

RESEARCH ARTICLE

Dexmedetomidine vs. Fentanyl for Awake Fiberoptic Intubation Among Adults in Tamil Nadu - A Randomized Control Trial

Rasika Priya M¹, Arjun Ganesan¹, Sabapathy VA¹, Sagana S^{2*}

¹Department of Anaesthesiology, Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Vinayaka Mission's Research Foundation (Deemed to be University), Salem, India.

²Consultant, Intensive Care Unit, Devaki Multi Speciality Hospital, Madurai, Tamil Nadu, India.

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ABSTRACT

Background: Dexmedetomidine and fentanyl are often administered medications for inducing conscious sedation, a technique employed for performing awake fiberoptic intubation. However, there is a scarcity of literature that directly compares the effects of these drugs when administered at equivalent doses. This study sought to assess the effectiveness and safety of using dexmedetomidine and fentanyl in adult patients undergoing Awake Fiberoptic Intubation (AFOI).

Methodology: The current research study undertaken was a randomized controlled trial conducted among adult patients at A hospital providing specialized medical services in Salem, Tamil Nadu. There were 60 study participants, 30 participants in each group. A group received the drug dexmedetomidine 1-µg/kg while B group received fentanyl 1-µg/kg intravenously. Primary outcomes measured were the efficacy of both drugs for sedation, patients' comfort and compliance during AFOI, cough score, BP, HR, post-intubation score, and the Ramsay sedation score and SpO₂ for 15 minutes intraoperatively.

Results: The study found that 80% of study participants in A group had cough score below 2, compared to only 6.7% in group B. Post-intubation cooperation was also higher in group A, with 83.3% of patients showing cooperation. The Ramsay sedation score showed significant differences between the groups. Intubation length was shorter in group A, while group B experienced HR increased, SBP, and oxygen saturation. These findings highlight the importance of individualized care in patient care.

Conclusion: Dexmedetomidine is superior to fentanyl for AFOI. Regarding the provision of heightened sedation, enhanced intubating circumstances, and increased tolerance to intubation, and greater hemodynamic stability, all within a shorter duration for intubation.

Keywords: Dexmedetomidine, Fentanyl, Intubation, Sedation, Oxygen saturation.

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INTRODUCTION

Management of difficult airways is a significant challenge faced by anaesthesiologists. The development of the fiber optic bronchoscope has changed the way difficult airway is managed. Tracheal intubation techniques in anesthesia care are still being improved upon with ongoing trials and the implementation of newer modalities.¹

Awake fiberoptic intubation (AFOI) is a highly successful method for managing patients with Challenging air passage in both emergency and elective settings.² It is used in patients where the conventional oro-tracheal process of intubation using a laryngoscope is difficult and inconvenient to carry out. AFOI has been the first choice in cases of difficult intubation in recent times because an awake patient breathes spontaneously,

maintains adequate ventilation oxygenation and protects his airway from aspiration, which is important for managing a difficult airway.³

The goal is to achieve the most favorable conditions for intubation and ensure maximum comfort for the patient essential for AFOI. Ensuring sufficient sedation while also preserving an unobstructed airway and natural breathing is crucial in these individuals. The following are characteristics of an ideal sedation regimen, i.e., the comfort of the patient. The administration of anesthesia aims to suppress airway reflexes, promote patient compliance, maintain stable blood flow, induce amnesia and provide unobstructed respiration with spontaneous breathing.⁴

*Author for Correspondence: dr.saganamahesh@gmail.com

Several drugs have been shown to successfully achieve conscious sedation for AFOI.⁵ The commonly used sedative agents, opioids and midazolam, are substances that can lead to respiratory depression, causing a decrease in oxygen levels and potentially resulting in hypoxia and aspiration.⁵

Dexmedetomidine is a brief-acting, extremely specific α_2 -adrenoceptor agonist that has received approval from the Food and Drug Administration (FDA) to authorize the use of sedation in ICU.⁶ Nowadays, it has also been employed to administer sedation to patients in other environments, such as AFOI, due to its capacity to induce drowsiness Providing pain relief without causing a decrease in respiration.^{7,8} Fentanyl, an opioid, is effective in reducing the study examines the physiological response and level of discomfort felt when a bronchoscope is passed into the vocal cords.⁹

Various studies have compared the two drugs Dexmedetomidine and Fentanyl for AFOI in India.¹⁰⁻¹² Still, these studies have been undertaken with either a combination of fentanyl or using different doses of the two drugs. There is a dearth of literature comparing the two drugs, dexmedetomidine and fentanyl for AFOI in the same doses. Therefore, this study was done with the objective of comparing the effectiveness and safety of dexmedetomidine and fentanyl measured using intubating conditions, patient comfort, level of sedation, hemodynamic stability and duration of intubation for Airway management using an alternative intubation technique in adult patients who are expected to have challenges with the standard intubation procedure.

