RESEARCH ARTICLE

A prospective randomized controlled study to assess the efficacy of fentanyl and dexmedetomidine for conscious sedation in awake fiberoptic intubation

Bony Baiju¹, Gopakumar G¹, Prathibha V K², Joji Antony³, Ranju Jayaprakash⁴

¹Department of Anaesthesiology, Azeezia Institute of Medical Sciences, Kollam, Kerala, India, ²Department of Pharmacology, Amala Institute of Medical Sciences, Thrissur, Kerala, India, ³Department of Anaesthesiology, Medical Trust Hospital, Cochin, Kerala, India, ⁴Department of Anaesthesiology, Royal Dental College, Chalissery, Palakkad, Kerala, India

Correspondence to: Ranju Jayaprakash, E-mail: dr.ranjujp@yahoo.co.in

Received: July 06, 2020; Accepted: July 28, 2020

ABSTRACT

Background: Awake fiberoptic intubation (AFOI) is usually the primary method for airway management in patients with anticipated difficult airway. To achieve optimal conditions for AFOI, the pharmacological agents chosen for sedation should be short acting and have little suppression of spontaneous ventilation. Aims and Objectives: The aim of this study was to compare the efficacy between dexmedetomidine and fentanyl for conscious sedation in AFOI. The objectives were to assess the intubating conditions, intubation attempts, and the hemodynamic responses between the groups receiving the two drugs. Materials and Methods: This prospective randomized double-blind study was done in 40 patients of the American Society of Anesthesiologists physical statuses I, II, and III, aged between 20 and 65 years. One group received fentanyl 2 mcg/kg infusion over 10 min. The other group received dexmedetomidine 1 mcg/kg infusion over 10 min. AFOI was done in both groups when patients achieved Ramsay sedation score of three. Time to sedation and time to intubation were noted. Intubating conditions were assessed with cough score. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were also monitored for 30 min with 3 min interval after starting the drug infusion. The number of intubation attempts was also noted. Results: We found that the time to sedation and the time to intubation were shorter with dexmedetomidine than with fentanyl. There were no significant differences in cough score, number of intubation attempts, heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation between the groups. Conclusion: Both dexmedetomidine and fentanyl can be used to achieve adequate sedation for AFOI along with regional block and topical anesthesia. However, dexmedetomidine achieved target sedation faster compared to fentanyl enabling early intubation.

KEY WORDS: Fentanyl; Dexmedetomidine; Awake Fiberoptic Intubation; Sedation

INTRODUCTION

Endotracheal intubation is one of the most fundamental skills that anesthesiologists acquire during their training

Access this article online			
Website: www.njppp.com	Quick Response code		
DOI: 10.5455/njppp.2020.10.07201202028072020			

period. The first intubation for the purpose of providing anesthesia was done by Dr. William Macewan, a surgeon in 1878.^[1]

The first awake intubation documented in the literature was done by direct laryngoscopy published by Bailenson *et al.*^[2] in 1967 using "fetacaine" as topical anesthetic. They suggested that the patient should be warned that as soon as intubation is done, he/she will be unable to speak and that he/ she will soon fall asleep. Luckily, we have made significant advances in techniques since then.

National Journal of Physiology, Pharmacy and Pharmacology Online 2020. © 2020 Ranju Jayaprakash, *et al.* This is an Open Access article distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creative commons.org/licenses/by/4.0/), allowing third parties to copy and redistribute the material in any medium or format and to remix, transform, and build upon the material for any purpose, even commercially, provided the original work is properly cited and states its license.

Awake nasal or oral flexible fiberoptic intubation (AFOI) is usually the primary method for airway management in patients with anticipated difficult airway. Experience with AFOI is not easily acquired, and success of the procedure is highly dependent on adequate preparation and sedation techniques.^[3]

Optimal conditions for AFOI include that the patient be comfortable, cooperative, free of oropharyngeal blood and secretions, and able to maintain airway with spontaneous ventilation. To achieve these conditions, the pharmacologic agent chosen for sedation should be short acting, easily titratable, provide the required amount of sedation and have little suppression of spontaneous ventilation. Techniques to improve success rate have included nasal over oral intubation (not always possible) and different protocols for sedation (sevoflurane, propofol, and fentanyl or remifentanyl with titrated or target controlled infusion).^[3-11]

Conscious sedation is a drug-induced depression of consciousness where spontaneous ventilation and cardiovascular functions are usually preserved and the patients respond to commands.^[12] Conscious sedation is an integral component for performing AFOI as deep sedation may cause loss of airway resulting in serious problems. Hence, the search for an ideal sedative regimen for AFOI is being constantly pursued by various clinical studies.

