

EVALUATION OF THE EFFECT OF NEBULISED DEXMEDETOMIDINE IN ATTENUATING HAEMODYNAMIC RESPONSE TO INTUBATION: A PROSPECTIVE RANDOMISED STUDY

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Abstract

Background: Laryngoscopy and tracheal intubation provokes a transient and marked sympathetic response that manifests as an increase in heart rate & blood pressure, with the potential for development of cardiovascular events. Since Dexmedetomidine has good bioavailability and rapid absorption through nasal mucosa, we conducted this study to evaluate the effects of nebulised dexmedetomidine. **Aim:** To evaluate the effect of nebulised dexmedetomidine in attenuating the haemodynamic response to laryngoscopy and tracheal intubation. **Methods:** This prospective, randomised, comparative study was conducted in 80 American Society of Anaesthesiologists (ASA) I&II patients. The primary outcome was to evaluate the effects of dexmedetomidine nebulisation in blunting the stress response to laryngoscopy and intubation. The study population was divided randomly into two groups. Control group C (n = 40) received nebulisation with 5 ml of normal saline and group D (n = 40) received 1 µg/kg dexmedetomidine 5 ml 10 min before induction in sitting position. **Results:** Demographics were comparable. Following laryngoscopy and intubation, systolic (SBP), diastolic (DBP) and mean arterial pressure (MAP) were markedly increased in the control group whereas in group D there was a fall in SBP, DBP, MAP & Heart rate at 1min, 5 min & 10 min following intubation, which was statistically significant (P < 0.001). **Conclusion:** Nebulised dexmedetomidine effectively blunts the stress response to laryngoscopy and intubation with no adverse effects.

Key words: Dexmedetomidine, intubation, laryngoscopy, nebulization

Introduction

Endotracheal intubation is a necessary skill done by numerous medical experts in order to secure a patient's airway and deliver oxygenation and ventilation. Multiple procedures are available, including laryngoscope viewing of the vocal cords, direct introduction of the endotracheal tube into the trachea through cricothyrotomy, and nasal or oral fiberoptic vision of the vocal cords.

A direct laryngoscopy enables the larynx to be visualised. It is used during general

anaesthesia, laryngeal surgery, and resuscitation. This tool is beneficial in a variety of medical settings, including the emergency room, critical care unit, and operating room. Visualizing the larynx facilitates endotracheal intubation. This is a crucial step for a variety of patients, including individuals with altered mental state and those having emergency surgery.

The evaluation of intubation should take potential complications into account. Hypoxemia is a feared consequence of intubation that may be triggered by many attempts with inadequate oxygenation between efforts and unsuccessful intubation.

Cardiovascular problems may emerge from both direct pharyngeal manipulation and induction drugs. During direct laryngoscopy, vagal stimulation may induce bradycardia. During the intubation of critically sick patients, some sedative drugs might produce hypotension, which can result in hemodynamic compromise and cardiac arrest.⁴

Direct laryngoscopy and intubation are linked with a hemodynamic response characterised by an increase in blood pressure and heart rate. This reaction happens within 30 seconds and lasts less than 10 minutes following intubation. Healthy individuals were well tolerated; these transitory reactions may be hazardous in those with reactive airways, hypertension, coronary artery disease, myocardial insufficiency, and cerebrovascular diseases. Numerous medications, including opioids, beta-blockers, and intravenous lignocaine, are used to suppress this hemodynamic response.

Direct laryngoscopy and intubation may cause tachycardia, hypertension, laryngospasm, bronchospasm, elevated intracranial pressure, and elevated intraocular pressure. These changes are often temporary, and healthy individuals were well tolerated. These hemodynamic disturbances may cause myocardial ischemia, ventricular dysrhythmias, ventricular failure, pulmonary edema, and Cerebrovascular accidents in individuals with cardiovascular and cerebrovascular illness.

Dexmedetomidine is an alpha-2 agonist having sedative, amnestic, and analgesic properties. After decrease the hemodynamic response to intubation, several dosages and administration methods of dexmedetomidine, such as intravenous, intranasal, intramuscular, and nebulized, have been investigated. The nasal mucosa contributes for 65% of nebulized dexmedetomidine's bioavailability, whereas the buccal mucosa accounts for 82%.

