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Original Article

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To Study the Efficacy of Oral Gabapentin for Attenuation of the Hemodynamic Response to Direct Laryngoscopy and Tracheal Intubation

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ABSTRACT

Introduction: Since the inception of general anesthesia it has been well recognized that laryngoscopy & tracheal intubation is a noxious stimulus, which is associated with hemodynamic changes in the form of increase in blood pressure & heart rate [1, 2 & 3]. We conducted a prospective, randomised, double- blind, clinical trial to examine whether a single preoperative dose of 800 mg oral gabapentin would be effective in blunting the hemodynamic response to laryngoscopy & tracheal intubation.

Aims and Objectives: The main objective of the study is to see the effect of administering oral Gabapentin 800 mg on direct laryngoscopy & tracheal intubation. The secondary objective is to study any side effect of oral dose of 800 mg of Gabapentin like, Dizziness, Somnolence, Nausea, Vomiting and others.

Methods: After obtaining institutional ethical clearance, study was conducted for 2 years from October 2020 to October 2022 at tertiary care center.60 patients of either sex (18–50 years of age) undergoing elective surgeries under general anesthesia were randomly allocated to two groups of 30 patients each. Patients of Group A received oral gabapentin 800 mg 2 hr before anticipated intubation, while patients in Group B received oral placebo at the same time.

Results: Patients receiving gabapentin 800 mg showed remarkable decrease in HR, MAP, SBP and DBP in response to tracheal intubation ($P < 0.05$) compared to placebo group.None of the patient has suffered from any side- effects.

Conclusion: Oral Gabapentin 800 mg is efficacious and safe in blunting the hemodynamic response to laryngoscopy and tracheal intubation.

Key Words: *Oral Gabapentin, Direct Laryngoscopy, Endotracheal Intubation, Hemodynamic Changes, Attenuation of Pressor Response*

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INTRODUCTION

Endotracheal intubation is required during general anesthesia for maintenance of the airway & protection against aspiration of the gastric content [1]. Since the inception of general anesthesia it has been well recognized that laryngoscopy & tracheal intubation is a noxious stimulus, which is associated with transient hemodynamic changes in the form of increase in blood pressure & heart rate [2, 3, 4 & 5]. It is well known that these hemodynamic changes are associated with the release of catecholamines [6, 7 & 8]. several techniques had been used in the clinical practice by anesthesiologists to prevent or attenuate the hemodynamic responses following direct laryngoscopy & tracheal intubation such as deepening of plane of anesthesia [9] omitting cholinergic premedication [10], pre-operative use of Vasodilators such as nitro glycerine [11], beta blockers [12], calcium channel Blockers [13], alpha agonist [14], lignocaine [15] and opioids [16, 17, 18, 19, 20, 21 & 22]. Gabapentin was originally introduced as an anticonvulsant drug [23], also proved to be effective in controlling neuropathic pain [24], post herpetic neuralgias [25], and nerve related pains, and reduce postoperative opioid requirements [26].

Gabapentin a structural analogue of gamma amino butyric acid [27], has been shown to have multi model effects which make it potentially useful drug for premedication in adults, providing postoperative analgesia, and preoperative anxiolysis while preventing chronic postsurgical pain, postoperative nausea & vomiting & delirium [28].

In addition, gabapentin has also been reported to successfully attenuate the cardio vascular responses following tracheal intubation [29, 30, 31, 32, 33, 34 & 35].

This beneficial effect of Gabapentin is probably due to inhibition of membrane voltage gated calcium channels, an action similar to calcium channel blockers in controlling the hemodynamic response associated with laryngoscopy & intubation [36].

The present study is undertaken to evaluate the efficacy of single pre-operative oral dose of 800mg Gabapentin in blunting the hemodynamic responses following direct laryngoscopy & tracheal intubation.

AIMS AND OBJECTIVES

AIM:

To evaluate the efficacy of oral Gabapentin 800 mg in attenuating the hemodynamic response to direct laryngoscopy & tracheal intubation.

OBJECTIVES

PRIMARY:

The objective of the study is to see the effect of administering oral Gabapentin 800 mg during direct laryngoscopy & tracheal intubation on

1) Heart Rate (HR)
2) Systolic Blood Pressure (SBP)
3) Diastolic Blood Pressure (DBP)
4) Mean Arterial Pressure (MAP)
5) ECG Changes
6) SpO_2 (%)

To compare the changes in above factors as baseline, before intubation, at the time of laryngoscopy & endo tracheal tube insertion, then at 2 min, 4 min, 6 min, 8 min, 10 min, 12 min, 14 min, 16 min, 18 min, 20 min after intubation.

SECONDARY

To study any side effect of single preoperative oral dose of 800 mg of Gabapentin like, Dizziness, Somnolence, Ataxia, Fatigue, Nystagmus, Headache, Tremors, Diplopia, Nausea, Vomiting and others.

