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A COMPARATIVE STUDY OF INTRAVENOUS V/S NEBULIZED DEXMEDETOMIDINE FOR ATTENUATION OF PRESSOR RESPONSE TO LARYNGOSCOPY & ENDOTRACHEAL INTUBATION.

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Abstract

Introduction: Numerous methods have been used to examine how effectively dexmedetomidine(Reel B & Maani CV, 2023) reduces the pressor response to laryngoscopy and intubation. The nasal passages may get irritated when dexmedetomidine is administered intranasally. Nebulized dexmedetomidine might be a superior option as drug deposition throughout the nasal, buccal, and respiratory mucosa occurs uniformly after nebulization(Shrivastava et al., 2022). Preoperative anxiety and stress responses are responsible for the activation of the sympathetic, parasympathetic, and endocrine systems(Geeta Singariya et al., 2022). On the other hand, during laryngoscopy, the intravenous method has shown quicker onset and potent inhibitory effects on the pressor response. The effect of premedication with nebulized (Neb) as compared to intravenous (IV) dexmedetomidine on the pressor response attenuation to laryngoscopy and endotracheal intubation was evaluated in this research. Evaluating its effects on the use of intraoperative analgesics and postoperative sore throat was a secondary objective.

Methodology: On the approval of the Institutional Ethical Committee, 60 ASA grade I and II patients in the age group of 18-65 years who were planned for elective surgery under general anesthesia were enrolled in the study(Shrivastava et al., 2022). 60 Patients were divided into two groups of 30 in each; Group A The IV-Dex was given 30 minutes before to the induction of anaesthesia (1 mcg/kg body weight in 100 ml 0.9% normal saline, administered over 10 mins). Group B: Neb-Dex (1 mcg/kg body weight diluted over 10 minutes with 4 cc of normal saline) 30 minutes prior to the anaesthesia induction. the mean arterial pressure (MAP), heart rate (HR), diastolic blood pressure (DBP), systolic blood pressure (SBP) and oxygen saturation of arterial blood (SpO2) were monitored. Postoperative sore throat and use of intraoperative analgesics were also evaluated.

Results: Patients receiving IV dexmedetomidine showed better attenuation of the pressor response as compared to patients with nebulized dexmedetomidine. However, The IV dexmedetomidine group exhibited a greater incidence of bradycardia and hypotension. There were no postoperative sore throat complaints from patients who were nebulized with dexmedetomidine. Analgesic and propofol use were lower in both groups.

Conclusion: Despite both nebulized and intravenous dexmedetomidine attenuating the pressor response to laryngoscopy and intubation, intravenous dexmedetomidine reduced the pressor response more effectively. Incidence of hypotension & bradycardia was observed more in patients receiving IV dexmedetomidine(Shrivastava et al., 2022) as compared to those nebulized with dexmedetomidine. The postoperative sore throat was lower in the nebulized group as compared to the intravenous group. Thus, we conclude that dexmedetomidine nebulization at a dose of 1µg/kg given 30 minutes before induction of general anesthesia is effective in attenuating the pressor response to laryngoscopy & intubation without any adverse effects like bradycardia & hypotension along with the lower incidence of postoperative sore throat.

Keywords: Dexmedetomidine, α2-adrenergic receptor agonist, laryngoscopy, intubation, pressor response

BACKGROUND

Hemodynamic parameters fluctuate briefly, erratically, and unpredictably during direct laryngoscopy and intubation(Sebastian et al., 2017). The sudden changes that occur in hemodynamic parameters in 30 seconds after direct laryngoscopy and endotracheal intubation and approach baseline in 10 minutes is known as the pressor response. Laryngoscopy, tracheal intubation, surgical stimulation, and extubation all trigger sympathoadrenal response and are linked to brief but significant hemodynamic changes(Singh et al., 2022). In patients with low cardiopulmonary reserves, this brief response may prove to be fatal(Lakhe et al., 2021). Numerous drugs and methods have been investigated to reduce this pressor response, including topical sprays, volatile agents, intravenous lignocaine, beta-blockers, calcium channel blockers, opioids, and α2 agonists(Arora et al., 2019). However, none of the medicines have shown to be the most effective(Shrivastava et al., 2022).

