuromuscular blocking agent which undergoes Hofmann elimination and ester hydrolysis for its breakdown, therefore, would not depend upon renal or liver function for elimination. The principal advantage of cisatracurium is that there has been no evidence of histamine release at doses up to eight times the ED95 where as atracurium causes histamine release in humans at doses greater than 2.5 of ED95.(3)

Hence the present study was done to evaluate the intubating conditions and hemodynamic stability of Cisatracurium at 3 times ED95 and 4 times ED95 dose.

2. MATERIAL AND METHODS

This study was randomized controlled trial conducted on Sixty patients between 20 to 65 years of age with ASA grade 1 and ASA grade 2 physical status posted for elective surgeries under general anaesthesia were considered for the study after ethical committee clearance.

Each patient were visited pre-operatively and the procedure explained and informed written consent were obtained. All the routine investigations required for pre operative evaluation and for the proposed surgery were done. Pre-medications were given to all patients included in the study,Patient were premedicated with Inj. Midazolam 1mg IV, Inj.Glycopyrolate 0.2mg/kg IV and Inj.Pentazocin (0.5 mg/kg).. Period of absolute fasting of at least 8 hours were allowed.

Inclusion criteria:

1. Consent to participate in study
2. Age – 20 to 65 years, of both sexes.
3. American Society of Anesthesiologist Grade I&II.
4. Mallamapati class I and II
5. Elective surgeries under general anaethesia.

Exclusion Criteria:

1. Patients other than ASA 1 and 2.
2. Patients with anticipated difficult airway.
3. Patient with history of allergy
4. Pregnant and lactating women.
5. Patients receiving drugs known to interact with neuromuscular blocking agents.
6. Patients with cardiovascular, neuromuscular, hepatic or renal disorder.

On arrival in the operating room, patients were randomly divided into two groups and drug to be given were decided on the basis of sealed envelope technique, which were picked randomly and administered by the anaesthesiologist unrelated to study.

¬ Group A: Cisatracurium of 0.15mg/kg 30 patients

¬ Group B:Cisatracurium of 0.2mg/kg 30 patients

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♣ Intra venous cannula (18G / 20G) were secured and standard monitoring - NIBP, SPO2, ECG were done .

♣ Baseline hemodynamic parameters recorded. (SBP, DBP, MAP, HR).

♣ All patients were premedicated with inj. Glycopyrolate 0.005mg/kg intra venously.

♣ After preoxygenation, general anesthesia technique was standardized for both the groups, induced with Inj Propofol 2mg/kg and Inj fentanyl 2mcg/kg intravenously.

♣ Muscle relaxant were given for patients according to previously mentioned initial doses for each group and ventilated with gas Oxygen until TOF count comes zero.

♣Endotracheal intubation were done using appropriate size Macintosh laryngoscope blade and endotracheal tube.

♣ The condition of intubation were assessed by the degree of jaw relaxation, resistance to laryngoscopy, vocal cord position, limb movements, and coughing.

conditions were noted clinically according to **Cooper et al score**[34] criteria as excellent(8-9), good(6-7), fair (4-5) and poor (0-2) as given in table below:

Table 1 -Assessment of intubating conditions by Cooper et al score

CRITERIA	0	1	2	3
Jaw relaxation	Impossible	Minimal	Moderate	Good
Vocal cord position	Closed	Closing	Moving	Open
Diaphragmatic status	Coughing or bucking	Mild coughing	Slight Diaphragmatic movement	none

♣ Anaesthesia was maintained with oxygen, nitrous oxide, volatile anaesthetic Isoflurane and intermittent positive pressure ventilation. Intermittent doses of Cisatracurium were given as and when required.

♣ Reversal were given with Inj Neostigmine 0.05mg/kg and Inj Glycopyrolate 0.01mg/kg intravenously.

Statistical Analysis were done using SPSS (statistical package for social science) for windows version 20.

Test of significance: Unpaired T test and chi square test. To compare between the 2 groups of Cisatracurium (0.15& 0.2 mg/kg) and results were given in necessary tables and graphs.