INCLUSION CRITERIA

1) Patient with written valid and informed consent.
2) Patients belonging to ASA grade I & II
3) Patients undergoing elective surgery under general anesthesia with endotracheal intubation.
4) Age between 18-50 years
5) Both sexes
6) Body Mass Index between 18-25
7) Duration of laryngoscopy less than 30 seconds
8) Intubated in single attempt.

EXCLUSION CRITERIA

1) ASA physical status grade III or higher
2) Patients who are not willing to enroll in the study
3) Patients posted for emergency surgeries
4) Age less than 18 years & more than 50 years
5) Patients with anticipated difficult intubation
6) Patients with co-morbid illness such as Hypertension, Diabetes Mellitus, Ischemic heart disease
7) Patients on medications like antihypertensive drugs, sedative, hypnotics, antidepressants
8) Allergy to study drugs
9) Requiring more than one attempt at intubation
10) Pregnant Patients.

METHODOLOGY

After obtaining Institutional Ethical committee (IEC) approval the present clinical, prospective, randomized, double blind study to evaluate the efficacy of oral Gabapentin for attenuation of the hemodynamic response to direct laryngoscopy and tracheal intubation was carried out in Department of Anesthesiology at our institute, during period of October 2020 to October 2022.

The sample size of 60 patients was decided in consultation with the statistician and it is calculated from mean and standard deviation of reference study with power 80% difference in heart rate 15% of baseline value considered to be significant.

Total of 60 patients who satisfied inclusion and exclusion criteria were enrolled for the study. Informed written consent was taken from the patient for participation in the study in local languages spoken in Maharashtra. Study was carried out according to guidelines laid down by the Declaration of Helsinki. The participants were free to withdraw anytime during the conduct of study.

Patients were randomly allocated using computer generated randomization list into 2 groups with 30 patients in each group with allocation ratio 1:1.
Group A – received oral Gabapentin 800mg 2Hr prior Intubation
Group B – received oral placebo 2Hr prior to intubation
In this study, placebo was given to remove the patient's bias**.**

A detailed pre anesthetic evaluation of each case was done. Detailed history, general examination was carried out to detect the presence of any systemic disorder. Baseline screening and recording of vital parameters like Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Oxygen Saturation (SpO2) was done. Routine and special investigations (CBC, LFT, KFT, ECG, CXR, Urine analysis) were done and noted. Procedure was explained to the patients in detail.

All the patients were fasted for 6 Hrs before surgery. On arrival in the preoperative room baseline HR, SBP, DBP, MAP, SpO2 were recorded using multipara monitor. Intravenous Ringer lactate administered as a maintenance fluid through 20 G IV cannula @100 ml/hr.

After shifting the patient in operation room, multipara monitors were attached.
Premedication was done with Inj. Midazolam 0.02mg/kg IV+ Inj. Fentanyl 2µg/Kg IV. Preoxygenation with 100% oxygen done for 5 min by mask.

After induction with Inj. Propofol 2mg/kg IV, followed by intubation performed by direct laryngoscopy and appropriate size endotracheal tube under effect of Inj. Vecuronium 0.1 mg/kg by trained anesthetist after an interval of 3 min when neuromuscular block achieved and tube position confirmed by auscultation and EtCO2.

Anesthesia maintained with O2+N2O (50:50) + Isoflurane 1% through closed circuit and Intraop relaxation maintained with intermittent doses of Inj. Vecuronium, as required throughout the surgery.At the end of surgery, patient was reversed with Inj. Neostigmine 50mcg/kg &Inj. Glycopyrolate 8µg/kg IV and extubated. After adequate recovery, patient shifted to post anaesthesia care unit.

As a primary outcome measured HR, Systolic, Diastolic and Mean Arterial blood pressure recorded, as a baseline, before intubation, before laryngoscopy & endotracheal intubation. At the time of laryngoscopy & intubation then at 2 min, 4 min, 6 min, 8 min, 10 min, 12 min, 14 min, 16 min, 18 min, 20 min post intubation. In the event that the SBP fell below 90 mmHg or 30% from baseline (Hypotension) treated with Intravenous fluids and/or Inj. mephentermine 3mg Intravenous as a rescue measure. In case of Bradycardia (HR below 60 beats/min) treated with Inj. atropine 0.6mg Intravenously. Post operatively patients observed for adverse effects like dizziness, somnolence, nausea, vomiting and others, every 6 hr for next 24 hrs in the ward.

