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Anesthesiology

A PROSPECTIVE RANDOMISED STUDY OF COMPARISON OF HAEMODYNAMIC RESPONSE TO LARYNGOSCOPY AND ENDOTRACHEAL INTUBATION USING ORAL IVABRADINE AND I. V. LIGNOCAINE

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ABSTRACT Rapid and dramatic hemodynamic changes are adversely affecting the patient. It may occur during perioperative period.

AIM AND OBJECTIVE: To compare the effect of oral ivabradine and i.v lignocaine on the hemo dynamics during laryngoscopy and endotracheal intubation in patients undergoing surgical procedures under general anaesthesia.

MATERIALS AND METHOD OF STUDY: Prospective Randomized Study involves ASA-I adult patients of age group 20-45 years who were scheduled for various surgical procedures under general anaesthesia .Sample size was 100.Groups were randomly divided into GROUP- I: received oral Ivabradine 5 mg one tab 2 hour before intubation 5ml of normal saline 90 seconds before intubation. GROUP-II: received Tab.B Complex 2 hours before intubation& I.V. Lignocaine1.5 mg/kg 90 seconds before induction .premedication, induction agent and muscle relaxant to facilitate intubation were standardized for both the groups. Changes in HR, systolic BP, diastolic BP, Mean arterial BP were monitored. Hemodynamic variables were recorded from preoperative(after premedication),At induction, At intubation,1min,3 min,5 min.8 min,10min,30 min ,I hour,2hours,4 hours, 6 hours, 12 hours after intubation.

RESULTS: GroupI(oral Ivabradine) patients showed statistically significant change in pvalue<0.0001. There was no statically significant change in blood pressure in both groups. Pvalue>0.0005.

INTERPRETATIONS AND CONCLUSION: In conclusion , oral Ivabradine has better heart rate control than Intravenous Lignocaine for attenuation of haemodynamics during laryngoscopy and endotracheal intubation in ASA I patients without side effects..

KEYWORDS : . Oral Ivabradine, Inttravenous Lignocaine, attenuation, hemodynamic changes, laryngoscopy, intubation response.

INTRODUCTION

In recent years, the role of anesthesia and its level of safety in patients have gained prime importance. Stable hemodynamics has become the key to safe and successful induction and intubation. The usual response to laryngoscopy and endotracheal intubation is hypertension and tachycardia. They cause little consequence in healthy patients, but may cause dangerous complications in patients with hypertension, raised intracranial pressure, aneurysmal vascular disease, and diseased cerebral vasculature or with ischemic heart disease[1]. There are many strategies used to blunt the intubation response[2].This study compares the haemodynamic response of oral ivabradine and intravenous lignocaine and highlights the advantage of ivabradine over lignocaine.

Ivabradine is a cardio tonic agent. It is a extremely selective inhibitor of funny current channel. [If].This channel inhibition results in diminution in the slope of spontaneous depolarization, leading to prolongation of the time interval between consecutive action potentials in the SA node, thus decreasing the heart rate. This drug combine with the intracellular place of the 'If' channel and hinders it in a dose and voltage dependent manner. As the binding site is situated intracellular, ivabradine needs an open 'If' channel to reach to its required site. Ivabradine reduces the heart rate without altering hemodynamics in unhealthy patients. This drug can be used in both hypertensive &normotensives[3]. Lignocaine is an amide group of local anesthetic. It is used in treatment of patients with ventricular dysarrthmias and as prophylaxis in treatment ofventricular tachyarrthmias especially in connection with myocardial infarction and mechanical irritation of cardiac fibers. The principal metabolite of lignocaine is monoethylglycine xylidide. This metabolite has approximately 80% of the activity of lignocaine for protection against cardiac dysarrythmias.

Lignocaine prevents conduction of nerve impulse (conduction blockade). It blocks passage of sodium ions thru ion selective sodium channels in nerve membrane. The Na+ channel is a definite receptor to lignocaine. Intravenous lignocaine is used to blunt raises in heart rate, B.P, intracranial & intraocular pressure [4]. These comprise a direct myocardial depressant effect, a peripheral vasodilating effect[5] .This study aims to compare the hemodynamic response of oral ivabradine and intravenous lignocaine during induction and intubation in ASA-I patients. The above study wasdone in the department of anesthesiology, Chengalpattu medical college, Chengalpattu.

