Evaluation of different doses of dexmedetomidine for awake fibreoptic nasotracheal intubation in patients undergoing oromaxillofacial and oral malignancy surgeries: A randomised, double-blind study

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ABSTRACT

Background and Aims: In patients undergoing cancer surgeries with anticipated difficult airway, awake fibreoptic nasotracheal intubation (AFONI) is critical for securing the airway. However, different doses of dexmedetomidine (DEX) are yet to be evaluated in these patients. Thus, we compared three doses of DEX for AFONI in patients undergoing oromaxillofacial and oral malignancy surgeries. Methods: In this randomised, double-blind study, 90 patients aged 18-60 years of either gender, with American Society of Anesthesiologists physical status I/II, and undergoing elective oromaxillofacial and oral malignancy surgeries were randomised to three groups: Group D1 (0.5 µg/kg DEX), Group D2 (1 µg/kg DEX), and Group D3 (1.5 µg/kg DEX). The primary outcome measure was the airway obstruction score. Secondary outcome measures were intubation scores (including vocal movement, coughing, and limb movements) and a 5-point fibreoptic intubation comfort score. Sedation was assessed using the Ramsay sedation score (RSS). One-way ANOVA and Chi-square test were used to assess the association between quantitative and qualitative variables, respectively. A P value of <0.05 was considered statistically significant. Results: The airway obstruction score was comparable between the groups (P = 0.78). Similarly, vocal movement (P = 0.15), coughing (P = 0.31), limb movement (P = 0.51), and 5-point fibreoptic intubation comfort score (P = 0.49) did not differ between the groups. The mean RSS was significantly greater in Group D3 than in Groups D1 and D2 (P = 0.001). Conclusions: In combination with topical spray and airway block, all three doses of DEX resulted in comparable airway obstruction scores and thus provided favourable conditions for AFONI.

Keywords: Airway obstruction, awake fibreoptic nasal intubation, dexmedetomidine, intubation, intubation scores, oral malignancy, oromaxillofacial surgery

INTRODUCTION

During airway management for general anaesthesia, 1.5%–20% of patients have a difficult airway,^[1] which may lead to hypoxemia, hypoventilation, aspiration, cerebral injury, or even death.^[2] Awake fibreoptic nasotracheal intubation (AFONI) is critical for securing the airway in these patients.^[3] Drugs such as propofol, midazolam, fentanyl, and remifentanil have been used to facilitate AFONI. However, these drugs result in adverse events (AEs), including respiratory failure, loss of airway control, and decline in cardiovascular function, particularly associated with higher doses, thereby escalating the chances of aspiration, hypoxaemia, bradycardia, and hypotension.^[4]

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Dexmedetomidine (DEX), a selective α_2 -adrenoceptor agonist, has analgesic-sparing and anxiolytic activity, produces sedation with easy arousability, and decreases salivation with minimal respiratory depression even at higher doses.^[4] In addition, DEX provides haemodynamic stability. All these desirable properties of DEX permit better visualisation through the fiberscope. For AFONI, available literature suggests the superiority of DEX over propofol, midazolam, fentanyl, and sufentanil.^[5-7]

In intensive care settings, standard-dose DEX (<1 μ g/kg/h) has been reported to produce more favourable results than high-dose DEX (>1 μ g/kg/h), while no difference is noted in AEs.^[8] For AFONI, high-dose DEX (1 μ g/kg as a bolus dose over 10 min, then 0.7 μ g/kg/h as a maintenance dose) resulted in a significantly better outcome relative to low-dose DEX (0.7 μ g/kg as a bolus dose over 10 min then 0.2 μ g/kg/h as a maintenance dose).^[9] However, different doses of DEX have not been evaluated in patients with difficult airway undergoing AFONI.

We hypothesised that high doses of DEX would provide more favourable intubation conditions. Thus, the study's primary objective was to compare three different sedation doses of DEX for AFONI. In addition, the three doses of DEX were compared regarding haemodynamic parameters, patient recall, satisfaction score, and AEs in patients with anticipated difficult airways undergoing AFONI.

