Journal of Cardiovascular Disease Research

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 08, 2023

Original research article

A Randomized trial to study the effect of fentanyl and dexmedetomidine for flexible diagnostic bronchoscopy

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Abstract

Introduction: Many anaesthesia techniques can be used for bronchoscopy. There are two types of bronchoscopies: flexible and rigid. Usually, flexible bronchoscopy is done under monitored anaesthesia care (MAC) or sedation and is commonly used for the diagnosis and management of a variety of pulmonary diseases, while rigid bronchoscopy is performed under general anaesthesia. Objectives were to determine the effect of fentanyl and dexmedetomidine on incidence of oxygen desaturation and assess haemodynamic variables, cough scores, satisfaction scores of patients and bronchoscopists.

Methods: A Randomised trail, double blinded study was conducted on 80 adult patients undergoing diagnostic flexible bronchoscopy. In one group propofol dexmedetomidine (PD) and another group propofol fentanyl (PF) was administered to 40 patients in each group.

Results: The incidence of oxygen desaturation was significantly lower in the PD group than in the PF group (P value). There were significant differences between groups in terms of mean arterial pressure (p value <0.0001) but, not with heart rate, cough scores, or patient satisfaction scores. However bronchoscopists satisfaction scores (P,0.01) were lower in the PD group.

Conclusions: PD group was associated with fewer incidents of oxygen desaturation than PF group. However, dexmedetomidine was associated with a longer recovery time and poorer bronchoscopists satisfaction score.

Keywords: Flexible bronchoscopy, fentanyl, dexmedetomidine, hypoxia

Introduction

Rigid bronchoscopy was initially done under local anaesthesia and was first described by Killian (1898) [1], who is referred to as the 'father of bronchoscopy'. The British Thoracic Society states that sedation for flexible bronchoscopy should be offered to the patients where there is no contraindication [2]. The aim of sedation is to facilitate patient comfort and satisfaction and to relieve patient anxiety, cough and dyspnoea while reducing complications of the procedure [3-5]. The majority of physicians now use pharmacological sedatives [6] and anxiolytics, improving procedural tolerance and patient satisfaction, as reported in several case-control studies and randomised controlled trials [7-10]. Dexmedetomidine is a selective α2-agonist with sedative and analgesic properties. It has the advantage of only causing mild respiratory depression at higher doses but does have sympathomimetic and vagolytic actions that may lead to bradycardia and hypotension [11]. These features are useful to attenuate the sympathetic response to intubation which it has been shown to do safely and effectively in flexible bronchoscopy for awake intubation [12]. Upper gastrointestinal endoscopy dexmedetomidine resulted in a shorter recovery time and increased patient satisfaction when compared to midazolam [13]. Fentanyl is 100 times as potent as morphine and has a more rapid onset of action and elimination half-life making it more suitable for use in bronchoscopy [14]. The recommended dose of fentanyl in moderate sedation is 50-200μg followed by supplemental doses of 50μg but, at the upper limit of this range, ventilatory depression is more likely, especially when co-administered with other sedatives; therefore, an initial dose of 25-50 μg is recommended with supplemental doses of 25 μg as required until the desired effect is achieved or a total dose of 200 μg has been reached. Continuous infusion at a rate of 0.05-0.08 $\mu g \bullet kg^{-1} \bullet min^{-1}$ may also be used [15].

Objectives: To determine the effect of fentanyl and dexmedetomidine on incidence of oxygen

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 08, 2023

desaturation and To assess haemodynamic variables, cough scores, satisfaction scores of patients and bronchoscopist.

