A prospective randomized double blind study to compare the effects of dexmedetomidine and fentanyl on intubating conditions during awake fiberoptic bronchoscopy guided intubation

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Abstract

Introduction: Various drugs have been used for sedation to provide adequate intubating conditions during awake fiberoptic intubation (AFOI) but these drugs may cause excessive sedation followed by respiratory depression which is undesirable in these patients. So this study was planned with aim to compare dexmedetomidine with fentanyl for conscious sedation during AFOI in adult patients posted for various elective surgical procedures under general anaesthesia.

Materials and Methods: Sixty adult patients were randomly allocated into two groups with 30 patients each. After pre operative evaluation and informed consent, patients were given pre anaesthetic medication followed by airway nerve blocks. Group A (n=30); Dexmedetomidine Group received intravenous (IV) dexmedetomidine 1.5 μ g/kg diluted in 100 ml normal saline (NS) over 10 min and Group B (n=30); Fentanyl Group received IV fentanyl 2 μ g/kg diluted in 100 ml NS over 10 min. After achieving adequate sedation (RSS \geq 2), awake fiberoptic bronchoscopy and intubation was done. Intubating conditions, oxygen desaturation caused, tolerance to intubation and haemodynamic changes along with adverse effects were observed and noted in both groups.

Results: Cough score and intubation comfort scores were significantly better in Group A when compared to Group B. (P < 0.05) The patients in Group A showed less oxygen desaturation as compared to Group B that was statistically significant. (P < 0.05) Post intubation score was also found to be significantly better in Group A. (P < 0.05) However, no significant haemodynamic changes and adverse effects were noted in patients of Group A (P > 0.05).

Conclusion: Dexmedetomidine (1.5 μ g/kg) is preferable over fentanyl (2 μ g/kg) for conscious sedation during AFOI as it provides more favourable intubating conditions with minimal haemodynamic changes and adverse effects.

Keywords: Awake fiberoptic intubation, Conscious sedation, Dexmedetomidine, Intubating conditions, Fentanyl, Oxygen desaturation.

Introduction

Flexible fiberoptic guided endotracheal intubation in awake patients is the mainstay of anticipated difficult airway management where conventional laryngoscopy becomes difficult due to either inadequate mouth opening or inability to extend the neck. During awake fiberoptic intubation (AFOI), spontaneous breathing and airway muscle tone is maintained which reduces the risk of hypoxia in failed intubation scenario and allows time for using other modalities to secure the airway.¹

For performing a smooth AFOI, the patient should be cooperative with spontaneous breathing and showing minimal airway reflexes during insertion of fiberoptic scope and endotracheal tube which can be achieved with adequate sedation. Various drugs have been used for this purpose which include propofol, midazolam, ketamine, fentanyl, alfentanil, and remifentanil. These drugs produce anxiolysis and sedation along with analgesia but most of these drugs lead to respiratory depression which is undesirable during this procedure. So we require an ideal drug which should provide anxiolysis along with conscious sedation, ensures patient's cooperation, provides smooth intubating conditions, maintains haemodynamic stability but at the same time also maintains a patent airway with spontaneous respiration, prevents respiratory depression and thus avoids hypoxaemia.^{1,2}

Dexmedetomidine, a selective α -2 adrenoceptor agonist, provides conscious sedation and analgesia with minimal respiratory depression. It also facilitates decrease in salivary secretions with anxiolytic and amnesic properties along with maintaining stable haemodynamics, which are desirable properties of a drug for AFOI and makes it an ideal and suitable drug to be used for this procedure.³⁻¹⁰ Fentanyl, a strong agonist at the µ-opioid receptor, is a synthetic opioid analgesic (75 to 125 times more potent than morphine) with a rapid onset and short duration of action. It also decreases haemodynamic response and blunts the airway reflexes to bronchoscopy and endotracheal intubation but may be associated with respiratory depression and postoperative nausea & vomiting (PONV).2,11

A very few studies have compared dexmedetomidine and fentanyl used for conscious sedation during awake fiberoptic intubation. So we hypothesized that dexmedetomidine in a dose of 1.5 μ g/kg would be more effective in terms of providing better intubating conditions, less oxygen desaturation along with minimal haemodynamic changes and adverse effects. In this prospective randomized study, we planned to compare IV dexmedetomidine (1.5 μ g/kg) with IV fentanyl (2 μ g/kg) for conscious sedation during AFOI in patients posted for various elective surgical procedures under general anaesthesia.

