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Safety and efficacy of dexmedetomidine sedation for elective fiberoptic bronchoscopy: A comparative study with propofol



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Dexmedetomidine;
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Abstract *Background:* Dexmedetomidine has sedative and sympatholytic effects. The use of dexmedetomidine in flexible fiberoptic bronchoscopy will attenuate hemodynamic response without respiratory depression. The aim of this study was to evaluate the clinical efficiency and safety of dexmedetomidine, and to compare it with the combination of propofol-fentanyl as sedation during flexible fiberoptic bronchoscopy.

Patients and methods: Seventy-two patients scheduled for elective fiberoptic bronchoscopy were included and divided into two equal groups. In propofol-fentanyl group (group PF) patients received 0.5–1 mg/kg propofol and 1 µg/kg of fentanyl. Boluses of 20 mg of propofol were given to give a sedation level of 3–4 according to Ramsay sedation score. In dexmedetomidine group (group D), dexmedetomidine 1 µg/kg over 10 min was given as a loading dose, followed by a maintenance infusion of 0.2–0.7 µg/kg/h to keep the same level of sedation. Heart rate, blood pressure and oxygen saturation were recorded.

Results: Heart rate and mean arterial blood pressure values were significantly lower in group D compared to group PF all over the procedure. Group D had higher oxygen saturation values than group PF. Incidence of desaturation was more frequent in PF group (16.66%) compared to 5.55% in group D. There was no significant difference in patient satisfaction between the two groups.

Conclusion: Dexmedetomidine and propofol-fentanyl are effective sedatives for patients undergoing flexible fiberoptic bronchoscopy. The sympatholytic and respiratory stability effects of dexmedetomidine make it an attractive and safe alternative for sedation during FOB.

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1. Introduction

Flexible fiberoptic bronchoscopy (FOB) is usually performed by pulmonologist, and is the gold standard for visualizing the airway allowing many diagnostic and therapeutic interventions. The widespread use of the flexible bronchoscope makes

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the physicians rising importance on the use of sedation as adjunct to topical anesthesia [1]. Many sedative protocols have been investigated. Midazolam in addition to an opioid is the most common combination used to improve patient tolerance and satisfaction [2]. Using intermittent propofol boluses provides good tolerance and fast recovery for patients undergoing FOB [3]. The addition of opioids may provide antitussive effect, and also they modify the pharmacokinetics of propofol, which decreases the required propofol dose [4,5]. Opioids are frequently used in FOB in combination with benzodiazepines as they provide analgesic, anti-tussive and sedative effects. Alfentanil is ideal for FOB as it has fast onset and short duration [6,7]. Fentanyl is 100 times as potent as morphine with rapid onset and short elimination half-life which makes it suitable for use in bronchoscope [1]. Dexmedetomidine (Precedex™, Dexmedetomidine HCl Injection, Hospira Healthcare Corporation) is a highly selective α_2 -adrenergic agonist; it has sedative and analgesic properties. Dexmedetomidine does not cause respiratory depression in comparison with other sedatives [8]. It has sympatholytic effect that causes reduction in heart rate and blood pressure, which correlates with reductions in plasma levels of catecholamines [9,10]. These effects make dexmedetomidine an attractive choice for sedation during FOB. This prospective randomized trial was designed to evaluate the clinical efficacy and safety of dexmedetomidine, and to compare it with the combination of propofol-fentanyl for sedation during flexible fiberoptic bronchoscopy.

2. Patients and methods

This prospective randomized study was conducted in Ain-Shams University hospital in a period of nine months. After obtaining approval from department ethical committee, 72 adult patients aged 18–70, ASA I to III scheduled for elective flexible fiberoptic bronchoscopy were studied. FOB was performed for diagnostic purposes, with or without lung biopsy e.g. in patients with a hilar mass or nodule, lung cancer staging, hemoptysis and interstitial lung disease.