MATERIALS AND METHODS

A research study was undertaken randomized controlled trial on 60 adult patients aged 18 to 50 in Salem, Tamil Nadu, for a year. The study received approval from the institutional ethics committee. Patients were classified as grade I and II by the American Society of Anaesthesiologists and Mallampati grading 1 and 2 due to anticipated difficult airway. Patients with heart rate below 50/min, emergency surgery, atrioventricular block, liver cirrhosis, heart failure, pregnant patients, bleeding disorders, thrombocytopenia, coagulopathy contraindicating nasal intubation, known alcoholics and patients allergies to the study medicines were not included.

The sample size was scientifically calculated using Yousuf A. *et al.*'s previous study a minimum of 9. As logistic support was available and, there was There was no maximum restriction to the sample size, and it consisted of 30 patients considered in each of the two groups. The participants were randomly assigned into groups using computer-generated numbers. Patient identity numbers of all 60 patients recruited for the study were entered in Microsoft excel, and the function RAND was used to generate random numbers corresponding to the identity numbers. These random numbers were then ranked to avoid duplicates. These rankings were then divided by 2 for the two groups and function roundup was used to round these rankings upwards.

This was an open-label trial and hence the anaesthesiologist was aware of the drug every patient was administered.

Group A was administered 1- μ g/kg of dexmedetomidine intravenously, whereas group B was administered 1- μ g/kg of fentanyl intravenously. The intervention for each patient was concealed using Envelopes that are numbered in a specific order, sealed shut, and cannot be seen through.

The research participants were subjected to the following investigations before the operative period- hemoglobin, random blood sugar, urea and creatinine levels, serum electrolytes, chest X-ray, electrocardiogram, blood grouping, coagulation profile, and serology.

The patient was premedicated with alprazolam, pantoprazole, ondansetron, and glycopyrrolate before surgery. The upper and lower airways were topicalized with 4% lidocaine, and xylometazoline nasal drops were instilled. The oropharynx and hypopharynx were anesthetized with 2% lidocaine. The patient was kept nil per oral overnight before surgery.

The first author administered dexmedetomidine or fentanyl injections to the patient with better patency for awake fiber optic intubation, as per randomization.

Primary outcomes measured were the efficacy of both the drugs for sedation, patient comfort and compliance during AFOI, cough score, post-intubation score, The Ramsay sedation score, blood pressure, heart rate, and SpO2 are being assessed for 15 minutes intraoperatively. Complications like respiratory depression, fall in SpO2, bradycardia and hypotension at baseline, after giving study drugs and postintubation were the secondary outcomes.

Ramsay sedation score values were recorded during preoxygenation and at AFOI immediately after intubation to determine The level of drug infusion and the quality of sedation are crucial factors to consider. If sedation was not adequate or the patient was agitated, a top-up of fentanyl or midazolam was given.

The study assessed intubation scores and patient tolerance using cough scores and post-intubation comfort scores, with scores ≤ 2 indicating favorable patient tolerance.

The OT ensured the readiness of anesthesia machines, emergency oxygen sources, laryngoscopes. Items required for emergency resuscitation include endotracheal tubes,

Table 1: Comparison of demographic characteristics between the study groups (N = 60)

Parameter	Group (Mean \pm SD)		p-value
	Group A (Dexmedetomidine) (N = 30)	Group B (Fentanyl) (N = 30)	
Age (Years)	29.37 \pm 6.98	32.8 \pm 8.31	0.088
Weight (Kg)	58.3 \pm 10.13	55 \pm 10.47	0.220
Gender			
Male	15 (50%)	14 (46.67%)	0.796
Female	15 (50%)	16 (53.33%)	
ASA			
I	25 (83.33%)	26 (86.67%)	1.000
II	5 (16.67%)	4 (13.33%)	