3. OBSERVATIONS AND RESULTS

Study design:

A comparative two group double blind randomized clinical study done with 0.15mg/kg and 0.2mg/kg Cisatracurium to assess the intubating conditions, hemodynamic responses and any untoward effects.

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Table 2: Demographic data of the patients

	Group		
	Group A	**Group B**	**p value**
Age(yr)	37.57±13.32	38.47±12.30	0.787
Gender(M/F)	7/23	12/18	0.165
Weight	56.27±7.92	57.60±8.64	0.536
ASA Grade(I/II)	7/23	9/21	0.559
Mallampati Grade(I/II)	17/13	18/12	0.793

The demographic profile of both groups were comparable.

Table 3: Comparison of mean Time from intubating dose till TOF count comes zero between the groups

Groups	**No.**	**Mean±SD**	**'t' value**	**P value**
Group A	30	3.12±0.34	10.947, df=55	.000*
Group B	30	2.25±0.24		

Unpaired 't' test applied. P value = 0.000, Highly Significant

Table shows that, mean time from intubating dose till TOF count comes 0 in group A were 3.12±.34 and in group B it was 2.25±.24. The mean time from Intubating dose till TOF count comes 0 was statistically highly significantly lower in group B compared to group A ($p<0.001$).

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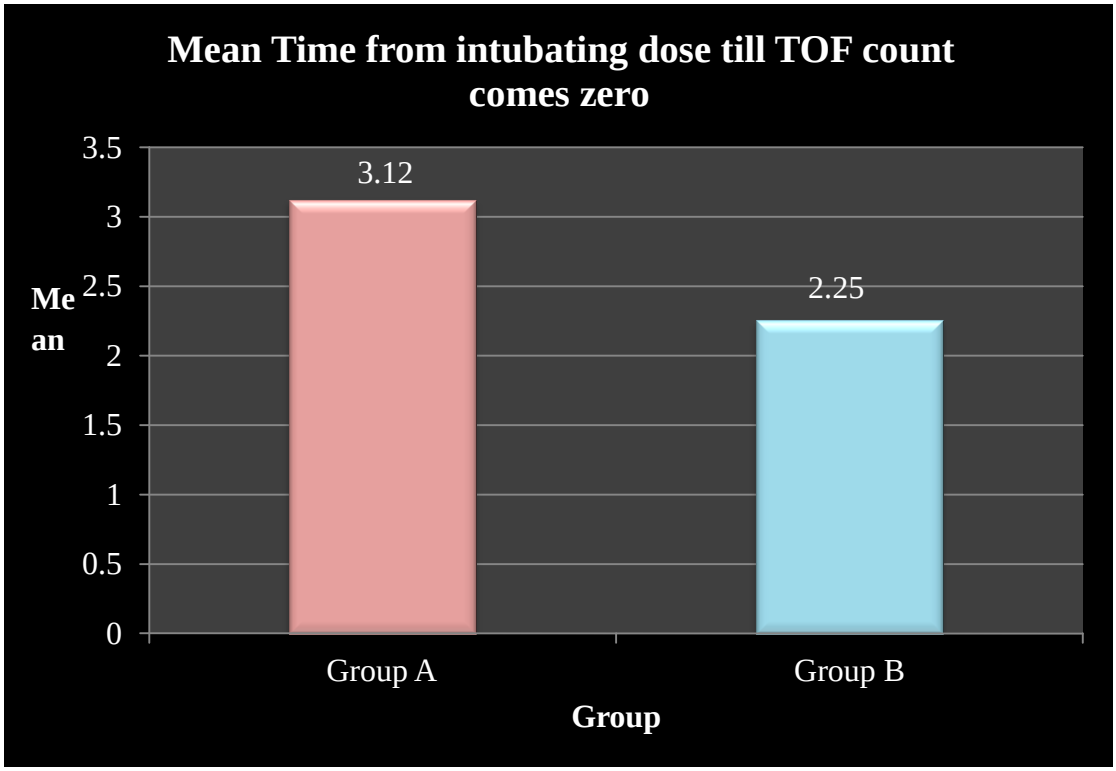

Graph 1 : Mean Time from intubating dose till TOF count comes zero

Table 4: Comparison of mean Time from intubating dose till first maintenance dose between the groups