Dexmedetomidine is a highly selective α2-adrenergic agonist (α2/α1=1600:1) having sedative, anxiolytic, hypnotic, analgesic & sympatholytic effects(Kaur & Singh, 2011). Three subtypes of α2 adrenoreceptors have been described in humans. The α2A adrenoreceptors are primarily distributed in the periphery, whereas α2B and α2C are in the spinal cord & brain. Presynaptic α2 receptors inhibit the release of norepinephrine, potentially attenuating the vasoconstriction. The most commonly reported hemodynamic adverse reactions associated with dexmedetomidine are hypotension and bradycardia (9%). The initial increase in arterial blood pressure is probably due to the vasoconstrictive effects of dexmedetomidine when stimulating peripheral α2 receptors.

Dexmedetomidine has a high bioavailability of 65% & 82% on nasal & buccal mucosa respectively. The nebulized route prevents temporary nasal discomfort, coughing, vocal cord irritation, and laryngospasm over intranasal administration. Dexmedetomidine improves the quality of emergence from general anesthesia in avoiding coughing, agitation, hypertension, tachycardia, and shivering along with opioid-sparing effects.

The widespread use of IV-Dex is impeded by side effects, such as hypotension, bradycardia, and delayed recovery (sedative). As a result, the search for alternative methods of administering dexmedetomidine continues. The intranasal route has been studied for its effectiveness, safety, and high patient acceptance. As the drug is widely distributed (the nasal, buccal, and respiratory mucosa), nebulized dexmedetomidine (Neb-Dex) may be an effective replacement(Kumar et al., 2020a). This will not only reduce pressure response but also prevent postoperative sore throat without causing systemic side effects such as bradycardia & hypotension which has always been a point of concern with intravenous route of administration.

Our study is based on null hypothesis stating that there is no difference in the effectiveness of intravenous and nebulized dexmedetomidine in attenuating the pressor response to laryngoscopy and endotracheal intubation. Due to the dearth of medical literature contrasting the effectiveness of IV-Dex and Neb-Dex at comparable doses, this study was conducted.

OBJECTIVES

Comparing the hemodynamic effects of IV vs. Neb-Dexmedetomidine given before surgery on laryngoscopy and intubation was the primary objective. The other objectives were to study the incidence of postoperative sore throat (POST) & intraoperative analgesic consumption.

METHODS

Inclusion & Exclusion Criteria

This study comprised 60 adult patients, either sex, in the 18–65 age group, with physical status I/II according to the American Society of Anesthesiologists (ASA), who were scheduled to undergo

elective surgery under general anesthesia requiring endotracheal intubation. The following patients were excluded: those who did not give the consent to participate in the study; patients with difficult airway and required more than 15 seconds or two attempts at laryngoscopy, those who were known to be allergic to dexmedetomidine, those who were taking antihypertensives, BMI was greater than 30 kg/m², parturient, and those who developed any complications during or after the procedure(Shrivastava et al., 2022).

Methodology

As the objective of this research paper is exploratory & this preliminary study wants to find out whether there is any significant difference between intravenous dexmedetomidine & Nebulized dexmedetomidine given before surgery attenuates the pressor response to laryngoscopy & intubation. As this is an exploratory research, convenience sampling under the fundamental category of non-probability sampling method was used for the selection of population & samples. Convenience sampling was used because it offers the easiest access of patients for the researcher available at the given period of time. The location of this study was People's College of medical sciences & research Centre, Bhopal, India. The sample was taken in duration of three months.

Study design, approval & trial registration

An analytical, observational study was conducted after taking written informed consent and following the approval of the institutional ethics committee (PCMS/OD/PS/2023/993/13) and registration with the Clinical Trials Registry of India (CTRI) (CTRI/2023/06/054006).

After getting approval from the committee for the study for the period of three months on the selected location 75 patients (population) were eligible for surgery under general anesthesia by Slovin's formula.

Slovin's formula is calculated as: $n = N / (1 + Ne^2)$ where:

- n = sample size
- N = population size (75)
- e = acceptable margin of error (5%)

Out of 75 patients (population) 15 patients met the exclusion criteria. Two groups, A and B, each with 30 patients, were randomly assigned out of 60 patients. On the day of surgery, sealed envelopes were opened in the preoperative area in order to achieve allocation concealment(Misra et al., 2021).

