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Research Article

Oral premedication with pregabalin and clonidine for hemodynamic stability during laryngoscopy: A comparative study

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ABSTRACT

Background: Airway instrumentation of direct laryngoscopy and tracheal intubation are noxious stimuli that should be attenuated by appropriate premedication, smooth induction, and rapid intubation. The present study evaluated the clinical efficacy of oral premedication with pregabalin or clonidine for attenuation of hemodynamic pressure response of airway instrumentation. The objective was to find out the efficacy of pregabalin and clonidine as an oral premedication and to observe hemodynamic stability during laryngoscopy.

Methods: A total of 100 healthy patients aged 30-70 years with American Society of Anesthesiology Physical Status I and II of both gender, who met the inclusion criteria of general anesthesia, were randomly received pregabalin (150 mg) Group I or clonidine (100 μ g) Group II, 60-70 mins before surgery as an oral premedication. Both groups were compared to pre-operative sedation, anxiety, heart rate (HR), and mean arterial pressure (MAP) at baseline, after premedication, induction, laryngoscopy, and extubation. Intraoperative analgesic drug requirement and any post-operative complication were recorded.

Results: Incidence of hypotension and bradycardia were observed in 4% case in the clonidine group. Pre-operative sedation level was higher in the pregabalin group as compared to clonidine group. p>0.05 which shows there is no difference in both the drugs in terms of control of HR and MAP perioperatively. Both drugs are equally good to maintain hemodynamic stability during laryngoscopy. None of the patients has suffered from any post-operative side effects.

Conclusion: Hemodynamic pressure response of airway instrumentation was attenuated with pregabalin and clonidine oral premedication without prolongation of recovery time and side effects.

Keywords: Clonidine, Pregabalin, Hemodynamic pressure response, Intubation, Laryngoscopy, Sedation

INTRODUCTION

Hemodynamic pressure response to airway instrumentation is a hazardous complication of general anaesthesia. Usually, these changes are well-tolerated by healthy patients but may be fatal in cardiac patients. Many pharmacological techniques were evaluated either in premedication or during the induction to attenuate the adverse hemodynamic response to airway instrumentation, such as pre-treatment with vasodilators, adrenoreceptor blockers, calcium channel blockers, and opioids with variable results. ^{2,3}

The present study was designed as a comparative, randomized controlled study to evaluate and compare the efficacy of pregabalin or clonidine as an oral premedication on sedation, anxiety, changes in heart rate (HR), and mean arterial blood pressure during laryngoscopy.

Pregabalin, a gabapentinoid compound, is described structurally as (s)-3 amino methyl-5-methylhexanoic acid. Pregabalin is structurally related to the inhibitory neurotransmitter gamma amino butyric acid (GABA), but is not functionally related to it. It acts by decreasing the synthesis of the neurotransmitter glutamate to act on the central nervous system, and possesses analgesic, anticonvulsant and anxiolytic activity and is effective in preventing neuropathic component of acute nociceptive pain of surgery. It is well-absorbed and tolerated after oral administration, with peak plasma concentration achieved within 1 hr. It undergoes negligible hepatic metabolism.

Clonidine activates the α 2-adrenergic receptors in the brain and spinal cord to decrease sympathetic outflow, causing sedation, analgesia, hypotension, and bradycardia without significant respiratory depression. It is well-absorbed after

oral administration with peak plasma concentration in 75-90 mins. The perioperative use decreases the intraoperative stress response by reducing nociceptive transmission and decrease norepinephrine concentration in serum, provided hemodynamic stability.⁵

METHODS

The study was approved by the Institutional Ethical Committee. This prospective double-blind, randomized controlled study includes 100 normotensive adult patients aged 30-70 years of both genders, scheduled for elective surgery under general anesthesia with American Society of Anesthesiology (ASA) Physical Status I and II. Patients with anticipated difficult intubation, history of cardiac, pulmonary or renal disease, obesity, allergy to any anesthetic medication and taking sedative, hypnotics or antihypertensive medications were excluded from the study.

After preanesthetic evaluation patients were randomly allocated in two groups of 50 patients, Group I received tablet pregabalin (150 mg) and Group II received tablet clonidine (100 μ g), given orally with sips of water about 1 hr before induction of general anesthesia. The observer was totally blind about the groups and medication received by the patients.

