European Journal of Clinical Pharmacy
Print ISSN: 2385-409X, **Online ISSN**: 3105-0409
Website: https://farmclin.com/

A comparative analysis of nebulised dexmedetomidine as a premedication to attenuate the hemodynamic response during laryngoscopy in laparoscopic surgeries

Article History:

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Received*:* 12-04-2026
Revised*:* 29-04-2026
Accepted*:* 04-05-2026
Published*:* 08-05-2026

Abstract: Background: Anaesthesiologist's traditional approach to anaesthesia for laparoscopic surgery has been an emphasis on maintaining hemodynamic stability. Preanesthetic medication forms an integral part of anaesthetic management and some form of premedication is universally administered before general anaesthesia. **Aim:** This study was conducted to assess the hemodynamic response attenuation using nebulised dexmedetomidine as a premedication in laparoscopy surgeries during laryngoscopy. **Method:** A prospective double-blinded study was carried out on 80 patients of either sex, aged between 20 and 50 years and American Society of Anaesthesiologist (ASA) grade I and II. Patients were randomly allocated into two groups of 40 patients in each group. In Group A (Dexmedetomidine group), dexmedetomidine was administered in nebulise form at a dose of 2mcg/kg in 10 ml of normal saline 30 minutes before induction. In Group B (NORMAL SALINE group), the patient was nebulised with 10 ml of normal saline 30 minutes before induction. Two groups were compared in terms of haemodynamic changes (HR, SBP, DBP, MAP), side effects of the drug and the dose sparing effect of dexmedetomidine on propofol used during general anaesthesia. **Results:** Both groups were comparable with regard to demographic variables. Baseline heart rate and blood pressure were comparable in both groups (p value>0.05). After 30 minutes of giving nebulisation dexmedetomidine drug, heart rate, SBP, DBP and MAP reduced significantly in group A (p value<0.01) and there were no such changes in group B. During laryngoscopy and intubation mean heart rate, SBP, DBP, MAP increased in both the groups, but it increased more in group B as compared to group A (p value<0.01). After nebulisation, the dose sparing effect of nebulise dexmedetomidine on the amount of propofol used during general surgery was significantly lesser in Group A during induction as compared to Group B (p value <0.001). **Conclusion:** Nebulisation with dexmedetomidine, 30 minutes before the surgery diminishes more effectively the pressor stress response to laryngoscopy endotracheal intubation compared to the nebulised normal saline (10ml) without any deleterious effects in general anaesthesia. Nebulised dexmedetomidine appears to be a promising drug to attenuate the hemodynamic response to laryngoscopy and intubation.

Keywords: Dexmedetomidine, propofol, pressure response, general anaesthesia.

INTRODUCTION

Laparoscopic surgeries under general anaesthesia have been increased in recent days because of multiple benefits like less cosmetic scars, magnified operative field, less postoperative complications along with reduced duration of hospital stay, morbidity and mortality. (1)

Direct laryngoscopy and endotracheal intubation (ETI) are associated with sympathetic stimulation induced hemodynamic changes. (2) Common reasons for the hemodynamic changes following laryngoscopy and intubation are elevation of epiglottis, difficulty in glottic visualization, displacement of tongue, duration of laryngoscopy, and insertion of the tracheal tube. (2,3)

The magnitude of stress response is greater with increasing force and duration of laryngoscopy. During laryngoscopy, elevation of blood pressure and heart rate typically starts within 5 seconds of laryngoscopy and peaks in 1-2 minutes and returns to baseline level within 5 to 10 minutes, so effective premedication for attenuation of the hemodynamic stress response is an important goal during laryngoscopy in general anaesthesia. (4)

Preanesthetic medication forms an integral part of anaesthetic management and some form of premedication is universally administered before general anaesthesia. Laryngoscopy and intubation are the most crucial steps during cardiac surgery as it leads to short lived, vague unpredictable haemodynamic stress response. (5)

Anaesthesiologist's traditional approach to anaesthesia for laparoscopic surgery has been an emphasis on maintaining hemodynamic stability by avoiding hypertension, hypotension or tachycardia. (6) Multiple drugs like opioids, beta-blockers, calcium channel blockers and local anaesthetic agents have been used to suppress the hemodynamic stress response with variable results. (1,7) Recently, there is considerable interest for using an alpha-2 adrenergic agonist to provide haemodynamic stability during laryngoscopy and endotracheal intubation. (4)

In this study, we used nebulised dexmedetomidine to prevent haemodynamic response associated with laryngoscopy and endotracheal intubation. (4) Dexmedetomidine in various doses and routes, such as intravenous, intranasal, intramuscular, and nebulised has been used to reduce hemodynamic response in laryngoscopy and endotracheal intubation during laparoscopic surgeries. (8)

Inhalation of a nebulised drug is an alternative method of administration that is relatively easy to set up, does not require venepuncture, and is associated with high bioavailability and least side effects of the administered drug. (9) Dexmedetomidine is an alpha-2 agonist with amnestic, sympatholytic, sedative and analgesic action without respiratory depression and faster recovery.