Data was collected by using a structure proforma. Data thus was entered in MS excel sheet and analysed by using SPSS 24.0 version IBM USA.Qualitative data was expressed in terms of percentages and proportions Quantitative data was expressed in terms of Mean and Standard deviation. Association between two qualitative variables was seen by using Chi square/ Fischer's exact test Comparison of mean and SD between two groups will be done by using unpaired t test to assess whether the mean difference between groups is significant or not Descriptive statistics of each variable was presented in terms of Mean, standard deviation, standard error of mean.

P value of <0.05 was considered as statistically significant whereas a p value <0.001 was considered as highly significant and $P>0.05$ is statistically non-significant.

RESULTS

Table No 1: Comparison of Height, Weight and BMI between two Groups

Parameters	Group A Mean ± SD	Group B Mean ± SD	P value	Inference
Age (years)	30.70 ± 7.91	30.67 ± 9.01	P=0.988	Not significant
Height (cm)	164.07± 0.42	161.90 ± 9.30	P=0.348	Not significant
Weight (Kg)	61.77± 7.31	59.97 ± 7.441	P=0.836	Not significant
BMI(Kg/m²)	22.91 ± 1.18	22.836 ± 1.64	P=0.836	Not significant

Table No 2: Distribution According to Gender

		Group A		Group B		Total	p
		Frequency	Percent	Frequency	Percent		
Gender	Male	14	46.7	16	53.3	30	0.096 Not significant
	Female	16	53.3	14	46.7	30	
Total		30	100.0	30	100.0	60	

Table No 3: Distribution According to ASA STATUS

		Group A		Group B		Total	p
		Frequency	Percent	Frequency	Percent		
ASA Grade	Grade I	26	86.7	26	86.7	52	1.00, Not significant
	Grade II	4	13.3	4	13.3	8	
Total		30	100.0	30	100.0	60	

Table No 1, 2 and 3 depict the demographic details of the patients were not statistically significant when compared between both the groups.

Table No 4: Comparison of Heart Rate between two groups

Parameters	Group A Mean ± SD	Group B Mean ± SD	P Value	INFERENCE
Baseline	81.53±9.24	80.27±10.66	0.625	Not significant
Before Intubation	84.67±10.15	86.67±12.45	0.498	Not Significant
At the time of Intubation	89.00±10.54	95.83±10.12	0.013	Highly significant
2 min after Intubation	83.67±10.96	94.23±18.70	0.010	Highly significant
4 min after Intubation	80.80±10.35	95.13±8.51	0.0001	Highly significant

6 min after Intubation	77.33±9.91	92.67±8.64	0.0001	Highly significant
8 min after Intubation	76.07±9.50	91.07±8.05	0.0001	Highly significant
10 min after Intubation	75.3±8.75	90.80±9.00	0.0001	Highly significant
12 min after Intubation	75.87±8.91	86.20±9.91	0.0001	Highly significant
14 min after Intubation	76.53±8.65	84.07±8.95	0.002	Highly significant
16 min after Intubation	76.53±8.66	83.13±9.97	0.0008	Highly significant
18 min after Intubation	75.13±8.56	82.33±10.94	0.006	Highly significant
20 min after Intubation	76.48±9.05	82.0±10.98	0.040	Significant