Groups	No.	Mean±SD	't' value	P value
Group A	30	29.17±.1.38	-8.246, df=58	.000*
Group B	30	33.97±2.87		

Unpaired 't' test applied. P value = 0.000, Highly Significant

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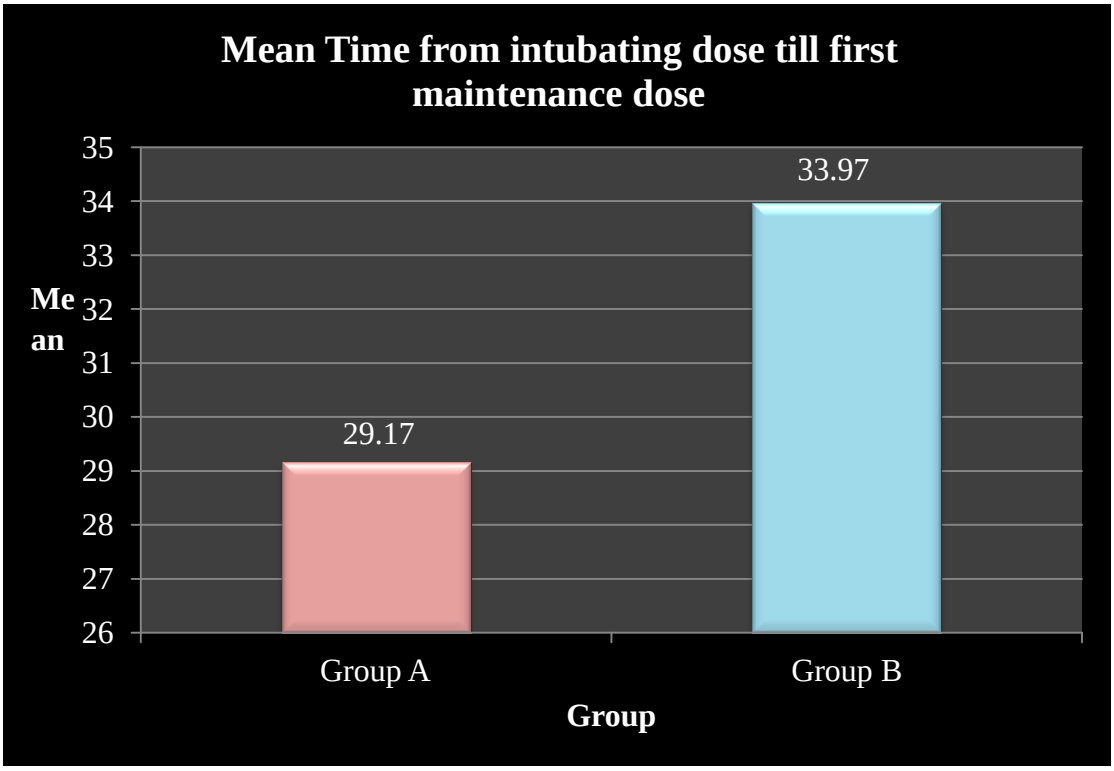

Graph 2: Comparison of mean Time from intubating dose till first maintenance dose between the groups

Mean time from intubating dose till first maintenance dose in group A were 29.17±.1.38 and in group B it was 33.97±2.87. The mean Time from intubating dose till first maintenance dose was statistically highly significantly longer in group B compared to group A ($p<0.001$).

Table 5: Intubating conditions as assessed by Cooper et al score

Intubation Grade	Group				Total	
	Group A		Group B			
	No.	%	No.	%	No.	%
Excellent	28	93.3%	29	96.7%	57	95.0%
Good	2	6.7%	1	3.3%	3	5.0%
Total	30	100.0%	30	100.0%	30	100.0%

