A randomized double-blind prospective study of comparison between dexmedetomidine and fentanyl during awake fiberopticbronchoscopic intubation

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Abstract:

Aim: The present study aimed to compare intubation conditions and the incidence of desaturation between the dexmedetomidine and fentanyl groups during awake fiberopticbronchoscopic intubation (AFOI).

Material & methods: This randomized double-blind prospective study was conducted on a total of 100 patients scheduled for elective laparotomies who were randomly allocated into two groups: Group A (n=50)received dexmedetomidine 1 mcg/kg and Group B (n=50) received fentanyl 2 mcg/kg over 10 min. Patients in both groups received glycopyrrolate 0.2 mg intravenous, nebulization with 2% lidocaine 4 ml over 20 min and 10% lidocaine spray before undergoing AFOI. Adequacy of intubation condition was evaluated by cough score and post-intubation score. Incidence of desaturation, hemodynamic changes and sedation using Ramsay sedation scale (RSS) were noted and compared between two groups.

Results: The various demographic parameters like mean age, sex, weight distribution and ASA physical status were comparable in two groups. When the two groups were compared with respect to cough score, in Group A, the number of patients with a Ramsay sedation scale (RSS) was significantly more as compared to Group B. 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 ± 12.20 which was more than mean baseline MAP. (P = 0.715) and in Group B, the mean MAP just after intubation was 95.97 ± 11.23 which was significantly more than the mean baseline MAP. (P = 0.0052) but both HR and MAP were found to be in clinically acceptable range in two groups.

Conclusion: Dexmedetomidine is more effective than fentanyl in producing better intubation conditions, sedation along with hemodynamic stability and less desaturation during AFOI.

***Keywords:*Awake Fiberoptic Intubation, Conscious Sedation, Dexmedetomidine, Intubating Conditions, Fentanyl, Oxygen Desaturation**

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1. Introduction

Predicted difficult airway has always been challenging for the anesthesiologist, and awake fiberoptic intubation (AFOI) has been accepted as one of the best techniques for its management [1].Difficult airway scenarios arise in various clinical syndromes, head and neck malignancies, trauma, and previous failed intubation attempts, and hence, adequate preparation is needed to prevent any airway compromise. AFOI is practiced for these recognized difficult airway conditions, and it needs expertise on the part of the anesthesiologist to master the technique and allay the anxiety and discomfort of the patient. AFOI is also known to

cause the sympathetic response in the patients [2, 3].

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. Hence, a sedative agent which allays anxiety and discomfort of the patient and decreases the sympathetic response without causing respiratory depression is ideal for such situations. Various drugs have been used previously such as benzodiazepines, opioids, and propofol. These drugs cause sedation, amnesia, and attenuate the hemodynamic response. However, they are known to cause respiratory depression and hence hypoxemia [4, 5].

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 [6, 7, 8, 9, 10, 11, 12].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) [4, 13].Hence, this study was undertaken to compare the effectiveness of dexmedetomidine and fentanyl plus midazolam combination for evaluating intubating condition during AFOI.

MATERIAL & METHODS

A double blinded randomized prospective study was conducted among 100 patients of either sex, aged 20-60 years, belonging to American Society of Anesthesiologists physical status (ASAPS) I and II, and posted for elective abdominal surgeries. An institutional ethical committee approval was obtained and written informed consent from study subjects were taken. Due to availability of logistic support 50 patients were taken in each group as there is no upper limit of sample size.

Inclusion criteria

- Patients aged 20-60 years
- ASA I and II patients
- Elective abdominal surgeries

Exclusion Criteria

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.

Methodology

Patients were allocated by randomly divided into two groups. Group A-dexmedetomidine group (n = 50) and Group B-fentanyl group (n = 50). Dose of study drug was calculated according to patient's body weight, diluted with normal saline to make equal volume of 50 ml and enveloped according to patient's inclusion number. 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.

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 2 h before surgery. In the operating room, intravenous line (i.v.) was secured with wide bore cannula (18 G) and multichannel monitor was applied to record baseline Heart rate (HR), Mean arterial pressure (MAP), SpO2 and electrocardiogram. Injection glycopyrrolate 0.2 mg i.v. was given. Patency of both nostrils was tested and the nostril with better patency was chosen for awake nasal fiberoptic intubation. Topicalization of both the upper and lower airway was accomplished by nebulization with 2% lidocaine 4 ml (80 mg) for 20 min. Xylometazoline nasal drops and lidocaine jelly were

applied to both the nostrils. Tongue and hypopharynx were sprayed with two puffs of 10% lidocaine (20 mg). After that dexmedetomidine (1 mcg/kg over 10 min) and fentanyl (2 mcg/kg over 10 min) was infused according to the subject's inclusion number. After lubrication bronchoscope was loaded with appropriate size cuffed polyvinyl chloride endotracheal tube. At the end of the study drug infusion, sedation was evaluated by Ramsay sedation scale (RSS) [14].After achieving Score ≥2, bronchoscopy was performed through nasal approach. After proper placement of tube in trachea general anesthesia was induced and surgery was allowed to proceed.

Intubation condition was evaluated by cough score during bronchoscopy as Score 1 = no cough, 2 = slight cough (no more than two cough in sequence), 3 = moderate cough (3-5 cough in sequence), 4 = severe cough (>5 cough in sequence).[15] Tolerance to intubation was evaluated by post-intubation score after placement of tube in the trachea as: 1 = Co-operative, 2 = minimal resistance, 3 = severe resistance [11].

