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A comparative study to assess the effect of oral gabapentin Vs oral clonidine in attenuating haemodynamic response of the patients undergoing laryngoscopy and tracheal intubation

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ABSTRACT

There are few studies that described that clonidine and gabapentin can be used for attenuating hemodynamic response to laryngoscopy and tracheal intubation. The present study was aimed to compare the safety and efficacy of a single preoperative oral dose of clonidine with a single preoperative oral dose of gabapentin in attenuating hemodynamic response to laryngoscopy and tracheal intubation. This randomised single-blinded controlled study was conducted in sixty patients. Group A and Group B patients received oral clonidine 0.2 mg and oral gabapentin 800 mg respectively 60 minutes prior to surgery. Haemodynamics were recorded at the baseline, pre-intubation, post-intubation one minute (T1), post-intubation three minutes (T3) and post-intubation five minutes (T5). *Primary outcome measures were* to compare haemodynamic parameters, whereas secondary outcome measures were to compare side effects and preoperative sedation caused by both the drugs. A comparison of quantitative and qualitative variables was done using unpaired student's t-test and the Chi-square test/Fisher's exact test respectively. The mean heart rate (HR) at pre-intubation, T1, T3 and T5 were significantly higher in Group B as compared to Group A. The mean systolic blood pressure, mean diastolic blood pressure and mean arterial pressure at pre-intubation, T1, T3 and T5 and incidence of side effects did not significantly differ between the two study groups. In Group A, a significantly higher percentage of patients were alert as compared to Group B. Oral clonidine provided good attenuation of HR to laryngoscopy and intubation as compared with oral gabapentin. Gabapentin produced more postoperative sedation than clonidine.

INTRODUCTION

Laryngoscopy and intubation are strong stimuli which can result in untoward effects on cardiovascular, respiratory, cerebrovascular and other physiological systems. The effects are seen in the form of hypertension, tachycardia, cardiac arrhythmias, ischemia, cerebrovascular stroke, pulmonary oedema and raised intracranial pressure. [1,2] It is postulated that circulatory changes occur due to the stimulation of cardio accelerator nerves and an increase in sympathetic tone. Direct laryngoscopy and intubation cause a reflex sympathetic discharge leading to this pressor response. It is associated with activation of the rennin-angiotensin system, the release of noradrenaline from the adrenal medulla and adrenergic nerve terminal releases of adrenaline. All these hemodynamic changes increase myocardial oxygen demand resulting in various grades of ischaemia. [1] Patients with hypertension, cardiovascular disease, elderly and other high-risk patients are more prone to develop myocardial ischemia leading to myocardial infarction due to these sudden and transient

haemodynamic changes during laryngoscopy and intubation.[1-3] Hence, it is necessary to find the way to blunt these responses at least in high-risk patients.Duration of laryngoscopy and the force applied during laryngoscopy also affect the haemodynamic response. [1,3] Thus, the aim should be to achieve laryngoscopy and intubation as fast and as smoothly as possible. Maximum changes are seen within 35 to 40 seconds after intubation and they more or less return to baseline in five minutes. [1]Various drug regimens and techniques have been used from time to time for attenuating the stress response to laryngoscopy and intubation such as topical lignocaine sprays, deeper planes of anaesthesia by inhalational/intravenous agents, beta-blockers, opioids, barbiturates, benzodiazepines, calcium channel blockers, vasodilators and alpha-2 agonists like dexmedetomidine. [4]

Although there are several methods, research is still going on for attenuation of pressor response to laryngoscopy and intubation. Clonidine is a selective alpha 2 adrenoreceptor agonist with sedative and analgesic effects. It decreases the haemodynamic response to laryngoscopy and intubation. [5,6] Clonidine causes a fall in the heart rate and blood pressure along with decreased systemic vascular resistance and cardiac output. Gabapentin is a structural analogue of Gamma-aminobutyric acid. Gabapentin is used as an anticonvulsant for the treatment of refractory partial seizures, neuropathic pain, as antinociceptive, and having antiallodynic properties, which also attenuate the pressor response of laryngoscopy and intubation. [7-9]

There are few studies that described that clonidine and gabapentin can be used for attenuating hemodynamic response to laryngoscopy and tracheal intubation. The present study was aimed to compare the safety and efficacy of a single preoperative oral dose of clonidine with a single preoperative oral dose of gabapentin in attenuating hemodynamic response to laryngoscopy and tracheal intubation.