High dose propofol may cause loss of the upper airway tone making the procedure difficult. The majority of patients receiving dexmedetomidine experienced clinically effective sedation yet were still easily arousable, a unique feature not observed with other clinically available sedatives.^[13] Dexmedetomidine is highly selective, centrally active alpha-2 agonist which produces amnesia, hypnosis, anxiolysis, sympatholysis, analgesia, and antisialogogue effects. All these effects are desirable during AFOI.^[14] Dexmedetomidine can cause bradycardia and hypotension but much less respiratory depression than other sedatives. Fentanyl is a potent opioid providing mild sedation, analgesia, and hemodynamic stability beneficial for AFOI, but it causes respiratory depression, chest wall rigidity, nausea, and vomiting.^[15]

Our aim was to compare the efficacy between dexmedetomidine and fentanyl for conscious sedation in AFOI. Our objectives were to measure the time to sedation, time to intubation, the quality of intubating conditions, and the hemodynamic responses between the dexmedetomidine group and the fentanyl group. The number of attempts to secure the airway in each group was also evaluated.

MATERIALS AND METHODS

This prospective randomized double-blind study was done on 40 patients aged 20-65 years belonging to ASA Grades 1, 2, and 3 scheduled for elective surgeries and planned for AFOI at a multispecialty teaching hospital in central Kerala over a period of 2 years after getting clearance from the hospital ethics committee. Written consent was obtained from all patients. Those patients allergic to local anesthetic agents, with grossly distorted anatomy, difficult airway with impending airway obstruction, fracture base of skull, penetrating eye injuries, and infection/contamination of the upper airway (blood, friable tumor, and open abscess) were excluded from the study.

The sample size was estimated based on the results of study conducted by Cattano *et al.*^[16] in 2012 comparing remifentanil and dexmedetomidine for sedation during AFOI. A sample size of 40 was calculated from the above study with a power of 80.

Patients selected for the study were assessed before the day of surgery with a detailed history, general examination, systemic examination, airway assessment, and necessary laboratory investigations were done. The procedure of AFOI was explained and informed consent from the patients was obtained. Patients were premedicated with tablet Alprazolam 0.5 mg before shifting to the operation theater.

The patients were randomly assigned by a computer generated table into two groups – group fentanyl and group dexmedetomidine. The randomization list was maintained by the operation theater technician by sealed envelope technique. In the operation theater, nil per oral status was confirmed. Baseline blood pressure, pulse rate, and SpO₂ were recorded. Intravenous access was obtained by cannulating a peripheral vein with an 18 gauge cannula and glycopyrrolate 0.2 mg was administered. A sterile autoclaved tray was used consisting of flexible bronchoscope, light source, suction tube, adequate cotton gauze, oxygen mask, infusion pump, sterile drapes, 2% lignocaine, 4% lignocaine, 10% lignocaine spray, disposable 5 cc/20 cc syringes, and 22G cannula. A tray containing emergency drugs and resuscitation equipment were kept ready.

Patients in fentanyl group were administered 2 mcg/kg fentanyl (diluted to 10 ml in 20 cc syringe) infused over 10 min. Patients in the dexmedetomidine group were administered 1 mcg/kg dexmedetomidine (diluted to 10 ml in a 20 cc syringe) infused over 10 min. Loading of drugs was done by a person not involved in the study. Both the patient and the anesthesiologist were blinded to the procedure. Cricothyroid (trans-tracheal) injection (2.5 ml of 4% Lignocaine), to anaesthetize subglottic region, vocal cords, and trachea were done using a 22 G needle. Supra laryngeal block was given with 5 ml of 2% lignocaine, 2.5 ml behind the hyoid bone on either side. After starting the infusion, Ramsay Sedation Score (RSS) score^[17] was assessed and once it reached RSS 3 (sedated but responding to commands), flexible bronchoscopic

intubation was attempted by an expert anesthesiologist. A single introduction of the fiberscope through nasal route for intubation was defined as one attempt.

