Original Research Article

Evaluation of intubating conditions using dexmedetomidine - fentanyl combination versus dexmedetomidine alone for awake nasal fiberoptic intubation

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Abstract

Aims and Objective: Awake fiberoptic intubation is one of the principal techniques of intubation in patients with difficult airway. The aim of our study was to compare the effectiveness of Dexmedetomidine- Fentanyl combination with Dexmedetomidine alone, for sedation and intubating conditions without respiratory depression, in patients with difficult airway undergoing awake nasal fiberoptic intubation. **Material and Method:** 60 patients with difficult airway, age group 18-60 years, of either sex ,belonging to American Society of Anaesthesiologist Physical status (ASA PS) I and II posted for elective surgeries under general anaesthesia were randomly allocated into two groups (30 each). Group D received infusion of Inj Dexmedetomidine 1µg /kg i.v diluted upto 50 ml over 10 min and Group DF received Inj Dexmedetomidine 1 µg /kg i.v with Inj Fentanyl 1 µg /kg i.v diluted upto 50 ml infused over 10 mins. Sedation score (RSS), Cough score, Patient comfort score, intubation time and attempts were noted during awake nasal fiberoptic intubation, along with hemodynamic parameters (heart rate, mean arterial pressure, arterial oxygen saturation) and side effects of drugs, if any. **Results:** Sedation score was comparable in both the groups (p=0.182). Cough score, patient comfort score and intubation time were significantly better (p<0.0001) in Group DF. Similarly hemodynamic parameters were better in Group DF than Group D. No adverse effects such as transient hypertension, asystole, airway obstruction, laryngospasm, apnea, severe hypoxia (< 90%) were seen in either of the group. **Conclusion:** Low dose Dexmedetomidine- Fentanyl (1µg /kg each) infusion provides effective sedation, excellent intubating conditions, good hemodynamic stability without airway compromise.

Key Word: Awake nasal fiberoptic intubation, Dexmedetomidine, Fentanyl

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INTRODUCTION

Awake nasalfiberoptic intubation is the gold standard for patients with difficult airway particularly those with restricted mouth opening. While preparing such patient for fiberopticintubation, the intubating conditions and patient comfort are of utmost importance. Sedation plays a vital role in providing better intubating conditions. However, the real challenge is to adequately sedate the patient without compromising the airway patency and ventilation. The ideal sedative should provide patient comfort, amnesia, blunting of airway reflexes, maintenance of patent airway with spontaneous ventilation and hemodynamic stability. Several agents are available for conscious sedation during awake fiberoptic

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intubation such as Midazolam[1], Fentanyl[2], Remifentanil[3], Propofol[4], Ketamine[5] and Dexmedetomidine[6,7]. But Benzodiazepines, Opioids, Propofol cause respiratory depression, particularly when used in higher doses. The undesirable effect associated with Ketamine use is increased airway secretions interfering with bronchoscopy. Dexmedetomidine, selective α_2 agonist is preferred over other drugs as it induces sedation and analgesia without respiratory depression. It also has anxiolytic, amnestic, antisialogogue properties which are desirable for fiberopticintubation[8,9].Dexmedetomidine alone in different doses has been used for sedation in awakefiberoptic intubation[10,11]. However, higher doses of Dexmedetomidine (1.5 µg/kg, 2 µg/kg) is associated with increased incidence of airway obstruction[10,11]. Some researchers have used Dexmedetomidine in combination with other agents[1,5] to improve its sedation criteria without airway obstruction. There are few studies of Dexmedetomidine – Fentanylcombination[10].Higher doses of both Dexmedetomidine and Fentanyl are associated with increased incidence of side effects. So in our study, we assumed that lower doses of both the drugs when used in combination will improve sedation criteria with minimal airway compromise. Hence, we usedDexmedetomidine Fentanyl combination (1µg/kg each) versus Dexmedetomidine alone (1µg/kg) in lower doses to evaluate intubating conditions for awake nasal fiberoptic intubation.