METHODS

This randomised single-blind controlled study was conducted between March 2019 and October 2019 in major operation theatres of Poona Hospital and Research Centre, Pune, India. After approval from the scientific advisory committee (RECH/SAC/2019-20/0030) and institutional ethics committee (RECH/EC/2019-20/0068), written informed consent was obtained from all the patients prior to enrollment explaining the risks and benefits of the procedure. Patients of either gender, having age between 18 and 50 years posted for elective surgeries of 1 h to 3 h duration under general anaesthesia and falling into American Society of Anaesthesiologist (ASA) grades I and II were included. Patients with a history of allergy or hypersensitivity to clonidine or gabapentin, patients on anti-psychotic, sedative, hypnotic drugs and patients with heart rate (HR) < 60/min or systolic blood pressure (SBP) < 90 mm of Hg were excluded from this study.Out of 80 patients assessed for eligibility, after the exclusion, 70 patients were randomly divided into two groups. Randomisation was done by keeping 70 coded slips in an envelope. Patients were asked to choose one slip (Fig 1). The patient did not know in which group he or she was allotted. Group A and Group B patients received oral clonidine 0.2 mg and oral gabapentin 800 mg respectively 60 minutes prior to surgery.

All the patients underwent routine pre-anaesthetic evaluation. Details regarding the clinical history and physical examination were recorded. All routine investigations were carried out. Patients were kept fasting for 6 h prior to surgery. Before administration of the oral premedication, each patient's baseline HR and systemic arterial blood pressure were recorded. In the pre-anaesthetic room, the Observer Assessment of Alertness/Sedation Scale (OAA/S Scale) was used. [10,11] Four parameters such as response, facial expression, eyes and speech were assessed and the score was given. In the operating room, standard monitors consisting of the electrocardiogram, pulse oximetry and non-invasive arterial blood pressure were applied and vital parameters were monitored and recorded. After the placement of intravenous (IV) line, a crystalloid IV infusion of 6 to 8 mL/kg per h was started. All patients were uniformly premedicated with glycopyrrolate (0.2 mg), and midazolam (1 mg). After preoxygenation for three minutes with 100% oxygen, anaesthesia was induced with propofol 2 mg/kg and atracurium 0.5 mg/kg as per the standard protocol. The patients were ventilated manually with 100% oxygen. Laryngoscopy was attempted with Macintosh curved blade 3 minutes after the administration of atracurium. The trachea was intubated with an appropriate size disposable endotracheal tube (ETT). After confirming the position and fixing ETT with adhesive tape, anaesthesia was maintained as per the standard protocol. Anaesthesia was maintained with a minimum alveolar concentration of 1% sevoflurane, oxygen: nitrous oxide-50:50. The patient's lungs were mechanically ventilated with minute ventilation adjusted to maintain normocapnia (End-tidal CO_2 between 35 and 40 mm of Hg). The supplemental neuromuscular blockade was achieved with atracurium 0.1 mg/kg.HR, SBP, diastolic blood pressure (DBP) and mean arterial pressure (MAP) were recorded at the baseline, pre-intubation, post-intubation one minute (T1), post-intubation three minutes (T3), and post-intubation five minutes (T5) as per the study proforma. No surgical intervention was allowed throughout the study period of 10 minutes. After the end of the surgery, in the post-operative recovery room, the patient was assessed for the presence or absence of side effects such as dry mouth, headache, drowsiness, dizziness, nausea and vomiting during the immediate post-operative period.*The primary outcome measures were* to compare haemodynamic parameters, whereas he secondary outcome measures were to compare side effects and preoperative sedation caused by both the drugs. On the basis of a previously published study,[12] a sample size of 30 patients in each group was calculated by a formula [13] with 80 % power and 5 % probability of Type I error to reject the null hypothesis.