Group A: The IV-Dex was given 30 minutes before to the induction of anaesthesia (1 mcg/kg body weight in 100 ml 0.9% normal saline, administered over 10 mins). Group B: Neb-Dex (1 mcg/kg body weight diluted over 10 minutes with 4 cc of normal saline) 30 minutes prior to the anaesthesia induction.

Demographic data were recorded prior to the day of surgery. Proper counseling of the patient about the study protocol was done & written informed consent was taken. The POST scale was explained to the patient. (a) 0, no sore throat; (b) 1, mild sore throat (reporting sore throat when enquired); (c) 2, moderate sore throat (reports without asking); and (d) 3, severe sore throat (voice change/ hoarseness/ pain in the throat).(Singh et al., 2022)

POST Scale		
S.No.	Score	Symptoms
1	0	No sore throat
2	1	Mild sore throat (reporting when enquired)
3	2	Moderate sore throat (reports without asking)
4	3	Severe sore throat (voice changes/ hoarseness/ pain in throat)

In the OR, all standard monitors were attached to the patient. Both groups received the allocated preparations 30 minutes prior to the induction of anesthesia under supervision. A 3 mg bolus injection of mephentermine was used when there was decline in systolic blood pressure (SBP) that was more than 20% of the baseline, IV atropine 0.6 mg bolus was given to treat bradycardia, (HR<50 bpm) after stopping dexmedetomidine infusion.

The patient was preoxygenated with 100% oxygen for 3 mins, following premedication with 1 mg injection midazolam along with 2 mcg/kg fentanyl, 1-2 mg/kg propofol was given in 10 mg aliquots titrated until loss of the verbal response. After attaining adequate bag and mask ventilation, succinylcholine 2mg/kg was given. Skilled anesthesiologist performed direct laryngoscopy and performed endotracheal intubation using an appropriate endotracheal tube size. Patients requiring more than one attempt for laryngoscopy were excluded from the study. After that, the patient was connected to a ventilator to begin controlled ventilation. Vecuronium boluses and oxygen/nitrous oxide/isoflurane combination were used to maintain anaesthesia. End-tidal carbon dioxide was maintained in the range of 32 to 35 mmHg. Parameters including SBP, diastolic blood pressure (DBP), mean arterial pressure (MAP), and pulse oximetry were recorded at baseline, after medication delivery, and one, five, and ten minutes after intubation. Ten minutes were permitted without intervention. Following the procedure, 0.05 μ/kg of neostigmine intravenously and a 10 μ/kg injection of glycopyrrolate were used to reverse the remaining neuromuscular blockade (Shrivastava et al., 2022). The patient was extubated after meeting the extubation criteria & shifted to post-anesthesia intensive care unit.

At baseline (TBl), following nebulization (TN), following induction (TInd), right after intubation (TInt), at 1 minute (T1), 3 minutes (T3), 5 minutes (T5), 7 minutes (T7), 10 minutes (T10), 15 minutes (T15), 30 minutes (T30), 45 minutes (T45), 60 minutes (T60), 75 minutes (T75), 90 minutes (T90), 105 minutes (T105), and 120 minutes (T120), the HR and MAP were recorded. Fentanyl at a dose of 0.5μ/kg was added as an analgesic. Esmolol 10 mg boluses were kept aside as a backup drug in case the HR or MAP increased after the first 10 minutes and by 20% during the surgical procedure.(Singh et al., 2022)

Postoperatively vitals were monitored & POST were evaluated 0, 4, 8, 12, and 24 hours postextubation.

STATISTICAL ANALYSIS

SPSS version 29.0 was used to conduct statistical analysis. For categorical variables, the chisquare test was used, and any significant variation in hemodynamic parameters from the baseline was evaluated using the paired t-test. P value of <0.05 was considered significant.(Singh et al., 2022)

RESULTS

The Consolidated Standards of Reporting Trials (CONSORT) diagram depicting the flow of patients through trial is shown in Figure.