MATERIALS AND METHODS

After obtaining Institutional Ethics committee approval and written informed consent from study subjects, this double blinded randomized, prospective study was conducted at Government Medical College and Cancer Hospital, Aurangabad. 60 patients between 18- 60 years of age, of either sex, belonging to American society of Anaesthesiologist physical status (ASA PS) I and II, having predicted difficult intubation undergoing elective surgeries were included in our study. Patients with bradycardia (heart rate< 60/min), hypertension, any type of atrio ventricular block (AV block) , heart failure, having hepatic, renal, pulmonary and psychiatric diseases, pregnant patients, known alcoholic or drug abusers, allergy to drugs involved in the study, any contraindication to nasal intubation like thrombocytopenia or coagulopathies, any facial deformity, patients with difficulty for tracheostomy were excluded from our study. All the study subjects were explained about the anaesthesia procedure and their consent was obtained. Based on results of previous study[10], we calculated the sample size of 8 in each group with a power of 0.8 and type I error of 0.05. Though the minimum sample size was calculated to be 8, considering the possibility of exclusion during the study (those with sedation score RSS< 2, those requiring >3 intubation attempts) we enrolled 30 subjects in each group. Patients were allocated by computer generated random numbers and were divided into two groups (30 each). All fiberoptic intubations were performed by the same anaesthesiologist who had an experience of performing >50 fiberoptic intubations, the second anaesthesiologist allocated the patients to the study groups and also prepared and administered the study drugs. While the third anaesthesiologist documented the vitals and other parameters. All the patients were fasted for atleast 8 hours and tablet Ranitidine 150 mg was given on night before surgery. No anxiolytic was administered on night before surgery due to the risk of airway compromise. In the operation theater, multipara monitors were attached and baseline hemodynamic variables (Heart rate (HR), Mean arterial pressure(MAP), SpO2, Respiratory rate (RR) and ECG changes if any) were recorded. Intravenous line was established and each patient received Ringer lactate infusion. All patients were premedicated with Inj. Glycopyrolate0.2mg i.v., Inj. Ondansetron 4mg i.v.A tracheostomy tray was kept ready, if needed. Patency of both nostrils were tested and the nostril with better patency was chosen for awake nasal fiberoptic intubation. Topicalization of both upper and lower airway was done by nebulization with face mask using 2ml of 4% Lignocaine (80mg) for 20 mins. Xylometazoline nasal drops 0.1% (2 drops in each nostril) and lidocaine jelly 2% were applied to the nostrils. Tongue and hypopharynx were sprayed with two puffs of 10% Lignocaine(20mg). After that study drugs were infused according to the subjects inclusion number. Group D- Inj. Dexmedetomidine 1µg/kg i.v. diluted upto 50 ml infused over 10 min with infusion pump. Group DF- Inj. Dexmedetomidine 1µg/kg i.v.and Inj Fentanyl 1µg/kg i.v. dilutedupto 50ml infused over 10 min with infusion pump. At the end of study drug infusion(10 min), sedation was evaluated by Ramsay Sedation Scale(RSS)[12].

Ramsay Sedation scale-

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 painful stimulus

Lubricated bronchoscope (Fujinon, 5.5 mm external diameter) loaded with appropriate sized cuffed polyvinyl endotracheal tube was kept ready.After achieving a RSS ≥ 2, bronchoscopy was performed through nasal

approach. After proper placement of tube in trachea and confirmation by EtCO2, general anaesthesia was induced and surgery was allowed to proceed. Patients with RSS< 2 at the end of study drug infusion were excluded from our study. During bronchoscopy, intubating condition was evaluated by using Cough Score[13].

Cough Score-

1. No cough
2. Slight Cough (No more than 2 coughs in sequence)
3. Moderate cough (3-5 cough in sequence)
4. Severe cough (> 5 cough in sequence)

Tolerance to intubation was evaluated by Patient comfort score[11] during tube placement.

Patient comfort score-

1. Cooperative
2. Minimal resistance
3. Severe resistance

Hemodynamic variables (HR, MAP,RR ,Spo_2 , ECG) were noted at baseline, after giving Inj. Glycopyrolate, at the start of study drug infusion and every 2 mins thereafter till tracheal intubation.

Hypotension (reduction of MAP> 20% from baseline) , bradycardia associated with hypotension (heart <50/min) , oxygen desaturation (spo2< 95% for >10 secs),if any, were treated with i.v fluid and / or Inj. Mephentermine 6mg i.v bolus, Inj. Atropine 0.6mg i.v. , oxygen supplementation 4 lit/min through oxygen port of bronchoscope or airway opening manoeuvers, respectively. If laryngospasm occurs, we planned for CPAP (Continuous positive airway pressure) with 100% oxygen and emergency tracheostomy, if needed. As our study subjects had difficult airway, deepening plane of anaesthesia or administration of Inj. Succinylscholine was not preferred. Intubation time was calculated from the time of insertion of fiberoptic bronchoscope in nasal cavity till the placement of tube in trachea and its confirmation with EtCO2.While performing bronchoscopy only 3 attempts were allowed. In case of failure to intubate after third attempt we shifted to plan B (tracheostomy) and those patients were excluded from our study. The primary objective of our study was to evaluate intubating conditions which was assessed by sedation score, cough score, patient comfort score and intubation time. The secondary objective was to study hemodynamic stability and side effects (if any). Numerical data were compared between two groups using independent t test and within the same group using paired t test. All results were discussed on 5% level of significance i.e, p< 0.05 was considered as statistically significant.

