



Original Research Article

The efficacy of propofol and etomidate for sedation in endoscopic bronchial ultrasound- A randomized controlled study

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ABSTRACT

Introduction: There is paucity of Indian data regarding the use of sedation for endobronchial ultrasound. We compared the efficacy of etomidate and propofol in patients undergoing endoscopic bronchial ultrasound for the achievement of satisfactory sedation.

Materials and Methods: Seventy patients aged more than 18 years posted for endoscopic bronchial ultrasound under sedation for diagnostic and therapeutic purpose were included in this randomised double-blind controlled study. Patients were randomly allocated to propofol and etomidate group. Comparison of cardiovascular adverse events and haemodynamic parameters were the primary objectives. Comparison of gag reflex, visual analogue scale score and recovery from sedation using Modified Aldrete Score were the secondary objectives.

Results: Patient satisfaction in terms of visual analogue scale score was the same in both propofol and etomidate groups. Endoscopist's satisfaction was significantly higher in etomidate group as compared to propofol group. The post-operative hypotension was significantly lower in etomidate group as compared to propofol group. The post-operative bradycardia was significantly lower in etomidate group as compared to propofol group.

Conclusions: Endoscopist's satisfaction and the haemodynamic control was better in etomidate group as compared to propofol group during endobronchial ultrasound.

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1. Introduction

For the diagnosis and staging of lung cancer endobronchial ultrasound (EBUS) is a standard procedure.^{1,2} The essential step in EBUS- transbronchial ultrasound needle aspiration procedures is sedation. The bronchoscopist can obtain adequate tissue if there is enough sedation for the patient.

Sedation reduces patient anxiety for invasive procedures and also reduces sympathetic response and maintains haemodynamic parameters. The sedation is given so that analgesia, amnesia, immobility should be achieved during the procedure and the patient can return to consciousness

speedily to pre-procedure level.^{3,4} Sedation reduces the risk of injuries during EBUS and facilitate the endoscopists' task.⁵

Sedation and analgesia include from minimal sedation to general anaesthesia.⁶ Due to large variability in the pharmacokinetics and pharmacodynamics of the sedative drugs, a standard dose of sedatives may produce under sedations in some patients and over sedations in others.⁷ Propofol along with other sedatives like midazolam or fentanyl is used for endoscopic procedures like EBUS because distribution and elimination of propofol is faster, has shorter recovery time and no cumulative effects after infusion.

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A conventional anaesthesia-inducing drug etomidate is a suitable hypnotic drug with speedy onset and recovery.^{8,9} There are negligible unfavourable effects on cardiovascular and respiratory parameters. The drug does not stimulate histamine release and also protects the brain.^{9,10} In patients with low blood pressure, etomidate maintains the hemodynamic stability. For patients with intracranial pathology and children the drug is suitable because it can avoid hypotension.¹¹ There is paucity of Indian data regarding the use of sedation for endobronchial ultrasound. The purpose of the present study was to compare the usefulness of etomidate and propofol in patients who underwent EBUS for the attainment of acceptable sedation.

2. Materials and Methods

The present study was conducted from May 2020 to February 2021 in the department of endoscopy of a tertiary care hospital, Pune, India. We received the consent from the institutional ethics committee for this randomised double-blind controlled study. The risks and benefits of the procedure were explained to the patients. A written informed consent form was signed by the patients before the commencement of the study.

Patients aged ≥ 18 years posted for EBUS under sedation for diagnostic purpose, and falling into American Society of Anaesthesiologist (ASA) grades I and II were included. Patients requiring conversion of sedation to general anaesthesia and whose body mass index was > 30 Kg/m² were excluded.

Eighty-two patients were assessed for eligibility. Twelve patients were excluded from the study. At random 70 patients were divided into two equal groups of 35 each with the help of www.randomizer.org (Figure 1). The program was known as research randomizer. The program produced two sets of random numbers out of the range of numbers provided (for e.g. 1- 70) by taking user input on having uniqueness of the numbers to be generated. For the present study, the program produced two sets of 35 unique numbers per set. The sheet of the random numbers was ready before the study was started. Patients were randomly allocated to propofol (Group P) and etomidate group (Group E). Both, the patients and endoscopists were blind for propofol and etomidate group.