After the collection, tabulation, and analysis of the data, the following inferences were drawn;

The mean age of group A was 33.8667± 10.77264 years, and group B was 31.5892± 11.5896 years. The mean age difference was statistically non-significant (P value= 0.4337). The duration of the surgery and anesthesia, the initial fentanyl and propofol bolus dose, and the intraoperative fentanyl rescue dose were all comparable across the two groups (pvalue>0.05).

Primary outcome measures were changes in HR and MAP during laryngoscopy & intubation as compared to baseline. At baseline, there was no significant difference in the mean HR (p=

0.081) & MAP (p= 0.070) in both groups, post-administration of the drug (p= 0.643), and post-induction (p=0.973). A significant fall in HR from the baseline was seen in group A patients, ($p<0.05$) In contrast, the corresponding values in group B showed no or less fall in HR. Similar trends were also observed in terms of MAP. At baseline there was no significant difference in MAP (p= 0.456), post administration of the drug (p= 0.667), post-induction (p=0.345), following laryngoscopy group B showed a modest increase in MAP which with values returning to baseline at 10 mins post intubation. Blood oxygen saturation levels were insignificant between both groups all the time.

Patients in group B experienced a considerably lower incidence of post-operative sore throat (p=0.007). Compared to the nebulized group, patients receiving IV dexmedetomidine experienced higher adverse effects (hypotension & bradycardia), though the P value was insignificant.

