



Original Research Article

To evaluate the efficacy of dexmedetomidine infusion versus fentanyl infusion for sedation during awake fiberoptic intubation (AFOI)

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ABSTRACT

Background: Awake fiberoptic intubation (AFOI) is a great aid in an anticipated difficult airway like in maxillofacial surgeries. For providing patient's comfort and cooperation various drugs are used. In this study we evaluated efficacy of Dexmedetomidine and Fentanyl for sedation during AFOI.

Materials and Methods: It is randomized prospective double blind study. It was conducted on patients electively posted for maxillofacial surgery. 60 patients were randomly divided in two groups. Group D received Dexmedetomidine 1 µg/kg and Group F received Fentanyl 2 µg/kg over 10 minutes. Patients from both groups were prepared with intravenous glycopyrrolate 0.2mg and nebulization with 4% lidocaine 4ml. Nasal AFOI was performed with spray (10% lidocaine) as you go technique. Parameters analysed are intubation score by cough score and vocal cord movement, post intubation score, Ramsay sedation score, hemodynamics with incidence of desaturation. Also satisfaction score and time taken for intubation were compared in 2 groups.

Result: Cough score, vocal cord movement, postintubation score, Ramsay Sedation Score (RSS), patient satisfaction score were favourable in dexmedetomidine group without much difference in time taken for intubation in both groups. Minimum hemodynamic response (p value < 0.05) with less oxygen desaturation (p value < 0.05) is seen in dexmedetomidine group.

Conclusion: Dexmedetomidine appeared to offer better intubation condition, better tolerance to intubation with higher patient satisfaction and hemodynamic stability. Also it provides adequate sedation without desaturation making it more effective for AFOI than fentanyl.

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1. Introduction

Maxillofacial surgeries pose a great challenge to anesthesiologists, where mouth opening is restricted and safety & control of airways are uncertain. Awake fiberoptic intubation (AFOI) is an effective technique in an anticipated difficult airway. Both optimal intubating conditions and patient comfort are paramount while preparing the patient for AFOI. One challenge associated with this procedure is to provide adequate sedation while maintaining a patent airway and ensuring ventilation.¹

Sedatives should blunt sympathetic responses during bronchoscope insertion and subsequent airway irritation.

Many agents have been reported to achieve conscious sedation for intubation including benzodiazepines, opioids, ketamine, propofol, dexmedetomidine etc., which are either used alone or in combination.^{1,2} Propofol in conscious sedation dose has quick onset of action and rapid recovery with profound amnesia. Overdose of propofol may cause unconsciousness, respiratory depression, hypoxia and hypotension.³

Fentanyl is a synthetic opioid with phenylpiperidine derivative which obtunds hemodynamic response and reduces discomfort during the passage of bronchoscope through vocal cords which is beneficial for AFOI.⁴ It also provides sedation and analgesia, but has side effects like risk of respiratory depression, chest wall rigidity, nausea and vomiting.⁵ However, all of them are respiratory depressants.

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Though the combination of these drugs may provide better intubation conditions, but increasing risk of hypoxemia and aspiration.^{1,6,7} Hence there is a search of an ideal agent for conscious sedation, which will ensure a patent airway, adequate ventilation without respiratory depression, adequate cooperation, smooth intubating conditions and stable hemodynamics.⁸

Dexmedetomidine is a drug whose clinical profile makes it especially well suited for this task. It is a highly selective, centrally acting α_2 -agonist with a unique property of sedation and providing analgesia without affecting the patient's respiration.⁹ It has anxiolytic, amnesic, and moderate analgesic effects as well as antisialagogue effects.¹⁰ It provides a unique form of sedation in which patients appear to be sleepy involving activation of endogenous sleep promoting pathway through postsynaptic α_2 receptors in locus ceruleus but, if stimulated, are easily aroused, cooperative, and communicative.^{1,11} Dexmedetomidine has a respiratory-escape effect, even when administered in large doses,¹² Dexmedetomidine has a rapid onset and equally rapid redistribution half life with quick recovery, it attenuates cardiovascular responses to laryngoscopy and intubation, thereby reducing the need for perioperative opioid and could have an amnesic effect.⁸

In this study we are comparing efficacy of dexmedetomidine $1\mu\text{g/kg}$ versus fentanyl $2\mu\text{g/kg}$ for sedation during AFOI.