Pre-anaesthesia check-up was done one day before the procedure for fitness and patient was kept nil by mouth for at least 6 h before the procedure. The patients were informed regarding visual analogue scale (VAS) score one day prior to the procedure. The VAS score was used by the patients to describe pain.¹² The recovery from sedation was assessed by using modified Aldrete score.¹³ The VAS score was used to find the patient's awareness of pain and distress following Aldrete score of 10/10 was achieved.

Patient's intravenous (IV) line was started. Before starting the procedure, we attached the standard monitors

and recorded baseline parameters. Patients were given oxygen at the rate of 2L/min before sedation and then the oxygen flow was increased to 6L/min after sedation. The standard procedure was followed for EBUS.

We noted the occurrence or lack of gag reflex and endoscopist's agreement. Haemodynamic parameters were recorded. The episodes of bradycardia (HR < 50 /min or 20.0% decrease in HR), hypotension (systolic BP < 90 mm of Hg or 20.0% decrease in systolic BP), and desaturation (SPO₂ $< 90.0\%$) were recorded. Bradycardia was treated with injection atropine 0.6 mg and hypotension was treated with IV fluids and vasopressor injection, mephentramine 3 mg IV bolus. We evaluated the post-procedure Modified Aldrete's score (0-10) at 0 minute and at a period of 5 min subsequently. We recorded the VAS score for pain following Modified Aldrete's score of 10/10 was achieved.

Min G et al. reported that the incidence of hypotension was 29.7% and 3.1% in propofol and etomidate group respectively (p-value < 0.01).¹⁴ The sample size was 30 patients in each group was calculated by formula $N^{15} = \{2p_{av}(1-p_{av})(Z_{\alpha} + Z_{\beta})^2\} / \Delta^2$. Z_{α} (a standard normal variate at 5% type I error) was taken as 1.96, whereas Z_{β} (a standard normal deviate for (β power 80.0% at type II error) was taken as 0.842. We included 35 patients to validate the results.

3. Results

In all we assessed 82 patients. Twelve patients were excluded. Seventy patients were randomized into two groups of 35 each. In all 70 patients were analysed (Figure 1).

The mean age, mean height, mean weight and ASA grades were comparable between Group P and Group E (p-value > 0.05) (Table 1). The haemodynamic parameters were comparable between the two groups (Figures 2, 3, 4 and 5). The endoscopists' satisfaction was significantly higher in Group E as compared to Group P [31/35 (88.6% Vs 23/35 (65.7%)]. There was no statistically significant difference in the median VAS score and the mean time to achieve Modified Aldrete's score of 10/10 between the two groups. The post-operative hypotension was observed in 6/35 (17.1%) and 1/35 (2.8%) patients in Group P and Group E respectively (p-value = 0.005). The post-operative bradycardia was observed in 2/35 (5.7%) and 1/35 (2.8%) in Group P and Group E respectively (p-value = 0.005) (Table 2).

4. Discussion

Absolute patient cooperation is required for EBUS; the increased risk of unfavourable events or procedure failure may occur if the patient's cooperation is poor. Supplementary administration of sedation may be required by the endoscopist to stabilize the patient. This may increase