We lubricated the fiberscope with aqueous gel/KY jelly and loaded it with the uncut endotracheal tube (ETT) size 6.0-7.0. After white balancing and properly orienting the scope, 2 puffs of 10% lignocaine were used to spray the nostril through which the fiberoptic scope had to be passed. We introduced the fiberscope through the nostril into the nasopharynx and then into the oropharynx and advanced further observing the three landmarks (epiglottis, trachea, and carina). After identifying the carina, the assistant was asked to hold the fiberscope in position and intubation was performed. The patient was alerted regarding discomfort as the tube was passed through the nose. We removed the fiberscope while visualizing, to ensure tip of the ETT was in the trachea and maintained the ETT in place with the tip at 3-5 cm above the carina. Then, we fixed the ETT in place and connected to the anesthetic breathing circuit. We confirmed the ETT position by capnography, auscultation of bilateral air entry, observation of bilateral chest movement and misting of the tube, and feeling air movement at the tip of the tube. Throughout the process of AFOI, nasal prongs were kept with 5 L/min oxygen flow.

Intubating conditions were assessed by cough score^[18] (1 -None, 2 - One or two coughs, 3 - Three to five coughs, 4 - more than 5 coughs, bucking, movement). After intubation, patient was given propofol and skeletal muscle relaxant. The heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, and oxygen saturation were monitored before starting the drug infusion and at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min after starting the drug infusion. Changes in heart rate and blood pressure were observed and treated accordingly. Crystalloids (5-10 mL/kg) were administered during the loading phase of the drug. Episodes of apnea >20 s or a drop in O_2 saturation <95% were treated by bag mask ventilation and supplemental oxygen provided as necessary. Time to achieve adequate sedation and time of intubation using fiberoptic bronchoscope after starting the drug infusion, cough score to assess the ease of intubation and the number of intubation attempts were observed in both groups. After completion of the entire study, the groups were revealed to the anesthesiologist.

Data collected were entered into a master chart. Data analysis was performed using SPSS package (version 20, Chicago). The results were represented as mean and standard deviation for parametric data. Continuous variables were tested for normality using Kolmogorov–Smirnov test. Paired *t*-test was used for statistical analysis between the groups. Intergroup comparison was done using independent *t*-test. Power of 80 was used in the study. The results were considered statistically significant, if P < 0.05.

RESULTS

In this study, two groups of patients with 20 patients in each group were studied for a period of 2 years. One group was administered fentanyl and the other group was administered dexmedetomidine for conscious sedation to facilitate AFOI. Fentanyl group had 17 male and 3 female patients. Dexmedetomidine group had 14 male and 6 female patients. The mean value of age in the fentanyl group was 32.35 ± 9.157 years. The mean value of body mass index (BMI) in the fentanyl group was 22.4 ± 2.38 kg/m² and in the dexmedetomidine group was 16.4 in fentanyl group and 14:6 in dexmedetomidine group. The distribution of ASA grades in study samples was similar.

Time to Sedation

The mean time to sedation in the fentanyl group was 7.750 \pm 1.499 min and in the dexmedetomidine group was 5.250 \pm 0.952 min. The *P* value determined by independent *t*-test was < 0.001 which was significant [Table 1].

Time to Intubation

The mean time of intubation in the fentanyl group was 14.10 \pm 1.861 min and in the dexmedetomidine group was 11.25 \pm 1.333 min. The p value determined by independent *t*-test was < 0.001 which was significant [Table 1].

Cough Score

Seventeen patients in both fentanyl group and dexmedetomidine group had cough score of 2. Three patients each in fentanyl and dexmedetomidine group had cough score of 3. The difference between the groups was statistically insignificant with a P = 0.1 [Table 2].

Intubation Attempts

In the fentanyl group, three patients were intubated in 2^{nd} attempt and 17 patients were intubated in 1^{st} attempt. In the dexmedetomidine group, two patients were intubated in 2^{nd} attempt and 18 patients were intubated in 1^{st} attempt. There was no significant difference between the two groups when number of intubation attempts was compared [Table 2].

Intragroup and Intergroup Comparison of Heart Rate

Heart rate in the fentanyl group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with the basal value by paired *t*-test. There was no significant deviation in heart rate at any time compared to the basal heart rate. Heart rate in the dexmedetomidine group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with basal value by paired *t*-test. There

was statistically significant drop in heart rate at 3^{rd} , 27^{th} , and 30^{th} min. There was no significant difference in the heart rate at any time when both the groups were compared [Table 3].