METHODS

This single-centre, randomised, double-blind study was performed from November 2021 to October 2022 after approval by the Institutional Ethics Committee for Biomedical and Health Research (vide approval number DYP/IECBH/2021/120; dated 29 July 2021). The study was registered in the Clinical Trials Registry–India (CTRI/2021/11/037832; https://ctri.nic. in/). Written informed consent was obtained from the patients for participation in the study and the use of the patient data for research and educational purposes. The study was carried out according to the principles of the Declaration of Helsinki (2013) and good clinical practice.

Patients aged 18–60 years (both inclusive), of either gender, American Society of Anesthesiologists (ASA) physical status I/II, and undergoing elective oromaxillofacial and oral malignancy surgeries were included in the study. Patients with coagulopathies, nasal mass or adenoids, severe (renal, liver, pulmonary or heart) disorders, infection at the site of block, neuromuscular diseases, any known allergy or contraindication to DEX, receiving anticoagulants, pregnant women, and lack of cooperation or effective communication were excluded.

Each patient was subjected to a comprehensive preanaesthetic assessment involving complete history, general physical examination, and systemic examination a day before the surgical procedure. In addition, routine laboratory investigations were carried out before the procedure, including complete haemogram, prothrombin time, international normalised ratio, kidney function tests, random blood glucose, chest X-ray, and electrocardiogram. All the patients remained nil per oral for a minimum of 6 h before the procedure for solids and 2 h for clear liquids.

On the day of surgery, 10-15 min before transfer to the operation theatre, patients were nebulised with 4 mL of 4% lignocaine for 10-15 min. On arrival in the operation theatre, intravenous (IV) glycopyrrolate (0.2 mg) and ondansetron (4 mg) were administered. Simultaneously, routine ASA standard involving electrocardiogram, monitoring pulse oximeter, non-invasive blood pressure, and baseline recordings were noted. Oxymetazoline 0.05% nasal drops and lidocaine jelly were applied to the nostrils. Subsequently, on both nostrils, an adequate size of the nasal airway was used to check the patency of the nostrils. Oxygenation via nasal cannula with oxygen (O_2) flow of 2–4 L/min was administered.

For the study, 200 μ g DEX was diluted in 50 mL of normal saline. Each patient received a DEX IV for over 10 min. Randomisation was performed before entering the operating theatre using computer-generated random numbers concealed in sealed opaque envelopes, assigning the patients into three groups. The patient, the intubating anaesthesiologist, the anaesthesiologist administering the DEX, and the investigator were blinded to the dose of DEX. Finally, 90 patients were randomised into three groups: Group D1 (0.5 μ g/kg DEX), Group D2 (1 μ g/kg DEX), and Group D3 (1.5 μ g/kg DEX).

Following administration of DEX, airway blocks were performed. The bilateral superior laryngeal nerve was blocked with 2 mL of 2% lignocaine. Transtracheal spray was performed using a 22-G needle attached to a 5-mL syringe comprising normal saline passed across the cricothyroid membrane. After piercing the membrane, the free air aspiration was confirmed, and 4 mL of 2% lignocaine was injected.

A larger nostril was preferred for nasotracheal intubation, while the other nostril was used for O₂ insufflation. O₂ insufflation (4 L/min) was done with nasal prongs through the nostril not used for fibreoptic intubation. An experienced anaesthesiologist with more than ten years of experience performed the fibreoptic intubation, and another anaesthesiologist prepared a drug infusion. Nasal fibreoptic intubation was performed using an armoured tube (Helmier Reinforced endotracheal tube with snuggle fit; cuff size: 8.5 mm (male) and 7.5 mm (female); Helmier Private Limited, Mumbai, India). A research investigator reported anaesthesia data and postoperative visits. The endotracheal tube was confirmed to be in correct position by waveform capnograph and visualisation of carina via fibrescope; the cuff was inflated, and the tube was fixed.