RESULTS

Of 60 patients enrolled for the study, 30 were randomly allocated to Group D (Dexmedetomidine) and remaining 30 to Group DF (Dexmedetomidine- Fentanyl). Demographic data (age, sex, weight, ASA PS) were comparable in both the groups.

Table 1: Age and weight

		Group D	Group DF	p value
Age (Years)	Mean	50.13	47.30	0.38
	SD	14.08	10.45	
Weight (Kg)	Mean	63.06	59.54	0.31
	SD	10.48	11.34	

(SD- Standard deviation)

	Group D	Group DF	p value
Male/Female	20/10	23/7	0.47
ASA I/II	22/8	24/6	0.63

p> 0.05 statistically not significant.

Table 2: Sedation score, Cough score, Patient comfort score

	Group D	Group DF	p
RSS (Mean)	2.9	3.06	
SD	0.54	0.36	p=0.182
Cough score≤ 2	24	28	
Cough score ≥3	6	2	
Mean	2.06	1.43	
SD	0.58	0.62	p<0.0001
Patient comfort score 1	5	26	
Patient comfort score ≥ 2	25	4	
Mean	1.9	1.13	
SD	0.48	0.345	p<0.0001

p<0.0001 indicates statistically highly significant.

There was no statistically significant difference in the sedation score between the two groups (p>0.05).All the patients achieved RSS≥2 at 10 mins and maximum sedation score of 4 was achieved in only 3 of 30 patients in each group. Cough score and Patient comfort score were highly significant (p<0.0001) in Group DF than Group D. Cough score ≤2 was considered as favourable intubating condition[2].28 of 30 patients (93.33%) in Group DF had cough score ≤2 as compared to 24 of 30 patients (80%) in Group D. None of the patients in either of the groups had severe coughing (cough score 4) during bronchoscopy. 26 patients (86.66%) in Group DF were co-operative during endotracheal tube placement (i.e, patient comfort score -1) as against only 5 patients (16.66%) in Group D. Severe resistance (patient comfort score -3) to tube placement was seen in 2 patients in Group D and none of the patients in Group DF.

The baseline hemodynamic parameters (HR, MAP, RR, Spo_2) were comparable between both the groups.

Table 3: Heart Rate

No.	Heart Rate (HR) (beats/ min)	Group D (mean± SD)	Group DF (mean± SD)	p value
1.	Baseline HR	83.1 ± 7.80	79.43 ± 10.01	0.21
2.	HR at the end of study drug infusion (10 min)	69.93 ± 6.28	59.76 ± 5.68	0.001
p value (1 and 2)		<0.0001	<0.0001	
3.	Post intubation HR	62.56 ± 5.52	64.03 ± 7.57	0.043
p value (1 and 3)		<0.0001	<0.0001	

There was a significant decrease in heart rate at the end of study drug infusion (10 min) (69.93 ± 6.28 beats/ min) and in post intubation period (62.56 ± 5.52 beats/min) in comparison with baseline value (83.1 ± 7.804 beats/ min) in Group D ($p<0.0001$). In Group DF, heart rate at the end of study drug infusion(59.76 ± 5.68 beats / min) and post intubation heart rate (64.03 ± 7.57 beats/min) decreased significantly compared with baseline (79.43 ± 10.01 beats/min) ($p<0.0001$). When compared between two groups, there was significant decrease in heart rate at the end of study drug infusion ($p <0.0001$) but the fall in heart rate in post intubation period was comparable ($p=0.39$) . One patient each in Group D and Group DF required Inj. Atropine for bradycardia (HR< 50/min).