Statistical Analysis

Data collected were entered in Excel 2007 and analysis of data was done using Statistical Package for Social Sciences for Windows, Version 20.0 from IBM Corporation, Armonk, NY, USA. The data on categorical variables are shown as n (% of cases) and the data on continuous variables are presented as mean and standard deviation (SD). The comparison of categorical variables such as gender, ASA grade, side effects and OAA/S scale was done using the Chi-Square test or Fisher's exact test. The comparison of continuous variables such as mean age, mean body mass index (BMI), duration of surgery, HR, SBP, DBP and MAP were done using unpaired t-test. The underlying normality assumption was tested before subjecting the study variables to unpaired t-test. The confidence limit for significance was fixed at 95% level with a p-value < 0.05.

RESULTS

Of 80 patients assessed for eligibility, 10 were excluded because of patients on anti-psychotic, sedative, hypnotic drugs (6), patient with a history of allergy or hypersensitivity to

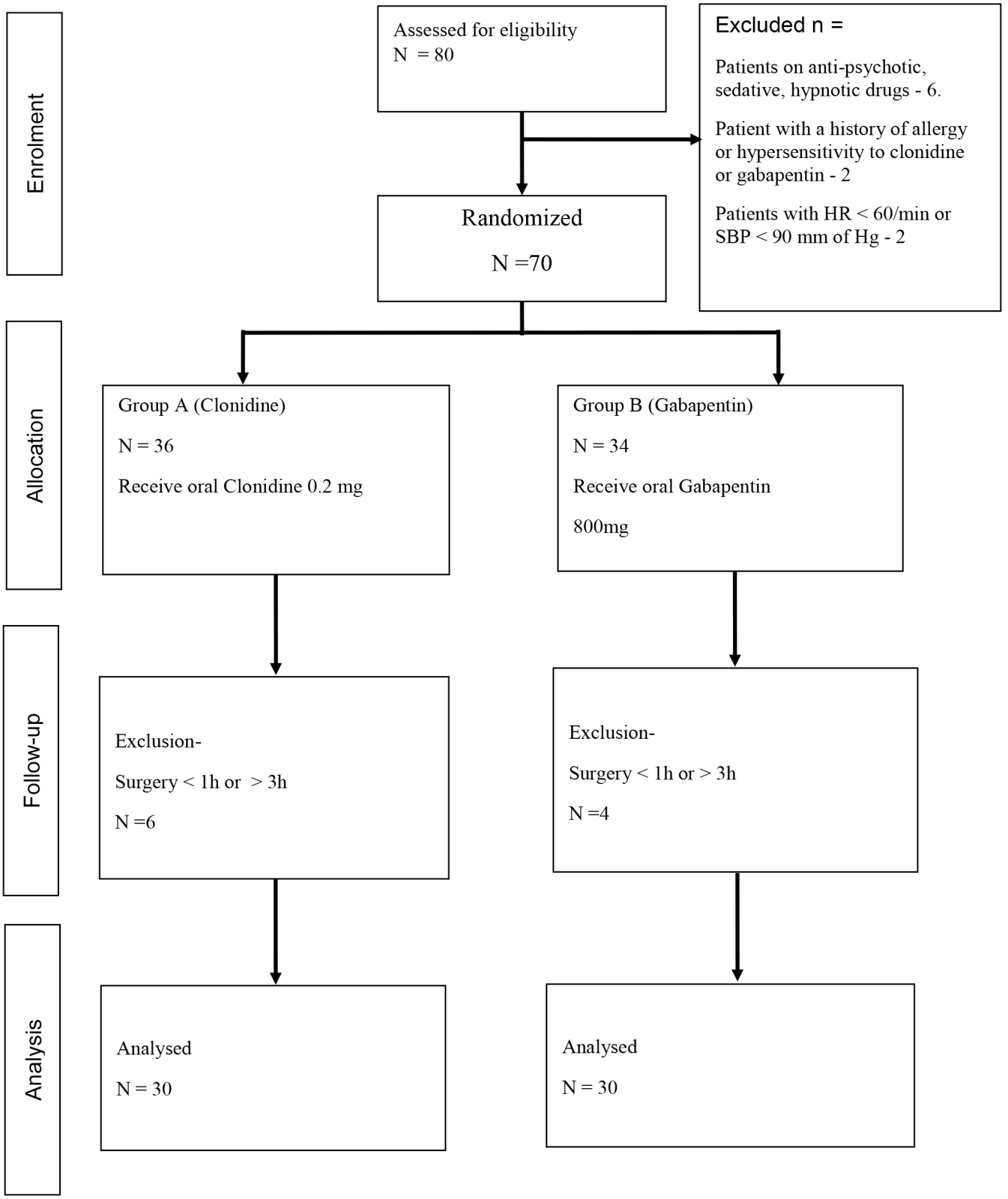

Fig 1 : Consort Diagram

clonidine or gabapentin (2) and patients with HR < 60/min or SBP < 90 mm of Hg (2). Seventy patients were randomized into two groups. Of 36 patients in Group A, six were excluded because of the duration of surgery < 1h or > 3h. Of 34 patients in Group B, four were excluded because of the duration of surgery < 1h or > 3h. In all 30 patients were analysed in both the groups (Fig. 1). Group A and Group B patients received oral clonidine 0.2 mg, and gabapentin 800 mg respectively 60 minutes prior to surgery.There was no statistically significant difference between Group A and Group B in relation to