Intragroup and Intergroup Comparison of Systolic Blood Pressure

Systolic blood pressure in the fentanyl group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with the basal value by paired *t*-test. Significant decrease in systolic blood pressure was noted at 3^{rd} (P = 0.018), 24^{th} (P = 0.042), 27^{th} (P = 0.01), and 30^{th} (P = 0.001) min after starting fentanyl infusion. Increase in systolic blood pressure was statistically significant at 12^{th} min (P = 0.027). Systolic blood pressure in the dexmedetomidine group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30^{th} min was compared with the basal value. There was significant drop in systolic blood pressure at 1^{st} (P = 0.004), 3^{rd} (P = 0.001), 24^{th} (P = 0.050), 27^{th} (P = 0.014), and 30^{th} min (P = 0.001). An increase in systolic blood pressure in the 9th, 12^{th} , and 15^{th} min was noted but was not significant statistically. There was no significant difference in systolic blood pressure at any time between the groups [Table 4].

Intragroup and Intergroup Comparison of Diastolic Blood Pressure

Diastolic blood pressure in the fentanyl group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with basal value by paired *t*-test. There was significant drop in diastolic blood pressure at 3rd (P = 0.001), 24th (P = 0.050), 27th (P = 0.014), and 30th min (P = 0.001). Diastolic blood pressure in the dexmedetomidine group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with the basal value by paired *t*-test. There was significant drop in diastolic blood pressure at 3rd (P = 0.011), 24th (P = 0.034), 27th (P = 0.005), and 30th min (P = 0.001). There was no significant difference in diastolic blood pressure between the groups at any point of time during the study period [Table 5].

Intragroup and Intergroup Comparison of Mean Arterial Blood Pressure

Mean arterial blood pressure in the fentanyl group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30^{th} min was compared with basal value by paired *t*-test. There was statistically significant

Table 1: Time to sedation and time to intubation in the study groups (in min)							
Groups Time to sedation Time to				Time to intubation			
	Mean	Standard deviation	<i>P</i> -value	Mean	Standard deviation	<i>P</i> -value	
Fentanyl	7.750	1.499	< 0.001	14.10	1.861	< 0.001	
Dexmedetomidine	5.250	0.952		11.25	1.333		

Table 2: Cough score (indicating ease of intubation) and intubation attempts in the study groups							
Score/Number	e/Number Cough score Intubation attem						
	Fentanyl	Dexmedetomidine	<i>P</i> -value	Fentanyl	Dexmedetomidine	<i>P</i> -value	
1	-	-	1.00	17	18	1.00	
2	17	17		3	2		
3	3	3		-	-		

	Table 3: Intragroup and intergroup comparison of heart rate (in beats per min)						
Time	Fentanyl (Mean±SD)	<i>P</i> -value (intragroup)	Dexmedetomidine (Mean±SD)	<i>P</i> -value (intragroup)	<i>P</i> -value (intergroup)		
Basal value	78.45±17.458	-	78.15±17.397	-	-		
T1	76.75±17.935	0.183	76.55±17.843	0.061	0.972		
Т3	75.20±20.297	0.225	71.75±15.764	< 0.001*	0.552		
T6	74.75±17.8694	0.237	73.70±16.040	0.055	0.846		
Т9	78.85±13.180	0.909	80.70±15.465	0.441	0.686		
T12	85.30±13.666	0.153	85.70±17.655	0.063	0.937		
T15	85.75±13.622	0.144	81.65±15.530	0.350	0.380		
T18	82.20±12.984	0.418	76.90±14.112	0.710	0.224		
T21	78.05±12.833	0.933	68.50±17.819	0.074	0.060		
T24	74.15±11.217	2.508	72.20±13.269	0.064	0.619		
T27	72.40±9.361	1.83	69.80±13.648	0.023*	0.487		
Т30	69.65±9.213	0.052*	67.20±12.526	0.004*	0.485		

TI, T3, T6, T9, T12, T15, T18, T21, T24, T27, and T30 indicate the values recorded at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min, respectively