Written informed consent was obtained from all patients. Exclusion criteria included patients with oxygenation failure (baseline oxygen saturation 90% or less), bronchial asthma, or had chronic obstructive pulmonary disease with forced expiratory volume in 1 s (FEV1) less than 50% of the predicted. Patients with heart rhythm disturbance, bradycardia (heart rate less than 60 BPM), hypotension (systolic arterial pressure < 100 mmHg), untreated coagulopathy, acute myocardial ischemia, chronic or acute intake of any sedative drugs or other α_2 agonists, and intubated patients were also excluded. None of the patients received any premedication.

All patients received topical airway anesthesia with lidocaine spray 10% in the oral cavity and injection of lidocaine 2% 8 ml aliquots via the bronchoscope suction port as it was advanced to suppress cough reflex, and this was performed by the bronchoscopist. Fiberoptic bronchoscopy was performed transorally in the supine position. During the procedure, supplementary oxygen via a nasal cannula 3 L/min was given to all patients. Continuous ECG, pulse oximetry and non-invasive blood pressure every 3 min were recorded. Patients were monitored during the procedure and until discharge from the post anesthesia care unit.

Patients were randomly allocated into two equal groups using computer-generated random list, and 72 sealed envelopes were prepared and coded (36 envelopes for each group). In propofol-fentanyl group (group PF), a loading dose 0.5–1 mg/kg of propofol and 1 μ g/kg of fentanyl were given to give a sedation level of 3–4 according to Ramsay sedation score (Table 1) [11]. A bolus of 20 mg of propofol was given to maintain the same level of sedation. Propofol boluses administration was based on clinical response. In the Dexmedetomidine group (group D), dexmedetomidine was given at a rate of 1 μ g/kg over 10 min as a loading dose, followed by a maintenance infusion rate of 0.2–0.7 μ g/kg/h to keep the same level of sedation. In both groups cough, movement or agitation, were considered indicators of inadequate sedation to adjust the rate of dexmedetomidine infusion or give bolus dose of propofol.

Time to start the procedure, defined as the time from giving the sedative drug to the beginning of bronchoscopy was recorded. Changes in mean arterial blood pressure, heart rate, and oxygen saturation were recorded at specific time intervals; before giving the sedation (baseline), after administration of the study drug and until the patient achieved a sedation score of 3 (T1), at the beginning of the procedure, during advancing the bronchoscope through the vocal cords (T2), and every 3 min for three successive times. Incidence of adverse events was recorded and managed as follows: Oxygen desaturation (sat < 90%) was managed by increasing oxygen flow to 6 L/min or jaw support if required. Persistent hypoxia for more than one min necessitated withdrawal of bronchoscope and mask ventilation. If desaturation is not corrected by mask ventilation for more than two minutes endotracheal intubation should be done. Hypotension (systolic BP < 90 mmHg) was managed by IV crystalloids resuscitation. Bradycardia (heart rate < 50 bpm) was treated with IV atropine 0.01 mg/kg. Any other adverse outcomes were reported if happened.

Drug administration was terminated and disconnected from the patient when the bronchoscopist indicated that the procedure was finished. Patients were transferred to the postanesthesia care unit and stayed until fully awake. Once the patients were oriented they were questioned how comfortable/uncomfortable they felt during the procedure, they were asked to rate their level of satisfaction during FOB on a three point scale (satisfied, neutral, or unsatisfied), and this was performed by independent nurse anesthetists blinded to the type of sedation regimen.

2.1. Sample size

In a study carried out by Ryu et al. [12] the incidence of oxygen Desaturation in the PR group (propofol-remifentanyl) group

Table 1 Ramsay sedation scale [11].

1	Patient is anxious or agitated
2	Patient is cooperative, oriented and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5	Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6	Patient exhibits no response

Table 2 Comparison between the two intervention groups (Dexmedetomidine) and (Propofol-fentanyl) as regard Age, Sex, Weight, Time to start Procedure, Duration of FOB.