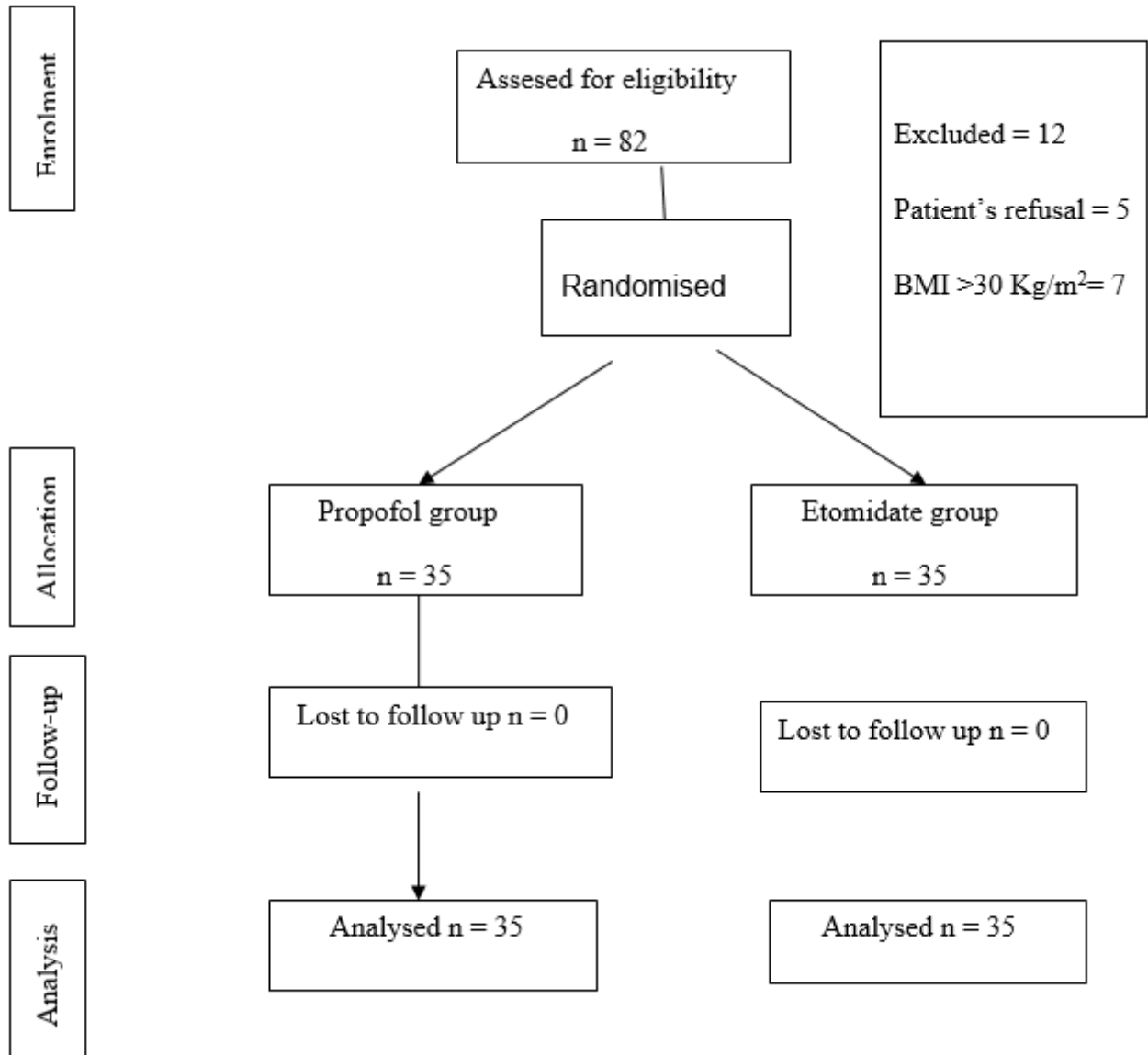


Fig. 1: Consort diagram

Table 1: Baseline characteristics

Characteristics	Group P n = 35	Group E n = 35	Total	p- value
Mean age in years ± SD	48.3 ± 9.3	47.6 ± 11.2		0.790*
Mean weight in Kg ± SD	62.9 ± 11.4	63.5 ± 10.9		0.847*
Mean height in cm ± SD	166.7 ± 14.8	166.15 ± 13.2		0.845*
ASA grade (%)				
Grade I	20 (57.1)	22 (62.8)	42 (60.0%)	0.807**
Grade II	15 (42.9)	13 (37.2)	28 (40.0%)	

*Unpaired t-test was used, **Chi square test was used

ASA - American Society of Anaesthesiologist

SD- Standard deviation

Table 2: Comparison of post-operative parameters

Characteristics	Group P n = 35 (%)	Group E n = 35 (%)	Total n = 70 (%)	p-value
Gag reflex				
Present	12 (34.3)	4 (11.4)	16 (22.9)	0.046*
Absent	23 (65.7)	31 (88.6)	54 (77.1)	
Median VAS score	1.26	1.40		0.519**
Mean time to achieve Modified Aldrete's Score of 10/10 ± SD	20.5 ± 2.3	21.7 ± 4.1		0.133***
Complications				
Nil	27 (77.2)	33 (94.4)	60(85.7)	
Hypotension	6 (17.1)	1 (2.8)	7(10.0)	0.005*
Bradycardia	2 (5.7)	1 (2.8)	3(4.3)	