	Table 4: Intragroup and intergroup comparison of systolic blood pressure (in mm of Hg)						
Time	Fentanyl (Mean ±SD)	P value (intragroup)	Dexmedetomidine (Mean ±SD)	<i>P</i> -value (intragroup)	<i>P</i> -value (intergroup)		
Basal value	144.15±19.126	-	145.10±17.134	-	-		
T1	133.75±33.144	0.184	141.95±17.134	0.004*	0.332		
Т3	139.50±22.472	0.018*	137.25±16.335	0.001*	0.719		
Т6	143.50±23.799	0.743	143.85±20.932	0.732	0.961		
Т9	150.00±22.354	0.104	151.65±24.737	0.177	0.826		
T12	155.50±27.035	0.027*	154.55 ± 24.208	0.054*	0.907		
T15	150.45±28.752	0.231	151.00±22.457	0.202	0.947		
T18	145.60±26.319	0.745	145.40±21.286	0.944	0.979		
T21	134.45±27.954	0.124	139.95±20.075	0.211	0.508		
T24	131.35±28.283	0.042*	136.95±20.075	0.050*	0.475		
T27	128.85 ± 25.828	0.01*	134.30±19.421	0.014*	0.455		
T30	125.30±24.121	0.001*	130.00±17.962	0.001*	0.489		

TI, T3, T6, T9, T12, T15, T18, T21, T24, T27, and T30 indicate the values recorded at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min, respectively

	Table 5: Intragroup and intergroup comparison of diastolic blood pressure (in mm of Hg)						
Time	Fentanyl (Mean±SD)	<i>P</i> -value (intragroup)	Dexmedetomidine (Mean ±SD)	<i>P</i> -value (intragroup)	<i>P</i> -value (intergroup)		
Basal value	77.45±12.301	-	75.90±9.931	-	-		
T1	75.05±10.741	0.104	74.95±11.473	0.290	0.977		
Т3	72.75±12.246	0.012*	72.95±11.095	0.011*	0.957		
Т6	74.75±12.100	0.187	76.15±9.778	0.918	0.690		
Т9	79.75±13.325	0.492	77.05 ± 20.582	0.814	0.625		
T12	82.60±17.043	0.192	76.70±20.202	0.876	0.324		
T15	79.25±15.389	0.604	78.50±11.687	0.401	0.863		
T18	75.25±15.214	0.539	73.60±11.000	0.422	0.696		
T21	72.00±15.934	0.175	69.55±11.208	0.068	0.577		
T24	67.75±13.688	0.032*	69.20±10.798	0.034*	0.712		
T27	66.25±12.867	0.012*	67.15±10.384	0.005*	0.809		
Т30	65.40±11.936	0.004*	64.85±10.179	0.001*	0.876		

TI, T3, T6, T9, T12, T15, T18, T21, T24, T27, and T30 indicate the values recorded at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min, respectively

drop in mean arterial blood pressure at 1st (P = 0.040), 3rd (P = 0.007), 24th (P = 0.039), 27th (P = 0.010), and 30th min (P = 0.002). Mean arterial blood pressure in the dexmedetomidine group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with basal value by paired *t*-test. There was significant drop in mean arterial blood pressure at 3rd (P = 0.004), 24th (P = 0.026), 27th (P = 0.008), and 30th min (P < 0.001). There was no significant difference in mean arterial blood pressure at any point of time when both groups were compared [Table 6].

Intragroup and Intergroup Comparison of Oxygen Saturation

Oxygen saturation in the fentanyl group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with basal value by paired *t*-test. In the 9th (P = 0.009) and 12th (P = 0.002) min, there was statistically significant decrease in oxygen

saturation. Oxygen saturation in the dexmedetomidine group at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30th min was compared with basal value by paired *t*-test. In 6th min (P = 0.024) and 9th min (P < 0.001), there was statistically significant decrease in oxygen saturation compared to the basal value. There was no significant difference in oxygen saturation at any point of time when both groups were compared [Table 7].

DISCUSSION

AFOI is most preferred these days for airway management in difficult airway situations. Many drugs have been studied for the purpose of conscious sedation to facilitate AFOI. In our study, we compared fentanyl 2 mcg/kg with dexmedetomidine 1 mcg/kg and found that dexmedetomidine $(t = 5.250 \pm 0.952 \text{ SD})$ achieved adequate sedation much faster compared to fentanyl $(t = 7.750 \pm 1.499 \text{ SD})$ (P < 0.001]. We found that