MATERIALS AND METHODS

After obtaining ethical committee approval, 100 ASA I adult patients undergoing surgical procedures under general anaesthesia are randomly allotted into two groups

STUDY DESIGN: A Prospective randomized study
SAMPLE SIZE: 100 patients were selected and allocated in two groups
Randomly.50 patients in each group.

INCLUSION CRITERIA:
· ASA -I patients who were posted for various procedures under G.A.
· Age group -20-45 years
· Both sexes
· Normal ECG
· Mallampatti grading I&II

EXCLUSION CRITERIA:
· Patient Refusal
· H/0 Chest pain /palpitations/syncope/H/o Respiratory problems,
· Hepatic or renal problems
· Base line HR<60, base line systolic BP <100 mm Hg.
· Patients with ECG abnormality
· Patients with difficult airway

PRE OP PREPARATION:
On the day of surgery Patients who satisfy the inclusion criteria were selected, written Informed consent obtained from all the patients. Preoperative evaluation including detailed history, clinical evaluation, investigations and airway assessment were done. Intravenous canulation was done with 18G cannula after shifting the patient into the waiting area of the operation theater, and connected to a drip of Ringers lactate.

PREMEDICATION:
Inj. Glycopyrrolate 0.2 mg I.M 45 Minutes before surgery and Inj. Ondensetron 4 mg sloe I.V and Inj. Fentanyl 2µg/kg before induction.

METHODOLOGY
Patients were randomly allocated into two groups, Test and Control [having 50 patients in each group]

GROUP- I: received oral Ivabradine 5 mg one tab 2 hour before

intubation and received 5 ml of normal saline 90 seconds before intubation.

GROUP-II: received Tab.B Complex 2 hours before intubation& I.V. Lignocaine 1.5 mg/kg 90 seconds before induction

These drugs were given by the anesthesiology residents who were not included in this study.

Monitoring:
Continuous ECG, automated intermittent noninvasive blood pressure monitoring, Spo2monitoring done.

Pre oxygenation: 100% o2 for 3 min.

Induction:
Inj.Thiopentone sodium 5 mg/kg I.v and succinylcholine 2 mg/kg I v. Inj .Lignocaine 1.5 mg/kg I.V (groupII).& Normal saline5ml (group I) given 90 seconds before intubation.

Intubation: after 120 min intubation was achieved with appropriate size cuffed,endotracheal tube by the aid of Macintosh laryngoscope blade. Time forintubation did not exceed 20 sec.

Maintenance: Atracurium bisylate 0.5 mg/kg top-up dose. N2O:O2 in 2:1,intermittent positive pressure ventilation using circle absorber systemconnected to the Boyles machine. Surgery was not allowed to commence tillthe recordings were completed up to 10 min.

Parameters recorded were heart rate, systolic BP, diastolic BP, Mean arterial pressure. Ten minutes after intubation, after taking the recordings ofhemodynamic parameters, inhalational agent was introduced into theanesthetic technique.

Reversal:
Inj.Neostigmine 0.05 mg/kg and Inj.Glycopyrrolate 0.01 mg/kg. All patients were monitored for adverse effect effects of ivabradine in post op period.

The recordings were noted at preoperative (after premedication),At induction,At intubation,1,3,5,8,10,30 min,1,2,4,6,12 hours after intubation

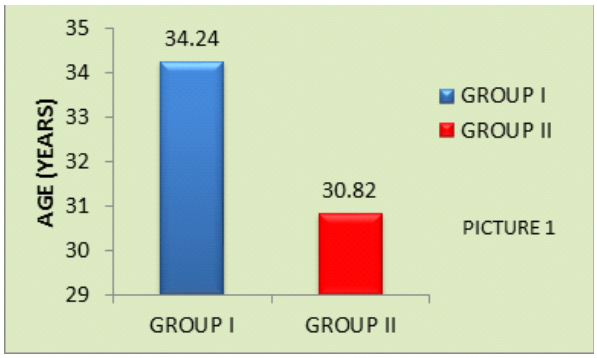
STATISTICAL ANALYSIS: Data were analyzed using SPSS16.0V. Software. Two sidedindependent students' t tests to analyze continuous data and chi square test for categorical data were used. P<0.05 was considered as statistically significant.

DEMOGRAPHIC DATA
The two groups were comparable with respect to their age, weight, sex. There is no statistically significant difference among two groups in demographic profile.