The primary outcome measure was the airway obstruction score (1 = No, 2 = Relieved by neckextension, and 3 = requiring jaw thrust).^[10] In addition, the intubation score (Vocal movement: 1 = open, 2 = moving, 3 = closing, and 4 = closed;Coughing: 1 = none, 2 = slight, 3 = moderate, and4 = severe; Limb movements: none, slight, moderate, and severe; and Patient tolerance assessed by a 5-point fibreoptic intubation comfort score: 1 = no reaction, 2 = slight grimacing, 3 = heavy grimacing, 4 = verbal objection, and 5 = defensive movement of head and hands). Sedation was assessed with the Ramsay sedation score (RSS).^[11] The score was measured at the start of the airway manipulation. During fibreoptic intubation, hypoxic episodes (oxygen saturation $(SpO_{o}) < 90\%$ and bradycardia (heart rate (HR) <60 bpm) were recorded. Bradycardia was treated with atropine 0.6 mg IV. Hypoxia episode was treated with administration of 100% $\mathrm{O_{_2}}$ only, after which another attempt of AFONI was performed. Hypotension (>20% reduction in mean arterial pressure from baseline) was treated with IV fluids and/or phenylephrine 50 µg IV bolus, repeat dose after 5 min.

Postoperatively, the study observer followed up with the patients on the day after surgery and assessed their level of recall, satisfaction, and AEs (such as sore throat and hoarseness). The postoperative recall was assessed as present or absent, while the satisfaction score was evaluated as excellent = 1, good = 2, fair = 3, and poor = 4.

The sample size was calculated using GIGAcalculator (www.gigacalculator.com). Considering a power of 0.8, type-1 error of 0.05, and a minimum detectable difference of 20% in airway obstruction score between 0.5 μ g/kg and 1.5 μ g/kg DEX, the sample size was calculated to be 27 patients in each group. Considering the 10% drop-out rate, the required sample size was enhanced to 30 patients in each group. The data were analysed using Statistical Package for the Social Sciences (SPSS, IBM, Armonk, NY, USA) version 23.0 for Windows. Continuous variables [age, body mass index (BMI), RSS, HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), respiratory rate (RR), and SpO₂] and categorical variables (gender, ASA physical status, airway obstruction, vocal movement, coughing, limb movement, 5-point fibreoptic intubation comfort score, postoperative recall, satisfaction score, and adverse events) are represented as mean [standard deviation (SD)] and frequencies (percentages), respectively. One-way ANOVA, followed bv Bonferroni's multiple comparison test, was used to assess the association between quantitative continuous variables. The Chi-square test followed by pairwise comparison was used to determine the association between qualitative variables. A two-tailed probability value (P value) of <0.05 was considered statistically significant.

RESULTS

A total of 104 patients were assessed for eligibility, of which six refused to participate, four had coagulopathy, and two each had nasal mass and severe renal disorder [Figure 1]. In total, 90 patients fulfilling the eligibility criteria were included, randomised, into three study groups. The groups were comparable regarding mean age, gender, mean BMI, and ASA physical status (P > 0.05) [Table 1].

Table 1: Demographic characteristics of the study population						
Characteristics	Group D1 (<i>n</i> =30)	Group D2 (<i>n</i> =30)	Group D3 (<i>n</i> =30)			
Age, years	41.7 (10.3)	42.1 (11.1)	42.33 (9.1)			
Gender, Male/Female	18/12	16/14	18/12			
BMI, kg/m ²	25.6 (0.82)	26.2 (0.74)	25.8 (0.85)			
ASA physical status -I/II	22/8	21/9	22/8			

Data expressed as mean (standard deviation) or numbers. BMI=Body mass index, ASA=American Society of Anesthesiologists, *n*=Number of patients

The airway obstruction score was comparable between the groups (P = 0.78) [Table 2]. Similarly, secondary outcome measures, including vocal movement (P = 0.15), coughing (P = 0.31), limb movement (P = 0.51), and 5-point fibreoptic intubation comfort score (P = 0.49) were comparable between the groups. In addition, the mean RSS was significantly greater in Group D3 compared to groups D1 and D2 (P = 0.001).