mean age, gender, mean BMI, ASA grades and mean duration of anaesthesia. In Group A, a significantly higher percentage of patients had OAA/S score five as compared to Group B (Table 1).The mean HR at the baseline did not differ significantly between the two study groups. The mean HR at pre-intubation, post-intubation (T1), post-intubation (T3) and post-intubation (T5) were significantly higher in Group B as compared to Group A. The mean SBP, mean DBP and mean MAP at the baseline, pre-intubation, post-intubation (T1), post-intubation (T3) and post-intubation (T5) did not differ significantly between the two study groups (Table 2). The incidence of side effects did not differ significantly between the two study groups (Table 3).

Table 1 : Baseline characteristics

Characteristics	**Group A** **n = 30**	**Group B** **n = 30**	**Total** **n = 60**	**p-value**
Mean age in years ± SD	30.6 ± 7.4	31.7 ± 6.6		0.559*
Gender (%)				
Male	16 (53.3)	14 (46.7)	30 (50.0)	0.999**
Female	14 (46.7)	16 (53.3)	30 (50.0)	
Mean BMI in Kg/m^2 ± SD	26.6 ± 2.6	27.4 ± 3.2		0.294*
ASA grade (%)				
Grade I	23 (76.7)	21 (70.0)	44 (73.3%)	0.771**
Grade II	7 (23.3)	9 (30.0)	16 (26.7%)	
Mean duration of surgery in hours ± SD	2.3 ± 0.6	2.5 ± 0.6		0.243*
OAA/S Score (%)				
2 (Deep Sleep)	1 (3.3)	2 (6.7)		0.024***
3	1 (3.3)	6 (20.0)		
4	13 (43.3)	17 (56.7)		
5 (Alert)	15 (50.0)	5 (16.7)		

*Unpaired t-test was used, **Chi square test was used, *** Fisher's exact test was used
BMI- Body mass index
ASA - American Society of Anaesthesiologist
SD- Standard deviation
OAA/S Scale- Observer Assessment of Alertness/Sedation Scale

Table 2 : Comparison of mean heart rate, mean systolic BP, mean diastolic BP, mean arterial pressure