AGE

	GROUP	N	Mean	Std. Deviation	p value
AGE	Group I	50.00	34.24	9.290	0.058
	Group II	50.00	30.82	8.535	
TABLE 1					

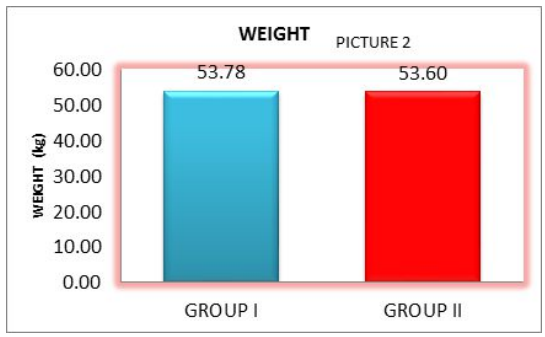
The mean age in years was 34.24± 9.290 (Years) in group I and 30.82 ± 8.535 (Years) in group II. There was statistically no significant difference between two groups (p>0.05)



WEIGHT

	GROUP	N	Mean	Std. Deviation	P value
WEIGHT	Group I	50.00	53.78	4.705	0.830
	Group II	50.00	53.60	3.580	
TABLE 2					

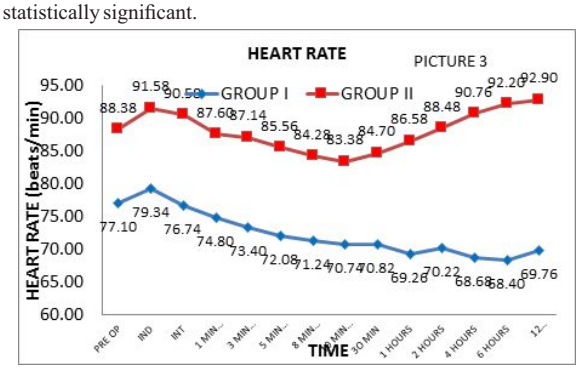
In our study mean Weight in kilograms was 53.78±4.705 (Kg) in group 1 and 53.60 ± 3.580(Kg) in group 2. There was statistically no significant difference between two groups(p>0.05)



HEART RATE

	GROUP	N	Mean	Std. Deviation	p value
PRE OP	Group I	50.00	77.10	7.947	<0.0001
	Group II	50.00	88.38	7.214	
AT INDUCTION	Group I	50.00	79.34	7.657	<0.0001
	Group II	50.00	91.58	6.737	
AT INTUBATION	Group I	50.00	76.74	7.575	<0.0001
	Group II	50.00	90.58	6.795	
1MIN AIT	Group I	50.00	74.80	7.426	<0.0001
	Group II	50.00	87.60	9.532	
3MIN AIT	Group I	50.00	73.40	7.253	<0.0001
	Group II	50.00	87.14	6.612	
5MINAIT	Group I	50.00	72.08	7.182	<0.0001
	Group II	50.00	85.56	6.181	
8 MIN AIT	Group I	50.00	71.24	7.061	<0.0001
	Group II	50.00	84.28	6.331	
10 MIN AIT	Group I	50.00	70.74	6.866	<0.0001
	Group II	50.00	83.38	5.966	
30 MIN	Group I	50.00	70.82	6.492	<0.0001
	Group II	50.00	84.70	5.776	
1 HOUR	Group I	50.00	69.26	11.091	<0.0001
	Group II	50.00	86.58	5.786	
2HOUR	Group I	50.00	70.22	6.254	<0.0001
	Group II	50.00	88.48	6.004	
4HOUR	Group I	50.00	68.68	10.580	<0.0001
	Group II	50.00	90.76	5.546	
6HOUR	Group I	50.00	68.40	10.508	<0.0001
	Group II	50.00	92.20	5.322	
12HOUR	Group I	50.00	69.76	6.150	<0.0001
	Group II	50.00	92..90	5.471	
TABLE 3					

In our series. The mean heart rate of all patients in both groups were calculated and compared from pre- operative to up to 12 hours post-operatively. The change in heart rate in.group I and group II were statistically significant.