Nebulization with 1 microgram/kg dexmedetomidine attenuates the hemodynamic response to laryngoscopy and intubation without producing hypotension and bradycardia. It is a novel method of administration for decreasing the hemodynamic response to laryngoscopy and intubation; thus, more study is necessary in this area. Dexmedetomidine administered through nebulization looks to be a potential agent for attenuating the hemodynamic response to laryngoscopy and intubation.

In this study, we hypothesised that nebulised dexmedetomidine will blunt the intubation response may be due to its rapid absorption and good bioavailability. The first of its kind in an attempt to investigate, its role in attenuating the stress response to laryngoscopy and intubation. This study was designed to evaluate the role of Nebulised Dexmedetomidine as a premedication in attenuating the stress response to laryngoscopy and intubation, with objectives to evaluate changes in haemodynamic stress response like SBP, DBP, SPO₂, HR and mean arterial pressure.

Aim And Objectives

Aim: Evaluation of the effect of nebulised Dexmedetomidine in attenuating haemodynamic response to intubation

Objectives:

- To evaluate changes in haemodynamic stress response like
- SBP (Systolic Blood Pressure)
- DBP(Diastolic Blood Pressure)
- SPO2(Saturation)
- HR (Heart Rate)and
- MAP (Mean Arterial Pressure)

Materials And Methods

Ethical issues:

Institutional ethical committee clearance taken, the informed anaesthesia written consent taken from study participants. Those who withdraw for the study will be offered treatment. The data collected will be confidential and no identity of the study participants will be revealed. Findings will be used only for the purpose of the study.

- **Study design:** A Prospective randomized controlled study
- **Study centre:** Government Thiruvarur medical college
- **Study duration:** June 2023 to November 2023
- **Study population:** 80 (40 in each group)

SAMPLE SIZE: Was determined on basis of pilot study. We calculated a minimum sample size of 38 patients was required in each group, assuming type1 error of and margin of error 5%. Therefore final sample selected was n = 40 in group D and n=40 in group C.

$$\frac{Z^2 \times P \times (1-P)}{n=M2}$$

Description

n = required sample size

t = confidence level at 95% (standard value of 1.96) p = estimated prevalence

m = margin of error at 5% (standard value of 0.05)

$$n = \frac{(1.96)^2 \times 0.025(1 - 0.025)}{(0.05)^2}$$

$$\frac{3.8146 \times 0.0243}{n = 0.0025} = 38 \text{ per group}$$

Total of 80 patients posted for elective surgery ,40 patients allotted to GROUP D (n=40) and 40 patients allotted to GROUP C (n=40)

RANDOMIZATION

Delivered in sealed opaque envelopes which are coded.

- GROUP C (n=40) will receive nebulisation with 5ml of normal saline
- GROUP D(n=40) will receive nebulisation with 5ml of dexmedetomidine(1microgram/kg)

Inclusion criteria:

- ASA Physical status I&II
- Patients posted for elective surgery under GA
- Age between 18 to 60yrs
- Body mass index <30kg/m2
- Normal Airway

Exclusion criteria:

- Patients refusal
- Predicted airway difficulty
- Seizure disorders
- Tumors and Trauma involving face
- Pregnancy
- Renal failure
- Uncontrolled hypertension
- Patients on Antidepressants/Antipsychotics
- BMI>30kg/m²

Basic blood investigations were taken.

- Complete blood count
- Renal function test
- Liver function test
- ECG
- Chest Xray
- Blood grouping & typing
- Viral markers

PREANAESTHETIC EVALUATION

Preoperative visit was made to allay anxiety, and a good rapport was established with the patient. Informed anaesthesia risk consent obtained. The patients were kept fasting overnight after 10:00 pm and received Tablet Ranitidine 150 mg orally and Tablet Diazepam 10mg orally as premedication at night before the day of surgery.