On arrival in pre-operative room, monitors were attached, and baseline HR and systolic, diastolic, and mean arterial blood pressure were recorded. The pre-operative level of sedation was assessed by the Ramsay sedation scale;

Ramsay sedation scale:

- 1 Anxious, agitated or restless
- 2 Co-operative, oriented and tranquil
- 3 Responds to command
- 4 Asleep with brisk response to the stimulus
- 5 Asleep with sluggish response to the stimulus
- 6 Asleep with no response

A crystalloid intravenous infusion of 6-8 ml/kg was started and all patients were pre-medicated with injection ondansetron (4 mg), injection glycopyrrolate (0.2 mg), injection midazolam (1 mg) and injection butorphanol (1 mg). After pre-oxygenation for 3 mins with 100% oxygen, induction was done with injection propofol (2 mg/kg). The direct laryngoscopy and intubation was facilitated with injection succinylcholine (1.5-2 mg/kg). Anesthesia was maintained with isoflurane, nitrous oxide 50% in oxygen and intermittent muscle relaxant injection vecuronium bromide. The patients were mechanically ventilated to maintain the normocapnia (ETCO₂ between 35 and 40 mmHg). After completion of surgery, residual neuromuscular block was reversed with appropriate doses of injection neostigmine (0.05 mg/kg), and injection glycopyrrolate (0.01 mg/kg) and extubation was performed.

Intraoperatively, the HR, mean arterial blood pressure, electrocardiogram, pulse oximeter (SPO₂), and ETCO₂ were continuously monitored and recorded before and

after induction, immediately after intubation and 1, 3, 5, and 10 mins, thereafter at every 15 mins interval till end of surgery. Patients were observed for complications like hypotension, bradycardia, hypertension, arrhythmias, hypoxia, bronchospasm, and treated accordingly.

Patients were transferred to the post-anesthesia care unit and monitored for at least 3 hrs. Any hemodynamic abnormalities need for postoperative opioid analgesic medication, and incidence of nausea and vomiting along with the requirement for rescue antiemetic were also noted. If any side effects were noted, they were treated accordingly.

RESULTS

A total of 100 patients, 50 patients in each group were evaluated and compared. Both groups were comparable with respect to demofigureic data. No significant differences were found among them with respect to age, sex, time between oral premedication to intubation, type of surgical procedure, duration of laryngoscopy, and anesthesia (Table 1).

The results obtained in the study are presented in tabulated manner and analyzed using Microsoft Excel and SPSS for Windows. Hemodynamic variables were represented by mean ± standard deviation. Statistical significance in the mean difference was done using analysis of variance, Student's t-test and Chi-square tests as appropriate. A p<0.05 was considered statistically significant.

The level of sedation before the premedication was comparable between the groups (Table 2); however they were anxious at baseline. Sedation was significantly higher in the pregabalin Group I at the preinduction stage as compared to clonidine Group II. In Group I, onset of sedation level 2

Table 1: Demofigureic profile.

Demofigureic profile	Group I (pregabalin)	Group II (clonidine)
Age (years)	42.56±7.81	42.12±8.11
Sex ratio (M/F)	32:18	26:24
ASA I: II (n)	30:20	19:31
Sedation level	Awake	Awake
Duration of	15.48±3.83	15.68±3.94
laryngoscopy (s)		
Type of surgery (n)		
Open cholecystectomy	8	7
MRM	15	12
Pyelolithotomy	3	1
Abdominal	5	2
hysterectomy		
Hemithyroidectomy	4	6
GI surgery	15	22

ASA: American Society of Anesthesiology, MRM: Modified radical mastectomy, GI: Gastrointestinal

was seen after 15 mins in 3 patients (6%) while level 4 in 30 patients (60%) after 60 mins. In clonidine Group II there was no onset of sedation till 45 mins while at 60 mins only 2 patients (4%) had level 3 sedation.

Cardiovascular effects

There was no significant difference in the HR and mean arterial pressure (MAP) among groups before and after premedication. Immediately after laryngoscopy and intubation, the HR increased significantly in both the groups, but the increase was less in clonidine Group II. Maximum increase in HR from baseline was observed after 1 mins of laryngoscopy. After 5 mins of intubation, HR was 76.92±8.13 in the clonidine group while 82.76±14.80 in the pregabalin group which shows marginal difference. Throughout the surgery, there was good control on HR in both the groups (Tables 3 and 4, Figures 1 and 2).

No significant difference was observed in the MAP after premedication in groups. After intubation, MAP was well-controlled and remained stabilized during the intraoperative period in both the groups.

Student's t-test was used to analyze the parametric data, and discrete (categorical) variables were analyzed using the χ^2

Table 2: Onset of sedation.