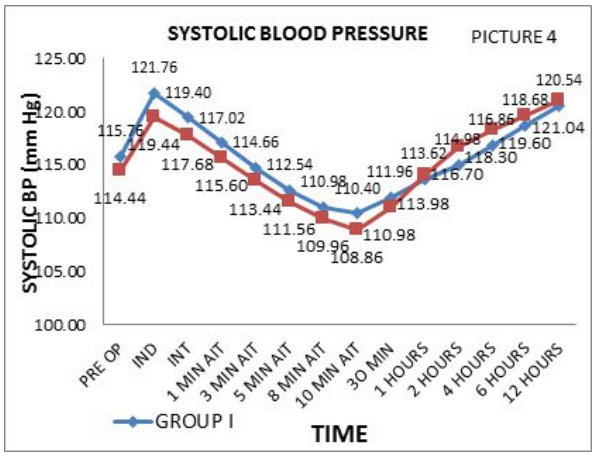


SYSTOLIC BLOOD PRESSURE

	GROUP	N	Mean	Std. Deviation	P value
PRE OP	Group I	50.00	115.76	6.620	0.362
	Group II	50.00	114.44	7.752	
AT INDUCTION	Group I	50.00	121.76	6.793	0.108
	Group II	50.00	119.44	7.506	
AT INTUBATION	Group I	50.00	119.40	6.540	0.226
	Group II	50.00	117.68	7.542	
1MIN AIT	Group I	50.00	117.02	6.653	0.327
	Group II	50.00	115.60	7.722	
3MIN AIT	Group I	50.00	114.66	6.675	0.392
	Group II	50.00	113.44	7.500	
5MINAIT	Group I	50.00	112.54	6.584	0.479
	Group II	50.00	111.56	7.180	
8 MIN AIT	Group I	50.00	110.98	6.268	0.450
	Group II	50.00	109.96	7.140	
10 MIN AIT	Group I	50.00	110.40	6.273	0.254
	Group II	50.00	108.86	7.120	
30 MIN	Group I	50.00	111.96	5.938	0.442
	Group II	50.00	110.98	6.720	
1 HOUR	Group I	50.00	113.62	5.678	0.763
	Group II	50.00	113.98	6.206	
2HOUR	Group I	50.00	114.98	5.408	0.119
	Group II	50.00	116.70	5.534	
4HOUR	Group I	50.00	116.86	5.718	0.179
	Group II	50.00	118.30	4.883	
6HOUR	Group I	50.00	118.68	5.332	0.348
	Group II	50.00	119.60	4.375	
12HOUR	Group I	50.00	120.54	5.338	0.605
	Group II	50.00	121.04	4.242	

TABLE 4

In our study series, mean systolic blood pressure was raised during induction and returned to preoperative level within 3 minutes of after intubation. Mean systolic pressures were within normal limits. There was statistically no significant difference between two group(p>0.05

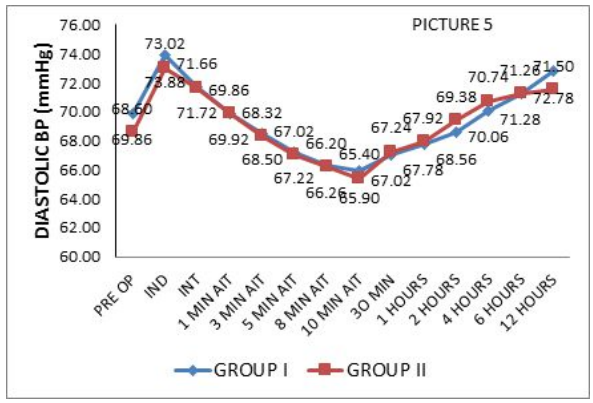


DIASTOLIC BLOOD PRESSURE

	GROUP	N	Mean	Std. Deviation	P value
PRE OP	GROUP I	50.00	69.86	5.548	0.334
	GROUP II	50.00	68.60	7.301	
INDUCTION	GROUP I	50.00	73.88	5.610	0.503
	GROUP II	50.00	73.02	7.100	
INTUBATION	GROUP I	50.00	71.72	5.620	0.963
	GROUP II	50.00	71.66	7.050	
I MIN AIT	GROUP I	50.00	69.92	5.721	0.963
	GROUP II	50.00	69.86	6.966	
3 MIN AIT	GROUP I	50.00	68.50	5.779	0.888
	GROUP II	50.00	68.32	6.915	
5 MIN AIT	GROUP I	50.00	67.22	5.604	0.873
	GROUP II	50.00	67.02	6.784	
8 MIN AIT	GROUP I	50.00	66.26	5.268	0.960
	GROUP II	50.00	66.20	6.676	
10 MIN AIT	GROUP I	50.00	65.90	5.108	0.675
	GROUP II	50.00	65.40	6.673	
30 MINS	GROUP I	50.00	67.02	5.332	0.862
	GROUP II	50.00	67.24	7.170	
1 HOUR	GROUP I	50.00	67.78	5.549	0.908
	GROUP II	50.00	67.92	6.490	
2 HOURS	GROUP I	50.00	68.56	5.350	0.476
	GROUP II	50.00	69.38	6.094	
4 HOURS	GROUP I	50.00	70.06	5.024	0.545
	GROUP II	50.00	70.74	6.107	
6HOURS	GROUP I	50.00	71.28	5.507	0.986
	GROUP II	50.00	71.26	6.141	
12HOURS	GROUP I	50.00	72.78	5.144	0.255
	GROUP II	50.00	71.50	6.011	