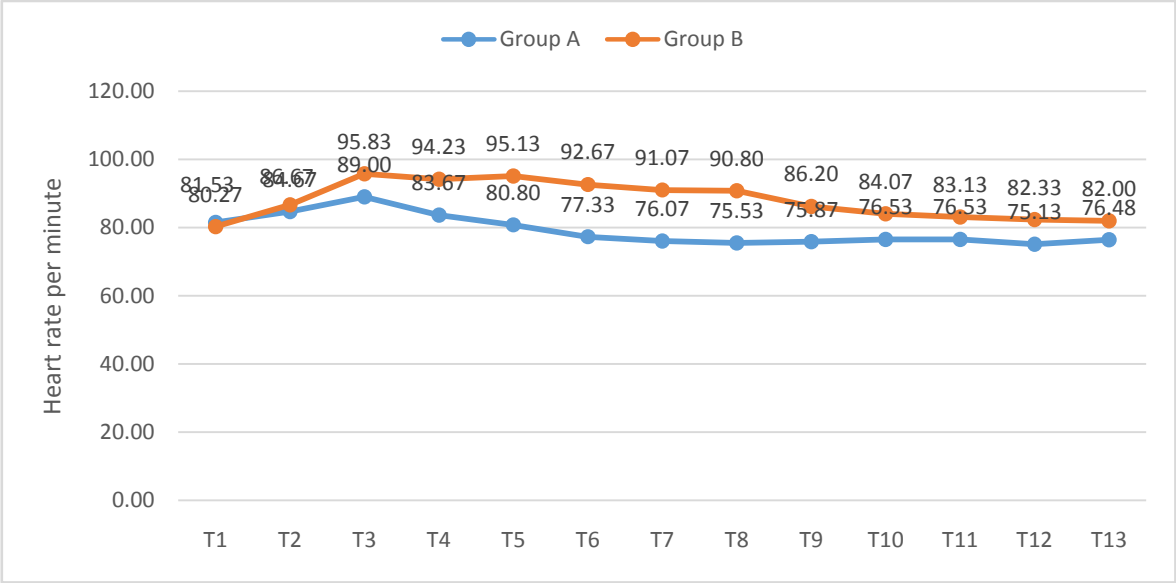

Figure 1: Comparison of Heart Rate between Two Groups

Table No 5: Comparison of Mean Arterial Pressure Between two groups

Parameters	**Group A Mean ± SD**	**Group B Mean ± SD**	**P VALUE**	**INFERENCE**
Baseline	90.81±8.19	88.37±7.62	0.237	Not Significant
Before Intubation	91.93±8.48	86.67±12.45	0.192	Not Significant
At the time of Intubation	93.34±8.34	96.26±8.05	0.173	NotSignificant
2 min after Intubation	89.72±7.75	94.99±8.42	0.015	Significant
4 min after Intubation	87.69±7.88	95.24±8.99	0.001	Highly Significant

6 min after Intubation	86.21±8.41	94.00±8.05	0.001	Highly Significant
8 min after Intubation	85.54±7.60	92.42±7.16	0.001	Highly Significant
10 min after Intubation	84.26±7.52	91.08±7.38	0.001	Highly Significant
12 min after Intubation	96.66±6.22	89.21±7.33	0.517	Not Significant
14 min after Intubation	85.79±8.06	88.82±7.98	0.150	Not Significant
16 min after Intubation	85.57±7.54	87.53±7.40	0.313	Not Significant
18 min after Intubation	86.08±8.51	87.81±6.92	0.390	Not Significant
20 min after Intubation	86.45±7.52	87.47±7.91	0.612	Not Significant

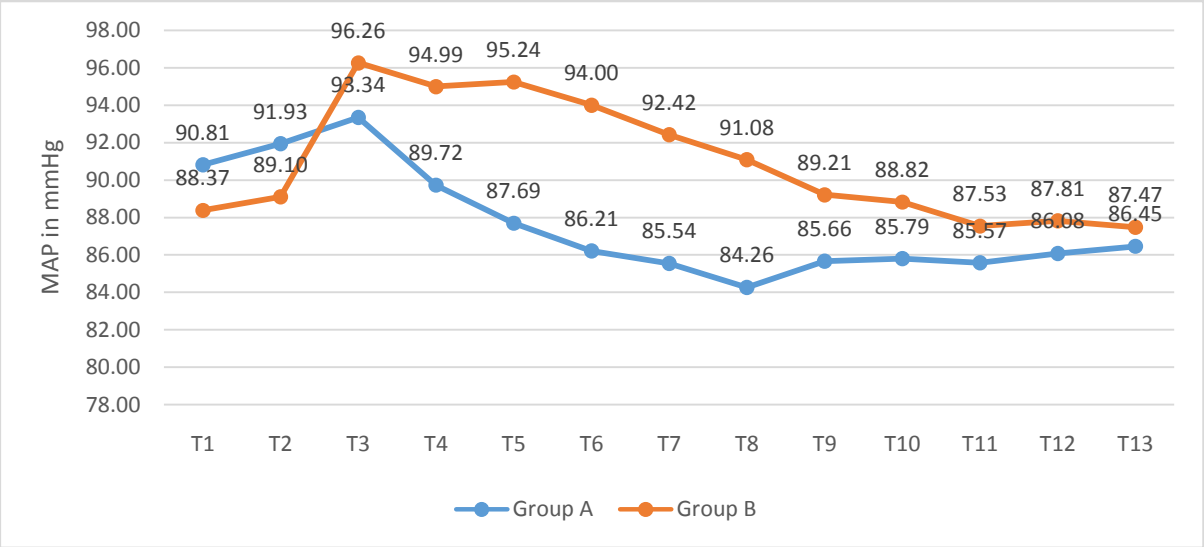

Figure 2: Comparison of Mean Arterial Pressure Between two groups

Table No 6: Comparison of SBP between two groups

Parameters	**Group A Mean ± SD**	**Group B Mean ± SD**	**P VALUE**	**INFERENCE**
Baseline	119.80±11.48	118.77±9.43	0.705	Not Significant
Before Intubation	123.60±10.76	120.03±21.47	0.419	Not Significant
At the time of Intubation	127.33±10.91	133.33±8.31	0.020	Significant
2 min after Intubation	123.27±11.38	133.27±8.49	0.0001	Highly Significant
4 min after Intubation	118.87±10.99	132.27±9.44	0.0001	Highly Significant