Patient Characteristics	Group D (n = 36)		Group PF (n = 36)		t-Value	P-value
Age (years)	50.3 ± 14.9		47.9 ± 15.3		0.502	0.619
Sex	No	%	No	%	CHI ² value*	
Male	23	63.9	25	69.4	0.250	0.617
Female	13	36.1	11	30.6		
Weight (kg)	77.9 ± 14.2		80.3 ± 14.0		-0.536	0.595
Time to start procedure (min)	10.5 ± 2.1		2.7 ± 0.73		15.431	0.000*
Duration of FOB (min)	21.8 ± 3.9		21.5 ± 3.6		0.251	0.803

Values are presented as Mean ± SD or number (%).

* Chi square test.

Table 3 Comparison between the two intervention groups (Dexmedetomidine) and (Propofol-fentanyl) as regard HR.

HR (BPM)	Group D (n = 36)		Group PF (n = 36)		t-Value	P-value
Baseline	86.0 ± 13.9		86.5 ± 14.1		-0.101	0.920
After Sedation (T1)	66.3 ± 10.5		77.5 ± 12.9		-3.002	0.0055*
At the start of FOB (T2)	85.6 ± 8.1		96.8 ± 11.9		-3.464	0.001*
3 Min	79.5 ± 7.4		93.5 ± 8.9		-5.365	0.000*
6 Min	78.3 ± 7.7		89.3 ± 7.6		-4.518	0.000*
9 Min	75.5 ± 8.4		89.3 ± 8.2		-5.218	0.000*

Values are presented as Mean ± SD.

BPM: Beat per minute.

After sedation (T1): the time the patients achieved a sedation score of 3.

At the start of FOB (T2): during advancing the bronchoscope through the vocal cords.

* Statistically significant at P < 0.05.

Table 4 Comparison between the two intervention groups (Dexmedetomidine) and (Propofol + fentanyl) as regards MAP.

MAP (mmHg)	Group D (n = 36)		Group PF (n = 36)		t-value	P-value
Baseline	90.9 ± 8.2		88.9 ± 8.5		0.772	0.445
After sedation (T1)	86.4 ± 6.8		80.4 ± 8.9		2.384	0.022*
At the start of FOB (T2)	86.4 ± 6.8		95.1 ± 8.1		-3.624	0.001*
3 min	80.7 ± 7.0		89.2 ± 7.8		-3.606	0.001*
6 min	78.0 ± 7.7		87.3 ± 7.4		-3.865	0.000*
9 min	77.3 ± 7.2		89.3 ± 8.0		-4.973	0.000*

Values are presented as Mean ± SD.

HR: heart rate.

MAP: mean arterial pressure.

After sedation (T1): the time the patients achieved a sedation score of 3.

At the start of FOB (T2): during advancing the bronchoscope through the vocal cords.

* Statistically significant at P < 0.05.

was **29%**, while the incidence of oxygen Desaturation in the PD group (propofol-dexmedetomidine) group was **3%** ($\alpha = 0.05$, power = 0.8). Sample Size Calculation was done using STATCALC Epi-Info version 7 showed that 32 subjects per group would be sufficient to detect a difference between the two groups. Assuming a **10%** dropout rate, the final sample size was set at **36 patients per group**.

2.2. Statistical methods

Analysis was performed using SPSS version 17.0 for Windows (SPSS, Chicago, IL, USA). Student's t-test (two-sided) was

used to compare group continuous variables. The Chi square test was used to analyze categorical variables. Data are presented as mean (SD) or as count (%). Two-sided P-values of 0.05 were considered significant.

3. Results

Seventy-two patients were included in this study and were divided into 2 groups, 36 patients each. No case had to be terminated prematurely because of patient intolerance or over sedation. There was no significant difference between the 2 groups with respect to age, weight, gender and duration of

Table 5 Comparison between the two intervention groups (Dexmedetomidine) and (Propofol-fentanyl) as regards O₂ saturation.

O ₂ Saturation (%)	Group D (n = 36)	Group PF (n = 36)	t-Value	P-value
Baseline	96.7 ± 1.8	97.1 ± 1.8	-0.756	0.454
After sedation (T1)	96.2 ± 1.8	96.2 ± 1.8	0.000	1.000
At the start of FOB (T2)	93.4 ± 2.8	90.9 ± 3.9	2.286	0.028*
3 Min	95.6 ± 1.8	93.6 ± 2.6	2.845	0.007*
6 min	95.6 ± 1.7	95.2 ± 1.6	0.643	0.524
9 min	96.0 ± 1.7	95.2 ± 1.6	1.551	0.129

Values are presented as Mean ± SD.

