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Efficacy of two different doses of nebulized dexmedetomidine for attenuation of hemodynamic response to laryngoscopy and intubation: A randomized controlled trial

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ABSTRACT

Background: Laryngoscopy and intubation cause augmented sympathoadrenal activity leading to hemodynamic alterations elicited by tachycardia and hypertension. Various drugs have been tried by multiple routes to attenuate the stress response, but none of them proved to be ideal. Dexmedetomidine nebulization at 1 mcg/kg used for negating this stress response resulted in a considerable drop in heart rate (HR) and blood pressure after induction of anesthesia. Hence, we intended to use dexmedetomidine at a lower dose and compare its efficacy with the conventional dose of 1mcg/kg in providing stable hemodynamics.

Materials and Methods: 100 patients scheduled for elective surgeries under general endotracheal anesthesia were randomized into group DA [received pre-operative dexmedetomidine nebulization at a dose of 1 mcg/kg] and group DB [received preoperative dexmedetomidine nebulization at a dose of 0.75 mcg/kg]. The HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded before nebulization, after nebulization, and at 1-, 3-, 5-, and 10-minute post-intubation. The induction dose of propofol, incidence of postoperative nausea and vomiting (PONV), and sore throat were also noted.

Results: A statistically significant reduction was seen in SBP after nebulization ($p=0.030$) and at 10 minutes post-intubation ($p=0.006$) in group DA compared to group DB. DBP in group DA was decreased significantly post-nebulization ($p=0.001$) at one-minute post-intubation ($p=0.014$), at three minutes post-intubation ($p=0.028$), and after ten minutes post-intubation ($p<0.001$). Group DA showed a significantly lower MAP compared to group DB after nebulization ($p=0.003$), one-minute post-intubation ($p=0.040$), and ten minutes after intubation ($p<0.001$). No statistically significant difference was seen in the attenuation of HR, reduction of induction dose of propofol, and reduction in the incidence of PONV between the two groups.

Conclusion: Nebulized dexmedetomidine at a dose of 0.75 $\mu\text{g/kg}$ effectively diminishes the stress response to laryngoscopy and intubation with better hemodynamic stability than the conventional dose of 1 $\mu\text{g/kg}$.

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1. Introduction

Endotracheal intubation and direct laryngoscopy enhance sympathoadrenal activity and may drive hemodynamic

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irregularities such as hypertension and tachycardia.^{1,2} These hemodynamic responses occur around 30 seconds after intubation and can last upto 10 minutes.³ The illeffects that can arise after laryngoscopy and intubation include hypertensive crisis, heart failure, abnormal heart rhythms, cerebral vascular stroke, and a rise in intracranial pressure in some patients.⁴ To mitigate the stress response, various pharmacotherapeutic interventions have been tried via different routes; however, none have shown to be absolutely effective.⁵

A highly selective $\alpha 2$ -adrenoceptor ($\alpha 2$ -AR) agonist, dexmedetomidine facilitates neurological, respiratory, and cardiac stability. Its effects include hypnotic, analgesic, anti-sialagogue, sedative, and sympatholytic.⁶ Bradycardia and hypotension are side effects of dexmedetomidine that may be caused by an intravenous (IV) bolus injection. Therefore, the nebulization approach has been chosen to prevent these side effects. Nebulized dexmedetomidine has substantial bioavailability through the buccal and nasal mucosa.^{7,8} Moreover, dexmedetomidine administered by nebulization avoids side effects like nasal irritation and cough.⁹

Multiple studies have shown that administering nebulized dexmedetomidine at concentrations greater than 1 mcg/kg may alter the stress response to laryngoscopy and intubation. However, no studies have investigated the hemodynamic response to these procedures when given at doses below 1 mcg/kg.

Hence, we aimed to use dexmedetomidine at a lower dose and compare its efficacy with the conventional dose of 1mcg/kg in providing stable hemodynamics. The primary objective of this study was to compare the effectiveness of nebulized dexmedetomidine at doses of 1 mcg/kg and 0.75 mcg/kg in blunting the hemodynamic response to laryngoscopy and intubation. The secondary objective is to compare the dose-sparing effects of two different doses of nebulized dexmedetomidine on the amount of propofol consumed during induction of general anesthesia, the incidence of PONV, and the incidence of sore throat.