Table 2: Descriptive analysis of Ramsay sedation score, cough score and post-intubation score among dexmedetomidine and fentanyl groups

Scores	Group A	Group B
<i>Ramsay sedation score</i>		
3	24 (80%)	13 (43.3%)
4	6 (20%)	17 (56.7%)
<i>Cough score</i>		
1	13 (43.3%)	0 (0%)
2	11 (36.7%)	2 (6.7%)
3	6 (20%)	28 (93.3%)
<i>Post-intubation score</i>		
1	25 (83.3%)	3 (10%)
2	3 (10%)	24 (80%)
3	2 (6.7%)	3 (10%)

connections, suction device with suction catheter, oropharyngeal airways, and emergency resuscitation medicines.

Once the patient has been transferred to the operating theater. Large bore IV cannula was secured after connecting the standard ASA monitors.

Hypotension, bradycardia, oxygen desaturation, hypertension, and tachycardia are conditions that require treatment. Hypotension is treated with IV fluids and/or phenylephrine, bradycardia is treated with atropine, oxygen desaturation is treated with oxygen supplementation, hypertension is treated with mean arterial blood pressure >20%, and tachycardia is treated with HR>30%.The data analysis in the study employed using coGudie software.¹³

RESULTS

Table 1 shows a *p-value* > 0.05 in demographic characteristics, such as age, weight, gender, and ASA (I/II), between the two groups.

In 80% of dexmedetomidine patients, a cough score below two was considered favorable for intubation compared to 6.7% in the Fentanyl group, indicating a significant difference (Table 2).

The study found that 83.3% of A group study participants had a cooperative post-intubation score, while only 10% in group B had the same score. The Ramsay sedation score demonstrated very high significant notable difference (*p* <0.001) (Table 3).

The study revealed that the dexmedetomidine group had shorter intubation duration and higher mean heart rate and SBP post-infusion compared to the fentanyl group. The mean DBP and mean MAP were insignificant at each time point, and at baseline, the fentanyl group had a higher mean SpO2 level. The average length of intubation was substantially shorter in the dexmedetomidine group (275.33 ± 61.35) compared to the fentanyl group (326.83 ± 52.07) (*p* <0.001). There is not much difference in HR among groups (*p* >0.05).

Nevertheless, following the delivery of fentanyl, there was a notable increase in HR compared to the dexmedetomidine

Table 3: Comparison of scores between the study groups (N = 60)

Parameters	Group (Median, IQR)		<i>p-value</i>
	Dexmedetomidine (N = 30)	Fentanyl (N = 30)	
Ramsay sedation score	3 (3–3)	4 (3–4)	0.004
Cough score	2 (1–2)	3 (3–3)	<0.001
Post-intubation score	1 (1–1)	2 (2–2)	<0.001

group (*p* <0.001), both after the infusion and after intubation. There is not much difference in BP among two groups at the beginning (baseline) and after intubation. Following the administration of the infusion, the average systolic blood pressure (SBP) was significantly greater in the fentanyl group compared to the dexmedetomidine group (*p* = 0.004). There was no statistically significant disparity in the average DBP and MAP between the two groups at each time point (*p* >0.05). At the start of the trial, the fentanyl group had a significantly higher average SpO2 compared to the dexmedetomidine group (*p* = 0.025). Nevertheless, there was no notable disparity in the mean SpO2 between the two groups following the administration of the infusion (*p* >0.05) and subsequent intubation (*p* >0.05) (Table 4).

DISCUSSION

This study investigates the effectiveness and safety of two medications, dexmedetomidine (group A) and fentanyl (group B), in adult patients who are expected to have difficulty with intubation. Group A was 29.37 ± 6.98 years, and group B was 32.8 ± 8.31 years of age. In group A, there was an equal distribution of male and female patients. However, in group B, there was a higher proportion of female patients. The majority of patients in both groups were categorized as ASA I. In a study conducted by Eldemdash *et al.*, The majority of the patients fell into the ASA I category, which aligns with the findings of the current study.¹⁴

A favorable cough score <= 2 in this study was achieved among the majority of patients in A group. The patients in group B exhibited significantly greater cough scores compared to the other group. Studies comparing dexmedetomidine with a combination of fentanyl-midazolam¹⁵ as well as other drugs like propofol¹⁶ show concordant results with better cough scores in dexmedetomidine group in both studies. Further, these differences were statistically significant with fentanyl-midazolam study similar to the present study but was insignificant with propofol which differed from the findings in this study.