TABLE 5

In our study series, mean diastolic blood pressure was raised during induction and returned to preoperative level within 3 minutes of after intubation. Mean diastolic pressures were within normal limits. There was statistically no significant difference between two groups (p>0.05)

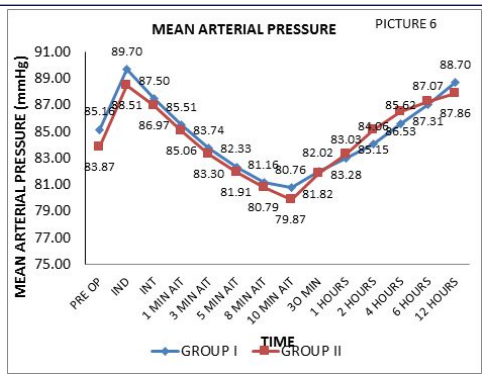


MEAN ARTERIAL PRESSURE

	GROUP	N	Mean	Std. Deviation	P value
PRE OP	GROUP I	50.00	85.16	4.792	0.279
	GROUP II	50.00	83.87	6.869	
INDUCTION	GROUP I	50.00	89.70	5.064	0.313
	GROUP II	50.00	88.51	6.588	
INTUBATION	GROUP I	50.00	87.50	5.025	0.648
	GROUP II	50.00	86.97	6.568	
I MIN AIT	GROUP I	50.00	85.51	5.058	0.704
	GROUP II	50.00	85.06	6.499	
3 MIN AIT	GROUP I	50.00	83.74	5.484	0.713
	GROUP II	50.00	83.30	6.420	
5 MIN AIT	GROUP I	50.00	82.33	5.004	0.714
	GROUP II	50.00	81.91	6.275	
8 MIN AIT	GROUP I	50.00	81.16	4.737	0.736
	GROUP II	50.00	80.79	6.117	
10 MIN AIT	GROUP I	50.00	80.76	4.654	0.416
	GROUP II	50.00	79.87	6.140	
30 MINS	GROUP I	50.00	82.02	4.770	0.863
	GROUP II	50.00	81.82	6.334	
1 HOUR	GROUP I	50.00	83.03	4.793	0.812
	GROUP II	50.00	83.28	5.643	
2 HOURS	GROUP I	50.00	84.06	4.717	0.274
	GROUP II	50.00	85.15	5.164	
4 HOURS	GROUP I	50.00	85.62	4.678	0.360
	GROUP II	50.00	86.53	5.153	
6HOURS	GROUP I	50.00	87.07	4.863	0.815
	GROUP II	50.00	87.31	5.089	
12HOURS	GROUP I	50.00	88.70	4.479	0.378
	GROUP II	50.00	87.86	5.028	

TABLE 6

In our study series, mean arterial pressures were elevated. There was statistically no significant difference between two groups (p>0.05)



DISCUSSION: Rapid and dramatic hemodynamic changes are adversely affecting the patient. It may occur during perioperative period. Hypertension and tachycardia have been recognized since 1950's as commonly associated with intubation under light anaesthesia and is most evident during laryngoscopy and manipulation of epiglottis. The effect is temporary arising in 30 seconds after endotracheal intubation and lasts for less than 10 minutes thereafter. Sympathetic response to laryngoscopy has been studied and managed in past by topical anaesthesia ofpharynx, superior laryngeal nerve block, tracheal spray of lignocaine, increasing the depth by inhalational agents, alpha and beta blockers, both alpha and beta blockers e.g. Labetalol, Nitroprusside, Calcium channel blockers, Nitroglycerine and strong narcotics etc."King et al in 1951 described pressor response to laryngoscopy and intubation in anaesthetised patients "' .

In the present study, oral Ivabradine and intravenous Lignocaine were used to attenuate the haemodynamics. Blood pressure and heart rate response to direct laryngoscopy and endotracheal intubation was studied in both the groups. The pre-induction parameters of haemodynamic (i.e. after premedication) values were taken as basal values. After induction and intubation the surgeon was not allowed to operate till ten minutes (duration of observation) because ivabradine has no analgesic properties and skin incision could have raised the heart rate and blood pressure giving false result.