2. Materials and Methods

2.1. Ethical consideration

The study was approved by the Institutional Ethical Committee of the Kalinga Institute of Medical Sciences (KIIT/KIMS/IEC/973/2022) and registered with the Clinical Trials Registry of India (CTRI/2022/09/045333).

2.2. Study design and eligibility criteria

The randomized trial was conducted from October 2022 to November 2023 at KIMS, Bhubaneswar, Odisha, in the Department of Anesthesiology, after the participants had given their written informed permission. 100 patients aged between 18 and 65 years belonging to the American Society of Anesthesiologists (ASA) physical status I or II

and scheduled for elective surgery under general anesthesia were enrolled for the study. Pregnancy, an allergy to study medications, a predicted difficult airway, obesity (BMI >30 kg/m²), antihypertensive medication, people with a seizure disorder, renal failure, and inadequate cardiopulmonary reserve were the exclusion criteria.

2.3. Randomization and blinding

Group DA and Group DB were formed using a computer-generated random sequence. Fifty patients met the inclusion criteria for each group. Following institutional norms, pre-anesthetic examination and laboratory tests were completed. Anesthesiologist not involved in data collection and analysis administered the medications, which were prepared by staff members not involved in any aspect of the investigation.

2.4. Nebulization procedure

Patients were required to fast for 8 hours before surgery, with no oral intake allowed. Pre-nebulization baseline hemodynamics were noted. The subjects received nebulization while seated using the Romsons Aeromist Nebulizer accessories set, manufactured in Delhi, India by Romsons Scientific and Surgical Pvt. Ltd. The study drug was diluted with normal saline Normal saline to make the volume 5 ml. About fifteen to twenty minutes before the beginning of anesthesia, subjects were nebulized with oxygen at a rate of six liters per minute, following the randomization protocol. The independent anesthesiologist observed that the nebulizer could spread the whole amount in ten to fifteen minutes, or until a fine mist was produced. Nebulization was stopped when tapping the volume chamber did not produce any visible mist. The primary researcher was assigned to observe for any adverse reactions to the nebulized medications, such as bradycardia, heightened sedation, and reduced peripheral oxygen saturation. In case of occurrence of any adverse reaction, nebulization was stopped and the patient was promptly treated. To ensure a smooth nebulization process, readings were obtained after the procedure. Group DA patients were nebulized with 1 mcg/kg of dexmedetomidine before surgery. In comparison, those in Group DB received a pre-operative nebulization of 0.75 mcg/kg dexmedetomidine.

2.5. Anesthetic management

Upon shifting the patients to the operating room, a standard multiparameter monitor was connected, which included ECG, NIBP, and pulse oximeter. The subjects were subsequently given a premedication that included fentanyl (2 mcg/kg), midazolam (1 mg), and glycopyrrolate (0.005 mg/kg). Patients were administered 100% oxygen throughout the three-minute preoxygenation period. Induction of anesthesia was carried out by inj. propofol

(1-2mg/kg) titrated to the cessation of verbal response and the dosage of propofol administered was recorded. Tracheal intubation was done by the senior anesthesiologist present in the operating theater after giving inj. vecuronium 0.1mg/kg. Cases where the intubation took longer than fifteen seconds were not included in the research. For ten minutes after intubation, the patient was barred from any surgical stimulation. Depth of anesthesia was maintained with isoflurane in a 50% oxygen-nitrous oxide mixture. Ventilation was adjusted to maintain an end-tidal carbon dioxide concentration of 35-45 mm Hg. Vecuronium dosages of 0.02 mg/kg were administered intermittently to sustain the neuromuscular blockade. One gram of paracetamol and eight milligrams of ondansetron were administered intravenously ten minutes before the surgery's conclusion. Injecting 0.05 mg/kg of neostigmine and 0.01 mg/kg of glycopyrrolate restored the neuromuscular blockade. After extubation patients were shifted to the post-operative care unit (PACU).