* Fisher's exact test was used

** Mann-Whitney U test was used

***Unpaired t-test was used

SD- Standard deviation

VAS- Visual analogue scale

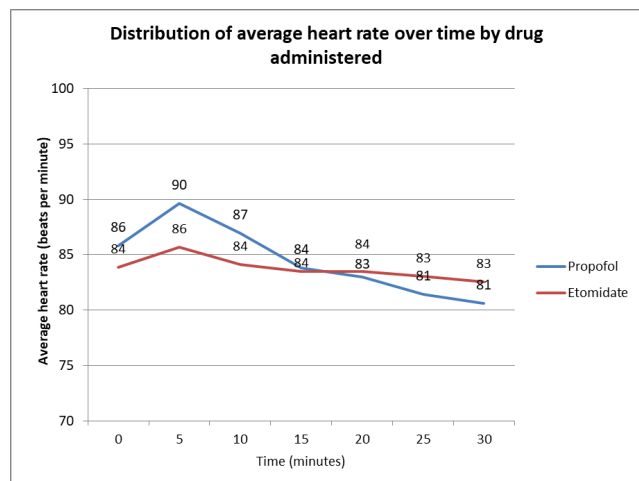


Fig. 2: Comparison of intraoperative mean heart rate - propofol vs etomidate group

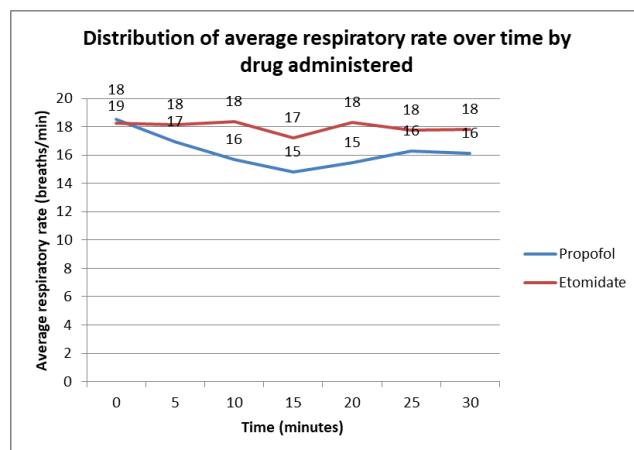


Fig. 4: Comparison of intraoperative mean respiratory rate - propofol vs etomidate group

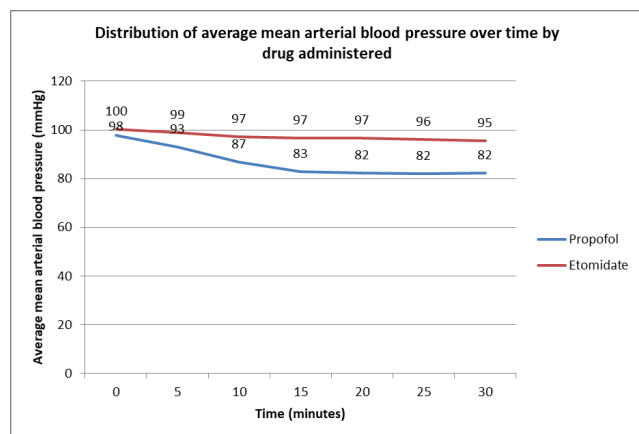


Fig. 3: Comparison of intraoperative mean MAP - propofol vs etomidate group (MAP- Mean arterial pressure)