Methodology: A Randomised trail, double blinded study was conducted on 80 adult patients undergoing diagnostic flexible bronchoscopy in Basaveshwara Medical College and Hospital, Chitradurga. The duration of study will be of 18 months i.e. from August 2021, to February 2023. Sample size is calculated using OPEN EPI software with significance level of 95%, power of 80%. Patients who provided written informed consent were initially randomized to the two groups by simple random method. Patients with baseline oxygen desaturation (resting hypoxaemia, 90%), asthma or chronic obstructive pulmonary disease or a forced expiratory volume in 1 s (FEV1) of 1.0 litre, bradycardia [baseline heart rate (HR), 60 beats min21], hypotension [baseline systolic arterial pressure (SAP), 100 mm Hg], in a pregnant state, and those intolerant or with an allergy to the study drug, and those unable or who refused to give informed consent were excluded. After premedication with i.v. midazolam 0.03 mg /kg in the pre-operative subjects were transferred to the operating theatre. Subjects were monitored with ECG, pulse oximetry, and non-invasive arterial pressure (NIBP) during the procedure and recovery period [until post-anaesthesia care unit (PACU) discharge].All subjects received supplemental oxygen (4 litre min21) via a nasal cannula. Oxygen saturation, HR, and mean arterial pressure (MAP) were recorded at six time points (T0, baseline; T1, passage of the bronchoscope through vocal cords; T2, 1 min after T1; T3, 3 min after T1; T4, 5 min after T1; T5, 10 min after T1). Flexible bronchoscopy. Topical anaesthesia was performed using 4% lidocaine spray in the oral cavity. A flexible bronchoscope (BF-1T60t, Olympus, Tokyo, Japan) was inserted transorally with subjects in the supine position. On visualizing the vocal cords and carina, 5 ml of 2% lidocaine was delivered through the bronchoscope channel for cough suppression. Additional topical anaesthesia was instilled at the discretion of the bronchoscopists. Subjects were randomly assigned to one of the two study groups: the propofol-fentanyl group (the PF group:- 40) or the propofol-dexmedetomidine group (the PD group:- 40). Bronchoscopists and subjects were unaware of group identities. Randomization to the two groups was performed using sealed envelopes by an anaesthesiologist. Study drugs were prepared by an anaesthetic nurse not involved in bronchoscopy; the syringe was labelled with the subject's inclusion number, and passed to another anaesthesiologist. In both groups, bolus propofol 0.5 mg/kgwas administered before infusion of the study drug. Fentanly (10 mcg/ ml) and dexmedetomidine (4 mg/ml) were prepared in separate syringes. Sedation was achieved initially with a bolus dose of the study drug (0.05 ml/kg) followed by 0.1-0.5 ml/kg continuous infusion at the discretion of the anaesthesiologist. A bolus dose of the study drug in proportional volumes was administered slowly to minimize known adverse effects, such as respiratory depression, hypotension and bradycardia. Cough and satisfaction scores were measured with a 0-100 NRS, where 0 indicates incessant cough and worst discomfort and 100 indicates no cough and no discomfort. Complications minimization:- Bradycardia (a HR of, 60 beats/min) was treated with intravenous (i.v.) atropine 0.6mg. Hypotension (SAP<90 mm Hg or a decrease of 20 mm Hg from baseline) was treated with i.v. ephedrine 6 mg. Hypertension (>than 140/90 mm Hg) and tachycardia (HR.>100 beats/min) additional bolus dose of study drug was administered.

Results: Overall, 80 patients were included in the study, 40 patients in the PF group and 40 PD Group. Results are expressed as means (SD). Oxygen saturation of the PF group was lower than that of the PD group at T1 &T2 (passage of the bronchoscope through the vocal cords) at p=0.001 and 0.028 respectively, but repeated-measures ANOVA shows no significant difference over time between the two groups (Table 1).

Table 1: Oxygen saturation during flexible bronchoscopy at different time intervals

	PF (Mean ± SD)	PD (Mean ± SD)	P Value
T0	95.75±2.44	96.5±2.2	0.1492
T1	92.2±2.2	94.1±2.6	0.0011
T2	92.1±3.2	93.8±3.6	0.0285
T3	92.4±2.3	92.4±2.6	1.0000
T4	94.2±1.6	94.5±2.5	0.5245
T5	96.2±1.8	95.5±2.2	0.1234

Table 2: Association of mean arterial pressure and heart rate between two groups

	Propofol with Fentanyl (Mean ± SD)	Propofol with Dexmedetomidine (Mean ± SD)	P Value
BP	96± 11.4	109.5± 11.6	<0.0001
HR	87.05± 21.5	87.7± 15.09	1.000

There were significant differences between groups in terms of mean arterial pressure (p value <0.0001) but, not with heart rate.

