



COMPARATIVE RANDOMIZED DOUBLE BLIND INTERVENTIONAL STUDY OF INTRAVENOUS CLONIDINE VERSUS ESMOLOL FOR ATTENUATION OF HEMODYNAMIC RESPONSE ASSOCIATED WITH LARYNGOSCOPY AND INTUBATION IN ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA.

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ABSTRACT

Aims – The study aims to compare the efficacy of bolus intravenous clonidine and esmolol for attenuation of hemodynamic responses associated with laryngoscopy and endotracheal intubation. **Method**- After institutional ethical committee approval 72 adult ASA I and ASA II patients of both sex were included in this study who went elective abdominal surgery under general anaesthesia were divided into two groups. Group-A (clonidine) receiving bolus dose of 1 microgram/kg clonidine, Group-B(esmolol) receiving bolus dose of 1mg/kg esmolol. All patients were given injection fentanyl 2microgram/kg before induction of anaesthesia. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were recorded as baseline, before study drug, after study drug, just before intubation, 1,3,5, and 10 minute thereafter. **Result**- Demographic data and baseline hemodynamic parameters were comparable among each group. The rise in heart rate was better controlled in esmolol group and was statistically significant. There was no significant rise in blood pressure in clonidine Group and it came to the baseline level within 1 minute post intubation and was statistically significant **Conclusion**- Esmolol 1mg/kg was a better drug to control increase in heart rate but pressure response was better controlled by clonidine 1microgram/kg. Hemodynamic parameters were better maintained throughout the procedure by clonidine.

KEYWORDS : Esmolol, Clonidine, Laryngoscopy, Intubation, Haemodynamic response.

INTRODUCTION

Laryngoscopy and endotracheal intubation is an integral part of anaesthesia. Despite the emergence of new airway devices in recent year, rigid laryngoscopy and tracheal intubation still remain gold standard in airway management. It maintains the patency of airway, it control the ventilation, and helps in delivering inhalation agent to the patient.

The present study was designed to compare the efficacy of two different class of drugs Esmolol versus Clonidine for attenuation of hemodynamic responses to laryngoscopy and endotracheal intubation in patient undergoing abdominal surgeries under general anaesthesia.

AIM OF THE STUDY

Primary Objective:

To determine the difference in variation in heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure from baseline to 1 minute, 3 minute, 5 minute, and 10-minute post intubation in both groups and to find out which drug is better.

Secondary Objective:

To determine the difference in percentage of cases who experience side effects within 24hr in both groups.

METHOD

Study design: Hospital based, Randomized, Double blind, Interventional study.

Sample size: The required sample size is 36 in each group at 95% confidence interval and 80% power to verify the expected minimum difference of 3.86(±4.2) of change in systolic blood pressure from baseline to 1-minute post intubation in both groups. This sample size is adequate to cover all other study variables too

Study groups: The study was conducted in the following 2 groups of patients. Each group were consist of 36 patients. (n=36/group)

➤ Group A: 36 Patients were receiving injection Clonidine,(1

microgram/kg body weight) diluted up to 10 cc, and given over 2 minutes, intravenously.

➤ Group B: 36 Patients were receiving injection Esmolol (1mg/kg body weight) diluted up to 10 cc, and given over 2 minutes, intravenously.

Inclusion Criteria:

- Age group- 20 to 55 years.
- ASA grade -II.
- Elective abdominal surgeries.

Exclusion Criteria:

- Unwilling to participate in study.
- Patients with difficult airway i.e more than 1 attempt of intubation or more than 20 seconds intubation time.
- Patients having known allergy to drug used in study.
- History of medications affecting heart rate and blood pressure.
- Patients with history of adrenal insufficiency, asthma, hypertension, psychiatric, endocrine illness, cardiorespiratory diseases.
- Heart rate <60 bpm.
- Bleeding disorder.

Thorough pre-anaesthetic checkup was done as per the protocol of our department.

Procedure

- On arrival in the operation theatre, fasting status, written informed consent and pre anaesthetic check up was checked. Standard monitoring including NIBP, SPO₂ and ECG were attached & baseline parameters i.e. Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), and Oxygen saturation (SPO₂) were noted.
- Intravenous line was secured, and i.v. fluid Ringer Lactate was started at 10 ml/kg/hour. Patients was premedicated with inj. Ranitidine 50 mg i.v, inj. Metoclopramide 10mg i.v, inj. Glycopyrrolate 0.004mg/kg i.v. and inj. Midazolam

0.01mg/kg i.v.,inj. Fentanyl 2mcg/kg i.v. 5minutes prior to study drug.