Materials and Methods

This prospective randomized double blinded study was conducted on sixty adult patients aged 18 to 60 years, of either sex with American Society of Anesthesiologists (ASA) physical status, class 1 and 2, posted for various elective surgical procedures under general anaesthesia after local institutional ethical committee approval. Patients with a history of allergy to any of the study drugs, epileptic patients, history of bronchial asthma, difficult airway, contraindication for nasal intubation, patients with bradyarrhythmias, haemodynamic instability, decreased compliance of the lungs, any hepatic and renal disease and deranged coagulation profile were excluded. (Fig. 1)

All the study participants were randomly allocated into two groups with 30 patients in each using computer generated random number tables. Group A (n=30); Dexmedetomidine Group received IV dexmedetomidine 1.5 μ g/kg diluted in 100 ml normal saline over a period of 10 min while Group B (n=30); Fentanyl Group received IV fentanyl 2 μ g/kg diluted in 100 ml normal saline over a period of 10 min.

A thorough pre-anaesthetic evaluation which included relevant patient history, pre anaesthetic examination and routine investigations, was done on the day before surgery. All patients were kept nil per oral for a minimum duration of 8 hours before surgery and a written informed consent was taken from all patients. Patients were explained about the procedure (AFOI) before giving premedication as ranitidine 50 mg iv and ondansetron 4 mg iv 15 min before surgery.

After arrival of the patient in operation theatre, ringer lactate solution was started through the secured iv line. The multipara monitor was attached thereafter to record baseline heart rate (HR), non invasive blood pressure (NIBP), mean arterial pressure (MAP), oxygen saturation (SpO₂) and electrocardiogram (ECG) of all the patients. The study drug infusions were prepared by a blinded anaesthesiologist who was not going to either perform or observe the procedure and the calculated doses of study drugs were further diluted in 100 ml normal saline to make equal volumes for double blinding. The other anaesthesiologists who performed and observed the procedure, both were blinded to the study drug used. The whole procedure of AFOI was performed by a single anaesthesiologist in all patients.

Glycopyrrolate 0.004 mg/kg iv was given thereafter as an antisialagogue. Both the nostrils were checked for their patency and the nostril with a better patency was preferred for the procedure. Xylometazoline nasal drops (0.1%) were instilled in both nostrils and a water soluble lignocaine jelly (2%) was used to lubricate the fiberoptic scope and the endotracheal tube.Superior larvngeal nerve block (bilateral) was performed using lignocaine (2%) 1.5 ml on both sides and transtracheal instillation of lignocaine (2%) 2 ml was done for sensory blockade of recurrent laryngeal nerve. Lignocaine spray (10%) was used for topical anaesthesia (2 puffs, 20 mg) of the posterior tongue and hypopharynx to avoid gag reflex while introducing fiberoptic bronchoscope. Dexmedetomidine $(1.5 \ \mu g/kg \text{ over } 10 \text{ min})$ or fentanyl $(2 \ \mu g/kg \text{ over } 10 \text{ min})$ min) infusions were then started through another iv line. During the mean time, 5.0-mm flexible fiberoptic bronchoscope (Model no. 11301BN1; Karl Storz GmbH & Co. KG, Tuttlingen, Germany) was loaded with an appropriate sized flexometallic cuffed endotracheal tube (6.0- 6.5 mm for females and 6.5- 7.0 mm for males) after proper lubrication of the fiberscope. Ramsay sedation score⁶ (RSS) was used to assess the desired level of sedation (Score ≥ 2) just after completion of the study drug infusion. Whenever the RSS ≥ 2 achieved, AFOI was performed via standard technique through nasal route and the endotracheal tube of appropriate size was secured thereafter. General anaesthesia was induced after confirming the proper placement of the endotracheal tube using capnography and surgery was allowed to proceed thereafter. The various study parameters were observed and noted throughout the procedure.