Pearson Chi-Square = .351, df = 1, p value = .554, Not Significant

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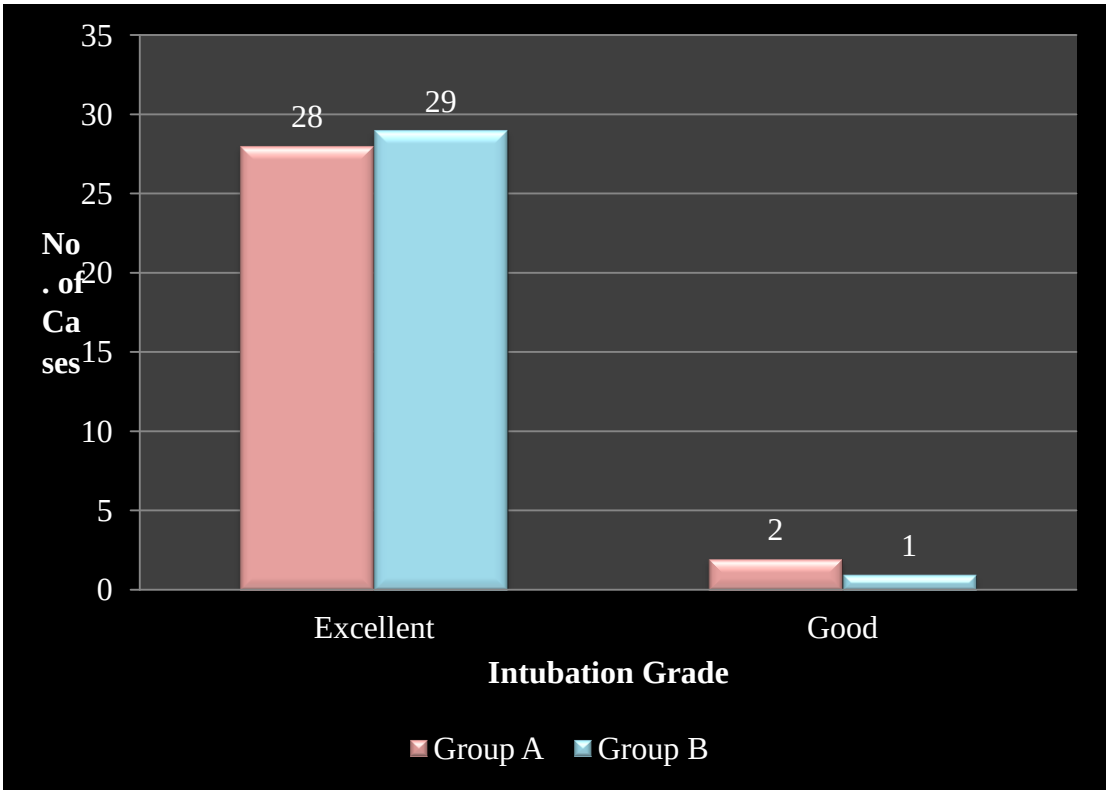

Graph 3 : Intubation grade

TABLE 6: INTRAGROUP STATISTICAL ANALYSIS OF MEAN ARTERIAL PRESSURE

Time (Minutes)	Pulse Rate					
	Group A			Group B		
	Mean ±SD	t value	P value	Mean ±SD	t value	P value
Basal value	90.90±7.02	NA	NA	90.07±9.534	NA	NA
After injection of muscle relaxant	90.70±10.97	.125	.901	89.13±9.723	2.474	.019
After attempt of intubation	90.77±9.81	.079	.938	89.03±9.619	.871	.391
5 minutes	91.67±8.89	-.621	.539	89.20±8.087	.790	.436
10 minutes	90.50±7.54	.306	.762	89.60±7.695	.380	.707
15 minutes	89.47±8.94	.841	.407	88.70±7.057	.939	.355
30 minutes	91.03±8.84	-.076	.940	89.87±7.722	.123	.903

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In the present study, mean arterial pressure values were noted
down at baseline, after injection of muscle relaxant, after attempt of intubation 5, 10 ,15 and 30 minutes after intubation for patients,the values were statistically insignificant in both the groups (group Aand group B). ($p>0.05$). No statistically significant change in mean arterial pressure was found in both the groups.