2. Materials and Methods

This is a randomized prospective double blind study. 60 patients posted for maxillofacial surgery would be selected for our study after informed and written consent in patients own language, The randomization is done using a computer generated randomization table and two groups are made;

Group-D (Dexmedetomidine) and

Group-F (Fentanyl) with thirty patients in each group.

2.1. Selection criteria

1. ASA I & II
2. Age 18 – 65 years
3. Patients electively posted maxillofacial surgery

2.2. Exclusion criteria

1. ASA III & IV
2. Pregnant or lactating female
3. Hepatic and renal diseases
4. Emergency surgeries
5. Bradycardia or AV block
6. Known case of coagulopathy and thrombocytopenia
7. Allergic to dexmedetomidine
8. Patients refusal
9. Uncooperative patient

Following protocol was observed for every patient.

Preoperative assessment: this was done in the preanesthetic visit and included

1. Detailed history
2. Thorough general and systemic examination
3. Airway examination
4. Review of investigations

After explaining the procedure and the nature of safety of the procedure, a written, valid, informed consent is obtained and adequate starvation confirmed.

2.3. Preparation of the patient

The preparation of patients in each group was standardized as much as possible. Patients were pre-medicated with tab alprazolam 0.5 mg night before surgery, tab ranitidine 150 mg and tab ondansetron 4 mg on the morning of surgery. Prior to surgery in preoperative area, an intravenous (IV) access was established, crystalloid infusion was started and IV glycopyrrolate 0.2 mg was administered after establishing monitoring system for electrocardiogram, non-invasive blood pressure and oxygen saturation (SpO_2) and baseline values were recorded and every 3 mins thereafter. Patency of nostrils was checked and two drops of xylometazoline (0.1%) was instilled in the nostril. Nasal oxygenation through the nasopharyngeal airway with 100% oxygen (2 L/min) was started 3 mins before the procedure. Lower airway was anesthetized by nebulisation with 4% lidocaine 4ml.

Study drugs were prepared in accordance to the patient's weight in kilograms and diluted in normal saline of 50 ml. Group D patients received a dose of dexmedetomidine $1\mu\text{g/kg}$ infused over 10 minutes and Group F received inj fentanyl $2\mu\text{g/kg}$ infusion over 10 minutes. The anesthesiologist preparing the study drug and the observer anesthesiologists were blinded to each other. Bronchoscopy was performed by a single anesthesiologist in all patients. The anesthesiologist who performed AFOI and who recorded data were all blinded to the group identities. Intubating conditions was graded by the consultant anesthesiologist who performed the fiberoptic intubation.

At the end of study drug infusion the anesthesiologist performing fiberoptic intubation used the Ramsay sedation score (RSS) to assess the level of sedation of the patient. If the RSS is less than 2, then rescue benzodiazepine inj midazolam 0.5 mg (upto 0.02mg/kg) is administered to achieve RSS 2 but those patients were excluded from the study.

Appropriate sized endotracheal tube (ETT) was put through nasal fiberoptic bronchoscopy. After confirming and securing ETT, general anesthesia was administered.

2.3.1. The primary outcome measurements

2.3.1.1. Intubation scores as assessed by Vocal cord movement. 1: Open, 2: Moving, 3: Closed

2.3.1.2. Cough score. 1: None, 2: Slight, 3: Moderate, 4: Severe

Lower the score, better the patient condition.

2.3.1.3. Post intubation score after placement of tube in the trachea. 1: Co-operative, 2: Minimal resistance, 3: Severe resistance

2.3.1.4. Ramsay sedation score. 1: Anxious, agitated or restless, 2: Cooperative, oriented and tranquil, 3: Response to command, 4: Asleep with brisk response to stimulus, 5: Asleep with sluggish response to stimulus; 6: Asleep with no response

2.3.2. Time taken for intubation

Hemodynamic variables [Heart rate, mean arterial pressure (MAP), oxygen saturation (SpO₂) and ECG] which were assessed at three different time intervals

1. Baseline
2. 2 mins after sedation
3. 2 minutes after endotracheal intubation

2.3.2.1. Patient satisfaction score postoperatively. 1: Excellent, 2: Good, 3: Fair, 4: Poor

2.4. Sample size calculation

Sample size calculated by using the proportion of cough score more than 2 in 2 treatment groups

Formula used to calculate the sample size is

$$n = \frac{(Z_{\alpha} + Z_{(1-\beta)})^2 \cdot (p_1q_1 + p_2q_2)}{d^2}$$

n = sample size

Z_{α} = Standard normal variate for $\alpha=0.05$ (95%CI) = 1.96

$Z_{1-\beta}$ = Standard normal variate for $1-\beta=0.80$ (80%) = 0.84

P1 = 25% Q1 = 100-P = 75%

P2 = 65% Q2 = 100-P = 35%

D = 35%

Substituting the values in above formula the minimum sample size per group is 26

2.5. Statistical analysis

All analyses are performed by SPSS version 25.0. Parametric data is compared by using Chi square test and non parametric data using Mann-Whitney test.