- Hemodynamic parameters were noted 5 minutes after premedication (just prior to injection of study drug). Study drug was given according to group allocation. Study drug in group-A patients received inj. Clonidine 1microgram/kg iv and group-B patients received inj. Esmolol 1mg/kg iv, drug was diluted with normal saline up to 10 cc ,and given over 2 minutes, 3 minutes prior to induction.Hemodynamic parameter was noted.
- Anaesthesia was induced with Inj Thiopentone 5mg/kg iv and tracheal intubation was done after injection Succinylcholine 1.5mg/kg iv.Patient was ventilated with 100% Oxygen for 30 seconds. Hemodynamic parameters were noted before intubation. Under direct laryngoscopy patient was intubated with appropriate size Endotracheal tube, Bilateral air entry checked & tube was fixed. Parameters were noted at 1,3,5, & 10 min after intubation. Intubation taken more than 1 attempt or more than 20 seconds were excluded from the study.
- Then surgery was allowed to proceed & anaesthesia was maintained with 66% Nitrous Oxide and 33% Oxygen , 1% Sevoflurane & inj. Atracurium 0.5 mg/kg stat & 0.1mg/kg i.v and inj. Fentanyl 30 mcg given to maintain hemodynamic variables within 20% of the baseline value intra-operatively.
- At the end of the surgery patient was reversed with Inj. Neostigmine (0.05mg/kg i.v.) and Inj. Glycopyrrolate (0.01mg/kg i.v.) and Extubation was done, when patient fully awake and obeying verbal commands. Patient was shifted to recovery room .Patient was observed for any side effects postoperatively.

Outcome Variables:

- Mean heart rate
- Mean systolic blood pressure
- Mean diastolic blood pressure
- Mean arterial blood pressure
- if any Side effects, Nausea ,Vomiting, Bradycardia, Hypotension, Hallucination.

Analysis Of Data:

The difference in mean of two groups analyzed using student t test. The difference in proportion analyzed using Chisquaretest. The level of significance was kept 95% for all statisticalanalysis.

RESULTS

Age in both groups varied between 18-55years. The mean age in both the groups were comparable. The sex in both the groups was comparable. ASA physical status of patients were comparable in both the groups.

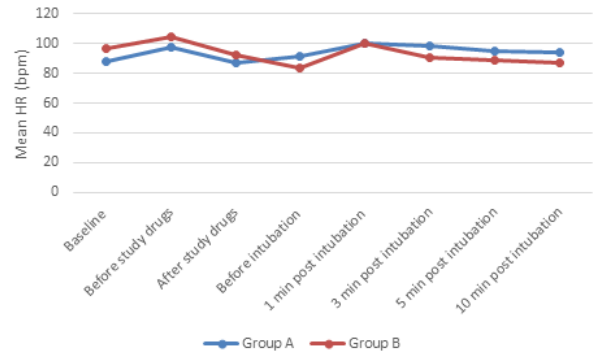
Table- Comparison of mean value of heart rate variation of patients in both groups (Beats/min) (Mean ± SD)

Table- Comparison of mean value of Systolic, Diastolic and Mean blood pressure variation of patients in both groups at various time interval (mm of Hg)(Mean ± SD)

Observation Time	Systolic blood pressure (mm of Hg)(Mean ± SD)			Diastolic blood pressure (mm of Hg)(Mean ± SD)			Mean arterial pressure (mm of Hg)(Mean ± SD)		
	Group A	Group B	Result (p value)	Group A	Group B	Result (p value)	Group A	Group B	Result (p value)
	Mean ± SD	Mean ± SD		Mean± SD	Mean ± SD		Mean± SD	Mean ± SD	
Baseline	124.53± 12.40	129.08± 12.42	0.123 (NS)	86.00± 14.85	84.64± 8.00	0.629 (NS)	97.97± 9.85	100.58± 9.66	0.259 (NS)
Before study drugs	123.67± 16.84	125.03± 14.22	0.712 (NS)	83.94± 13.71	82.78± 10.26	0.683 (NS)	96.14± 11.73	95.39± 10.11	0.772 (NS)
After study drugs	113.67± 14.03	112.25± 15.18	0.682 (NS)	77.17± 12.06	78.33± 12.17	0.684 (NS)	88.78± 10.03	89.25± 12.16	0.857 (NS)
Before intubation	100.89± 14.58	108.69± 14.81	0.027 (S)	69.47± 12.23	75.56± 9.62	0.021 (S)	79.31± 11.14	86.69± 10.30	0.004 (S)

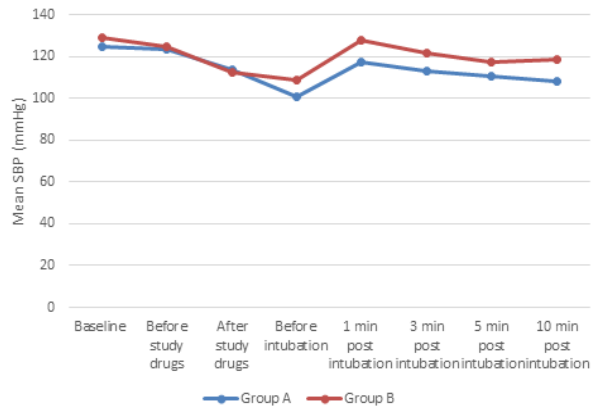
Observation Time	Group A		Group B		Result (p value)
	Mean	SD	Mean	SD	
Baseline	87.56	16.13	96.42	17.80	0.030
Before study drugs	97.08	18.36	104.75	18.74	0.083
After study drugs	87.11	16.15	92.14	14.71	0.171
Before intubation	91.72	15.04	83.78	12.95	0.018 (S)
1 min post intubation	99.83	22.12	99.92	14.23	0.984
3 min post intubation	98.36	14.81	90.81	15.32	0.036 (S)
5 min post intubation	95.19	14.58	88.33	15.35	0.047 (S)
10 min post intubation	94.06	14.61	86.83	13.72	0.034 (S)

S = Significant ; NS = Non Significant



This shows that there was no significant rise in heart rate after laryngoscopy and intubation in Group-B and it came to the baseline level within 3 minute post intubation.