Table 7: Adverse effects in terms of sign of histamine release

Sign of histamine release	Group				Total	
	Group A (n=30)		Group B (n=30)			
	No.	%	No.	%	No.	%
Erythema	0	0.0%	0	0.0%	0	0.0%
Flushing	0	0.0%	0	0.0%	0	0.0%
Other side effects	0	0.0%	0	0.0%	0	0.0%

No sign of histamine release like Erythema, Flushing were noted in any of the study participants, no other side effects were seen in both the groups.

4. DISCUSSION

While selecting neuromuscular blockade agent for intubation or skeletal muscle relaxation, main aim of anAnesthesiologists is to select an agent with rapid onset, excellent intubating conditions, better haemodynamic stability and good spontaneous reversal. Cisatracurium is one such non depolarizing muscle relaxant, new isomer of Atracurium with greater potency and stable hemodynamics without histamine release. Cisatracurium is a newer and infrequently used drug with wide range of intubating doses [2×ED95 to 8×ED95] described in literature. So in the present study we used two doses [3×ED95 and 4×ED95], to show the increased potency of the drug with desired clinical effects and to avoid any adverse effects associated with increased/decreased dosage of any drug.

In the present study, we had done clinical comparison between two intubating doses of Cisatracurium (0.15mg/kg) and Cisatracurium (0.20mg/kg). All patients were assessed for intubating conditions clinically by **Cooper et al score**[4] and by TOF score using neuromuscular monitor as well as for time to reach TOF count zero, duration of action, haemodynamic parameters and any signs of histamine release.

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In our study, as shown in table no 2 the demographic profiles in terms of age, weight, sex, ASA status and Mallampati grade were comparable between the two groups and statistically insignificant (p value>0.05).

The adequacy of conditions for tracheal intubation is a function of several factors which includes depth of anaesthesia and the level of neuromuscular blockade at the time of intubation attempt . We assessed intubating conditions both clinically and correlated them with the Train of four count at the time of intubation. Intubation was done when TOF count comes zero.[5]

TIME OF ONSET AND DURATION OF ACTION

In our study as shown in table no. 3 onset time was counted as time interval from the end of muscle relaxant injection until TOF count 0 (indicating complete muscle relaxation).

In our study we found that mean time of onset in group A was 3.12±0.34 minutes and in group B it was 2.25±0.24 minutes (p value = 0.000) which was statistically highly significant and mean duration of action as shown in table no

4 (time from intubating dose till first maintainance dose given at TOF recovery) was 29.17±1.38 minutes in group A and 33.97±2.87 minutes in group B with p value of 0.000 meaning result was highly significant.

In a similar study done by **Amini S et al**[6]he compared effects of different doses of cisatracurium and found out that time of onset in 0.15 mg/kg group was 191.50±35.16 seconds which was significantly longer than time of onset in group receiving 0.20 mg/kg cisatracurium which was 145.40±25.08 seconds (p value<0.001). The duration of action (time for TOF recovery) in group 0.15 mg/kg group was 2696.20±324.25 seconds which was also statistically significantly lower than group which received 0.20 mg/kg cisatracurium as intubating dose which was 3422.20±253.00 seconds(p value <0.001) supporting our findings. This study also involved 0.25 mg/kg dose of cisatracurium which further yielded highly significant longer duration of action

(3378.90±626.15 seconds than both other doses and mean onset time was also significantly lower which was 100.20±25.59 seconds, which may be due to higher dose of the drug.

Our study in accordance with study conducted by **Bluestein et al**[3] estimated time of onset as time to maximal depression of T1 after injection of muscle relaxant and found mean time of onset in group C(cisatracurium 0.20 mg/kg) was 2.8 minutes which was significantly shorter than group D(0.15 mg/kg cisatracurium) which was 3.4 minutes with p value<0.05 showing that the result was statistically significant, and the duration of action in group C was found to be 61.4 minutes which was also longer as compared to group D which was 54.5 minutes but the difference was not statistically significant(p value of >0.05). However with lower dose of cisatracurium 0.1 mg/kg(group A) the mean time of onset (4.6 minutes) and duration of action(45.2 minutes) was significantly lower (p value <0.05) with respect to group C and D and was comparable with 0.5 mg/kg dose of atracurium(group B).