6 min after Intubation	116.13±11.54	129.87±8.14	0.0001	Highly Significant
8 min after Intubation	114.53±11.12	128.73±8.48	0.0001	Highly Significant
10 min after Intubation	113.33±10.63	127.67±7.43	0.0001	Highly Significant
12 min after Intubation	114.33±10.04	123.33±8.01	0.0003	Highly Significant
14 min after Intubation	114.20±10.09	121.20±9.62	0.008	Highly Significant
16 min after Intubation	113.40±10.37	118.53±9.07	0.046	Significant
18 min after Intubation	115.47±11.57	118.97±9.15	0.199	Not Significant
20 min after Intubation	115.93±10.94	117.93±9.75	0.458	Not Significant

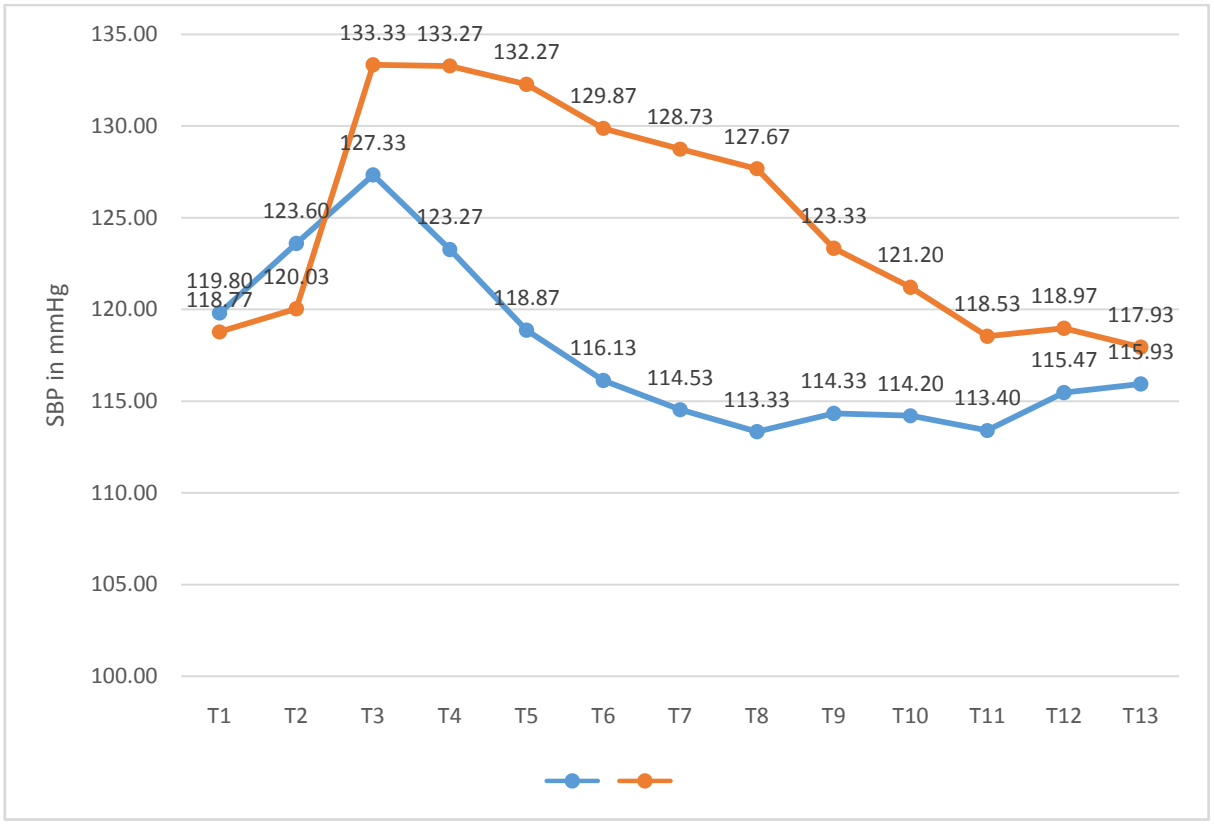

Figure 3: Comparison of SBP between two groups

Table No 7: Comparison of DBP between two groups

Parameters	**Group A Mean ± SD**	**Group B Mean ± SD**	**P VALUE**	**INFERENCE**
Baseline	76.53±7.77	73.40±7.56	0.119	Not Significant
Before Intubation	76.33±8.42	73.87±7.61	0.239	Not Significant