3. Results

Cough score ≤ 2 which was considered favorable intubation condition was achieved in 26 out of 30 patients in group D

but only 3 out of 30 patients in group F. The difference was statistically significant (p value < 0.05).

Vocal cords were open in 24 patients out of 30 patients in group D whereas in only 14 patients out of 30 patients in group F and the difference was found to be statistically significant (p value < 0.05).

Post intubation score 1 which is considered better was found in 22 patients out of 30 patients in group D and only 4 patients out of 30 patients in group F. This difference was also statistically significant (p value < 0.05).

At the end of study drug infusion, higher RSS was achieved in Group D (3.5 ± 0.63) than in Group F (2.27 ± 0.583). This difference was also statistically significant (p value < 0.05).

Higher SPO₂ saturation was maintained during the procedure in group D (SPO₂% 96.07 ± 1.741) than in group F (SPO₂% 92.43 ± 2.402). The difference was found to be statistically significant (p value < 0.05).

Patient satisfaction as assessed by four point verbal rating scale was found to be more with group D (50% patients rated excellent) as compared with group F (15% patients rated excellent). and difference was found to be statistically significant (p value < 0.05)

The time taken for intubation was found to be slightly more for Group F (9.47 ± 1.38 min) than Group D (9.33 ± 1.15 min). However the difference was not statistically significant.

There was significant increase in heart rate after intubation in Group F (Baseline 79.2 ± 12.50 beats/minute to stage3: 94.67 ± 14.09 beats/minute) whereas there is no significant increase in heart rate after intubation in group D (Baseline 78.40 ± 12.48 beats/minute to stage3: 72.10 ± 9.30 beats/minute). Rather heart rate decreased after intubation but this was not significant and no patient had developed bradycardia which required administration of Atropine.

Baseline MAP, HR, and SPO₂ were comparable between the two groups. There was a rise in MAP after intubation as compared with baseline values in both groups. Increase in MAP in group D was minimal (Baseline: 92.43 ± 7.87 mm of Hg to stage3: 95.16 ± 8.21 mm of Hg) and was found to be non significant. Whereas rise in MAP in Group F was statistically significant (Baseline: 89.86 ± 6.45 mm of Hg to Stage 3: 104.31 ± 6.42 mm of Hg, p value < 0.05).

4. Discussion

AFOI is the preferred method of securing airway in conditions like maxillofacial surgeries where mouth opening is restricted.¹ With adequate sedation analgesia and amnesia AFOI can be made tolerable to patient with optimizing outcome.¹³ Various drugs either used alone or in combination with other drugs are used for achieving this conscious sedation.

In this study we compared dexmedetomidine $1 \mu\text{g/kg}$ (Group D) and fentanyl $2 \mu\text{g/kg}$ (Group F) for AFOI in view

Table 1: Demographic Parameters

Parameters	Mean± SD		P value
	Group D	Group F	
Age (years)	41.97±12.61	39.57±12.92	Not significant
Weight (kilogram)	64.77±10.45	64.10±10.30	Not significant
ASA (I/II)	17/13	18/12	Not significant

Demographic characteristics like age, weight, ASA grade were comparable in both groups.