After sedation (T1): the time the patients achieved a sedation score of 3.

At the start of FOB (T2): during advancing the bronchoscope through the vocal cords.

* Statistically significant at $P < 0.05$.

Table 6 Comparison between the two intervention groups (Dexmedetomidine) and (Propofol + fentanyl) as regard incidence of complications and patient satisfaction.

Type of complications	Group		P-value
	Group D (n = 36)	Group PF (n = 36)	
Bradycardia HR < 55 bpm	No	8	0.084
	%	22.22%	
Hypotension MBP < 55 mmHg	No	6	0.478
	%	16.66%	
O ₂ desaturation (apnea or airway obstruction that needs mask ventilation)	No	2	0.260
	%	5.55%	
Patient satisfaction			0.883
Satisfied	30 (83%)	29(80.5%)	
Neutral	5 (14%)	5 (14%)	
Unsatisfied	1(3%)	2(5.5%)	

Fisher Exact Test was used as expected count less than 5.

bpm: beat per minute.

FOB. Time to start the procedure was significantly shorter in group PF compared with group D (Table 2).

Tables 3 and 4 demonstrate that baseline hemodynamics (HR and MAP) were comparable between the 2 groups. After sedation (T1) group D showed significant decrease in HR values compared to group PF (P -value 0.0055), and at the start of the procedure (T2) there was significant increase in HR and MAP in group PF compared to group D (P -value 0.001 at start of FOB). During the procedure heart rate and MAP values were significantly lower in group D compared to group PF.

After sedation there was no statistically significant difference in SpO₂ between both groups. At the start of FOB Group D had significantly higher SpO₂ than group PF (P -value 0.028). Comparing SpO₂ afterward group D had higher values than group PF during the procedure, however the changes were not statistically significant except after 3 min where P -value was 0.007 (Table 5).

Incidence of complications is summarized in Table 6, and there was no statistically significant difference between the two groups. Bradycardia HR < 55 Beat/min was a common adverse event in group D (22.22% versus 5.55% in PF group); however, it was not statistically significant (P -value 0.084). More patients in group D had MAP of less than 55 mmHg 16.66% versus 8.33% in group PF, but the difference is statistically insignificant. Three cases, two in group D and one in group PF, had an episode of both hypotension and bradycar-

dia. All patients in both groups responded well to medical treatment, and there was no hemodynamic compromise as a result of changes in HR or BP.

Apnea or airway obstruction was the causes of O₂ desaturation < 90%, that was not responding to increased O₂ flow to 6 L/min or jaw support and needed mask ventilation. The numbers shown in Table 6 represent the number of patients that had desaturation < 90% (based on SpO₂). Desaturation occurred more frequent in PF group (16.66%) in comparison with 5.55% in group D, however the difference is statistically insignificant. No patient in both groups had persistence desaturation which needed ETT.

There was no significant difference in patient satisfaction between the two groups (Table 6), and more than 80% of patients in both groups were satisfied by the procedure.

4. Discussion

Dexmedetomidine is a lipophilic α -2 agonist which sedates through its action on the locus coeruleus, the predominant noradrenergic nucleus in the brain [13].

It was theorized that the use of dexmedetomidine sedation in FOB would attenuate hemodynamic responses without respiratory depression, so this prospective randomized study was conducted to compare dexmedetomidine with intermittent

propofol boluses together with fentanyl in flexible bronchoscopy in terms of respiratory depression, and hemodynamic stability. Oxygen desaturation is a common complication during FOB, with or without O₂ supplementation. It may be caused by many factors, including hypoventilation secondary to using sedation, application of local anesthetic, or partial airway obstruction caused by the bronchoscope itself [14,15].