In a comparative study done by **Bhandari HR et al**[7] he compared 0.15 mg/kg dose of cisatracurium with 0.6 mg/kg dose of atracurium and found that the mean time of onset of atracurium group was 3.14±0.23 minutes which was statistically significantly lower than cisatracurium group which was 4.44±0.45

minutes) but the duration of action of cisatracurium group was 50.09±5.3 minutes as compared to 41.03±1.69 minutes of atracurium group the difference was statistically significant, showing longer duration of action of cisatracurium group.

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In a study conducted by **Jammar P et al**[8]they discovered duration of action of 0.20 mg/kg cistracurium as intubating dose was 44.42±3.41 minutes as compared to 35.15±4.13 minutes in cisatracurium 0.15 mg/kg group. Showing longer duration of action if 0.20 mg/kg cisatracurium as compared to 0.15 mg/kg dose which supports the findings of our present study.

In our study intubating conditions were assessed by **Cooper et al score**[4], consists of 3 criteria i.e. jaw relaxation, vocal cord status and diaphragmatic status which given points as 0,1,2 and 3. In Jaw relaxation Impossible-0 Minimal-1 Moderate-2 Good-3; Vocal cord status: Closed-0 Closing-1 Moving2 Open-3 and diaphragmatic status Severe-0 coughing or bucking-1 Mild coughing-2 Slight diaphragmatic movement-3. Scoring was done as excellent (8-9),good(6-7) fair(3-5) and poor as (0-2). In accordance with our study, **Athaluri et al**[(13)], **Gogoi et al**[29]and **Shah P et al**[21] , also used **Cooper et al score**[4] for clinical assessement of intubating conditions.

In our study as shown in table no. 5 intubating conditions, assessed clinically by **Cooper et al score**[4], were excellent in 28 patients and good in 2 patients in group A. While in group B, intubating conditions were found to be excellent in 29 patients and good in 1 patient. This indicates comparable intubating conditions in both groups which was statistically insignificant. (P value > 0.05). Also, the assessment of vocal cords showed good vocal cord relaxation in 28 patients while in 2 patients vocal cords were moving whereas in group B vocal cords in 29 patients were completely relaxed while in 1 patient they were moving. In group A 25 patient had no movement at all, while 2 patient had mild coughing and 3 had slight diaphragmatic movement while doing laryngoscopy. Where as in group B only 1 patient had mild coughing, 3 patient showed slight diaphragmatic movement and 26 patient showed no movement. In our study few patients has mild coughing and slight diaphragmatic movements which might be due to technical error manifested in the monitor or due to light plane of anaesthesia, but the incidence was statistically insignificant. The difference between both the groups was statistically not significant (p value > 0.05).

In a study conducted by **Jammar P et al**[8], They found comparable intubating conditions at 2 minutes with 0.15 mg/kg dose of cisatracurium and 0.20 mg/kg dose of Cisatracurium.

In study conducted by ***Bluestein et al***[3]also they found good to excellent intubating conditions in 100 percent of the patients in 1.5 minutes who received
0.15 mg/kg and 0.20 mg/kg dose of cisatracurium besylate.

When assessed clinically, similar results for 0.20 mg/kg dose was found in study conducted by **Kale J et al**[9] **.Sahu et al**[10]compared the 0.20 mg/kg dose of cisatracurium with 0.5 mg/kg dose of atracurium and found that 36 out of 50 patient in cisatracurium group showed excellent intubating conditions whereas 12 showed good and 2 showed fair intubating conditions. **Surbhi et al**[11] assessed quality of muscle relaxation with 0.20 mg/kg dose of cisatracurium solely on clinical basis and found good to excellent intubating condition in all the subjects using Copenahgan consensus scoring system.

Mohanty AK et al[12]in his study found that 0.15 mg/kg dose of
Cisatracurium resulted in excellent intubating conditions in 70 percent of the group subjects while 30 percent showed good intubating conditions.

HAEMODYNAMIC COMPARISON:

In our study as shown in table no. 6 mean arterial pressure were calculated at baseline, after injection of muscle relaxant, after attempt of intubation, 5 minutes, 10 minutes, 15 minutes, 30 minutes in both the groups.