Characteristics	Group A n = 30	Group B n = 30	p-value
Mean heart rate per min ± SD			
Baseline	75.4 ± 7.6	73.1 ± 6.9	0.218
Pre-intubation	67.5 ± 7.6	71.4 ± 7.3	0.049
Post-intubation (T1)	71.6 ± 7.3	78.1 ± 8.1	0.002
Post-intubation (T3)	69.8 ± 7.2	76.8 ± 8.6	0.001
Post-intubation (T5)	66.7 ± 7.5	74.8 ± 8.6	0.001
Mean systolic BP in mm of Hg ± SD			
Baseline	124.4 ± 9.3	126.1 ± 8.6	0.456
Pre-intubation	116.8 ± 9.0	119.9 ± 8.4	0.181
Post-intubation (T1)	117.8 ± 8.6	121.4 ± 8.4	0.105
Post-intubation (T3)	116.4 ± 8.4	120.1 ± 8.1	0.087
Post-intubation (T5)	115.1 ± 8.6	118.6 ± 8.2	0.117
Mean diastolic BP in mm of Hg ± SD			
Baseline	70.9 ± 6.0	72.2 ± 6.5	0.437
Pre-intubation	66.3 ± 6.1	68.4 ± 6.5	0.195
Post-intubation (T1)	67.4 ± 6.4	69.3 ± 6.1	0.254
Post-intubation (T3)	67.0 ± 6.6	68.3 ± 5.9	0.423
Post-intubation (T5)	66.3 ± 6.3	67.4 ± 5.5	0.449
Mean arterial BP in mm of Hg ± SD			
Baseline	88.6 ± 6.2	90.1 ± 6.8	0.374
Pre-intubation	83.2 ± 6.2	85.6 ± 6.8	0.159
Post-intubation (T1)	84.2 ± 6.0	86.7 ± 6.6	0.132
Post-intubation (T3)	83.4 ± 6.3	85.6 ± 6.3	0.198
Post-intubation (T5)	82.6 ± 6.2	84.5 ± 6.1	0.244

Unpaired 't' test was used
SD- Standard deviation, BP- Blood Pressure,
T1 time 1 min, T3 time 3 min, T5 time 5 min

Table 3 : Incidence of side effects

Side effects (%)	Group A n = 30	Group B n = 30	Total n = 60	p-value
Nil	28 (93.3)	29 (96.7)	57 (95)	0.389
Nausea	1 (3.3)	0 (0.0)	1 (1.7)	
Headache	0 (0.0)	1 (3.3)	1 (1.7)	
Dry mouth	1 (3.3)	0 (0.0)	1 (1.7)	
Total	30 (100.0)	30 (100.0)	60 (100.0)	

Fisher's exact test was used.

DISCUSSION

In the present study, the mean HR at pre-intubation, post-intubation (T1), post-intubation (T3) and post-intubation (T5) were significantly higher in Group B as compared to Group A. The mean SBP, DBP, mean MAP and the incidence of side effects did not differ significantly between the two groups. In Group A, a significantly higher percentage of patients were alert as compared to Group B.Clonidine is an alpha 2 adrenergic agonist, stimulates alpha 2A subtype of alpha 2 adrenergic receptors in the brain stem resulting in a reduction in the sympathetic outflow from the central nervous system thus causing the lowering of arterial pressure by affecting cardiac output and peripheral resistance. By its central sympathetic action, it tends to attenuate the hemodynamic response to any surgical nociceptive stimulus and to improve overall peri-anaesthetic cardiovascular stability. Gabapentin, as a single dose, when used as premedication, decreases hyperalgesia and allodynia associated with surgical manipulation by inhibiting membrane voltage-gated calcium channels and prevents peripheral and central sensitization. Since gabapentin inhibits the membrane voltage-gated calcium channels, it is possible that it may have a similar action to calcium channel blockers. As yet there is no data on the possible role of gabapentin in the attenuation of other aspects of the stress response during surgery.The doses of these two drugs for premedication were selected based on previous studies. Studies reported that oral gabapentin in the range of 300-1600 mg (in both single and multiple doses) and oral clonidine in the range of 0.1-0.3 mg were used.[8,14] In the present study, 800 mg gabapentin and 0.2 mg clonidine orally was used.