2.6. Outcome measures

We measured systolic blood pressure (SBP) one-minute following intubation as our primary outcome. The secondary outcomes were: SBP (mmHg) at 3, 5 and 10 minutes after intubation, diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) at 1,3,5 and 10 minutes after intubation. Additional secondary outcomes were propofol requirement for induction (in mg), the incidence of postoperative sore throat (POST), postoperative nausea, and vomiting (PONV) in the first 24-hour post-operative period.

2.7. Sample size calculation

From the previous study by Shrivastava et al,¹⁰ considering mean and SD values of the baseline record of SBP and the record after 1 minute of intubation i.e. 121.96 ± 13.046 & 113.2 ± 14.503 , at a 5% level of significance, 95% confidence interval and 80% power, the minimum required sample size for each group was 45. Hence, we have taken a total sample size of 100 taking 10% attrition in consideration.

2.8. Statistical analysis

We used IBM Corp.'s (Armonk, NY) SPSS statistics version 29.0 for this data. Mean \pm standard deviation (SD) was used to display continuous data, while frequencies and percentages were used to display categorical variables. Statistical analysis was performed using Chi-square tests and Fisher's exact tests to ascertain the type of relationship between the two datasets. Students' t-tests were used to evaluate the continuous variables. To be deemed statistically significant, a p-value had to be lower than 0.05.

3. Results

The study included a well-balanced population, as depicted in the Consolidated Standards of Reporting Trials (CONSORT) (Diagram 1). Both groups were comparable in terms of age, weight, body mass index, sex distribution, American Society of Anesthesiologists (ASA) grades, and procedure duration, with no statistically significant differences between them (Table 1).

Regarding the primary outcome, systolic blood pressure (SBP) measured one-minute post-intubation showed no significant difference between the groups, with group DA recording a mean of 124.02 ± 18.72 and group DB 127.48 ± 16.18 ($p=0.325$) (Figure 1).

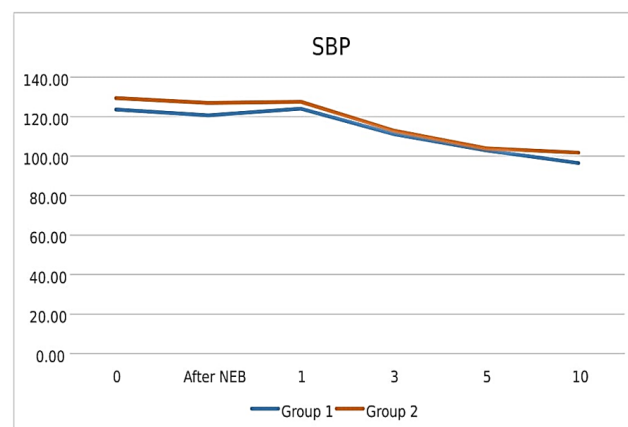


Figure 1: Mean distribution of SBP at different time intervals. The X-axis represents the time interval, and the Y-axis represents SBP values (mm of Hg)

However, significant differences emerged in several secondary outcomes. SBP was lower in group DA compared to group DB immediately after nebulization ($p=0.030$) and ten minutes post-intubation ($p=0.006$) (Figure 1). Similarly, diastolic blood pressure (DBP) showed significant reductions in group DA post-nebulization ($p=0.001$), at one minute ($p=0.014$), three minutes ($p=0.028$), and ten minutes post-intubation ($p<0.001$) (Figure 2). Mean arterial pressure (MAP) also demonstrated lower values in group DA, with significant differences observed after nebulization ($p=0.003$), at one minute post-intubation ($p=0.040$), and ten minutes post-intubation ($p<0.001$) (Table 2).

In contrast, heart rate (HR) attenuation did not differ significantly between the two groups throughout the measurement period (Table 3).

The induction dose of propofol showed no statistically significant difference, with group DA receiving 57.50 ± 11.12 mg and group DB 60 ± 16.96 mg ($p=0.425$), indicating similar dose-sparing effects in both groups.