	Table 6: Intragroup and intergroup comparison of mean arterial blood pressure (in mm of Hg)					
Time	Fentanyl (Mean±SD)	<i>P</i> -value (intragroup)	Dexmedetomidine (Mean±SD)	<i>P</i> -value (intragroup)	<i>P</i> -value (intergroup)	
Basal value	99.40±13.994	-	99.10±10.780	-	-	
T1	96.80±13.934	0.040*	92.15±21.595	0.224	0.423	
Т3	94.50±15.763	0.007*	92.65±12.219	0.004*	0.680	
T6	97.45±15.527	0.301	98.75±12.148	0.901	0.770	
Т9	103.25±15.293	0.255	104.20±15.074	0.195	0.844	
T12	106.40±19.168	0.094	105.70±15.594	0.100	0.900	
T15	103.05±19.549	0.359	101.20±15.443	0.597	0.742	
T18	$98.60{\pm}18.986$	0.837	97.65±12.558	0.655	0.853	
T21	92.85±18.033	0.147	93.05±12.713	0.102	0.968	
T24	89.00±18.428	0.039*	90.25±13.549	0.026*	0.808	
T27	87.20±16.491	0.010*	89.90±11.562	0.008*	0.552	
T30	85.30±15.482	0.002*	85.65±9.933	< 0.001*	0.933	

TI, T3, T6, T9, T12, T15, T18, T21, T24, T27, and T30 indicate the values recorded at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min, respectively

Table 7: Intragroup and intergroup comparison of oxygen saturation (%)						
Time	Fentanyl (Mean±SD)	<i>P</i> -value (intragroup)	Dexmedetomidine (Mean±SD)	<i>P</i> -value (intragroup)	<i>P</i> -value (intergroup)	
Basal value	99.05±0.759	-	99.30±0.571	-	-	
T1	94.70±19.955	0.527	99.40±0.571	0.649	0.299	
Т3	98.90±0.718	0.545	99.10±0.641	0.330	0.359	
Т6	93.00±21.682	0.068	98.50±0.946	0.024*	0.264	
Т9	96.40±3.899	0.009*	97.25±1.209	0.000*	0.358	
T12	97.45±1.761	0.002*	97.10±1.483	0.086	0.501	
T15	93.55±19.736	0.217	98.45±1.317	0.285	0.275	
T18	99.00±0.795	0.841	94.70±19.958	0.681	0.342	
T21	99.05±0.686	1.000	99.45±0.759	0.379	0.089	
T24	99.65±0.489	0.070	99.65±0.587	0.069	1.000	
T27	99.45±0.510	0.059	99.45±0.686	0.453	1.000	
T30	99.50±0.531	0.046	99.45±0.759	0.527	0.089	

TI, T3, T6, T9, T12, T15, T18, T21, T24, T27, and T30 indicate the values recorded at 1, 3, 6, 9, 12, 15, 18, 21, 24, 27, and 30 min, respectively

we were able to intubate patients in the dexmedetomidine group much earlier ($t = 675 \text{ s} \pm 1.33 \text{ SD}$) compared to fentanyl group ($t = 846 \text{ s} \pm 1.80 \text{ SD}$). There was no significant difference in the number of attempts of intubation between the dexmedetomidine and the fentanyl group. About 90% of patients in the dexmedetomidine group and 85% of patients in fentanyl group were intubated in the 1st attempt. In our study, intubating conditions were assessed with cough score. About 85% of patients in both dexmedetomidine and fentanyl group had cough scores 2 and 15% of patients in both groups had cough score 3. There was no significant difference between groups when cough score were compared. We also assessed hemodynamic changes while doing AFOI. There were no significant differences in heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation between the dexmedetomidine group and the fentanyl group.

In our study, on intragroup analysis, there was statistically significant drop in heart rate at 3rd, 27th, and 30th min in comparison with the baseline value in dexmedetomidine group. However, there was no significant change in heart rate in the post-intubation period in comparison with baseline value in the fentanyl group. One patient each in both groups had bradycardia requiring atropine 0.6 mg intravenously. After successful intubation, we had given propofol and a skeletal muscle relaxant. The hemodynamic effects of dexmedetomidine result from a decrease in the sympathetic tone by central mechanism and increased vagal activity. Dexmedetomidine infusion may cause bradycardia, atrial fibrillation, hypotension, or hypertension particularly in higher dose. However, there are reports of unaltered hemodynamics even in higher doses of dexmedetomidine infusion. Furthermore, there was decrease in systolic blood pressure, diastolic blood pressure, and mean blood pressure noted in post-intubation period (10–15 min after giving propofol) in

both dexmedetomidine and fentanyl group of patients. In our study, there was no significant change in oxygen saturation when both groups were compared. However, on intragroup analysis, there was mild drop in oxygen saturation noted in the 9th (96.40 \pm 3.899) and 12th (97.45 \pm 1.761) min in fentanyl group of patients, and in the 6th (98.70 \pm 0.801) and 9th (97.25 \pm 1.209) min in dexmedetomidine group of patients, which was statistically significant when compared to baseline. This corresponded to peak sedation and introduction of fiberscope in either group. In our study, all patients were premedicated with alprazolam and glycopyrrolate. We used glycopyrrolate as an antisialogogue which might have prevented side effects like bradycardia in both the groups.