PREANAESTHETIC PREPARATION

- 18G IV cannula inserted
- Monitors connected– NonInvasiveBloodPressure,ECG,SpO₂
- Premedication half an hour before induction & monitored for 10min: Inj.Glycopyrrolate0.2mgIntramusculargiven as premedication

Dexmedetomidine at a dose of 1 µg/kg (mixed with saline to a total volume of 5 ml) nebulisation was administered to Group D (study group) with a nebuliser face mask and a continuous flow of 100% oxygen at 6 L/min for 10 min before induction of anaesthesia in sitting position & the control group (group c) received nebulisation with 5ml of normal saline. Preoxygenation with 8 liters of 100% oxygen for 3minutes

- Induction:
 - Inj. Fentanyl 2mcg/kg Inj.atracurium0.5mg/ kg iv Inj. Propofol 1 - 2mg/ kg iv
- Laryngoscopy with Macintosh laryngoscope blade
- Endotracheal Intubation with appropriate size cuffed endotracheal tube
- Anaesthesia Maintenance:

N₂O:O₂=1:1

Isoflurane0.2-1.2%

Inj. Atracurium 0.1mg/kg IV

Patient parameters recorded in terms of HR (Heart Rate), SBP(Systolic Blood Pressure), DBP(Diastolic Blood Pressure) & MAP(Mean Arterial Pressure) and SPO₂at baseline, after Nebulisation, after 1minute, 5minutes and 10 minutes of intubation by an anaesthesia resident who was not involved in the study.

After surgery, reversal of residual neuromuscular blockade achieved with neostigmine and glycopyrrolate

Clinical recovery from neuromuscular blockade to be confirmed by attainment of swallowing reflex, gag reflex, cough reflex, head lift, leg lift & sustained handgrip for 5sec then patient will be shifted to Post anaesthesia care room for observation.

Statistical analysis

- The data will be entered is entered in Microsoft Excel and analysed using SPSS software.
- Continuous variables will be summarized using mean (SD), Categorical variables like sex, will be summarized using proportion.

To study the association between categorical variables Chi square test applied as a test of significance. P value <0.05 will be considered as statistical significant.

Observation And Results

The two groups are comparable with respect to age, sex and ASA grading.

Heart Rate from Baseline to Post Intubation:

The mean Baseline Heart rate among Group D was 77.53 (\pm 12.68) which is lower by 1.6 but not statistically significant compared to mean Baseline heart rate among Group C which was 79.13 (\pm 12.29). The mean HR after nebulization among Group D was 75.93 (\pm 11.3) which is lower by 2.07 but not statistically significant compared to mean HR after nebulization among Group C which was 78 (\pm 10.73). The mean HR 1 minute Post intubation in Group D was 62.3 (\pm 9.21) which is lower by 14.4 and statistically significant compared to mean HR 1 minute Post intubation among Group C which was 76.73 (\pm 10.48). The mean HR 5 minutes Post Intubation among Group D was 58.27 (\pm 8.23) which is lower by 9.43 and statistically significant compared to mean HR 5 minutes Post Intubation among Group C which was 67.7 (\pm 9.27). The mean HR 10 min Post Intubation among Group D was 62.83 (\pm 8.27) which is lower by 20.46 and statistically significant compared to mean HR 1 min Post Intubation among Group C which was 83.3 (\pm 10.19).

Table 1

Heart Rate	Drug group	N	Mean	Std. dev.	Mean diff.	p value by 't' test
Baseline	Group D	40	77.53	12.68	1.600	0.622
	Group C	40	79.13	12.29		
AFTER NEBULIZATION	Group D	40	75.93	11.30	2.067	0.470
	Group C	40	78.00	10.73		
1 Min after intubation	Group D	40	62.30	9.21	14.433	0.001
	Group C	40	76.73	10.48		
5 MIN	Group D	40	58.27	8.23	9.433	0.001
	Group C	40	67.70	9.27		
10 MIN	Group D	40	62.83	8.27	20.467	0.001
	Group C	40	83.30	10.19		