Time	Group I (pregabalin) (%)	Group II (clonidine) (%)
0 mins	-	Nil
15 mins	3 (6)	Nil
30 mins	8 (16)	Nil
45 mins	12 (24)	Nil
60 mins	30 (60)	2 (4)
No effect	20 (40)	48 (96)

Table 3: Changes in HR during anesthesia.

_	_	
HR/min	Group I (pregabalin)	Group II (clonidine)
Baseline	85.80±8.72	83.06±9.88
After premedication	81.84±8.90	79.16±9.77
After induction	84.40±11.74	80.54±8.49
After intubation		
1 mins	85.84±13.59	80.26±9.22
5 mins	82.76±14.80	76.92±8.13
10 mins	76.40±10.05	76.74±9.58
15 mins	78.64±13.86	75.58±9.59
30 mins	76.20±11.01	73.86±8.91
45 mins	76.16±14.55	74.38±10.40
60 mins	76.54±8.50	74.82±7.82
After extution	86.98±7.80	83.06±11.08
TID II		

HR: Heart rate

test, with p>0.05 which shows there are no difference in both the drugs in terms of control of HR, MAP and anxiety score. Both drugs are equally good to maintain hemodynamic stability during laryngoscopy (Tables 5 and 6).

Anesthetic and analgesic requirements during surgery

There were decreased requirement of propofol and volatile anesthetic agents intraoperatively in both the groups. Two

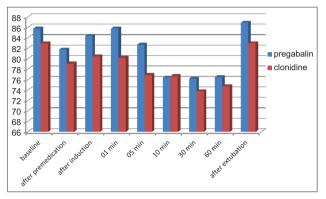


Figure 1: Changes in heart rate during anesthesia.

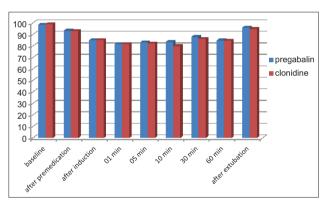


Figure 2: Changes in mean arterial pressure during anesthesia.

Table 4: Changes in MAP during anesthesia.

MAP	Group I (pregabaline)	Group II (clonidine)
Baseline	98.66±8.30	99.08±7.61
After premedication	93.46±9.51	93.28±9.23
After induction	85.28±10.53	85.18±10.80
After intubation		
1 mins	81.82±11.82	81.82±11.31
5 mins	83.36±12.91	82.32±10.72
10 mins	83.64±11.51	80.72±9.83
15 mins	85.46±10.65	83.04±11.01
30 mins	88.08±10.83	86.28±12.10
45 mins	86.24±10.05	85.36±11.22
60 mins	84.94±8.83	84.72±8.11
After extubation	96.10±4.89	94.98±5.11
3.64D-3.6		

MAP: Mean arterial pressure

Table 5: Age in years in both groups.

Group I (pregabalin)	42.56±7.81
Group II (clonidine)	42.12±8.11

Table 6: Duration of laryngoscopy (sec).

Group I (pregabalin)	15.48±3.83
Group II (clonidine)	15.68±3.94

patients of the clonidine group developed bradycardia (HR < 50/mins) 10 mins after intubation while no one had bradycardia in the pregabalin group. Hypotension was noted in 2(4%) patients among clonidine group which was treated by rapid intravenous infusion of isotonic fluids. Intraoperatively all patients were given injection dynapar as an analgesic in both the groups.

Recovery and post-operative follow-up

Awakening and recovery time were similar in both the groups. Post-operative nausea and vomiting were not found in any groups.

DISCUSSION

Present study evaluates the efficacy of pregabalin and clonidine as an oral premedication to attenuate hemodynamic pressure response during laryngoscopy. Pregabalin and clonidine act as a sedative, anxiolytic and mild analgesic.

The analgesic effect of gabapentin has been investigated during the past few years and because of its good analgesic and opioid sparing effect, it is used in post-operative pain management.^{6,7}

Clonidine and pregabalin effectively blunt sympathetic response and maintain hemodynamic stability during laryngoscopy and throughout the surgery. 8,9 In this study, patients were given oral premedication with pregabalin 150 mg or clonidine 100 µg and found them effective for perioperative hemodynamic stability.

Shribman et al.³ reported that laryngoscopy and tracheal intubation increases blood pressure, HR and catecholamine levels, whereas Hassan et al.¹⁰ reported high incidence of cardiac arrhythmias, myocardial ischemia, and acute left ventricular failure.

Reid and Brace.¹¹ described the hemodynamic response to laryngoscopy and intubation, probably due to intense sympathetic discharge caused by stimulation of epipharynx and larynx.