The study done by Mondal et al.^[19] in 2015 showed that RSS was better with dexmedetomidine group (RSS 3 ± 0.37) compared with fentanyl group (RSS 2.07 ± 0.254). They compared RSS score between two groups rather than time to sedation. This finding was in agreement with our study. The study conducted by Cattano et al.[16] showed that patients in the dexmedetomidine group took longer time to attain adequate sedation compared to remifentanyl group for doing AFOI. A study by Liu et al.^[20] showed that the time to intubate patients with dexmedetomidine was 673.1 s \pm 8.3 SD. This is similar to the findings in our study. The study conducted by Cattano et al.^[16] showed that the number of intubation attempts was more in the dexmedetomidine group compared to remifentanyl group. This was different from our study. This could be due to the lower dose of dexmedetomidine they used for loading (0.4 mcg/kg over 10 min). We used 1 mcg/kg dexmedetomidine for infusion over 10 min which might have provided better sedation which, in turn, reduced our intubation attempts. The skill of the endoscopist and the heterogeneity of the study groups would also have influenced the findings. The study conducted by Mondal et al.[19] showed that 93.3% patients in dexmedetomidine group had cough score ≤ 2 and 90% of patients in fentanyl group had cough score \geq 3. This difference from our study might be because of the pattern of anesthetising the airway. In their study, they anesthetized the airway by nebulizing 4 ml of 2% lignocaine for 20 min and sprayed the tongue and nasopharynx with 10% lignocaine and also used ligocaine jelly in the nostrils. We used 2.5 ml of 4% lignocaine for transtracheal block and 2% lignocaine for superior laryngeal nerve block and also 2 puffs of 10% lignocaine spray in the nostril through which fiberoptic scope had to be passed. This technique might anesthetize the airway much better compared to nebulization and spraying the upper airway with lignocaine which provided similar intubating conditions in both the study groups. The hemodynamic changes studied are in agreement with the previous studies conducted by Bergese et al.^[21] in 2010 and by Cattano et al.^[16] in 2012. The study done by Ryu et al.[22] in 2012 also showed no significant difference in mean arterial pressure and heart rate. However, the incidence of desaturation was lower in dexmedetomidine group compared to remifentanyl group.

Our study proved that both dexmedetomidine and fentanyl can be used to achieve satisfactory sedation along with regional block and topical anesthesia. However, dexmedetomidine achieves target sedation faster compared to fentanyl enabling early intubation.

This was a small study involving forty patients. We have not assessed the level of patient comfort or the incidence of recall of the procedure by the patients.

CONCLUSION

Both dexmedetomidine and fentanyl can be used to achieve adequate sedation for AFOI along with regional block and topical anesthesia. However, dexmedetomidine achieved target sedation faster compared to fentanyl enabling early intubation. Hemodynamic responses following administration of both drugs were similar.

ACKNOWLEDGMENTS

We are extremely thankful to the faculty at the Departments of Anaesthesiology at Azeezia Institute of Medical Sciences, Kollam and Medical Trust hospital, Cochin, for the conduct and completion of this research. We also extend our gratitude to the Pharmacology Department at Amala Institute of Medical Sciences, Thrissur, and the staff at Royal Dental College, Palakkad, for the preparation of the manuscript.