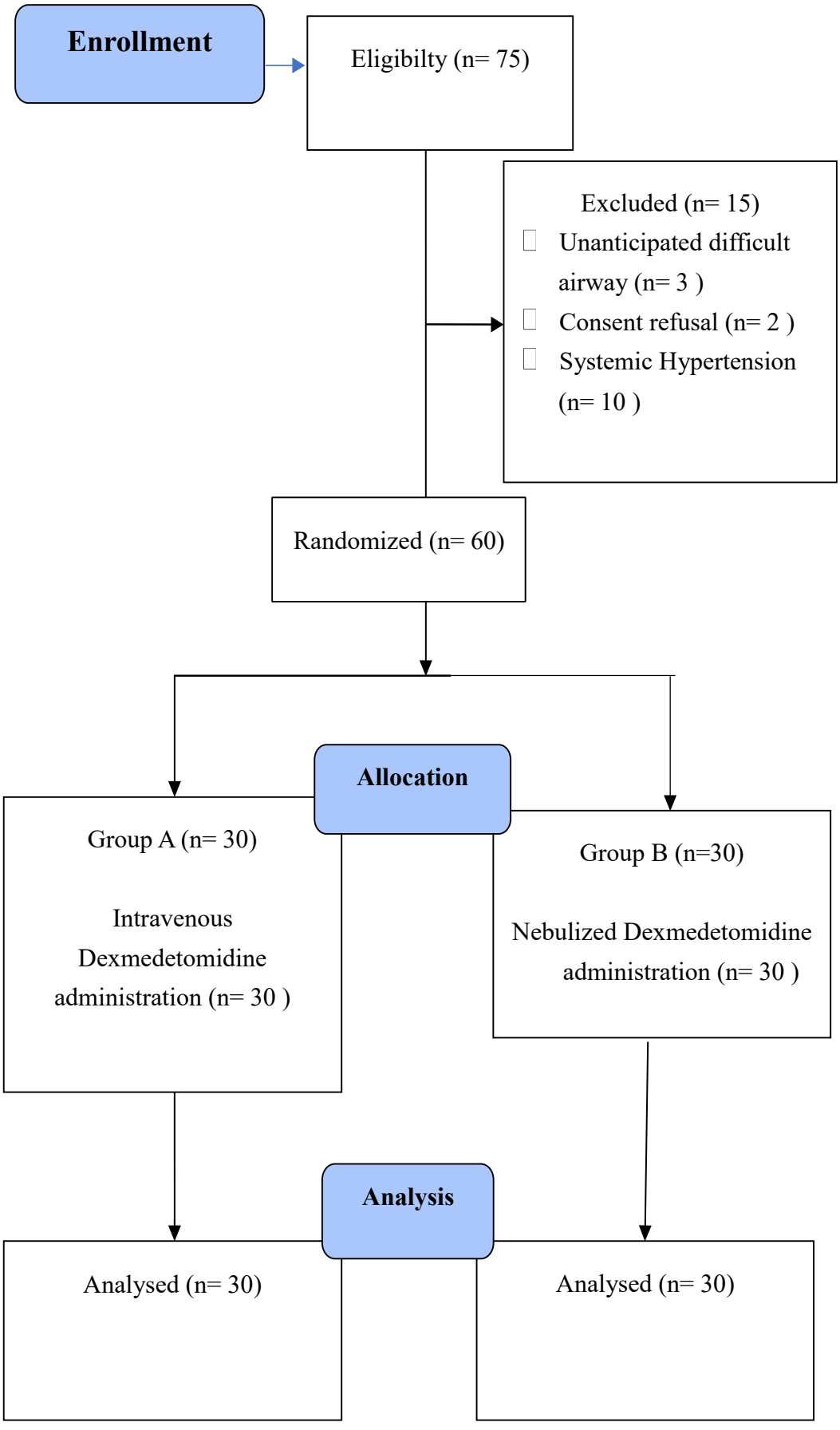
DISCUSSION

Dexmedetomidine given via intravenous or nebulized route both were able to attenuate the pressor response to laryngoscopy effectively but nebulized dexmedetomidine had no systemic side effects as observed in patients given dexmedetomidine intravenously making it a safer alternative option. The hemodynamic changes occurring during laryngoscopy and intubation were initially reported by Reid and Brace. Following laryngoscopy, the response begins in seconds, peaks in one to two minutes, and returns to normal in ten minutes. The attenuation of centrally mediated pressor response is a point of concern for anesthesiologists to avoid any morbid complications. A selective α-2 agonist dexmedetomidine has hypnotic, analgesic, sedative, anxiolytic, and sympatholytic properties(Kumar et al., 2020b).

Numerous studies have used intravenous dexmedetomidine to attenuate the hemodynamic response to intubation. Alternative routes for dexmedetomidine delivery are constantly being investigated to avoid side effects like bradycardia & hypotension from intravenous administration. The comparison of dexmedetomidine administered intravenously versus nebulized is a unique feature of this analytical study. By using its quick onset and good bioavailability through the mucosa's large surface area, the nebulized route is a noninvasive way in attenuating the pressor response associated with intubation without causing laryngospasm, vocal cord irritation, coughing, or nasal irritation.(Shrivastava et al., 2022)

Nebulization provides an advantage over the intranasal route by having cheaper and easier administration (making it available even in resource-limited settings) homogenous deposition of the drug in the nasal/ pharyngeal tract, and attenuation of POST.(Shrivastava et al., 2022)

Very few randomized controlled trials have been done to study the effect of nebulized dexmedetomidine on the attenuation of pressor response to laryngoscopy and intubation. Our findings partially corroborated the findings reported by Singh V et al. and Misra et al., who found that although nebulized dexmedetomidine reduced HR ascend, it was unable to prevent MAP increase.