Adverse outcomes were minimal and comparable between groups. Postoperative nausea and vomiting (PONV) occurred in two patients (4%) in group DA and

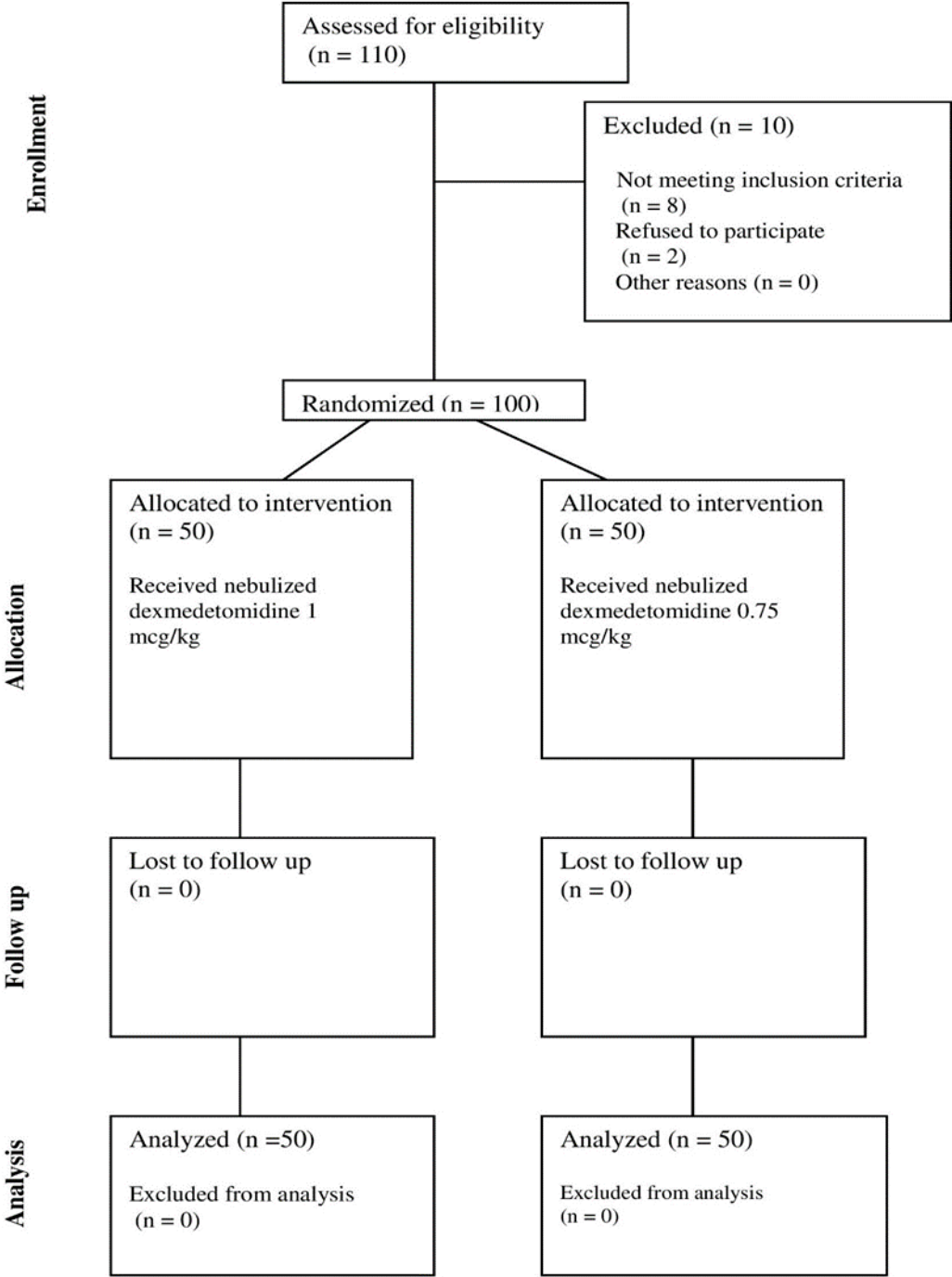


Diagram 1: Consort flow diagram

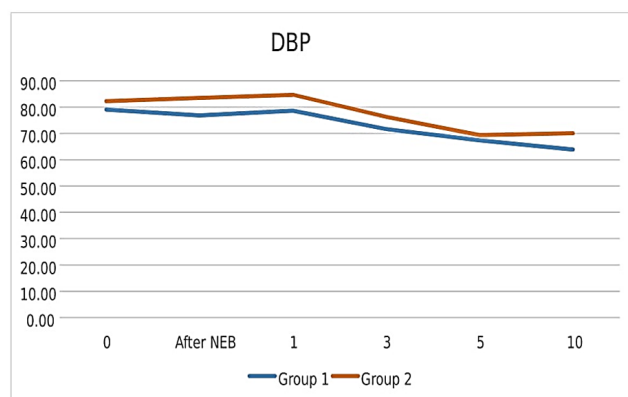


Figure 2: Mean distribution of DBP at different time intervals. The X-axis represents the time interval, and the Y-axis represents DBP values (mm of Hg).

one patient (2%) in group DB ($p=1.000$). The incidence of postoperative sore throat (POST) was 22% in group DA and 28% in group DB ($p=0.488$), with no significant differences noted.

After being evaluated with a student t-test or chi-square test, the data is depicted as the mean plus or minus the standard deviation, or as a numerical value (%).

4. Discussion

Two doses of dexmedetomidine administered via nebulization were examined to reduce the hemodynamic reaction to intubation and laryngoscopy. The incidence of PONV, sore throat, and the amount of propofol required for induction has been documented. The goal was to find out whether dexmedetomidine's hemodynamic response-taming benefits might be achieved with a lower dosage while avoiding the adverse effects associated with a higher dose.

Earlier studies have concluded that a standard dose of 1 mcg/kg of dexmedetomidine was efficacious when administered through both intranasal and IV routes.^{9–11} We employed a lower dose of 0.75 mcg/kg to provide stable post-intubation hemodynamics. We found that both doses mitigate the sympathoadrenal response". When comparing the two groups at various time points following nebulization, the DA group demonstrated substantially lower SBP, DBP, and MAP.

Patients who are susceptible to myocardial ischemia and abrupt heart failure may have a poorer prognosis after laryngoscopy and endotracheal intubation.¹² Even subjects with optimal cardiovascular status can encounter a substantial rise in blood pressure and heart rate during tracheal intubation.¹³ A diverse range of drugs have been tried to curb these cardiovascular responses, yet none have proven ideal.¹⁴ Lignocaine, opioids, nitroglycerin, calcium channel blockers, and alpha 2 agonists have been utilized

for lowering the intubation response.⁵ Dexmedetomidine is a newer option being tried for the same.