At the time of Intubation	76.60±8.41	78.00±8.55	0.525	Not Significant
2 min after Intubation	73.20±7.08	76.13±9.51	0.181	Not Significant
4 min after Intubation	72.33±6.95	77.00±9.51	0.034	Significant
6 min after Intubation	71.47±7.48	76.33±9.08	0.027	Significant
8 min after Intubation	71.27±6.76	74.53±7.72	0.086	Not Significant
10 min after Intubation	69.93±7.82	73.07±8.69	0.126	Not Significant
12 min after Intubation	71.53±7.14	72.40±8.09	0.662	Not Significant
14 min after Intubation	71.80±8.01	72.87±8.22	0.612	Not Significant
16 min after Intubation	71.87±7.20	72.27±7.31	0.832	Not Significant
18 min after Intubation	71.60±7.94	72.47±6.51	0.646	Not Significant
20 min after Intubation	71.93±6.53	72.47±7.52	0.771	Not Significant

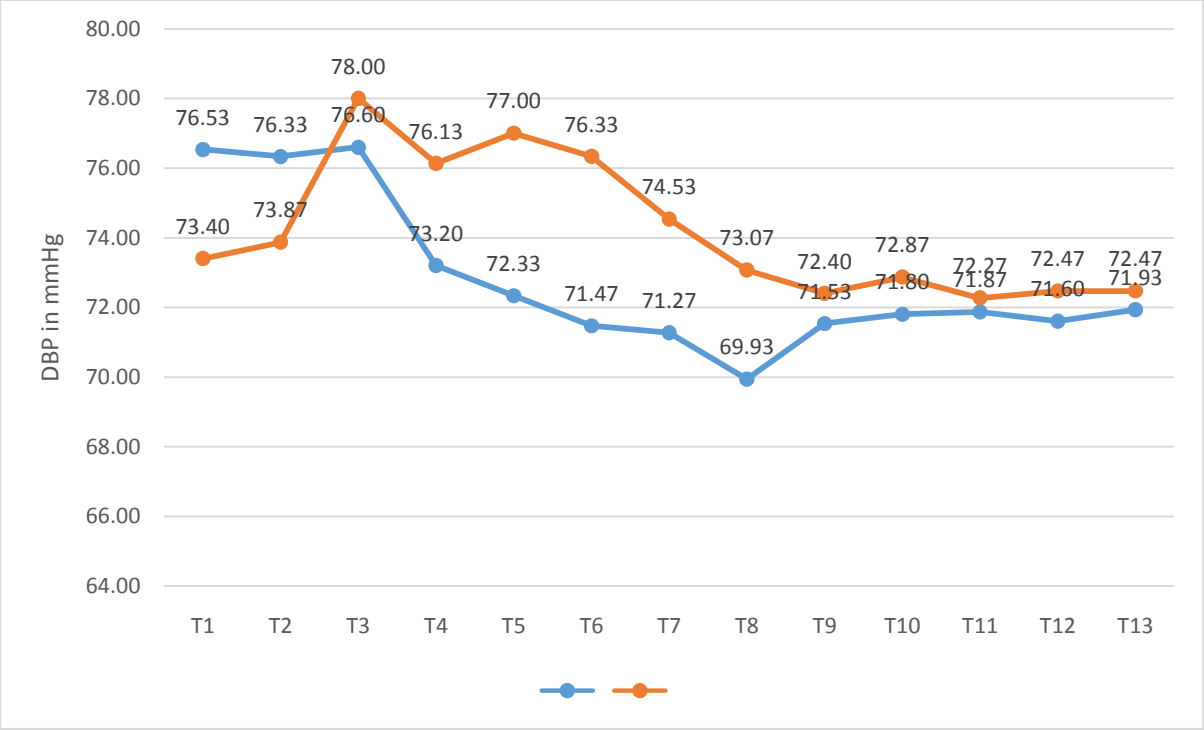

Figure 4: Comparison of DBP between two groups

Table No 8: Distribution according to side effects

		Group A		Group B		Total
		Frequency	Percent	Frequency	Percent	
Side effects (Dizziness, Somnolence, Nausea, Vomiting, Others)	Absent at 6 hours	30	100	30	100	60
	Absent at 12 hours	30	100	30	100	60
	Absent at 18 hours	30	100	30	100	60
	Absent at 24 hours	30	100	30	100	60