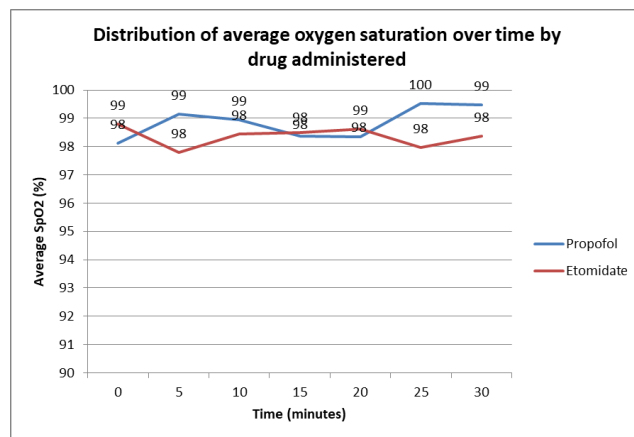


Fig. 5: Comparison of intraoperative mean oxygen saturation (SpO₂) -propofol vs etomidate group

the risk of sedation associated unfavourable events. To maintain the stability of patients during the procedure, it is recommended that propofol-based sedation may be suitable. In patients relating therapeutic echoendoscopic procedures, this may ensure successful outcomes.^{16–19} During time consuming intervention, several endoscopists vacillate in administering propofol because it may lead to possible cardio-pulmonary unfavourable events.^{5,19}

In our study, the endoscopists' satisfaction was significantly higher in Group E as compared to Group P [31/35 (88.6% Vs 23/35 (65.7%)] (p-value = 0.046). The post-operative hypotension was observed in 6/35 (17.1%) and 1/35 (2.8%) patients in Group P and Group E respectively (p-value = 0.005). The post-operative bradycardia was observed in 2/35 (5.7%) and 1/35 (2.8%) in Group P and Group E respectively (p-value = 0.005). The haemodynamic parameters were comparable between the two groups. The results of Kim MG et al.,²⁰ and Grendelmeier P et al.²¹ are similar to our study.

In our study, the intraoperative mean SpO₂ between the two groups was similar. In a study conducted by Grendelmeier P et al. 22.0% of the subjects had oxygen saturation < 90.0% after receiving propofol and one required endotracheal intubation.²¹ Falk J et al. reported that hemodynamic effects were not significant; though, 10.0% of patients developed apnea or respiratory depression (oxygen desaturation < 90.0%) who underwent sedation with etomidate with or without analgesia.²² Vinson DR et al. stated that 5 (3.3%) patients > 55 years of age who were given 0.23 mg/Kg etomidate, oxygen desaturation was < 94.0%.²³

Kim MG et al. reported hypotension in 0 (0.0%) in etomidate and 3 (4.69%) in propofol group (p-value = 0.243) and bradycardia in 10 (15.62%) in etomidate group and 12 (18.75%) in propofol group (p-value=0.815).²⁰ Min G et al., stated that the occurrence of hypotension was considerably higher in the propofol group (3.1% vs 29.7%, p-value < 0.01).¹⁴ Meng QT et al. stated that hypotension was considerably higher in propofol group as compared to etomidate group [44 (88.0%) Vs 6 (12.0%) with p-value < 0.05], but the occurrence of bradycardia was similar between the two groups [5 (10.0%) Vs 6 (12.0%)].²⁴

In our study, Gag reflex was absent in 88.6% and 65.7% patients in etomidate group and propofol group respectively (p-value = 0.046). Kim MG et al., stated that the endoscopist agreement was considerably higher in etomidate group (8.42 ± 2.07) as compared to propofol group (7.73 ± 1.70).²⁰ Similar findings were reported by Jain K et al.²⁵ whereas Min G et al., stated that the endoscopist' satisfaction scores were comparable between propofol and etomidate groups.¹⁴ The results of Kim MG et al.²⁰ and Meng QT et al.²⁴ regarding the median VAS score and the mean time to achieve Modified Aldrete's score of 10/10 were alike to our study.

5. Conclusions

From the above study, it can be concluded that the efficacy of etomidate is better than propofol in patients undergoing endoscopic bronchial ultrasound for the achievement of satisfactory sedation.

6. Source of Funding

None.

7. Conflict of Interest

Dr. Ganesh Ghongate, Dr. Naveen Gavel, Dr. Rajendra Gosavi, and Dr. Deepak Phalgune declare that they have no conflict of interest.

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