The alpha-2(α -2A) receptor agonist dexmedetomidine considerably lowers the blood pressure spike during tracheal intubation compared to other drugs currently in use.^{15,16} It works by activating the α -2A receptors in the locus coeruleus before the transmission of nerve impulses.¹⁷ The effects include lowering anxiety, analgesia, sedation, hypnosis, sympatholytic, and antisecretory properties, without causing respiratory depression.

When the sympathetic nervous system's alpha-2 receptors are activated, it decreases sympathetic activity and causes bradycardia and hypotension.¹⁸ Some studies have linked IV dexmedetomidine to postoperative bradycardia and hypotension, even though it helps reduce the hemodynamic response to intubation.¹⁹ This problem is being addressed by exploring alternative delivery methods for dexmedetomidine. Effective reduction of the hemodynamic surge after intubation can be achieved with IV dexmedetomidine at doses ranging from 0.5 to 1 mcg/kg.^{20,21}

The bioavailability of dexmedetomidine is 65% when administered by intra-nasal route and 82% when absorbed by buccal mucosa.^{7,8} The intranasal route of drug delivery may cause brief discomfort and occasional coughing. To overcome these problems, the drug is nebulized as an atomized spray. By using a thin coating of a drug, this method covers the maximum surface area while improving clinical efficacy and patient acceptance. In addition, its effect on hemodynamics is less than that of the IV route.^{7,8} Nebulized dexmedetomidine has been contemplated as a suitable premedicant because of its brief distribution half-life of 6 minutes and elimination half-time of 2 hours, which helps evade the unfavorable effects on hemodynamics encountered with IV dexmedetomidine.^{9,22}

In our study, we observed a significant reduction in systolic blood pressure (SBP) immediately after nebulization and at 10 minutes post-intubation. Similarly, diastolic blood pressure (DBP) decreased significantly after nebulization, and at 1, 3, and 10 minutes post-intubation. Mean arterial pressure (MAP) also showed a notable decline following nebulization, at 1 minute, and 10 minutes post-intubation in group DA compared to group DB.