The primary outcome measure was to assess the incidence of oxygen desaturation (SpO₂ values \leq 94%) caused during AFOI. The secondary outcome measures were to assess the patient comfort using Cough score and Intubation comfort score, tolerance to intubation using Post intubation score, haemodynamic changes and adverse effects or complications, if any.¹² The haemodynamic parameters (HR and MAP) were noted at baseline and just after intubation while various adverse effects observed and noted were hypotension (defined as decrease in MAP >20% from baseline values), bradycardia (defined as decrease in HR < 60 beats/min), sustained oxygen desaturation (SpO₂ \leq 94% for >10 s duration while performing AFOI)), pruritus and postoperative nausea & vomiting (PONV).

Cough score ≤ 2 , Intubation comfort score ≤ 2 , lowest recorded SpO₂ value > 94% and Post intubation score = 1 were considered as favourable conditions during AFOI. (Table 1) Hypotension was managed either with fluids and/or mephentermine 6 mg iv bolus, repeated if no response. Inj. atropine 0.6 mg iv bolus was given to treat bradycardia while sustained oxygen desaturation (SpO₂ \leq 94% for >10 s) was managed with oxygen inhalation via nasal cannula. (O₂ @ 4L/min).

Statistical Analysis

A sample size of 60 patients was calculated with a power of 0.9 and type one error of 0.05 to demonstrate a difference of at least 20% in various intubation scores during AFOI which was based on the standard sample size calculation methods and results obtained from previous studies.¹² Numerical data are expressed as mean with a standard deviation and categorical data as numbers and percentages. Categorical data between two groups were compared using Chi-square/ Fischer's test. Student's unpaired and paired t-test were used to analyze the quantitative parametric data (numerical data) while Mann-Whitney U test was used to compare the non-parametric data. Statistical analysis was done using the statistical package for the social sciences (SPSS) version 16.0 (SPSS Inc. Chicago, Illinois, USA) P value < 0.05 was considered statistically significant.

Results

The various demographic parameters like mean age, sex, weight distribution and ASA physical status were comparable in two groups. (P > 0.05), (Table 2)

When the two groups were compared with respect to cough score, in Group A, the number of patients with a favourable cough score (cough score ≤ 2) were significantly more (24 out of 30 in Group A compared to 16 out of 30 in Group B) as compared to Group B. (P = 0.0285), (Table 3), (Fig. 3)

Similarly, we have also used Intubation comfort score to assess patient comfort during AFOI. On comparing the two groups, in Group A, the number of patients with a favourable intubation comfort score (intubation comfort score ≤ 2) were significantly more (21 out of 30 in Group A compared to 13 out of 30 in Group B) as compared to Group B. (P = 0.037), (Table 3), (Fig. 3)

In group A, only 10 patients recorded lowest SpO₂ values $\leq 94\%$ while 20 patients maintained the SpO₂ values > 94% during the whole procedure which was a favourable outcome for the patients in dexmedetomidine group. However, in Group B, 18 patients had lowest recorded SpO₂ values $\leq 94\%$ while only 12 patients maintained SpO₂ values > 94%. So in

Group A, significantly less number of patients showed SpO₂ values \leq 94%. (P = 0.038), (Fig. 2)

On comparing the two groups for post intubation score, in Group A, favourable post intubation score (post intubation score = 1) was observed in significantly more number of patients (27 out of 30 in Group A compared to 18 out of 30 in Group B) when compared to Group B. (P = 0.017), (Table 3), (Fig. 3)

Baseline SpO₂ values were noted and compared in both groups. The mean baseline SPO₂ in Group A and Group B were 98.33 ± 1.028 and 98.53 ± 1.008 , respectively and was found to be statistically insignificant between two groups. (P = 0.449)

In Group A, the mean HR just after intubation was 77.20 ± 11.12 bpm which was less than mean baseline HR but was statistically insignificant, (P = 0.9748) while in Group B, the mean HR just after intubation was 80.67 ± 11.78 bpm which was more than mean baseline HR which was statistically significant but clinically acceptable.(P = 0.010)

Similarly In Group A, the mean MAP just after intubation was 92.83 \pm 12.20 which was more than mean baseline MAP. (P = 0.717) and in Group B, the mean MAP just after intubation was 95.97 \pm 11.23 which was significantly more than the mean baseline MAP. (P = 0.007) but both HR and MAP were found to be in clinically acceptable range in two groups. (Table 4), (Fig. 4)