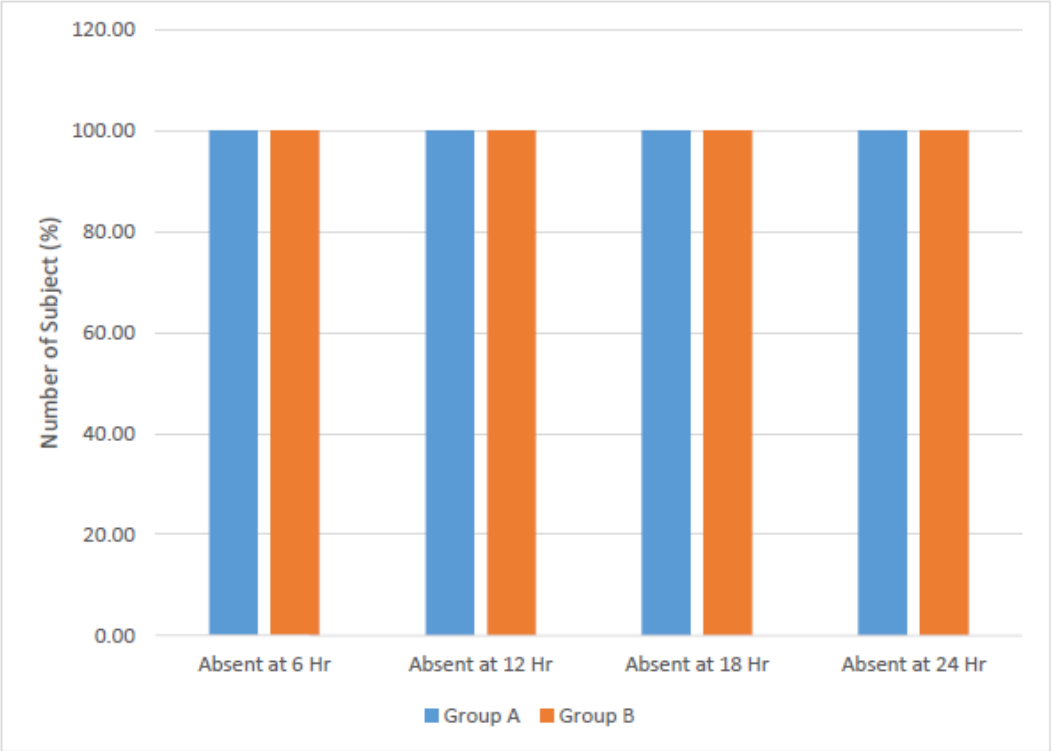

Figure 5: Distribution according to side effects

DISCUSSION

Transient hemodynamic changes occur during Endotracheal intubation [1, 2, 3, 4 & 5]. associated with stimulation of autonomic nervous system [6, 7] and the release of catecholamines [8, 9], may manifest as myocardial insufficiency, pulmonary oedema, left ventricular failure, cerebrovascular accident in susceptible individuals and it is essential to suppress reflex circulatory responses in such patients.

Gabapentin a structural analogue of gamma amino butyric acid [27, 28], have multi model effects which make it useful drug for premedication in adults, providing anxiolysis, post-operative analgesia, while preventing chronic post-surgical pain, post-operative nausea & vomiting & delirium [27, 28]. This effect of Gabapentin is due to inhibition of membrane voltage gated calcium channels, an action similar to calcium channel blockers in controlling the hemodynamic response associated with laryngoscopy & intubation [37].

Gabapentin bioavailability is not dose dependant; i.e., as dose is increased, bioavailability decreases. effective single doses of Gabapentin seem to lie somewhere between 800 and 1000 mg. Thus, we chose the 800 mg oral dose which we thought would give us a bioavailability of 34% (2400 mg in three divided doses) [38].

In our study, demographic data as age, weight, height and sex ratio were comparable among both groups.

In our study, patients who received Oral Gabapentin had decrease in heart rate and blood pressure during laryngoscopy and following intubation that were significantly lower than patients who received oral placebo. our results

weresimilar with Montazeri, et al. [39] Group P received placebo; Group G was given Gabapentin 800 mg and Group C clonidine 0.3 mg they found that HR significantly reduced in Group G and Group C as compared to Group P just before laryngoscopy. No significant difference was noted between Group G and Group C with respect to variables SBP, DBP, MAP. Contrary to that Parida, et al. [22] evaluated (1) whether a single preoperative dose of 800 mg Gabapentin would be as effective as 2 μg/kg of intravenous (IV) fentanyl in blunting the haemodynamic response to tracheal intubation and (2) whether a combination of both would be more effective in this regard in 75 patients and concluded that Oral Gabapentin does not produce significant reduction sympathetic responses as compared to IV fentanyl or the combination of Gabapentin and fentanyl.

S Kiran & D Verma, et al. [32] have found that gabapentin attenuates the pressor response to tracheal intubation as systolic blood pressure, diastolic blood pressure and mean arterial pressure are significantly reduced as compared to base line as well as placebo. The heart rate is not significantly attenuated as compared to baseline value; although mean increase in heart rate occurs less with gabapentin as compared with placebo.

However, in our study we found that Gabapentin attenuates the pressor response to tracheal intubation as heart rate, mean arterial pressure, systolic blood pressure are significantly reduced as compared to baseline as well as placebo.

In our study Duration of laryngoscopy and intubation was comparable for both the groups. Laryngoscopy alone or followed by tracheal intubation increases arterial pressure and catecholamine levels while intubation significantly increases HR. We did not measure levels of catecholamine during the study and can be considered as limitation of our study.