Level of sedation was evaluated by Ramsay sedation score (RSS) just after completion of infusion of study drug as:

1. Anxious, agitated or restless,
2. Cooperative, oriented and tranquil,
3. Sedated but responds to command,
4. Asleep, brisk glabellar reflex responds to loud noise.
5. Asleep, sluggish glabellar reflex or responds to loud noise.
6. Asleep with no response to a painful stimulus.

MAP and HR were noted as a baseline and immediately after intubation. SpO_2 was monitored throughout the procedure and lowest one was noted. Hypotension (reduction of MAP >20% from baseline) was treated with i.v. fluid and/or phenylephrine 50 mcg i.v. bolus, repeat dose after 5 min. Bradycardia (HR 10 s) was treated with oxygen supplementation either through a nasal cannula or oxygen port of bronchoscope.

Statistical Analysis

Statistical analyses were carried out using the statistical package for the social sciences 16.0 statistical software packages. Numerical data were compared between two groups using independent t-test and within the same group using paired t-test. Categorical data were compared between two groups using Chi-square test. All analysis was two tailed and $p<0.05$ was considered statistically significant.

RESULTS

Table 1: Demographic profile in two groups

Demographic parameters	Group A (n=50)	Group B (n=50)	P value
Age (yr)	44.26 ± 11.80	42.18 ± 10.07	>0.05 (Non sig.)
Sex (M / F) (n)	20 / 30	22 / 28	>0.05 (Non sig.)
Weight (kg)	59.67 ± 8.895	57.67 ± 8.066	>0.05 (Non sig.)
ASA Physical status (I / II)(n)	45 / 5	44 / 6	>0.05 (Non sig.)

The various demographic parameters like mean age, sex, weight distribution and ASA physical status were comparable in two groups.

Table 2: Patients with favourable conditions for AFOI in two groups

Favourable Conditions	Group A (n=50)		Group B (n=50)		P value
	n	%	n	%	
Ramsay sedation scale (RSS)	3±0.371		2.07±0.254		<0.05 (Sig.)
Intubation comfort score ≤2	35	70	20	40	<0.05 (Sig.)
SPO2 > 94%	34	68	20	40	<0.05 (Sig.)
Post intubation score = 1	45	90	30	60	<0.05 (Sig.)

Test applied: Independent sample t-test & chi-square test

When the two groups were compared with respect to cough score, in Group A, the number of patients with a Ramsay sedation scale (RSS) was significantly more as compared to Group B.

Table 3: Comparison of mean HR and MAP in two groups

Haemodynamic parameters	**Group A (n=50)**	**Group B (n=50)**
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	>0.05 (Non sig.)	<0.05 (Sig.)
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	>0.05 (Non sig.)	<0.05 (Sig.)

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 = >0.05) 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 = <0.05). Similarly In Group A, the mean MAP just after intubation was 92.83 ± 12.20 which was more than mean baseline MAP. (P = >0.05) and in Group B, the mean MAP just after intubation was 95.97 ± 11.23 which was significantly more than the mean baseline MAP. (P = <0.05) but both HR and MAP were found to be in clinically acceptable range in two groups.

Table 4: Incidence of adverse effects in two groups

Adverse effects	**Group A (n=50)**		**Group B (n=50)**	
	n	**%**	**n**	**%**
Sustained oxygen desaturation requiring O2 (SPO2 ≤ 95% for >10sec)	0	0	14	28
Bradycardia(HR <60/min)	3	6	2	4
Hypotension(reduction in MAP by > 20% from baseline)	2	4	0	0
Postoperative nausea and vomiting (PONV)	0	0	0	0
Pruritus	0	0	0	0

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, 14 patients developed sustained oxygen desaturation (SpO2 ≤ 94% for > 10 sec) so required oxygen inhalation by nasal cannula. In Group A, 3 patients developed bradycardia (HR < 60/ min) whereas only 2 patients developed bradycardia in Group B at the completion of drug infusions.

Discussion

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 [13].

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 [12, 15].The various demographic parameters like mean age, sex, weight distribution and ASA physical status were comparable in two groups. When the two groups were compared with respect to cough score, in Group A, the number of patients with a Ramsay sedation scale (RSS) was significantly more as compared to Group B. Our findings with regard to cough score are similar to Tsai et al[16] and Mondal et

al[17] who also obtained favourable cough scores with dexmedetomidine.

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 [11].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>0.05) 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 ± 12.20 which was more than mean baseline MAP. (P>0.05) and in Group B, the mean MAP just after intubation was 95.97 ± 11.23 which was significantly more than the mean baseline MAP. (p<0.05) but both HR and MAP were found to be in clinically acceptable range in two groups. Similar results have been obtained in studies by Demiran*et al*. [18], Tsai *et al*. [16] Ryu *et al*. [19] and Mondal *et al*. [17] where less oxygen desaturation was seen with dexmedetomidine.

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, 14 patients developed sustained oxygen desaturation (SpO2 ≤ 94% for > 10 sec) so required oxygen inhalation by nasal cannula. In Group A, 3 patients developed bradycardia (HR < 60/ min) whereas only 2 patients developed bradycardia in Group B at the completion of drug infusions.

CONCLUSION

The present study concluded that using dexmedetomidine (1.5 µg/kg) for conscious sedation in patients during awake fiberoptic bronchoscopy guided intubation, was found to be better than using fentanyl (2 µg/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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