The mean HR during infusion (10 min), post-block, during intubation, and post intubation was significantly lower in Group D3 compared to groups D1 and D2 (P = 0.001, 0.001, 0.01, and 0.001,



Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram. DEX = Dexmedetomidine, n = Number of patients

Variables	Group D1 (<i>n</i> =30)	Group D2 (<i>n</i> =30)	Group D3 (<i>n</i> =30)	Р
Airway obstruction				
None	28	26	23	0.78
Relieved by neck extension	1	3	4	
Requiring jaw thrust	1	1	3	
Vocal movement				
Open	10	14	16	0.15
Moving	11	11	13	
Closing	5	4	1	
Closed	4	1	0	
Coughing				
None	13	16	20	0.31
Slight	9	8	9	
Moderate	6	5	1	
Severe	2	1	0	
Limb movement				
None	16	18	23	0.51
Slight	8	7	6	
Moderate	5	4	1	
Severe	1	1	0	
5-point fibreoptic intubation comfort score				
No reaction	14	17	20	0.49
Slight grimacing	7	6	6	
Heavy grimacing	5	3	3	
Verbal objection	2	4	1	
Defensive movement of head and hands	2	0	0	
Ramsay Sedation Score	2.1 (0.2)	2.6 (0.4)	3.3 (0.5)	0.001

Data expressed as mean (standard deviation) or numbers, n=Number of patients

respectively) [Figure 2]. During intubation and post intubation, SBP, DBP, and RR dropped significantly in Group D3 compared to groups D1 and D2 (P = 0.001 and 0.01, 0.001 and 0.04, 0.001, and 0.001, respectively). The groups did not differ significantly in MBP and SpO₂ (P > 0.05).

The groups did not differ significantly in the postoperative recall, satisfaction score, and AEs (P > 0.05) [Table 3].

DISCUSSION

We observed that graded doses of DEX were comparable regarding the degree of airway obstruction. The doses also produced comparable vocal cord movement, coughing, limb movement, 5-point fibreoptic intubation comfort score, and postoperative characteristics, including postoperative recall, satisfaction score, and AEs. In addition, graded doses of DEX were comparable regarding MBP and SpO_2 ; however, 1.5 µg/kg DEX led to a significant decrease in HR (during infusion at 10 min, post block, during intubation, and post intubation) than 0.5 µg/kg and 1 µg/kg DEX. Similarly, 1.5 µg/kg DEX led to a significant decline in SBP, DBP, and RR compared to 0.5 µg/kg and 1 µg/kg DEX.

We observed that high doses of DEX resulted in favourable conditions for tracheal intubation concerning vocal cord movement, coughing, limb movements, and intubation comfort score. Higher doses required airway manoeuvres such as neck extension and jaw thrust to relieve airway obstruction. Though clinically significant, these findings were not statistically significant. Similarly, Dhasmana^[12] also reported that 25% and 20% of patients required airway manipulation with 1.5 μ g/kg and 1 μ g/kg DEX, respectively. Though not statistically significant, findings suggest that a higher dose of DEX increased



Figure 2: Comparison of vital parameters. Mean heart rate (a), systolic blood pressure (b), diastolic blood pressure (c), mean blood pressure (d), oxygen saturation (e) and respiratory rate (f), * = P < 0.05

Table 3: Comparison of postoperative characteristics						
Characteristics	Group D1 (<i>n</i> =30)	Group D2 (<i>n</i> =30)	Group D3 (<i>n</i> =30)	Р		
Postoperative recall- Present/Absent	13/17	7/23	6/24	0.16		
Satisfaction score -Excellent/Good/Fair/Poor	13/10/4/3	20/9/1/0	21/9/0/0	0.14		
Hoarseness/Sore throat	2/1	1/1	4/2	0.12/0.25		

Data expressed as numbers, n=Number of patients

the chances of airway obstruction. In addition, 1.5 µg/kg DEX, compared to 1 µg/kg DEX, led to favourable intubation conditions concerning various parameters evaluated in the present study; however, this was not statistically significant. In another study, Sharma et al.^[13] found no significant difference between 0.5 µg/kg DEX and 1 µg/kg DEX, though 1 µg/kg DEX produced good intubation conditions with various parameters. In addition, 2 µg/kg DEX is reported to have significantly higher airway obstruction than 1 μ g/kg DEX and 1 μ g/kg DEX and 1 μ g/kg fentanyl. Though the intubating conditions concerning vocal cord movement, cough, and intubation comfort score was clinically better with 2 μ g/kg DEX compared to the other two groups, it was not statistically significant.^[10] Thus, a higher dose of DEX provides favourable intubation conditions by decreasing cough and limb movements and opening the vocal cords but increases the risk of airway obstruction and desaturation.