As far as adverse effects during our study are concerned, in Group A, no patient required oxygen inhalation by nasal cannula but in Group B, 8 patients developed sustained oxygen desaturation (SpO₂ \leq 94% for > 10 sec) so required oxygen inhalation by nasal cannula. In Group A, 2 patients developed bradycardia (HR < 60/ min) whereas only 1 patient developed bradycardia in Group B at the completion of drug infusions. In group A, 1 patient developed hypotension (decrease in MAP by > 20% from baseline values), whereas no patient in Group B developed hypotension however these adverse effects were managed effectively. Other adverse effects like postoperative nausea & vomiting and pruritus were not observed in any of the patients in both groups. (Table 5)

Scores	Cough score	Intubation	Post intubation score	
		Comfort score		
Score 1	No cough	No reaction	Cooperative	
	Slight cough (no more than two cough in	Grimacing	Minimal resistance	
Score 2	sequence)	_		
Score 3	Moderate cough (3-5 cough in sequence)	Verbal objection	Severe resistance	
Score 4	Severe cough (>5 cough in sequence)	Defensive movements of		
		head and hands		

 Table 1: Various scores used to assess patient comfort and tolerance during AFOI

Table 2: Demographic profile in two groups

Demographic parameters	Group A (n=30)	Group B (n=30)	P value
Age (yr)	43.23 ± 10.83	41.13 ± 10.05	0.6850
Sex (M / F) (n)	12 / 18	10 / 20	0.8663
Weight (kg)	59.67 ± 8.895	57.67 ± 8.066	0.3654
ASA Physical status	27 / 3	26 / 4	0.8336
(I / II)(n)			

*Group A- Dexmedetomidine group, Group B - Fentanyl group

 \pm Data expressed as Mean (Standard deviation) and numbers (n)

Table 3: Patients with favourable conditions for AFOI in two groups

Favourable Conditions	Group A (n=30)		Group B (n=30)		P value
	n	%	n	%	
Cough score ≤ 2	24	80	16	53.33	0.0285
Intubation comfort score ≤ 2	21	70	13	40.33	0.0371
$SPO_2 > 94\%$	20	66.66	12	40	0.0384
Post intubation score $= 1$	27	90	18	60	0.0171

*Group A- Dexmedetomidine group; Group B- Fentanyl group.

 \pm Data are expressed as numbers and percentage

Table 4: Comparison of mean HR and MAP in two groups

Haemodynamic parameters	Group A (n=30)	Group B (n=30)
Heart rate baseline (bpm)	77.23 ± 11.30	77.73 ± 11.08
Heart rate just after intubation (bpm)	77.20 ± 11.12	80.67 ± 11.78
P value	0.9748	0.0101
MAP baseline (mm Hg)	92.37 ± 8.985	92.27 ± 8.085
MAP just after intubation (mmHg)	92.83 ± 12.20	95.97 ± 11.23
P value	0.7177	0.0072

*Group A - Dexmedetomidine group, Group B - Fentanyl group.

 \pm Data are expressed as mean (standard deviation)

Table 5: Incidence of adverse effects in two groups

Adverse effects	Group A (n=30)		Group B (n=30)	
	n	%	n	%
Sustained oxygen desaturation requiring O_2 (SPO ₂ \leq 95% for >10sec)	0	0	8	26.66
Bradycardia (HR <60/min)	2	6.66	1	3.33
Hypotension (reduction in MAP by > 20% from baseline)	1	3.33	0	0
Postoperative nausea and vomiting (PONV)	0	0	0	0
Pruritus	0	0	0	0

*Group A - Dexmedetomidine group, Group B - Fentanyl group.