In our study none of the patients had hypotension before induction of anesthesiaandno oneneeded active treatment for hypotension during the study period, this documented the safety of Gabapentin administration.

Though we did not compare the vital parameters among both the groups during surgery in current study it was observed that the hemodynamic parameters remain stable not only during laryngoscopy and post tracheal intubation but also remains stable during surgery in Gabapentin group, similar results have been documented by Neogi M et al [40] in 60 patients, undergoing elective laparoscopic cholecystectomy.

Another limitation of our study was that it was conducted in normotensive ASA grade I and II patients without cardiac dysfunction, therefore the results are only applicable to individuals who have no major risk factors.

To conclude, we found that oral Gabapentin helps in attenuating the elevation of Heart rate and blood pressure during and after tracheal intubation and thereby providing hemodynamic stability during surgery and it also has wide safety margin. As the results of this study are encouraging, we propose conducting a similar study with oral Gabapentin in patients with compromised cardiac function in future.

SUMMARY & CONCLUSION

Following observations made during the study:

1) Both the groups were comparable with respect to age, weight, height, BMI, ASA grade and gender.
2) We compare the mean heart rate between two groups that is Group A and Group B at different time interval. It was observed that there was no statistically significant difference between the mean value at baseline and before intubation, we found that during laryngoscopy and post intubation till 20 minutes statistically significant difference in the mean heart rate between two groups it means that the heart rate in Group A was significantly decrease compared to Group B.
3) We compare the mean arterial pressure between two groups that is Group A and Group B at different time interval.it was observed that there was no statistically significant difference between the mean value at baseline and before intubation, and during laryngoscopy, we found that from 2 min after intubation till 20 min statistically significant difference in the mean value of MAP between two groups it means that the MAP in Group A was significantly decrease compare to Group B.
4) We compare the mean value of systolic blood pressure between two groups that is Group A and Group B at different time interval.it was observed that there was no statistically significant difference between the mean value at baseline and before intubation, we found that during laryngoscopy and post intubation till 20 min statistically significant difference in the mean value of SBP between two groups it means that the SBP in Group A was significantly decrease compare to Group B.
5) We compare the mean value of diastolic blood pressure between two groups that is Group A and Group B at different time interval from baseline to 20 min post intubation, it was observed that there was no statistically significant difference between two groups except at 4 min and 6 min post intubation.
6) No ECG changes like Tachyarrthmias, Bradyarrthmias observed in both the groups.

7) No adverse complications were noted in either group.

CONCLUSION

We conclude from present study that, Oral Gabapentin 800 mg is efficacious and safe in blunting the hemodynamic response to direct laryngoscopy and tracheal intubation.

ABBREVIATIONS: HR - Heart Rate, SBP - Systolic Blood Pressure, DBP - Diastolic Blood Pressure ,MAP - Mean Arterial Pressure,SpO2 - Oxygen Saturation, min – Minute, VGCC – Voltage Gated Calcium Channel ,ASA - American Society of Anesthesiologist, IOP - Intraocular pressure ,ECG – Electrocardiogram,EtCO2 - End Tidal Carbon Dioxide ,CBC - Complete Blood Count, Hb– Haemoglobin ,PCV - packed cell volume ,TLC - Total Leukocyte count ,DLC - Differential leukocyte count, RBSL - Random Blood Sugar Level ,LFT - Liver Function Test, RFT - Renal Function Test, CXR - Chest x ray, mg – Milligram, mcg – Microgram, µg – Microgram ,IV – Intravenous,G – gender,F – Female, M – Male, Ht – Height,Wt – Weight, BMI – Body Mass Index,T1 – Baseline,T2 – Before intubation,T3 – at the time of direct laryngoscopy and tracheal intubation, T4 – 2 minutes after intubation, T5 – 4 minutes after intubation,T6 – 6 minutes after intubation,T7 – 8 minutes after intubation,T8 – 10 minutes after intubation,T9 – 12 minutes after intubation,T10 – 14 minutes after intubation, T11 – 16 minutes after intubation,T12 – 18 minutes after intubation,T13 – 20 minutes after intubation, D – Dizziness, S – Somnolence, N – Nausea ,V – Vomiting ,O – Other

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Conflict of interest: The authors declare that they have no conflict of interest
Ethical approval: The study was approved by the Institutional Ethics Committee

Authors' contributions:

Dr. ANQ developed the study proposal, managed the research implementation, data collection, analyzed data and wrote the manuscript. Dr. SAC developed the study proposal, assisted with data analysis and reviewed the manuscript. Dr. SAC participated in development of the study proposal, participated in research team meetings to monitor study progress, reviewed preliminary results and reviewed the manuscript. Dr. GVT assisted with development of the study proposal, reviewed preliminary results and reviewed the final manuscript. All authors have read and approved the manuscript.

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