Table 2: Non Hemodynamic Parameters

Parameters	Mean ± SD		P value
	Group D	Group F	
Cough score ≤ 2	26 patients	3 patients	< 0.05
Vocal cord (opened)	24 patients	14 patients	<0.05
Postintubation score 1	22 patients	4 patients	<0.05
Ramsay Sedation Score (RSS)	3.5±0.63	2.27±0.583	<0.05
SPO2 (%)	96.07±1.741	92.43±2.42	<0.05
Patient Satisfaction score (Excellent)	15 patients	5 patients	<0.05
Time taken for intubation (minutes)	9.33±1.15	9.47±1.38	not significant

Table 3: Hemodynamic Parameters

Parameters	Mean ± SD		P value
	Group D	Group F	
Baseline Pulse rate (beats/minute)	78.40±12.48	79.2±12.50	Not significant
Post intubation (Stage 3) pulse rate (beats/minute)	72.10±9.30	94.67±14.09	
P value	Not significant	< 0.05	
Baseline Mean Arterial Pressure (MAP) (mm of Hg)	92.43±7.87	89.86±6.45	Not significant
Postintubatin (stage 3) MAP (mm of Hg)	95.16±8.21	104.31±6.42	
P value	Non significant	<0.05	

of conscious sedation, perioperative hemodynamics, airway control, patient satisfaction and side effects.

In literature, studies by Chu et al.,¹⁴ Kumkum et al.,¹⁵ Mondal Ghosh et al.¹ and Hesham Fathy Soliman et al.⁶ reported better intubation conditions with dexmedetomidine at 1µg/kg. In our study also intubation condition as assessed by cough score and vocal cord movement was better with dexmedetomidine at dose 1µg/kg as compared to fentanyl at dose 2µg/kg with statistical significance which correlates with available literature. The difference in time taken for intubation in both the groups was not significant which correlates with the available literature.^{6,15}

Studies by Chu et al.,¹⁴ Mondal Ghosh et al.¹ and Kolli et al.³ found to have better postintubation scores with dexmedetomidine when compared with other sedative agents. In our study we also found that post intubation score was better with dexmedetomidine than fentanyl.

Sedation induced by dexmedetomidine involves activation of endogenous sleep promoting pathway through the post synaptic α-2 receptors in the locus ceruleus which modulates wakefulness. Thus dexmedetomidine provides unique conscious sedation wherein patient is sedated but is easily arousable and also provides analgesia

with minimal respiratory depression.⁹ Whereas Fentanyl provides mild sedation, analgesia with risk of respiratory centre depression, chest wall rigidity, nausea and vomiting. Hesham Fathy Soliman et al.⁶ found in their study that higher RSS was better achieved with Dexmedetomidine as compared to fentanyl-propofol. In our study we also found that dexmedetomidine group achieved higher RSS than fentanyl group which correlates with available literature. Also the dexmedetomidine group maintained significantly higher SPO2 saturation during procedure as compared to fentanyl group which also correlates with the literature.⁷

In our study MAP increased in both groups after intubation but increase in MAP was minimal and not significant in Dexmedetomidine group whereas increase in MAP was significant in Fentanyl group. This finding is partially in concurrence with study by Hesham Fathy Soliman et al.⁶ who have found hypertension in propofol-fentanyl group. But hypotension as seen in Dexmedetomidine in their study and one other study by Kollim S Chalam et al.³ is not observed in our study may be because we only gave bolus dose of 1µg/kg and not the continuous infusion of dexmedetomidine.

Dexmedetomidine causes reduction in centrally mediated sympathetic outflow and augmentation vagal activity which is usually expected to decrease heart rate. In studies by Hesham Fathy Soliman et al.⁶ and Nitesh Goel et al.,¹⁶ they found that occurrence of bradycardia more with Dexmedetomidine. In our study also we found decrease in heart rate after intubation in Dexmedetomidine group but it was not significant statistically and no patient in our study developed bradycardia. There is study by Peden et al.¹⁷ which suggested administration of glycopyrrolate for prevention of bradycardia and sinus arrest in young volunteers following dexmedetomidine. In our study we have given glycopyrrolate as an antisialogogue that might have been a reason for no event of bradycardia. In fentanyl group we observed that heart rate was significantly increased after intubation. This is in concurrence with study by Hesham Fathy Soliman et al.⁶ who reported significant tachycardia with propofol-fentanyl.

So in our study dexmedetomidine is found to be more haemodynamically stable than fentanyl.

Studies by Chu et al.¹⁴ and Hesham Fathy Soliman et al.⁶ reported better patient satisfaction with dexmedetomidine. Our findings also correlates showing significantly better patient satisfaction with Dexmedetomidine (50% excellent) as compared to Fentanyl (15% excellent).

5. Conclusion

Dexmedetomidine appeared to offer better intubation condition, better tolerance to intubation with higher patient satisfaction and hemodynamic stability. Also it provides adequate sedation without desaturation making it more effective for AFOI than fentanyl.

6. Source of Funding

None.

7. Conflict of Interest

None.

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