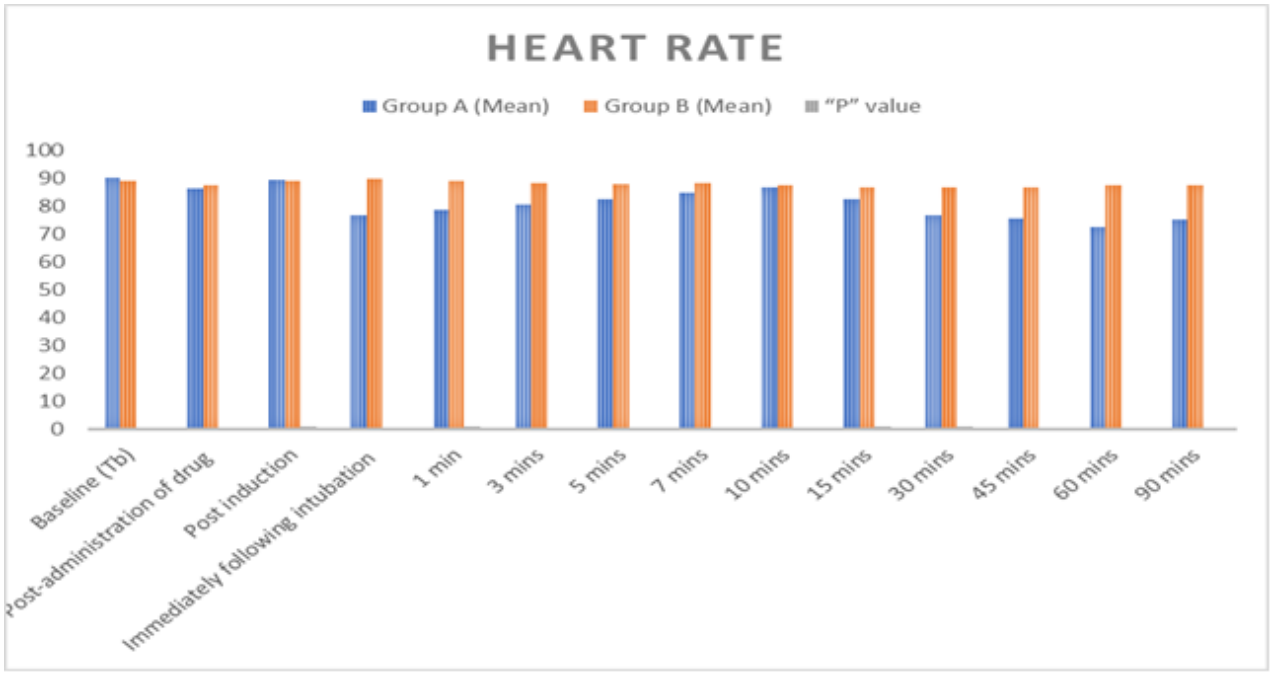

Enrollment
Eligibilty (n= 75)
Excluded (n= 15)
Unanticipated difficult airway (n= 3)
Consent refusal (n= 2)
Systemic Hypertension (n= 10)
Randomized (n= 60)
Allocation
Group A (n= 30)
Intravenous Dexmedetomidine administration (n= 30)
Group B (n=30)
Nebulized Dexmedetomidine administration (n= 30)
Analysis
Analysed (n= 30)
Analysed (n= 30)

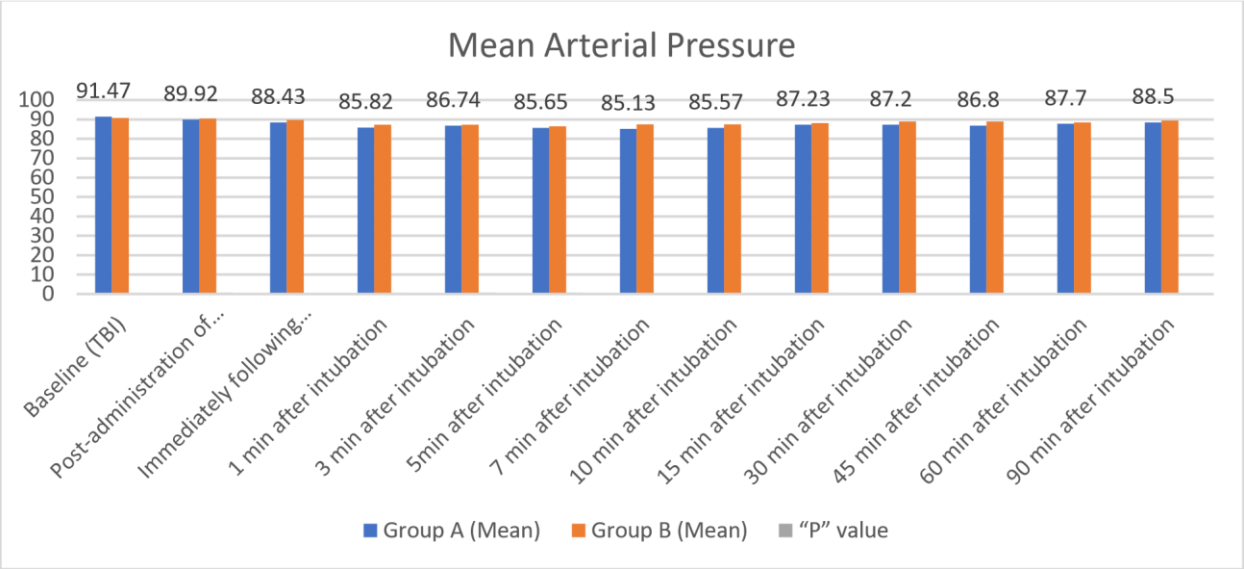
Age: Descriptive Statistics (P value = 0.4337)					
	Group	Minimum	Maximum	Mean	SD
Age (yrs)	A	18	65	33.8667	10.77264
	B	18	65	31.5892	11.5896