Table -shows that the change in mean heart rate were significant just before intubation , 3 ,5 and 10 minute post intubation.

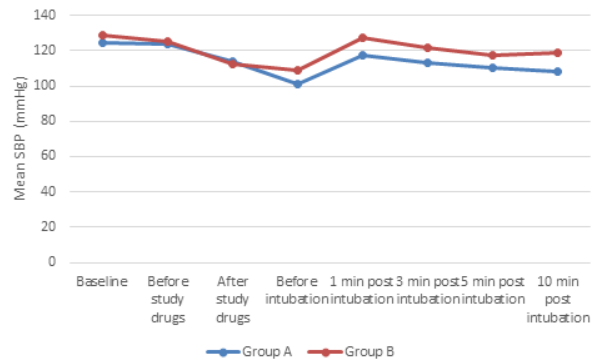


This shows that there was no significant rise in systolic blood pressure after laryngoscopy and intubation in Group-A and it came to the baseline level within 1 minute post intubation.

Table -6 shows that the change in mean systolic blood pressure were significant just before intubation ,1 , 3 ,5 and 10 minute post intubation.

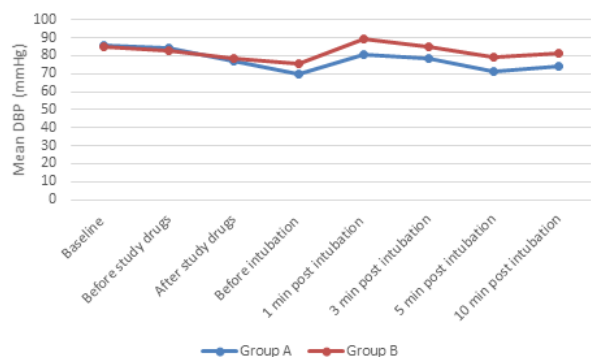
1 min post intubation	117.31 ± 17.39	127.67 ± 17.59	0.014 (S)	80.39 ± 15.77	89.03 ± 13.29	0.014 (S)	92.56 ± 12.99	100.25 ± 12.89	0.013 (S)
3 min post intubation	113.00 ± 15.57	121.69 ± 15.07	0.018 (S)	78.61 ± 12.86	84.97 ± 11.07	0.027 (S)	89.33 ± 12.20	95.00 ± 12.00	0.050 (S)
5 min post intubation	110.33 ± 14.50	117.61 ± 14.32	0.035 (S)	71.19 ± 12.94	78.97 ± 11.19	0.008 (S)	84.89 ± 11.41	91.44 ± 11.74	0.018 (S)
10 min post intubation	108.22 ± 14.52	118.89 ± 12.56	0.013 (S)	73.92 ± 12.02	81.58 ± 10.37	0.005 (S)	85.17 ± 14.69	93.64 ± 10.00	0.005 (S)

S = Significant ; NS = Non Significant



This shows that there was no significant rise in mean diastolic blood pressure after laryngoscopy and intubation in Group-A and it came to the baseline level within 1 minute post intubation.

Table -7 shows that the change in mean diastolic blood pressure were significant just before intubation ,1, 3, 5 and 10 minute post intubation.



This shows that there was no significant rise in mean arterial blood pressure after laryngoscopy and intubation in Group-A and it came to the baseline level within 1 minute post intubation.

Table shows that the change in mean arterial blood pressure were significant just before intubation ,1, 3, 5 and 10 minute post intubation.

No respiratory depression, no ECG changes and no sedation were noted in any patient intraoperatively and postoperatively in both groups.

CONCLUSIONS

The present study concluded that esmolol is a better drug to control increase in heart rate as compare to clonidine after laryngoscopy and intubation. Clonidine is a better drug to control hypertensive responses after laryngoscopy and intubation. Hemodynamic parameters were better maintained throughout the procedure by clonidine.

Esmolol and clonidine both were effective in stabilizing the hemodynamic response of patients during and after laryngoscopy and intubation. Esmolol was a better drug to control increase in heart rate as compare to clonidine after laryngoscopy and intubation but it was not very effective in attenuating the pressure response related to laryngoscopy and intubation. Clonidine is a better drug to control

hypertensive responses after laryngoscopy and intubation but not as effective as esmolol in controlling the heart rate response after laryngoscopy and intubation. Hemodynamic parameters were better maintained throughout the procedure by clonidine. Also there is no significant increase in incidence of side effects in any group.

Thus we conclude that :-Among the two drugs (esmolol and clonidine), clonidine showed better attenuation of hemodynamic response after laryngoscopy and intubation and after that throughout the procedure hemodynamic parameter were more stable which is highly significant.

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