 \pm Data are expressed as numbers and percentage

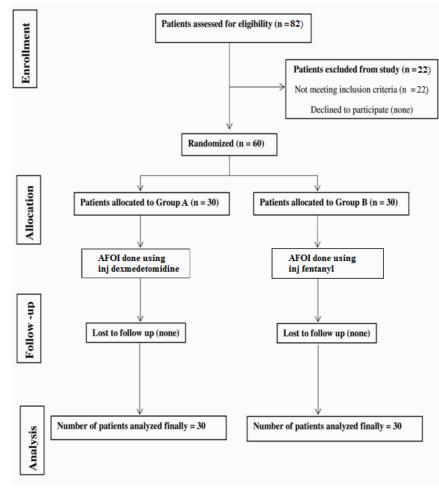


Fig. 1: Consort flow diagram

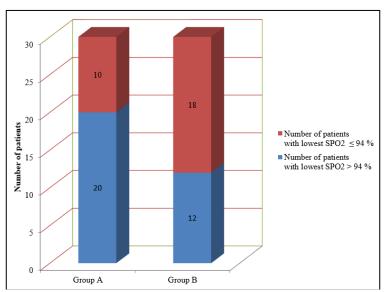


Fig. 2: Patients with lowest SPO₂ values observed in two groups *Group A - Dexmedetomidine group, Group B - Fentanyl group.

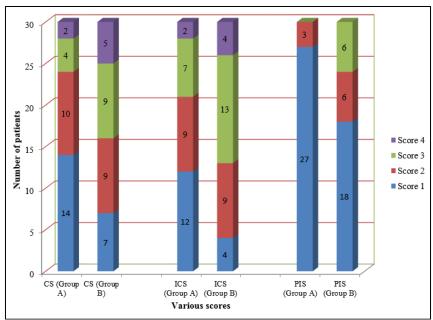


Fig. 3: Comparison of various scores in two groups *Group A - Dexmedetomidine group, Group B - Fentanyl group ± CS - Cough score; ICS - Intubation comfort score; PIS - Post intubation score

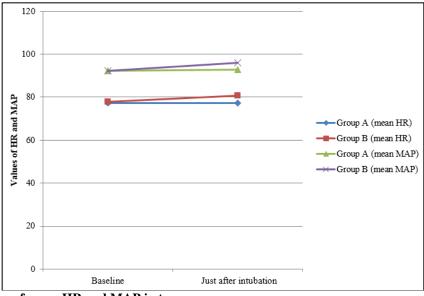


Fig. 4: Comparison of mean HR and MAP in two groups *Group A - Dexmedetomidine group, Group B - Fentanyl group. ± HR – Heart rate; MAP – Mean arterial pressure

Discussion

Awake intubation means securing endotracheal tube in correct position without inducing general anaesthesia and without using any muscle relaxant. So to reduce the likelihood of failure in securing airway and subsequent oxygen desaturation after induction and relaxation of the patient, the concept of securing airway in an awake patient came into practice. Although it is termed awake, the patient is adequately sedated to allay the anxiety, providing patient comfort and maintain stable haemodynamics during the procedure.^{1,2,9,10} The

problems commonly faced with introduction of fiberoptic scope and endotracheal tube in an awake patient are coughing, verbal objection, defensive movements of hand and poor tolerance of tube once placed endotracheally which requires adequate sedation before performing this procedure. So although securing the airway is the main objective, creating good intubating conditions is equally important for successful awake fiberoptic intubation. Along with the drugs used, good intubation conditions also depend on successful application of nerve blocks which depress the airway reflexes but sedation, anxiolysis, haemodynamic stability and amnesia during the procedure depend solely on the drugs being administered which are desirable characteristics of a drug to be used.^{2,14,15}

Another major concern is oxygen desaturation during the procedure and minimal oxygen desaturation during fiberoptic bronchoscopy allows adequate time for the procedure. If desaturation occurs, attention is diverted from performing the procedure towards managing the oxygen saturation.² So it is in this context that we conducted our study as a part of ongoing search for an ideal agent for sedation during awake fiberoptic bronchoscope guided intubation.