REFERENCES

- 1. Ramkumar V. Preparation of the patient and the airway for awake intubation. Indian J Anaesth 2011;55:442-7.
- 2. Bailenson G, Turbin J, Berman R. Awake intubation-indications and technique. Anesth Prog 1967;14:272-8.
- Guglielmi M, Urbaz L, Tedesco C, Pusceddu A, Sogni A, Ronzoni G. A structured training program for awake fiber optic intubation: Teaching the complete package. Minerva Anestesiol 2010;76:699-706.
- 4. Péan D, Floch H, Beliard C, Piot B, Testa S, Bazin V, *et al.* Propofol versus sevoflurane for fiberoptic intubation under spontaneous breathing anesthesia in patients difficult to intubate. Minerva Anestesiol 2010;76:780-6.
- 5. Donaldson AB, Meyer-Witting M, Roux A. Awake fibreoptic intubation under remifentanil and propofol target-controlled infusion. Anaesth Intensive Care 2002;30:93-5.
- 6. Neidhart G, Kovacs AF, Bremerich DH, Kessler P. Remifentanil-propofol for bronchoscopic fiber optic intubation under capnographic control. *Anaesthesist* 2000;49:523-6.
- Machata AM, Gonano C, Holzer A, Andel D, Spiss CK, Zimpfer M, *et al.* Awake nasotracheal fiberoptic intubation: Patient comfort, intubating conditions, and hemodynamic stability during conscious sedation with remifentanil. Anesth Analg 2003;97:904-8.
- 8. Puchner W, Egger P, Pühringer F, Löckinger A, Obwegeser J, Gombotz H. Evaluation of remifentanil as single drug for awake

fiberoptic intubation. Acta Anaesthesiol Scand 2002;46:350-4.

- Reusche MD, Egan TD. Remifentanil for conscious sedation and analgesia during awake fiberoptic tracheal intubation: A case report with pharmacokinetic simulations. J Clin Anesth 1999;11:64-8.
- 10. Mingo OH, Ashpole KJ, Irving CJ, Rucklidge MW. Remifentanil sedation for awake fibreoptic intubation with limited application of local anaesthetic in patients for elective head and neck surgery. Anaesthesia 2008;63:1065-9.
- Rai MR, Parry TM, Dombrovskis A, Warner OJ. Remifentanil target-controlled infusion vs propofol target-controlled infusion for conscious sedation for awake fibreoptic intubation: A double-blinded randomized controlled trial. Br J Anaesth 2008;100:125-30.
- American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002;96:1004-17.
- 13. Venn RM, Bradshaw CJ, Spencer R, Brealey D, Caudwell E, Naughton C, *et al.* Preliminary UK experience of dexmedetomidine, a novel agent for postoperative sedation in the intensive care unit. Anaesthesia 1999;54:1136-42.
- Hall JE, Uhrich TD, Barney JA, Arain SR, Ebert TJ. Sedative, amnestic, and analgesic properties of small-dose dexmedetomidine infusions. Anesth Analg 2000;90:699-705.
- 15. Dhasmana S, Singh V, Pal US. Awake blind nasotracheal intubation in temporomandibular joint ankylosis patients under conscious sedation using fentanyl and midazolam. J Maxillofac Oral Surg 2010;9:377-81.
- Cattano D, Lam NC, Ferrario L, Seitan C, Vahdat K, Wilcox DW, et al. Dexmedetomidine versus remifentanil for sedation during awake fiberoptic intubation. Anesthesiol Res

Pract 2012;2012:753107.

- Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxalone-alphadolone. Br Med J 1974;2:656-9.
- Xue FS, He N, Liao X, Xu XZ, Xu YC, Yang QY, *et al.* Clinical assessment of awake endotracheal intubation using the lightwand technique alone in patients with difficult airways. Chin Med J (Engl) 2009;122:408-15.
- Mondal S, Ghosh S, Bhattacharya S, Choudhury B, Mallick S, Prasad A. Comparison between dexmedetomidine and fentanyl on intubation conditions during awake fiberoptic bronchoscopy: A randomized double-blind prospective study. J Anaesthesiol Clin Pharmacol 2015;31:212-6.
- 20. Liu HH, Zhou T, Wei JQ, Ma WH. Comparison between remifentanil and dexmedetomidine for sedation during modified awake fiberoptic intubation. Exp Ther Med 2015;9:1259-64.
- Bergese SD, Khabiri B, Roberts WD, Howie MB, McSweeney TD, Gerhardt MA. Dexmedetomidine for conscious sedation in difficult awake fiberoptic intubation cases. J Clin Anesth 2007;19:141-4.
- 22. Ryu JH, Lee SW, Lee JH, Lee EH, Do SH, Kim CS. Randomized double-blind study of remifentanil and dexmedetomidine for flexible bronchoscopy. Br J Anaesth 2012;108:503-11.

How to cite this article: Baiju B, Gopakumar G, Prathibha VK, Antony J, Jayaprakash R. A prospective randomized controlled study to assess the efficacy of fentanyl and dexmedetomidine for conscious sedation in awake fiberoptic intubation. Natl J Physiol Pharm Pharmacol 2020;10(09):813-820.

Source of Support: Nil, Conflicts of Interest: None declared.