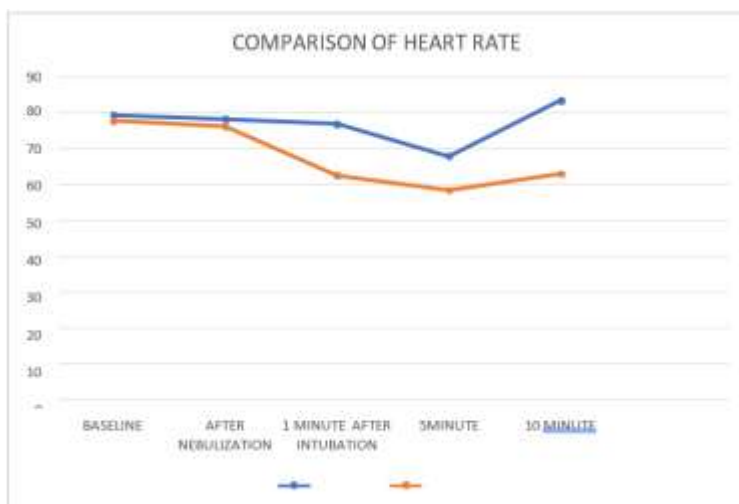


Figure 1: Heart Rate from Baseline to Post Intubation

Systolic Blood Pressure from Baseline to Post Intubation:

The mean SBP Baseline among Group D was 137.33 (\pm 14.89) which is higher by 2.37 but not statistically significant compared to mean SBP Baseline among Group C which was 134.97 (\pm 15.25). The mean SBP After nebulization among Group D was 136.4 (\pm 13.55) which is higher by 0.97 but not statistically significant compared to mean SBP After nebulization among Group C which was 135.43 (\pm 12.4). The mean SBP 1 min Post Intubation among Group D was 113.73 (\pm 10.42) which is lower by 21 and statistically significant compared to mean SBP 1 min Post Intubation among Group C which was 134.73 (\pm 10.53).

The mean SBP 5 min Post Intubation among Group D was 98.37 (\pm 7.69) which is lower by 12 and statistically significant compared to mean SBP 5 min Post Intubation among Group C which was 110.37 (\pm 6.44). The mean SBP 10 min Post Intubation among Group D was 106.33 (\pm 8.02) which is lower by 33.9 and statistically significant compared to mean SBP 10 min Post Intubation among Group C which was 140.3 (\pm 9.83)

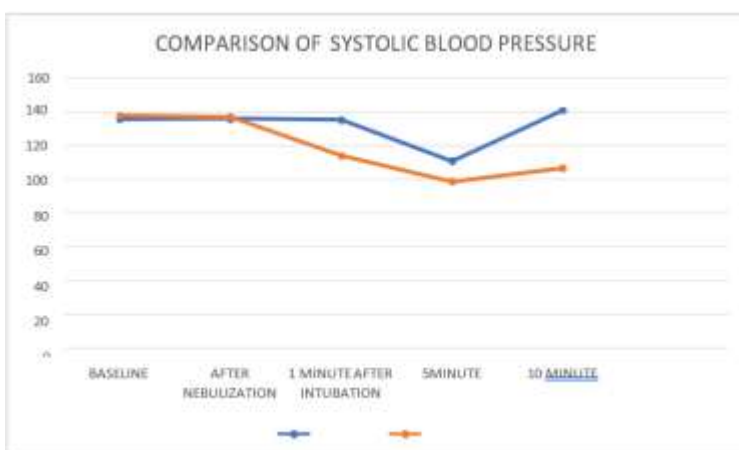


Figure 2: Systolic Blood Pressure from Baseline to Post Intubation

Diastolic Blood Pressure from Baseline to Post Intubation:

The mean DBP Baseline among Group D was 86.27 (\pm 7.46) which is higher by 2.7 but not statistically significant compared to mean DBP Baseline among Group C which was 83.57 (\pm 4.7). The mean DBP after nebulization Drug among Group D was 86.37 (\pm 5.73) which is higher by 2.67 and statistically significant compared to mean DBP after

nebulization among Group C which was 83.7 (\pm 4.21). The mean DBP 1 min Post Intubation among Group D was 72.5 (\pm 5.23) which is lower by 11.1 and statistically significant compared to mean DBP 1 min Post Intubation among Group C which was 83.6 (\pm 4.39).