In our study we have used nerve blocks (and not nebulization or spray as you go technique) for blunting the airway reflexes as this technique results in better intubating conditions, lesser cough and more tolerance by the patient as reported in studies done by Chatrath et al and Gupta B et al.¹³⁻¹⁵ We have used dexmedetomidine in a dose of 1.5 µg/kg as dexmedetomidine was associated with better sedation and tolerance to intubation with more favourable intubation scores without significant oxygen desaturation as reported by Dhasmana et al (who also used the similar dose) which favours our use of dexmedetomidine at this particular dose in our study.¹⁶

The our study results showed that the number of patients with a favourable Cough score, Intubation comfort score and Post intubation score, were significantly more in Group A (dexmedetomidine group). Our findings with regard to cough score are similar to Tsai et al¹⁷ and Mondal et al¹² who also favourable cough obtained scores with dexmedetomidine.¹⁹ Although Tsai et al and Mondal et al used dexmedetomidine in a dose of 1 µg/kg, Dhasmana et al obtained more favourable cough scores using even a higher dose of dexmedetomidine (1.5 µg/kg). Our findings regarding intubation comfort score are similar to Bergese et al,18 Agrawal et al20 and Mondal¹² et al who obtained a favourable intubation comfort score with dexmedetomidine $(1 \mu g/kg)$.

Dexmedetomidine provides dose-dependent increase in anxiolysis and sedation, exerts analgesic effects and has a opioid sparing action. The intubating conditions are further enhanced as dexmedetomidine facilitates decrease in saliva production and airway secretions. These properties of dexmedetomidine are responsible for a favourable cough score and intubation comfort score and makes it an ideal agent for sedation during AFOI.^{2,4,5,12,16}

Our results regarding Post intubation score are similar to those obtained by Tsai et al, Chu et al,²² Agrawal et al and Mondal et al who reported that tolerance to intubation is much more with studies.12,17,22 dexmedetomidine in their The dexmedetomidine's property of providing conscious sedation and adequate analgesia was thought to be responsible for better tolerance during intubation where

patients were sedated but were easily arousable and cooperative.²

In Group Α (dexmedetomidine group), significantly less number of patients showed SpO₂ values \leq 94%. Similar results have been obtained in studies by Demiraran et al,¹⁹ Tsai et al,¹⁷ Ryu et al²¹ and Mondal et al¹² where less oxygen desaturation was seen with dexmedetomidine. In a study by Dhasmana et al,¹⁶ who compared two different doses of dexmedetomidine, 1 µg/kg and 1.5 µg/kg, none of the patients in both groups showed clinically significant oxygen desaturation requiring face mask ventilation, which concurs with our study as we had used dexmedetomidine in a dose of 1.5 µg/kg with similar results. This advantage of lesser oxygen desaturation in patients of Group A is explained by properties of dexmedetomidine which have sedative, anxiolytic, hypnotic and analgesic effects without causing any clinically relevant respiratory depression even at a dose of 1.5 µg/kg. The dexmedetomidine provides a unique form of sedation in which patients remained arousable (conscious sedation) even at deeper levels of sedation which desirable feature is of а dexmedetomidine.^{2,3,12,16,23-26}

No significant difference in HR and MAP was noted in dexmedetomidine group but in fentanyl group there was significant, though clinically acceptable increase was noted just after intubation which favours the dexmedetomidine's property of maintaining stable Although haemodynamics. bradycardia and hypotension did not occur (except transiently in 3 cases) at the dose which we have used (1.5 μ g/kg), dexmedetomidine decreases heart rate and blood pressure usually in a dose dependent manner. This property is of considerable benefit in haemodynamically unstable patients, where it improves haemodynamic stability in the perioperative period. Dexmedetomidine also prevents the sympathetic response associated with intubation.2,3,12,16

As far as limitations of our study are concerned, our study included the patients with all airway grades so results cannot be simply drawn on the basis of this study only as fiberoptic intubation is usually indicated in cases with difficult airway, so further studies are required for more accurate results. Although airway blocks were performed by the same anaesthesiologist in all patients but the effectiveness of the block may vary from patient to patient. The sample size appears to be small since various parameters were studied which may requires larger sample size for further studies to be conducted.

Conclusion

To conclude, our study revealed that using dexmedetomidine $(1.5 \ \mu g/kg)$ for conscious sedation in patients during awake fiberoptic bronchoscopy guided intubation, was found to be better than using fentanyl (2 $\ \mu g/kg$), as dexmedetomidine was associated with less

cough, more patient comfort, less oxygen desaturation, better tolerance to intubation along with stable haemodynamics and minimal adverse effects, which is desirable in these patients.

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Conflicts of Interest: None

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