Propofol has been described as an ideal agent for flexible bronchoscopy sedation due to its fast onset and rapid recovery profile [16]. However controversy continues because of individualized patient response to propofol and easy shift to deeper levels of sedation with an associated risk of cardiopulmonary depression [17].

The addition of an opioid to propofol can be useful because of the antitussive effect of opioids and the enhancement of sedation quality. Many studies performed using combination of propofol and opioids had been accepted for patient sedation during bronchoscopy [18,6,19]. On the other hand, a prospective study was performed by Yoon et al. [20] to compare propofol-only sedation with propofol–alfentanil combination sedation in patients undergoing FOB, and they concluded that the combination of propofol and alfentanil resulted in a greater respiratory depression than propofol alone; furthermore, the addition of an opioid did not improve the quality of sedation. Stolz et al. [16] reported that, if supplemental oxygen is routinely provided during bronchoscopy propofol does not cause a greater fall in arterial oxygen saturation than does the combination of midazolam and hydrocodone.

Lin and colleagues [21] used propofol sedation in FOB and they noted that reducing or even managing without opioids may reduce the rate of hypoxemia.

In the present study patients in dexmedetomidine group had higher oxygen saturation values, throughout the procedure, compared to propofol group, though there was no significant difference, except at the start and 3 min from the start of FOB. Oxygen desaturation that required intervention occurred more frequently in patients of propofol group, with no significant difference, patients responded to jaw thrust and mask ventilation for one minute or less. No patient had prolonged desaturation that needed ETT. The addition of fentanyl did not cause significant effect on ventilation. Prophylactic oxygen supplement by nasal cannula was important and may had led to reduce the hypoxic episodes. Also monitoring the patients with pulse oximetry is an essential guideline during bronchoscopy [22].

The outcome of this study that dexmedetomidine caused less incidence of desaturation is supported by many previous studies, which were tested sedation with dexmedetomidine in FOB. Ryu and colleagues [12] compared it with remifentanyl and reported that dexmedetomidine was associated with lower incidences of oxygen desaturation than remifentanyl during flexible bronchoscopy.

Another pilot study was conducted by Abouzgheib et al. [23]. They tested the efficiency and safety of dexmedetomidine sedation for bronchoscopy in patients with moderate to severe COPD, they enrolled patients with forced expiratory volume in one second less than 50% of the predicted, and they found that no patient demonstrated marked hypotension or hypertension, bradycardia, apnea, or desaturation during the procedure. Liao et al. [24] showed that dexmedetomidine offered better oxygen saturation and steadier hemodynamics than midazo-

lam when used for conscious sedation for postoperative patients undergoing bronchoscopy.

Another favorable characteristic Dexmedetomidine has is its sympatholytic effects that further differentiate it from benzodiazepines, narcotics, and propofol. Dexmedetomidine blunts the deleterious cardiovascular responses (hypertension, tachycardia) to noxious stimuli, [25] and the hemodynamic response to awake fiberoptic intubation [26].

This study showed that in patients sedated with dexmedetomidine the hemodynamic response to insertion of FOB (HR and BP values) throughout the procedure was significantly lower than patients in propofol group. However no patient in propofol-fentanyl group had severe tachycardia and/or hypertension which required treatment. The significant difference in hemodynamics between both groups mostly because propofol, in the current study, was compared with dexmedetomidine which has a great sympatholytic effect, in contrast to Oztürk et al's study [27], in which propofol caused lower hemodynamic side effects when used as sedative for FOB when compared with midazolam.

Patients in both groups tolerated well the procedure and had high satisfaction scores.

There are two limitations of this study, first that the study was not blind, which was because the way of insertion and the color of both drugs were different. Second, patients with FEV1 less than 50% of predicted were excluded, which may have prevented serious O₂ desaturation to occur in both groups.

In conclusion, dexmedetomidine and propofol are effective for sedation in patients undergoing flexible fiberoptic bronchoscopy with high patient satisfaction. The sympatholytic and respiratory stability effects of dexmedetomidine make it an attractive and safe alternative for sedation during FOB.

Conflict of interest

None.

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