The mean DBP 5min Post Intubation among Group D was 64.93 (\pm 3.74) which is lower by 7.27 and statistically significant compared to mean DBP 5 min Post Intubation among Group C which was 72.2 (\pm 4.79). The mean DBP 10 min Post Intubation among Group D was 68.17 (\pm 4.4) which is lower by 17.3 and statistically significant compared to mean DBP 10 min Post Intubation among Group C which was 85.47 (\pm 7.08).

Mean Arterial Blood Pressure from Baseline to Post Intubation:

The mean MAP Baseline among Group D was 103.28 (\pm 9.19) which is higher by 2.56 but not statistically significant compared to mean MAP Baseline among Group C which was 100.72 (\pm 6.94). The mean MAP After nebulization among Group D was 103.07 (\pm 7.79) which is higher by 2.14 but not statistically significant compared to mean MAP After nebulization among Group C which was 100.93 (\pm 5.99). The mean MAP 1 min Post Intubation among Group D was 86.23 (\pm 6.26) which is lower by 14.4 and statistically significant compared to mean MAP 1 min Post Intubation among Group C which was 100.7 (\pm 5.77).

The mean MAP 5 min Post Intubation among Group D was 76.03 (\pm 4.61) which is lower by 8.87 and statistically significant compared to mean MAP 5 min Post Intubation among Group C which was 84.9 (\pm 4.35). The mean MAP 10 min Post Intubation among Group D was 80.9 (\pm 4.85) which is lower by 22.7 and statistically significant compared to mean MAP 10 min Post Intubation among Group C which was 103.67 (\pm 6.5).

Saturation from Baseline to Post Intubation:

The mean SpO2 Baseline among Group D was 98.73 (\pm 0.52) which is higher by 0.1 but not statistically significant compared to mean SpO2 Baseline among Group C which was 98.63 (\pm 0.61). The mean SpO2 After nebulization among Group D was 98.73 (\pm 0.52) which is higher by 0.1 but not statistically significant compared to mean SpO2 After nebulization among Group C which was 98.63 (\pm 0.61). The mean SpO2 1 min Post Intubation among Group D was 97.9 (\pm 0.92) which is lower by 0.2 but not statistically significant compared to mean SpO2 1 min Post Intubation among Group C which was 98.13 (\pm 0.82). The mean SpO2 5 min Post Intubation among Group D was 98.77 (\pm 0.43) which is same as compared to mean SpO2 5 min Post Intubation among Group C which was 98.77 (\pm 0.43). The mean SpO2 10 min Post Intubation among Group D was 98.33 (\pm 0.71) which is lower by 0.067 but not statistically significant compared to mean SpO2 10 min Post Intubation among Group C which was 98.4 (\pm 0.67).