These findings align with previous research. Kumar et al. demonstrated that nebulized dexmedetomidine significantly attenuated SBP, DBP, and MAP responses at 1, 5, and 10 minutes post-intubation compared to normal saline.²³ Shrivastava et al. similarly replicated these results, confirming the efficacy of dexmedetomidine in blunting the hemodynamic response to intubation.¹⁰ Further supporting evidence comes from Grover et al., who explored the effects of nebulized fentanyl, dexmedetomidine, and magnesium sulfate in reducing hemodynamic reactivity during tracheal intubation and laryngoscopy, highlighting

Table 1: Comparison of baseline characteristics

Variables		Group DA (n=50)	Group DB (n=50)	P Value
Age (years)		38.28 ±11.63	40.82 ±12.44	0.294
Gender	Male	12	11	0.812
	Female	38	39	
ASA	1	43	41	0.585
	2	7	9	
BMI (kg/m ²)		23.04 ±3.06	22.54 ±3.10	0.426

Abbreviations: ASA: American Society of Anesthesiologists; BMI: Body mass index

Table 2: Comparison of MAP at different time intervals

MAP	Group DA		Group DB		P value
	Mean ± SD	Min- Max	Mean ± SD	Min-Max	
Baseline	79.09±7.35	76-111	82.18±9.31	76-120	0.068
After nebulization	76.80±7.98	73-112	83.44±10.74	72-124	0.001
After 1 minute of Intubation	78.56±11.12	67-129	84.68±13.24	71-126	0.014
After 3 minutes of Intubation	71.62±10.04	65-104	76.20±10.49	65-111	0.028
After 5 minutes of Intubation	67.32±8.87	65-104	69.30±8.67	65-108	0.262
After 10 minutes of Intubation	63.88±7.03	64-93	70.04±8.92	69-110	<0.001

Abbreviations: MAP: Mean arterial pressure; SD: Standard deviation; Min-Max: Minimum-maximum. The data are assessed using a student t-test, which is shown as the mean ± standard deviation

Table 3: Comparison of HR at different time intervals

HR	Group DA		Group DB		P Value
	Mean ± SD	Min- Max	Mean ± SD	Min-Max	
Baseline	83.86±14.16	62-123	89.10±14.76	59-132	0.073
After nebulization	79.50±16.32	57-129	85.32±16.21	59-138	0.077
After 1 minute of Intubation	86.18±13.84	55-121	90.82±15.20	63-130	0.114
After 3 minutes of Intubation	83.62±12.57	59-112	87.56±15.28	65-123	0.162
After 5 minutes of Intubation	82.10±13.60	57-125	84.78±14.56	60-118	0.344
After 10 minutes of Intubation	79.42±12.20	55-107	81.20±13.68	60-115	0.494

Abbreviations: HR: Heart rate; SD: Standard deviation; Min-Max: Minimum-maximum. Data are presented as mean ± standard deviation and analyzed using a student t-test

their effectiveness in maintaining hemodynamic stability during these critical phases.²⁴

Consistent with our result, the dexmedetomidine group also had a progressive decrease in MAP, SBP, and DBP upon intubation. We used a lower dosage of dexmedetomidine in our experiment compared to Hussain et al., who also examined the impact of nebulization (2 mcg/kg) on hemodynamic response to laryngoscopy.²⁵ In contrast, Misra et al. discovered that compared to the placebo group, nebulized dexmedetomidine at 1 µg/kg administered half an hour before anesthesia induction did not affect systolic blood pressure (SBP) following intubation.²⁶ However, the results from our study showed that nebulized dexmedetomidine at doses of 1 mcg/kg or 0.75 mcg/kg was found to decrease the increase in MAP, SBP, and DBP that occurs during tracheal intubation. This precipitous decrease

in blood pressure might be due to the sympatholytic effects of dexmedetomidine.