In group A post-intubation score was cooperative in the majority of the patients but the number of patients showing such a score was group B had a much lower value compared to other groups. Similarly, maximum patients scored 3 on the Ramsey sedation score, belonging to group A, but not belonging to group B. scored varied between 3 and 4. The results of this study align with the findings of Patodi *et al.*¹⁷ and Chu *et al.*,¹⁸ who also reported positive intubation ratings while using

Table 4: Comparison of duration of intubation, HR, SBP, DBP, MAP and SPO2 between the study groups (N = 60)

Parameter	Group (Mean ± SD)		p-value
	Dexmedetomidine (N = 30)	Fentanyl (N = 30)	
Duration of intubation	275.33 ± 61.35	326.83 ± 52.07	<0.001
HR (beats/min)			
Baseline	82.6 ± 9.64	83.83 ± 10.72	0.641
Post-infusion	61.43 ± 8.53	81.63 ± 10.93	<0.001
Post-intubation	64.77 ± 13.51	87.43 ± 11.73	<0.001
Systolic BP (mmHg)			
Baseline	120.13 ± 8.15	122.87 ± 9.58	0.239
Post-infusion	102.9 ± 8.4	109.93 ± 9.78	0.004
Post-intubation	110.33 ± 14.44	111 ± 16.47	0.868
Diastolic BP (mmHg)			
Baseline	75.13 ± 14.71	75.5 ± 11.38	0.914
Post-infusion	62.67 ± 11.82	67.57 ± 10.53	0.095
Post-intubation	69.4 ± 16.36	65.93 ± 12.88	0.366
MAP (mmHg)			
Baseline	82 ± 11.06	86.53 ± 9.44	0.093
Post-infusion	70.53 ± 11.43	75.93 ± 10.65	0.063
Post-intubation	76.07 ± 14.12	76.83 ± 15.01	0.839
SpO2 (%)			
Baseline	98.33 ± 0.92	98.83 ± 0.75	0.025
Post-infusion	99.23 ± 0.82	99.43 ± 0.5	0.260
Post-intubation	99.37 ± 0.67	99.37 ± 0.49	1.000

dexmedetomidine. The findings regarding Ramsey's sedation score are also similar to these studies.

At baseline, the study found no notable disparity in the average HR, systolic BP, and SpO2 between the two groups, post-intubation, post-infusion, and post-intubation, and $p > 0.05$ is for in the average diastolic BP and MAP at each time point

The study found that patients taking dexmedetomidine demonstrated improved hemodynamic stability. When comparing the Fentanyl group to the dexmedetomidine group heart rate was statistically significantly higher post-infusion ($p < 0.001$) and intubation ($p < 0.001$), mean SBP was statistically significantly higher post-infusion ($p = 0.004$) and mean SpO2 was statistically significantly higher at baseline ($p = 0.025$).

These findings are in direct opposition to the findings of Verma *et al.*, who did research an analysis of the impacts of dexmedetomidine against the combined administration of fentanyl and ketamine. Significant increases in HR and BP were observed in individuals who received a combination of fentanyl and ketamine from the beginning of the operation to the completion of AFOI.¹⁹ This result may be due to the use of a katamine combination, which was not the case in

the present study. Certain other studies conducted by Ryu *et al.*²⁰, Demiraran *et al.*²¹ and Mondal *et al.*¹¹ that compared dexmedetomidine with drugs like remifentanyl, midazolam as well as fentanyl also favored the use of dexmedetomidine for hemodynamic stability such as in the present study.

The patients were blinded for the drug there is a risk of potential bias as the study is an open-label trial. The assessment utilized several scores derived from subjective replies. Further studies using a more robust blinding strategy and objective assessment could be planned. Nevertheless, this study proves that difficult airway situations can be managed using AFOI with the drug dexmedetomidine, which is more effective and has fewer side effects than fentanyl.

CONCLUSION

Dexmedetomidine administered at 1- μ g/kg dosage 1- μ g/kg dosage over a period of 10 minutes is superior to fentanyl administered at the same dose and duration for awake fiberoptic intubation. Dexmedetomidine provides better sedation while also reducing the duration required for intubation.

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