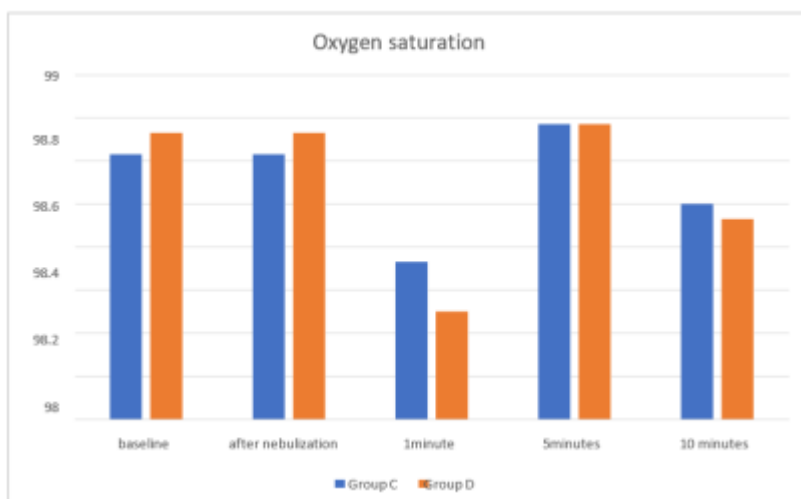


Figure 3

Discussion

This is a Randomized controlled study, among 80 patients was conducted to evaluate the effect of nebulized dexmedetomidine in attenuating hemodynamic response to intubation Group D- (n=40) received dexmedetomidine 1 µg/kg mixed with saline as nebulization over 10 min, before induction of anaesthesia Group C- (n=40) received 0.9% normal saline as nebulization over 10 min, before induction of anaesthesia.

The HR, SBP, DBP, MBP, SpO₂ were continuously monitored and recorded at baseline in the preoperative period, after nebulization, 1 min, 5 min, and 10 min after intubation, skin incision The key objective of the study is to determine the efficacy of dexmedetomidine, in attenuating hemodynamic response to laryngoscopy In our study dexmedetomidine given through nebulization route.it is a non-invasive method of blunting of intubation stress response, the positive effect due to the drug absorption through the large mucosal surface area and increased bio availability

Baseline Parameters: The age, gender, and weight were not significantly different between the groups.

Age: The Age group of 18 years to 60 years were included in our study. In this study, The mean Age among Group D was 47.87 (± 8.4) which is lower by 0.60 but not statistically significant compared to mean Age among Group C which was 48.47 (± 6.3).

Gender: Various studies have proven that gender have no influence on the side effects such as postoperative shivering, bradycardia and other side effects.

In this study, Considering the Gender of the subjects with Drug group distribution, 53 % of the Group D group were Males and 47% were Females compared to Group C group of whom 63 % were Males and 37 % were Females and the difference was not statistically significant (p > 0.05).

Haemodynamic parameters: MK Sturaitis *et al.*, (brain tumor resection), A Bekker *et al.*, (craniotomy), S Rajan *et al.*, (craniotomy), KM Nelson *et al.*, (septic shock), G Sezen *et al.*, (hypertensive patients) studied the perioperative Hemodynamics of dexmedetomidine, in various surgeries and observed a beneficial result.

Heart rate: In this study, the heart rate was significantly lower among the dexmedetomidine after 1 minute after intubation.

Systolic Blood Pressure: In this study, The Systolic Blood Pressure was significantly lower among the dexmedetomidine group following 1 minute post intubation

Diastolic Blood Pressure: In this study, The Diastolic Blood Pressure was significantly lower among the dexmedetomidine group following 1 minute post intubation.

Mean Arterial Blood Pressure: In this study, The Mean Arterial Blood Pressure was significantly lower among the dexmedetomidine group following 1 minute post intubation. Similar to our study results, Manoj Kamal *et al.*, observed dexmedetomidine was attenuating the haemo-dynamic response to intubation

Spo2: In this study, The Spo2 level was not significantly different between the groups Zanaty and El Metainy compared nebulised dexmedetomidine, nebulised ketamine and their combination. They concluded that the combination resulted in better sedation, smoother induction and more rapid recovery. Another study by Abdel-Ghaffar HS *et al.* comparing nebulised dexmedetomidine, ketamine and midazolam found that nebulised dexmedetomidine provided more satisfactory sedation with shorter recovery time. But most of these studies done in paediatric populations.

In several studies, dexmedetomidine given intravenously 10 min before induction was associated with adverse effects like bradycardia, hypotension, hypertension and respiratory depression. In this study, nebulised dexmedetomidine did not produce a significant change in HR at any time point throughout the study period. The absence of bradycardia could probably be explained by the omission of the IV bolus dose of the drug. This finding suggests that nebulised dexmedetomidine may be safer than IV dexmedetomidine in patients receiving beta- blockers or with a low basal heart rate.

Conclusion

The hemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure was significantly lower among the dexmedetomidine group following 1 minute 5, 10 minutes after intubation. We conclude from this study that nebulised dexmedetomidine (1µgm/kg) is efficacious in attenuating hemodynamic response to laryngoscopy and intubation.

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