Table 4: Mean arterial pressure

No.	Mean arterial pressure (MAP) (mm of Hg)	Group D (mean±SD)	Group DF (mean±SD)	p value
1.	Baseline MAP	78.96 ± 4.9	76.06 ± 4.48	0.144
2.	MAP at the end of study drug infusion (10 min)	68.76 ± 5.1	65.18 ± 4.9	<0.0001
p value (1 and 2)		<0.0001	<0.0001	
3.	Post intubation MAP	65.23 ± 4.16	67 ± 4.47	0.064
p value (1 and 3)		<0.0001	<0.0001	

In Group D, significant fall in MAP was seen at 10 mins (68.76 ±5.1 mm of Hg) and in post intubation period (59.23 ± 4.16 mm Of Hg) compared to baseline ($p<0.001$). Similarly in Group DF, there was significant fall in MAP at 10 mins (65.18 ±4.9 mm Of Hg) and in post intubation period (57 ± 4.74 mm of Hg) than baseline values ($p<0.001$). On comparison between two groups there was highly significant decrease in MAP at the end of study drug infusion ($p< 0.0001$) but drop in MAP was comparable in post intubation period ($p=0.064$). Hypotension (MAP < 20% of baseline) was seen in 1 patient in Group D (bradycardia with hypotension) who responded to Inj. Atropine. 3 patients in Group DF had hypotension, all patients responded to single dose of Inj. Mephentermine. Only for hemodynamic evaluation, we excluded the study subjects who required treatment for bradycardia and/or hypotension (i.e, 1 patient from Group D and 4 patients from Group DF), so as to know the actual effect of study drugs on hemodynamics. 29 patients of Group D and 26 patients of Group DF were compared with baseline for hemodynamic evaluation.

Table 5

	Group D (Mean ± SD)	Group DF (Mean ± SD)	p value
Baseline HR (beats/ min)	83.1 ± 7.80	79.43 ± 10.01	0.21
Post intubation HR (excluding patients who received treatment) (beats / min)	62.01 ± 5.82 (29 patients)	60.49 ± 6.02 (26 patients)	0.001
p value	<0.0001	<0.0001	
Baseline MAP (mm of Hg)	78.96 ± 4.9	76.06 ± 4.48	0.144
Post intubation MAP (excluding patients who received treatment) (mm of Hg)	64.9 ± 4.7	62.47 ± 4.16	<0.001
p value	<0.0001	<0.0001	

The post intubation heart rate and MAP were significantly better ($p < 0.001$) in Group DF than Group D, after exclusion of patients who were treated with Inj. Atropine and Inj. Mephentermine.

Table 6: Arterial oxygen saturation (Spo_2)

	Group D	Group DF	p value
Baseline $Spo_2 \geq 95\%$	30	30	0.143
Spo_2 (%)at 10 mins			
≥ 95/ ≤ 94	29/1	24/6	0.00011
p value	0.24	0.0014	

We observed that 29 patients of Group D and 24 patients in Group DF were able to maintain oxygen saturation (Spo_2) ≥ 95 % (p <0.0001) at the end of study drug infusion. None of the patient in our study desaturated below 90%. In patients with $Spo_2 \leq 94\%$, oxygen was administered through the bronchoscope port. No significant difference was seen in respiratory rate in both the groups at the end of 10 mins (p= 0.26) The mean intubation time in Group D was 2:45 sec and Group DF was 2:10 secs which was statistically highly significant (p < 0.0001). All 60 patients underwent successful fiberoptic intubation. None of the patient required Plan B (Tracheostomy). There was no statistically significant difference in number of intubation attempts in both groups (p=0.324).In Group D, only one patient required second attempt for intubation while in Group DF, all patients were intubated in first attempt. None of the patient had incidence of transient hypertension, asystole, airway obstruction, laryngospasm, apnea, severe hypoxia (<90%) in our study.