In the present study, the RSS was significantly higher with 1.5 μ g/kg DEX than the other two groups. Other studies have used the observer's alertness/sedation score (OAA/S) assessment.^[12,13] Sharma et al.^[13] reported that 0.5 µg/kg DEX produced significantly higher OAA/S scores during stages II and III of intubation than 1 µg/kg DEX. In contrast, Dhasmana^[12] demonstrated that OAA/S was significantly higher with 1 µg/kg DEX than 1.5 µg/kg DEX. This variation could be attributed to the difference in the assessment method and time points at which sedation was assessed. Sharma et al.^[13] waited for the OAA/S score to reach <15-17before initiating the airway manipulation. In contrast, Dhasmana^[12] assessed OAA/S before starting the study medication and then every 2 min during airway manipulation. However, in the present study, RSS was measured at the start of the airway manipulation.

In the present study, 1.5 μ g/kg DEX significantly reduced HR during infusion (10 min), post-block, during intubation, and post intubation compared to 0.5 μ g/kg and 1 μ g/kg DEX. However, other studies have reported no significant difference in HR.^[10,12,13] Contrarily, other studies have demonstrated that 1 μ g/kg DEX reduces the HR significantly relative to 0.5 μ g/kg and 0.8 μ g/kg DEX.^[14,15] In the present study, 1.5 μ g/kg DEX significantly reduced SBP and DBP during intubation and post intubation periods compared to 0.5 μ g/kg and 1 μ g/kg DEX. Similarly, other studies have reported a significant decrease in SBP and DBP with high-dose relative to low-dose DEX.^[14,15] The post-synaptic activation of central $\alpha_2 A$ receptors leads to a sympatholytic effect, which may lead to hypotension and bradycardia.^[14] In addition, high-dose DEX could lead to bradycardia, hypotension, hypoxia, and atrial fibrillation.^[16] Further analysis revealed no significant difference between the groups regarding MBP. Other studies have reported similar findings.^[12,13]

Though 1.5 μ g/kg DEX provided superior intubation conditions, the satisfaction scores did not differ significantly compared to 0.5 μ g/kg and 1 μ g/kg DEX. Similarly, no significant difference in satisfaction scores with various doses of DEX has been reported by other studies.^[12,13] In the present study, the recall was greater with 0.5 μ g/kg DEX than with 1 and 1.5 μ g/kg DEX; though clinically significant, this was not statistically significant. Similarly, studies have reported higher recall with lower doses of DEX, though the difference was not statistically significant.^[12,13] The groups were comparable regarding AEs, including sore throat and hoarseness. Similar findings have been reported by other studies,^[12,13] thereby suggesting an excellent tolerability profile of DEX.

The study's strength includes evaluating various doses of DEX in patients with anticipated airway obstruction. However, the present study had certain limitations. First, subjective responses to various variables were assessed by the investigator, thus leading to variability in responses. Second, for the same level of sedation, each patient may tolerate pain experienced during AFONI, thereby introducing a bias. Third, adequate airway topicalisation and successful airway block improve intubation conditions and decrease sedation dose. Thus, correct methods of topicalisation and good knowledge of anatomical landmarks are confounding factors that interfere with intubation conditions. Further prospective randomised trials with large sample sizes are required to evaluate the role of DEX as a single agent for conscious sedation.

CONCLUSION

In patients with anticipated difficult airway, all three doses of DEX in combination with topical spray and airway block with local anaesthetics provided favourable intubation conditions for AFONI. Though intubation conditions were clinically better with $1.5 \ \mu g/kg$ DEX, but was statistical insignificant relative to $0.5 \ \mu g/kg$ and $1 \ \mu g/kg$ DEX.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Conflicts of interest

There are no conflicts of interest.

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