Anaesthesia Parameters	Group A (Mean ± SD)	Group B (Mean±SD)	P Value
Duration of surgery (hrs)	82.25±11.25	88.62±14.35	0.0606
Duration of anesthesia (hrs)	102.26±15.25	108.26±15.28	0.1334
Propofol (mg)	104.22±20.58	108.90±10.56	0.2703
Fentanyl bolus (mcg)	119.56±22.41	120.00±10.56	0.9228
Fentanyl (intraoperative) (mcg)	25.35±15.84	30.56±10.98	0.1441

Post Operative Sore Throat (p = 0.007)		
POST	Group A	Group B
Yes	22.00	9.00
No 8.00	21.00	

Side Effects	Group A	Group B	P value
Bradycardia	2 (6.5)	0 (0.0)	0.11
Hypotension	2 (6.5)	0 (0.0)	0.11
Nausea/vomiting	0 (0.0)	0 (0.0)	0
Others	0 (0.0)	1(3.0)	0.5





The response of nebulized dexmedetomidine on the attenuation of pressor response by Kumar et al. indicated the efficacy of the nebulized route, which is similar to ours but the control group in their study was nebulized with 0.9% NS thus limiting the comparison between different routes of administration which is filled by our study. The intra-operative anesthetic drug consumption was equivalent in both groups. Our findings are supported by Misra et al., Kumar et al., and Shrivastava et al.(Shrivastava et al., 2022)(Misra et al., 2021)(Kumar et al., 2020b)

POST is a severe problem with a 22–60% incidence that is documented in the post-operative phase. POST was evaluated which showed that group B using the nebulization method had a significantly reduced incidence of sore throat compared to the intravenous group. The effect of Neb-Dex on POST in patients undergoing thyroidectomy was investigated by Thomas et al., Jandial, and Tabassum, who came to a favorable conclusion. Both groups showed favorable outcomes on POST(Dr Ketki Jandial & Dr Shagufta Tabassum, 2022); however, NebDex responded better because of its local/topical effects on the laryngotracheal mucosa by nebulization, which were consistent with our findings.

The two groups did not differ significantly in terms of side effects; However, the IV-Dex group experienced bradycardia and hypotension, which was managed with medication. PONV did not occur in any of the patients in any group. This shows the comparable effectiveness of nebulized dexmedetomidine in preventing PONV.

LIMITATIONS

The limitations of our research are as follows; The study excluded patients presenting with difficult airway, and the time needed for laryngoscopy and intubation was not taken into account. Our findings cannot be applied to concurrent high-risk individuals. To prove their safety and superiority over other methods in achieving this goal, further RCTs with bigger sample sizes are needed(Kumar et al., 2020b).

CONCLUSION

After careful analysis of the observations, we conclude that intravenous as well as nebulized dexmedetomidine both attenuated pressor response but the systemic side effects with nebulized route were negligible as compared to the intravenous route. Even though the pressor response to laryngoscopy and intubation were attenuated by both routes, intravenous dexmedetomidine exhibited better pressor response attenuation. The incidence of hypotension & bradycardia was higher in patients receiving IV dexmedetomidine as compared to those nebulized with dexmedetomidine. The postoperative sore throat was lower in the nebulized group as compared to the intravenous group. Thus, we conclude that dexmedetomidine nebulization at a dose of 1µg/kg given 30 minutes prior to

induction of general anesthesia can be a better alternative in attenuating pressor response without any systemic side effects (bradycardia & hypotension) with an advantage in the lesser incidence of POST.

CONFLICT OF INTEREST

The authors have no conflict of interests to this publication.

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