Fassoulaki A et al. reported that gabapentin attenuated the pressor response (SBP and DBP) but not tachycardia associated with laryngoscopy and tracheal intubation.[7] Mohammadi SS et al. reported that oral clonidine as a premedication was effective in attenuating the stress response (HR) to laryngoscopy and tracheal intubation. [15] Sung CS et al. reported that oral clonidine as a premedication was associated with stable hemodynamics and protection against stress response. [16] Doleman B et al. reported that gabapentin was associated in an attenuating the increase in HR and blood pressure following intubation. [17] Singhal SK et al. concluded that the oral clonidine 200 µg when given 90 minutes before anaesthesia, provided good attenuation of hemodynamic response to laryngoscopy and intubation as compared with oral gabapentin (900 mg), which also fairly obtunded the hypertensive response, but not the tachycardiac response. The study further stated that clonidine also provided better sedation and anxiolysis when compared with gabapentin. [18]

Kapse UK et al. reported that both oral clonidine and oral gabapentin given as premedication 90 minutes prior to surgery were effective in the obtunding pressor response to direct laryngoscopy, clonidine being better in terms of controlling HR. The study further stated that gabapentin produced more postoperative sedation than clonidine. [19] Marashi SM et al. reported that both clonidine and gabapentin had effective roles in blunting the hyperdynamic responses following laryngoscopy, more so with gabapentin. [20] Nishikawa T et al. concluded that oral clonidine as a preanaesthetic medication could attenuate the pressor response associated with laryngoscopy and tracheal intubation. [21] Singh S et al. reported that in patients who underwent laparoscopic cholecystectomy, there was an improvement in perioperative haemodynamic stability and a reduction in the intra-operative anaesthetic and postoperative analgesic requirements by the administration of oral clonidine 150 µg as a premedication.[22]

Memis D et al. studied the effect of 800 mg oral gabapentin for attenuation of stress response to laryngoscopy and intubation. They reported that oral gabapentin effectively controlled the rise in haemodynamic response at T1, T3 and T5 minutes after intubation. [8] Kong VKF and Irwin MG reviewed many controlled trials of gabapentin and suggested that gabapentin caused dose-dependent effects on the stress response. The study further stated that the changes in HR were inconsistent. They concluded that the effects of gabapentin on attenuating haemodynamic response to tracheal intubation, preventing

postoperative nausea vomiting and reducing postoperative delirium were promising but, as yet, inconclusive and more studies are expected in the near future. [23]

Hossain M S et al. reported that 0.2 mg of oral clonidine provided good attenuation of hemodynamic response to laryngoscopy and intubation as compared with 900 mg oral gabapentin. They further stated that clonidine had a better sedative effect than gabapentin. The study further stated that the most of the patients after gabapentin were wide awake while most of the patients of the clonidine group were comfortably sleeping and responding to verbal commands. This finding is contradictory to our study, but this difference in result can be due to differences in weight, age and drug dosage of the two studies [24]. Hossain M S et al. further stated that the dry mouth was observed in patients treated with clonidine premedication, whereas headache, drowsiness and dizziness were seen among gabapentin pre-treated patients in the post-operative period. [24]

LIMITATIONS

There are few limitations to the present study. The study was conducted in a single centre with a small sample size which included only stable ASA class I or II patients. Therefore, our findings cannot be extrapolated to patients with significant co-morbidities. Our study excluded paediatric and geriatric population, so the safety and efficacy of these medications in these age groups need to be studied. Stress mediators like endogenous plasma catecholamines or cortisol values were not measured perioperatively. Multicentric studies with a large sample size are needed to validate our results.

CONCLUSION

The mean HR at pre-intubation, post-intubation (T1), post-intubation (T3) and post-intubation (T5) were significantly higher in Group B as compared to Group A. The mean SBP, mean DBP, mean MAP and the incidence of side effects did not significantly differ between the two groups. In Group A, a significantly higher percentage of patients were alert as compared to Group B.

CONFLICT OF INTEREST

Dr. Rajendra Gosavi, Dr. Khan Afreen Rais Alam, Dr. Ganesh Ghongate, and Dr. Deepak Phalgune declare that they have no conflict of interest. The manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work

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