Dexmedetomidine when given as a premedication, acts on the locus coeruleus to induce sedation and modulates nociceptive neurotransmission. (10) It acts on various brain stem and medullary nuclei (nucleus tractus solitarus, lateral reticular nucleus) and the hypothalamus to decrease the sympathetic nervous activity and attenuate the hemodynamic response to laryngoscopy and intubation. (11)

Nebulised dexmedetomidine may offer an attractive alternative to intravenous as well as other routes of administration because drug deposition following nebulisation takes place over nasal, buccal and respiratory mucosa. (12) This route may be preferred over intranasal administration, as it avoids transient nasal irritation, cough, vocal cord irritation or laryngospasm. (10) Dexmedetomidine's nebulised form has an additional advantage of relieving bronchospasm. Drug deposition over a greater surface area, results in better systemic absorption and prevention of hemodynamic changes. (13) It also prevents shivering and at the same time, it offers potential benefits for neuroprotection, cardio protection and renoprotection.

Looking at the above facts, the primary purpose of our study was to evaluate the attenuation of hemodynamic response of premedication of nebulise dexmedetomidine in laryngoscopy under laparoscopic surgery along with the secondary object of dose sparing of the drug on the amount of propofol during general anaesthesia.

MATERIAL & METHODS:

A double-blinded randomized study was conducted at our tertiary care hospital after obtaining the institution's ethical committee approval [No.F.3 () Acad /Ethical Clearance/Batch 2022/2023/47]. A total of 80 patients of either sex, belonging to ASA grade I & II, having Mallampati airway Grade I/II, aged between 20 and 50 years and weighing between 50 and 70kg were posted for elective abdominal surgery under general anaesthesia. Patients were randomly divided into 2 groups with 40 patients in each group using a shuffled opaque sealed envelope method.

Group A (DEXMEDETOMIDINE group) patients received dexmedetomidine in nebulise form for a dose of 2mcg/kg dexmedetomidine in 10 ml of normal saline 30 minutes before induction. Group B

(NORMAL SALINE group) patients were nebulised with 10 ml of normal saline 30 minutes before induction.

Patients with haematological diseases, allergic to local anaesthetics, having diabetes, cardiac & psychiatric problems and having difficult airway (Mallampati grade III &IV) were excluded from the study.

Pre-anaesthetic assessment was done and written informed consent was obtained before surgery. All patients were kept nil by mouth (NBM) for 6 hrs preoperatively. After arriving in the preoperative room, routine monitoring (NIBP, ECG, pulse oximetry) was applied. All baseline parameters were recorded. Intravenous line secured with a 20G cannula. The drugs for nebulization (saline or dexmedetomidine) were prepared and administered by an independent investigator in the preoperative area. Nebulization was carried out with a nebulizer machine, capable of creating a fine mist, until the entire volume was dispersed, usually within 10 minutes.

Group A patients were nebulised with dexmedetomidine in the dose of 2 mcg/kg made to a total volume of 10 ml by mixing normal saline and Group B patients were nebulised with 10 ml normal saline, 30 minutes prior to induction. Patients were taken to the operating table and all essential monitors were attached like NIBP, ECG and pulse oximetry. All the subjects were premedicated with an injection of midazolam (0.02mg/kg), glycopyrrolate (0.004mg/kg), and fentanyl(1mcg/kg).

Patients were pre-oxygenated with 10L/min. 100 percent oxygen for 3-5 minutes. Induction was done by an injection propofol (2.5mg/kg) and endotracheal intubation was facilitated by an I.V. injection succinylcholine (1mg/kg).

Maintenance of anaesthesia was done by isoflurane, and a non- depolarising muscle relaxant injection atracurium and intraoperative analgesia achieved with an injection of Paracetamol 15 mg/kg. Patients were mechanically ventilated to maintain $EtCO_2$ 35 to 40 mm of Hg. After intubation, all parameters were recorded at 0,1, 2, 3, 5,10 minutes. During surgery, the dose sparing effect of nebulised dexmedetomidine on the amount of propofol used was noted. The incidence of untoward effects of drugs like bradycardia (HR<55/min), hypotension (systolic BP<100 mm Hg), hypertension (systolic BP>150), laryngospasm, bronchospasm or desaturation etc. were noted and treated accordingly.