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The mean and standard deviation of all the parameters was calculated.

As shown in table no.6 Both the groups were comparable in terms of baseline hemodynamic parameters and remained so before intubation (p value>0.05).

The results obtained from analysis, as shown in table no 6 showed that there was increase in heart rate, compared to baseline in Cisatracurium 0.15 mg/kg group (group A)just after attempt of intubation but the difference from baseline was statistically insignificant (p value>0.05) and may be due to stress response due to laryngoscopy. There was no statistically significant difference seen in both the groups at different time intervals. Mean arterial pressure did not show any changes either from baseline or when intergroup comparison was done.

It was found out that the changes mean arterial blood pressure were comparable in both the groups at different intervals and had no statistically significant difference.

This haemodynamic stability can be attributed to slow administration of injection of muscle relaxant, rapid injection of which is usually associated with fall in blood pressure and transient tachycardia and cisatracurium being devioid of release of histamine and associated with 3-4 times lesser production of laudanosine which is responsible for cardiovascular effects and central nervous
system stimulation.

Similar results were seen in study by **Jammar P et al**[8], the study showed comparable baseline hemodynamic variables in pre induction period. Only >20% variation in vitals was considered significant in their study. They observed rise in pulse rate and mean arterial pressure in 5-10 minutes after intubation but that was not significant. In their study also group B (0.20 mg/kg cisatracurium) showed more hemodynamic stability than group A (0.15 mg/kg group).

Gogoi et al[13]compared 2ED95,3 ED95 dose of cisatracurium with 2 ED95 dose of atracurium and found comparable haemodynamics in all three groups and stated that increase in haemodynamic parameters at 1 minute due to intubation stress response which may return to baseline values at 5 minutes and was not statistically significant.

Cistracurium leads to five times lesser production of laudanosine which might be associated with lesser side effects.

El kasaby et al[14] in their study concluded that haemodynamic stability for both mean arterial pressure and heart rate were more evident when cisatracurium with higher dosage (4ED 95 and 6ED95) as compared to (2ED 95 dose of atracurium and 2 ED95 dose of cisatracurium which was statistically significant(p value<0.05) which can attributed to absence of dose dependent histamine release in cisatracurium group.

Similarly, **Subha PD et al**[15] carried out a study comparing efficacy of 6ED95 dose cisatracurium with 2ED95 dose of atracurium observed better haemodynamic stability with the cisatracurium group as compared to atracuriumgroup. They associated this results with the fact that cisatracurium does not lead to histamine release and causes five times lesser production of laudanosine.

Yazdanian F et al[16], in his study concluded that there were comparable haemodynamic effects between atracurium and cisatracurium but atracurium was more cost-effective.

As shown in table number 7, None of our study subjects had episodes of hypotension, tachycardia, bronchospasm, erythema,rash or urticaria.

The signs of histamine release are often noted following administration of benzylisoquinolinium class of muscle relaxants. This effect lasts for short duration (1-5 mins) which is dose related and clinically insignificant in healthy patients and this side effect can be

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considerably reduced by slow administration of drug. Erythema of neck and upper torso develop when large doses are given. The clinical effects of histamine are observed when plasma concentration exceeds 200% to 300% that of the baseline values and these are due to chemical displacement of contents of mast cell granules containing histamine,prostaglandin and other vasoactive substances. The serosal mast cells located in skin, connective tissue as well as near blood vessels and nerves is principally involved in degranulation process.

ShangGuanet al[17] in his study found that even with the higher doses of cisatracurium (8 x ED95) bolus dose, there was no sign of histamine release because of its stereospecific property and hence no significant haemodynamic changes were described in his study.

In **El kasaby et al**[14] study, no signs of histamine release were found in any of the doses of (2ED95,4ED95 ,6ED95) cisatracurium while 2 cases (1case showed flush and other showed erythema) were noted in Atracurium group. Overall the signs were statistically insignificant.

Similar to **El kasaby et al**[14], study by **utpal et al**[18] observed no signs of histamine release in Cisatracurium group of their study but in atracurium group, 3 participants showed signs of histamine release.

No other adverse effects were noted in any of the study subjects in both the groups.

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