Previous research by Shrivastava et al., Kumar et al., Misra et al., and Saxena et al. demonstrated that heart rate (HR) decreases following intubation, and our findings were consistent with this trend.^{10,23,26,27} However, no significant difference was observed between groups DA and DB. Unlike prior studies involving intravenous dexmedetomidine, which reported bradycardia,^{28,29} none of our subjects experienced this complication. The nebulization route used in our study may account for the absence of bradycardia, supporting the evidence that patients on HR-lowering medications or with low baseline HR are at a lower risk of bradycardia with nebulized dexmedetomidine than with the intravenous form.³⁰

Both DA and DB groups also required less propofol for induction, a finding that aligns with studies by Shrivastava et al., Kumar et al., Misra et al., and Sharma et al.^{10,23,26,31} These studies similarly reported no statistically significant difference in propofol consumption between groups.

The incidence of postoperative nausea and vomiting (PONV) is generally reported to range between 16% and 31%.³² In our study, however, the incidence was significantly lower, at 4% in group DA and 2% in group DB. This suggests that pre-operative nebulized dexmedetomidine may have contributed to the reduction in PONV.

Postoperative sore throat (POST) has been reported to occur in 21% to 60% of cases following general endotracheal anesthesia.^{33,34} In our study, the incidence of POST was 22% in group DB and 28% in group DA. Similar to the findings by Misra et al.²⁶ we did not observe any significant benefit of nebulized dexmedetomidine in reducing POST.

5. Limitations

Our study has certain limitations. It included only ASA 1 and 2 patients, excluding ASA 3 and 4 patients who typically exhibit a more pronounced stress response to laryngoscopy and intubation. Additionally, patients with potentially difficult intubations were not included, even though they could have been benefitted more from preoperative dexmedetomidine nebulization. The laryngoscopy duration was limited to 15 seconds, preventing the assessment of dexmedetomidine's effect in prolonged or difficult intubations. Furthermore, opioid-based anesthesia (fentanyl) was used for all patients, which may have attenuated the pressure response in both groups. Lastly, the absence of bispectral index (BIS) monitoring may have influenced the accuracy of propofol consumption assessment during induction.

Despite these limitations, our study highlights the unique efficacy of nebulized dexmedetomidine at 0.75 mcg/kg and 1 mcg/kg in attenuating the hemodynamic response to laryngoscopy and intubation without causing hypotension or bradycardia. Preoperative nebulized dexmedetomidine proves to be a novel and effective administration method, reducing stress responses and stabilizing intraoperative hemodynamics, supporting existing evidence. Therefore, nebulized dexmedetomidine at 0.75 mcg/kg can be recommended as an efficacious premedication for patients more vulnerable to the detrimental effects of laryngoscopy and intubation.

6. Conclusion

This study demonstrated a dose-sparing effect on propofol consumption with both doses of dexmedetomidine. A noticeable reduction in the incidence of postoperative nausea and vomiting (PONV) was observed, while there was

no significant decrease in the incidence of postoperative sore throat (POST). Post-intubation hemodynamics were more favorable with 0.75 mcg/kg dexmedetomidine nebulization compared to 1 mcg/kg, although both doses provided similar beneficial effects. Lowering the hemodynamic response to laryngoscopy and intubation may be more tolerable at a dose of 0.75 mcg/kg. Hence, multicentric studies with a focus on a lower dose of nebulized dexmedetomidine, including difficult airway situations along with BIS monitoring, are needed to validate these findings.

7. Source of Funding

Nil.

8. Conflicts of Interest

There are no conflicts of interest.

9. Authors' Contributions


Conceptualization and design: Dr. Amit Pradhan, Dr. Laxman Senapati; Literature search: Dr. Soumya Ranjan Sahoo, Dr. Laxman Senapati; Data collection: Dr. Soumya Ranjan Sahoo; Data analysis: Dr. Soumya Ranjan Sahoo, Dr. Priyadarsini Samanta; Manuscript Preparation: Dr. Laxman Senapati, Dr. Amit Pradhan; Manuscript review and editing: Dr. Amit Pradhan, Dr. Rajendra Sahoo.


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