STATISTICAL ANALYSIS:

All data compiled, and statistical analysis was done using the Statistical Package for Social Sciences (SPSS version 29).

Normally distributed continuous variables were analysed using student t' test and categorical variables were analysed with 'CHI-SQUARE' test. All data were expressed either as mean ± SD (standard deviation) or number and percentage. Value of $p<0.05$ was considered significant.

RESULTS:

There was no statistically significant difference in the demographic variables between the two groups (Table-1).

Table 1: Demographic Variables

Variables	Group A(n=40)	Group B(n=40)
Age (years) (mean ±SD)	31.47±9.9	30.78±8.8
Sex (M/F)	19/21	22/18
Weight(kg) (mean ±SD)	63.65±9.94	63.88±8.86
ASA physical status(I/II)	18/22	17/23

The baseline heart rate was comparable in both the groups (Table No.2). It was 82.65±8.36 in group A and 80.82±5.47in group B (p value=0.12). After 30 min of giving nebulisation dexmedetomidine nebulization, heart rate reduced significantly in group A (79.77±7.72) and there were no such changes in group B (84.82±7.21). During laryngoscopy and intubation mean heart rate increased in both the groups but it increased more in group B (87.60±7.40) as compared to group A (83.35±8.02) (p value=0.001).

Baseline mean of MAP was comparable in both the group (Table 3). Changes in MAP when both groups were compared after 30 min and after induction, were statistically significant. During laryngoscopy and intubation MAP increased in both groups both it was increased more in group B (100.92±10.31) as compared to group A (95.40±8.18). Then MAP decreased significantly in group A at 10 min (mean 79.80±5.00) as compared to group B (85.52±7.81). So, the results shows that MAP was significantly higher in group B at all times as compared to group A (p value=<0.001).

Table-2 Heart rate comparison

Time	Heart rate (bpm)		p value
	Group A (Mean±SD)	Group B (Mean±SD)	
Baseline	82.65±8.36	80.82±5.47	0.12
30 min after study drug	79.17±7.72	84.82±7.21	0.0005
Just after induction	77.37±7.65	81.67±6.33	0.003
During laryngoscopy and intubation	83.35±8.02	87.60±7.40	0.008
1min	81.32±7.66	89.95±8.26	<0.001
2min	79.95±8.47	89.72±7.98	<0.001
3min	77.57±9.21	83.32±6.3	<0.001
5min	76.82±8.99	82.30±7.1	<0.001
10min	76.17±8.16	81.47±6.5	<0.001

Baseline systolic and diastolic BP in both groups were comparable and statistically insignificant. After taking nebulisation dexmedetomidine drug mean systolic BP drug mean DBP decreased significantly in group A at 30min (119.20±6.74) and (77.65±5.26) whereas in group B it was (124.02±6.75) and (81.95±6.53) at 30min respectively. During laryngoscopy and intubation increase in mean systolic BP and diastolic BP was lesser in group A as compared to group B and statistically significant. Mean systolic BP and diastolic BP further decreased at 1min, 2min till 10min after intubation whereas it increased in group B at 1min, 2min till 10min after laryngoscopy and intubation.

Table-3 Comparative analysis of Mean Arterial Pressure (MAP)

Time	MAP (Mean arterial Pressure) (mm of Hg)		P value
	Group A(Mean±SD)	Group B(Mean±SD)	
Baseline	92.77±4.48	93.85±4.45	0.142
30 min after study drug	89.60±5.05	92.92±6.58	0.006
Just after induction	87.32±3.30	91.17±7.37	0.001
During laryngoscopy and intubation	95.40±8.18	100.92±10.31	0.004
1min	94.40±9.45	101.70±11.09	<0.001
2min	91.90±9.15	98.15±7.38	<0.001
3min	90.72±7.74	95.65±6.05	<0.001
5min	86.75±5.41	90.75±6.50	<0.001
10min	79.80±5.00	85.52±7.81	<0.001

In Group A after the nebulisation the dose of propofol (90.75±7.64) requirement was low as compared with Group B (112.50±6.61). The dose sparing effect of nebulise dexmedetomidine on the amount of propofol used during general surgeries was lesser in Group A whereas it was increased in Group B during induction (p value <0.001).