Many pharmacological techniques were introduced and evaluated either in the premedication or during induction to attenuate the hemodynamic pressure response to airway instrumentation, but results were controversial. More attention is given to the use of selective beta-adrenergic blockers to prevent the reflex sympathoadrenal discharge-mediated tachycardia and hypertension during laryngoscopy and intubation. Hypotensive agents, including sodium nitroprusside, nitroglycerin, adrenoreceptor blockers, calcium channel blockers and opioids, have been used effectively to attenuate these hemodynamic responses.

Intranasal nitroglycerine tends to block the hypertensive response to airway instrumentation. The intravenous lidocaine (1.5 mg/kg) prevent increase in MAP with no effect on HR. Among opioids remifentanil (1 μg/kg), alfentanil (10-20 μg/kg) or fentanyl (0.5-1 μg/kg) have been used successfully to attenuate hemodynamic pressure response to laryngoscopy and tracheal intubation, but these are associated with bradycardia, hypotension, and post-operative respiratory depression. Glossopharyngeal and superior laryngeal nerve blocks along with topical analgesia may also be effective methods. Helfman et al. Feported that 150 mg esmolol bolus was superior to intravenous high-dose lidocaine or low-dose fentanyl in preventing the tachycardia associated with intubation.

In our study, 1mini after intubation HR in the pregabalin group was (85.84±13.59) while in the clonidine group was (80.26±9.22) which shows there was a marginal difference between two groups. There was good control on HR throughout surgery and after extubation in both groups. 1 min after laryngoscopy MAP was 81.82±11.82 in the pregabalin group and 81.81±11.31 in the clonidine group which shows both drugs are excellent for hemodynamic stability during laryngoscopy Both drugs having sedative and analgesic action. In post-operative ward, there were no obvious side effects like respiratory depression, hypotension or bradycardia in any group.

Clonidine is α_2 agonist produce clinical effect by binding to α_2 a receptor which produces sedation, analgesia and sympatholysis manifesting as peripheral vasodilation, decrease systemic blood pressure, HR, and cardiac output.¹⁷

The pregabalin and clonidine possess several properties to make them valuable premedicants to attenuate the hemodynamic response of laryngoscopy. Pregabalin, an antiepileptic drug, is effective in controlling neuropathic component of acute nociceptive pain of surgery by inhibiting membrane voltage-gated calcium channels. It does not interact with GABA receptors. However, only few data are available in the literature regarding the effect of pregabalin on the cardiovascular system. Its analgesic, anticonvulsant, and anxiolytic activities make it useful oral premedicant. It is well-absorbed after oral administration, with peak plasma concentrations occurring within 60 mins.

Hayashi and Maze¹⁸ and Sung et al.¹⁹ reported that clonidine increases perioperative circulatory stability in patients undergoing laparoscopic cholecystectomy and potentiates

parasympathetic nervous system. Laisalmi et al.²⁰ concluded that premedication with clonidine blunts the stress response to surgical stimuli and reduces the requirement for narcotic and anesthetic doses.

Pre-operative anxiety and post-operative pain remain problems for many outdoor patients during the perioperative period. Although benzodiazepines are effective in reducing pre-operative anxiety in the ambulatory setting, ²¹ but it may be accompanied by undesirable sedation. Prevention and treatment of postoperative pain with opioid analgesics contributes to postoperative nausea and vomiting and can delay recovery of bowel function, as well as adversely affect many other organ systems in the body. ²² Opioid – related side effects contribute to delay recovery and discharge after ambulatory surgery. ²³

Recently, none- opioid analgesic drugs are emphasized routinely as a part of multimodal regimen for preventing pain in the perioperative period. Novel compounds, e.g., α -2 agonists, ketamine, esmolol, and capsaicin are being examined as an adjuvant for minimizing pain after surgery. Provided the surgery of the surgery of the surgery of the surgery of the surgery.

Oral gabapentin administered for premedication has been found to improve the quality of recovery in the early post-operative period comparable to a cyclooxygenase-2 inhibitor. ³¹⁻³³ Pregabalin is an analog of gabapentin, which has been alleged possess anxiolytic, analgesic, and antiepileptic activity.

Gupta et al.³⁴ concluded that oral premedication with pregabalin 150 mg or clonidine 200 µg causes sedation and anxiolysis with hemodynamic stability during laryngoscopy and laparoscopic cholecystectomy, without prolongation of recovery time and side effects which is similar to our study.

CONCLUSION

The pregabalin and clonidine effectively blunt hemodynamic pressure response to laryngoscopy without prolongation of recovery time and side effects.

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Ethical approval: The study was approved by the Institutional

Ethics Committee

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