Heart Rate: In our study, oral ivabradine reduces heart rate significantly than intravenous Lignocaine. Mean heart at intubation in oral ivabradine group (group I) was 76.74 ±7.575, whereas in group II mean heart rate at intubation was about 90.58± 6.795. C. G. Raghu ram, Deep raj Singh, Aditya Vikram Kabra observed that there was not a very significant rise in the heart rate in response to direct laryngoscopy and endotracheal intubation in ivabradine group, when compared to the control group. There was a raise in heart rat returned to baseline within a minute. In the control group the baseline reading was high and the increase in pulse rate though decreased was above the normal value.Kunwar et al [6] concluded that Ivabradine is a useful drug to blunt the abnormal increase in heart rate &blood pressure during direct laryngoscopy and endotracheal intubation.

Blood Pressure: In our study, mean systolic blood pressure in group I is119 ± 6.540 mmHg during intubation and returned tonormal within 3 minutes. In group II mean systolic blood pressure is 117.68 ± 7.542 & returned to normal within a minute. But there was no statistical significance between two groups.The mean diastolic pressure during intubation is 71.72 ± 5.620 in group I and 71.66±7.050 in group II . There is a small raise in diastolic pressure during induction and come to base line within 3 minutes.The mean arterial pressure during intubation is 87.50±5.025 in group I an86.97±6.56in group II. Mean arterial pressure was mildly elevated in both groups. There was no statistically significant change mean arterial pressure in both groups. C. G. Raghu ram, Deep raj Singh, Aditya Vikram Kabra found that oral Ivabradine minimizes hypertension during laryngoscopy and endotracheal intubation. Kunwar et al [6] evaluated that haemodynamic parameters were more stable in ivabradine and also it prevents abnormal increase in heart rate & blood pressure during direct laryngoscopy and endotracheal intubation.

Shruthi Jain et al [7] found that the increase in pulse rate &mean arterial pressure are less in i.v .lignocaine group during intubation as well as extubation. Malde and sarode et al[8] evaluated the efficacy of single bolus doses of Fentanyl (2µg/kg) or Lignocaine (1.5 mg/kg) for attenuation haemodynamic responsethat Lignocaine blunt the increase in blood pressure with endotracheal intubation. But fentanyl prohibited it totally.Gulabaní et al [9] compared the efficacy of lignocaine with two different doses of dexmedetomidine for attenuating the pressor response and concluded that dexmedetomidine 1µg/kg adequately attenuated the hemodynamic response to laryngoscopy and endotracheal intubation when compared with dexmedetomidine 0.5µg/kg and lignocaine 1.5mg/kg.C .D. Miller and S .J .Warren [10] used intravenous lignocaine to blunt the cardiovascular responses to direct laryngoscopy and endotracheal intubation. There was no significant change in haemodynamics in I.V. Lignocaine group in that study.

SIDE -EFFECTS: All the patients in the study group were monitored for 12 hours. There were no side effects were found in the patients.

SUMMARY "This Prospective randomised study was conducted to compare the effect of oral ivabradine and i.v lignocaine on the haemodynamics during laryngoscopy and endotracheal intubation in patients undergoing surgical procedures under general anaesthesia in 100 patients.50 patients in each group.Premedication, induction agent and muscle relaxant to facilitate intubation were standardized for both the groups. In both groups surgery was not allowed for 10 minutes till the recordings were completed. Changes in heart rate, systolic blood pressure, diastolic blood pressure &mean arterial pressure were monitored. According to this study significant changes in heart rate were observed. Heart Rate: Group I (oral Ivabradine) patients showed statistically significant change Heart rate. Blood Pressure: There was no statically significant change in blood pressure in both Groups. And also these patients were monitored post –operatively for upto 12 hours. Side effects like bradycardia and visual disturbances were not found in the patients.

Advantages of oral Ivabradine in this study is

- Good attenuation of heart rate response
- There was good heart rate control during perioperative period.
- There was good heart reduction during extubation also.
- The drug has minimal side effects. No side effects were observed during the study. The drug is easily available &easy to administer.

CONCLUSION

To conclude that oral Ivabradine has better heart rate control than Intravenous Lignocaine for attenuation of haemodynamics during laryngoscopy and endotracheal intubation in ASA I patients without side effects.

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