Table-4 Intergroup comparison of amount of propofol

Time	Amount of propofol(mg)		p value
	Group A (Mean±SD)	Group B (Mean±SD)	
During induction	90.75±7.64	112.50±6.61	.001

DISCUSSION

In this study, we compared the effect of nebulised dexmedetomidine 2mcg/kg (Group A) in 10ml normal saline and nebulised normal saline 10ml (Group B), to observe the haemodynamic changes during laryngoscopy and endotracheal intubation.
Laryngoscopy and endotracheal intubation violate the patient's protective airway reflexes and this leads to hypertension and tachycardia when performed under "light" planes of general anaesthesia. The noxious airway stimuli lead to a cardio-vascular response initiated by proprioceptors responding to the supraglottic and the tracheal tissue irritation. (14)
In our study, the administration of dexmedetomidine through a nebulised route, a non-invasive method for

attenuation of intubation stress response making use of its rapid onset and good bioavailability through the large surface area of the mucosa. Further, nebulised drug administration avoids transient nasal irritation, cough, vocal cord irritation or laryngospasm over intranasal administration (15,16) and also transient adverse effects of bradycardia and hypotension as compared to its intravenous route.

Previous research by Shrivastava et al., Kumar et al. (8,10) demonstrated that nebulised dexmedetomidine was effective in blunting the haemodynamic response to laryngoscopy without any adverse effects. Nebulisation is an alternate method of drug delivery with higher bioavailability, greater ease of administration. (10,15,16)

The alpha-2(α-2A) receptor agonist dexmedetomidine considerably lowers the blood pressure spike during tracheal intubation compared to other drugs currently in use. (17,18) It works by activating the α-2A receptors in the locus coeruleus before the transmission of nerve impulses. (19) The effects include lowering anxiety, analgesia, sedation, hypnosis, sympatholytic, and antisecretory properties, without causing respiratory depression.

In our study, after giving study drug, the mean pulse rate decreased in Dexmedetomidine treated group and slightly increased in the control group, compared to baseline values and the change was statistically significant (p value=0.0006). The decrease in heart rate is due to a reduction in sympathetic outflow in group A. The anxiety was the main cause of increase in the heart rate in group B.

During laryngoscopy and intubation, the heart rate increased in both groups (81.05±7.56 versus 87.66±6.99 in group A and Group B, respectively), but increased more in group B as compared to group A. Thereafter, it settled down in the next 10 minutes in both groups.

Comparing the two groups, we observed that there was a significant difference in pulse rate between the two groups except at baseline when the values were comparable. When the mean changes in pulse rate were compared in both the groups, significant differences were found at all the points of study.
In Group A, we found lower values of systolic BP compared to baseline values at all points of observation after intake of the drug except for some rise at the time of laryngoscopy and intubation. This was in contrast to Group B, where there was a significant rise in blood pressure at all times of observations. Similar trends were observed in diastolic BP and mean BP.

Our observations were also supported in a study done by Nimmagadda R, Kumar R, Jonnavithula N et al (10) in 2020 on the role of evaluation of nebulised dexmedetomidine in blunting haemodynamic response to intubation: A prospective randomised study. Heart rate and systolic blood pressure were higher than baseline values in Group B during laryngoscopy and intubation. Thereafter, this increase persisted at all points of time until 10 min ($P < 0.0001$).

In contrast to our study, Gupta M, Rohilla R, Gupta P et al. (2) and Satyajeet Misra S, Behera BK et al (7) found a significant decrease in SBP, DBP, HR and MAP at 1, 5 and 10 min after laryngoscopy and intubation in group A as compared to the group B. The prevention of the stress response to laryngoscopy by dexmedetomidine resulted in a significant decrease in BP from the baseline. In several studies (20-22), dexmedetomidine given intravenously 10 minutes before induction was associated with adverse effects like bradycardia, hypotension, hypertension and respiratory depression. In this study, nebulised dexmedetomidine did not produce any adverse effect at any time point throughout the study period. This finding suggests that nebulised dexmedetomidine may be safer than IV dexmedetomidine in patients receiving beta-blockers or with a low basal heart rate.
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 1,2, 3, 5 and 10 minutes post-intubation. Mean arterial pressure (MAP) also showed a notable decline following nebulization, at 1,2,3,5 and 10 minutes post-intubation in group A compared to group B.

CONCLUSION

In our study, we concluded that use of nebulisation of dexmedetomidine 2mcg/kg, 30minutes before surgery, is a more effective method for diminishing the hemodynamic response to laryngoscopy and endotracheal intubation in general anaesthesia without the incidence of hypotension and bradycardia.
It is a new route of administration for reducing the hemodynamic response to laryngoscopy and intubation. Nebulised dexmedetomidine appears to be a promising drug to attenuate the hemodynamic response to laryngoscopy and intubation.

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