Table 3: Cough and satisfaction scores of subjects and bronchoscopists

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	Propofol with Fentanyl (Mean ± SD)	Propofol with Dexmedetomidine (Mean ± S)	P Value
Cough score	84.05± 4.3	82.7± 2.9	1.000
Satisfaction Score	81.1±1.4	87.4± 4.8	<0.0001

The cough score NRS of the subjects were not significant between the two groups. Whereas the NRS score by bronchoscopist for satisfaction was significantly lower in the PD group than in the PF group and is statistically significant (P<0.0001).

Discussion

Randomized controlled study was conducted to compare two sedative medications for the conscious sedation in diagnosctic flexible bronchoscopy. Propofol has significantly faster induction time and less recovery time with better bronchoscopists satisfaction. Propofol intravenous slow bolus with or without infusion has been previously studied and it was well tolerated [24, 25]. However, hypotension, bradycardia and apnoea were demonstrated in propofol anaesthesia [25, 26, 27]. Similarly, fentanyl has been a well-established medication especially for short procedures. It has been used as bolus and infusions with minimal adverse effects though post administration bradypnea and cardiovascular instability have been reported [28]. Previous studies of Bergese SD, Patrick Bender S, Sage K. A comparative study of dexmedetomidine with midazolam and midazolam alone for sedation during elective awake fiberoptic intubation, found that dexmedetomidine provided favourable patient and anaesthesiologist satisfaction responses and blunted haemodynamic responses to fibreoptic intubation, in one more study conduted by J. H. Ryu1, S. W. Lee2 shows the incidences of hypertension, hypotension and tachycardia tended to be higher in the remifentanil group, than dexmedetomidine although the differences did not reach statistical significance. Which is as comparable with our study also as There were significant differences between groups in terms of mean arterial pressure (p value <0.0001) but, not with heart rate.

The main concerns with sedation during flexible bronchoscopy was shared airway worring for apnoea and oxygen desaturation. Along with other factors, such as airway secretions and airway reflexas bronchoconstriction in response to insertion and bronchoscope manipulation, might be related to this sedation-related adverse event [29, 30]. The incidence of oxygen desaturation in this studies of J. H. Ryu1, S. W. Lee2shows as result similar to those found in other studies of Ozturk T, Cakan A, A. Sedation for fiberoptic bronchoscopy: fewer adverse cardiovascular effects with propofol than with midazolam. Anasthesiol Intensivmed Notfallmed Schmerzther 2004; 39: 597-602 and of studies by Silvestri GA, Vincent BD, Wahidi MM, Downie GH. A phase 3, randomized, double-blind study to assess the efficacy and safety of fospropofol disodium injection for moderate sedation in patients undergoing flexible bronchoscopy, on midazolam and opioids (21-32%). In the our, study Oxygen saturation were similar to that previous study, oxygen saturation of the PF group was lower than that of the PD group at T1 & T2 (passage of the bronchoscope through the vocal cords) at p=0.001 and 0.028 respectively, but repeated-measures ANOVA shows no significant difference over time between the two groups and all subjects recovered from oxygen desaturation after increase in oxygen flow, verbal and tactile stimulation, chin lift, and jaw thrust step wise approach, It's interesting to know that subjects in both groups reported high scores for coughing and satisfaction than bronchoscopists This means that subjects in both groups were generally satisfied with the procedure without any discomfort or coughing. The cough score NRS of the subjects were not significant between the two groups. Whereas the NRS score by bronchoscopist for satisfaction was significantly lower in the PD group than in the PF group and is statistically significant (P<0.0001).

Recovery time is one of the determinants of duration of hospital stay and duration of post procedure monitoring. Therefore, it influences the utilization of resources and manpower in the institution. Lower recovery time would improve cost effectiveness and patient safety. The strength of this study was a randomized trail design with adequate sample size. In summary, dexmedetomidine group was associated with lower incidences of oxygen desaturation than fentanyl group during MAC for flexible bronchoscopy. However, dexmedetomidine seemed to be less effective bronchoscopist satisfaction scores than fentanly.

Conclusions

Dexmedetomidine PD group was associated with fewer incidents of oxygen desaturation than PF group. However, dexmedetomidine was associated with a longer recovery time and poorer bronchoscopist satisfaction score.

ISSN:0975 -3583,0976-2833 VOL14, ISSUE 08, 2023

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