DISCUSSION

Awake fiberoptic intubation is the preferred method for securing difficult airway during elective surgeries as per ASA difficult airway algorithm. Several agents have been used for conscious sedation during awake nasal fiberoptic intubation. Dexmedetomidine is a highly selective, centrally acting α_2 agonist. It acts on presynaptic α_2 receptor causing decrease in Noradrenaline release, diminished centrally mediated sympathetic tone and increased vagal activity. The primary site of action is locus coeruleus, a nucleus in pons, which is involved in physiological response to stress and anxiety. It produces hypnosis, amnesia, analgesia, anxiolysis, sympatholysis and antisialogogueeffects[8,9].The unique feature of Dexmedetomidine is providing sedation without respiratory depression, thus making it a better choice in patients with difficult airway. Fentanyl is a synthetic μ agonist opioid which provides sedation, analgesia, hemodynamic stability. But there is associated risk of respiratory depression, nausea, vomiting and chest wall rigidity[14]. In our study we compared Dexmedetomidine 1 μg/kg–Fentanyl 1μg/kg (Group DF) combination with Dexmedetomidine 1μg/kg (Group D) alone to know which group provides better intubating conditions, as also studied by Mohamed Hasan *et al*[10]. In our study, all patients achieved RSS≥ 2 at the end of study drug infusion. In Group DF more number of patients achieved higher score(RSS≥3) than Group D, however it was comparable. In study by Mondal *et al*[2], RSS was better in Dexmedetomidine group (1 μg/kg) than Fentanyl group (1 μg/kg) (p <0.0001). Mohamed Hasan *et al*[10] did not use sedation score in his study. In our study, higher RSS was seen in Group DF due to additive effect of both Dexmedetomidine and Fentanyl. In present study, Cough score and patient comfort score were better in Group DF than Group D (p= 0.0001). Mondal *et al*[2] (Dexmedetomidine 1 μg/kg vs Fentanyl 2 μg/kg) and Chu *et al*[6] (Dexmedetomidine 1 μg/kg vs Fentanyl 1 μg/kg) found favourable intubating conditions (i.e, cough score and patient comfort score) in Dexmedetomidine group as compared to Fentanyl group. Mohamed Hassan *et al*[10] compared different doses of Dexmedetomidine (1 μg/kg, 2 μg/kg) and Dexmedetomidine(1 μg/kg)-Fentanyl (1 μg/kg) combination, and they found better cough score(≤2) and patient comfort score in Dexmedetomidine-Fentanyl group than Dexmedetomidine (1 μg/kg), similar with our results. In our study, additive effect of sedation and analgesia by Dexmedetomidine and Fentanyl combination provided better cough and patient comfort score in Group DF. Intubation time was significantly lower in Group DF, indicating that Group DF had better intubating condition. Sunil Kumar Sinha *et al*[5], compared Inj. Dexmeditomidine (1 μg/kg bolus over 10 min followed by 0.5μg/kg continuous infusion) and Inj. Ketamine (15 mg i.v bolus followed by 20mg/hr infusion) combination with Inj Dexmedetomidine alone (1 μg/kg bolus over 10 min followed by 0.5μg/kg continuous infusion), they found no significant difference in intubation time in both the groups. Baseline hemodynamic parameters (HR, MAP, RR, Spo_2) were comparable in both the groups in our study. The maximum fall in HR and MAP were noted at 10 mins in both the groups (Group DF > Group D) which were easily managed by Inj Atropine and InjMephentermine. In post intubation period HR and MAP in both the groups were comparable. Mohamed Hassan *et al*[10], in their study found that all groups were similar in hemodynamic values at all time points. The rise in post intubation HR and MAP in Group DF was may be because 4 of 30 patients were treated for bradycardia (1 patient) and hypotension (3 patients). To find out whether Inj Atropine and InjMephentermine attributed to this rise in post intubation

HR and MAP, we excluded these 4 patients from Group DF for hemodynamic evaluation. Similarly one patient (bradycardia with hypotension) was excluded from Group D.On exclusion of these patients we found that, the p value was significantly better in Group DF than Group D in post intubation period, indicating that Group DF had better hemodynamic stability than Group D. Fall in saturation < 95% was seen in 6 patients of Group DF and 1 patient in Group D which was easily managed by oxygen supplementation. None of the patients required airway opening maneuvers like chin lift or jaw thrust. Mondal *et al*[2] observed that the incidence of desturation (≤ 94%) was in Dexmedetomidine than Fentanyl Group (p <0.0001). No adverse effects such as transient hypertension, asystole, airway obstruction, laryngospasm, apnea, severe hypoxia (<90%) were seen in either of the groups, in our study. Addition of Fentanyl to Dexmedetomidine did not increase the incidence of apnea or severe hypoxia, as we have used Inj Fentanyl in low dose (1 µg/kg). Thus, cough score and patient comfort score were significantly better in Group DF in our study, thereby reducing the intubation time significantly. Though 1 patient had fall in heart rate and 3 patients had fall in blood pressure, they were easily managed with drugs.

CONCLUSION

We conclude, low dose Dexmedetomidine- Fentanyl (1 µg/kg each) infusion provides effective sedation, excellent intubating condition, good hemodynamic stability without airway compromise.

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