Original Article

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Anaesthesia Section

Safety and Efficacy of Nebulised Dexmedetomidine as an Adjuvant to Topical Anaesthesia in Patients Undergoing Endobronchial Ultrasound under Moderate Sedation: A Randomised Double-blinded Controlled Study

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ABSTRACT

Introduction: Anaesthetic sedatives are widely used for bronchoscopy and Endobronchial Ultrasound (EBUS) to ensure patient cooperation and minimise patient discomfort. Dexmedetomidine is an α2 adrenergic agonist used for sedation.

Aim: To evaluate the safety and efficacy of nebulised dexmedetomidine in EBUS.

Materials and Methods: In this randomised double-blinded controlled study, conducted in the Department of Anaesthesiology and Pulmonary Medicine at Sher-i-Kashmir Institute of Medical Sciences, Srinagar, Jammu and Kashmir, India from 2020 to 2022, 52 patients aged between 18 and 70 years undergoing EBUS were included. Patients were randomly assigned to the study group (S) and the control group (C). Group C received nebulised lidocaine (2%) 10 mL for 10-15 minutes in a sitting position. Group S received nebulised lidocaine (2%) 8 mL + Dexmedetomidine 2 mL (1 mcg/kg) for 10-15 minutes in a sitting position. Haemodynamic parameters, cough severity scores, patient and operator satisfaction scores, Midazolam requirements, and any complications were recorded and compared. The data were analysed statistically using the Student's t-test and Chi-square test, whichever was feasible. A p-value of <0.05 was considered statistically significant.

Results: The demographic parameters including the mean age (years) of 46.3±14.01 in Group C vs. 44.5±14.35 in Group S, mean weight (kg) of 61.6±8.27 in Group C vs. 63.5±10.06 in Group S, and male/female ratio of 12/14 in Group C vs. 9/17 in Group S were comparable. Haemodynamic parameters were better postnebulisation in Group S compared to Group C. The authors observed that the incidence of coughing was significantly higher in Group C compared to Group S (73.1% vs. 46.2%). It was found that Group C had a significantly higher requirement for midazolam doses compared to Group S (53.8% vs. 19.2%). When the patient satisfaction score assessed on the Numerical Rating Scale (NRS) was analysed, it was found that Group S patients were highly satisfied compared to Group C patients, and the difference was highly significant (p-value <0.05). No drug or procedure-related complications were observed in the two groups.

Conclusion: The present study demonstrated that nebulised dexmedetomidine-lidocaine was well-tolerated during bronchoscopies under moderated sedation and was associated with stable Haemodynamics, decreased incidence of severe coughing, and a lower consumption of sedation drugs.

Keywords: Haemodynamics, Lignocaine, Nebulisation, Numerical rating scale

INTRODUCTION

Endobronchial Ultrasound (EBUS) is an essential procedure for lung cancer diagnosis and staging [1]. Appropriate sedation is essential to ensure patient cooperation and minimise patient discomfort throughout the procedure [2-4]. Sedatives commonly used include benzodiazepines, propofol, dexmedetomidine, and opioids [5]. Dexmedetomidine, an alpha 2 adrenergic receptor agonist, is a sedative agent that provides sleep-like sedation with little respiratory suppression. However, compared to intravenous (i.v.) dexmedetomidine, there hasn't been much work done to study the relative effectiveness of nebulised dexmedetomidine [6,7]. Nebulised dexmedetomidine may provide a favourable alternative to the intravenous route in patients who are poor candidates for tolerating hypotension, bradycardia, and postoperative sedation undergoing short-duration procedures without any significant side-effects. An anaesthetist is ideally required when intravenous dexmedetomidine is administered, which adds to the procedure cost. Nebulised dexmedetomidine is an easy, non invasive method of administering sedation in situations where manpower is not trained in intravenous sedation and in high turnover settings where prolonged sedation due to intravenous dexmedetomidine is not preferred. Some studies have proven that using the nebulised form of dexmedetomidine in Flexible Bronchoscopy (FB) is more effective in patient comfort and tolerance, with a shorter recovery time compared to the existing methods used for premedication, while being safer than intravenous dexmedetomidine [6,7]. Dexmedetomidine can relieve bronchospasm in its nebulised form [8]. The main hypothesis was that patients undergoing EBUS would cough less frequently when nebulised dexmedetomidine was used as an adjuvant to lidocaine. The primary aim of the study was to evaluate cough suppression with nebulised dexmedetomidine in EBUS. The secondary outcomes were to record the midazolam-sparing effect, haemodynamic stability, patient satisfaction, and bronchoscopist satisfaction.

MATERIALS AND METHODS

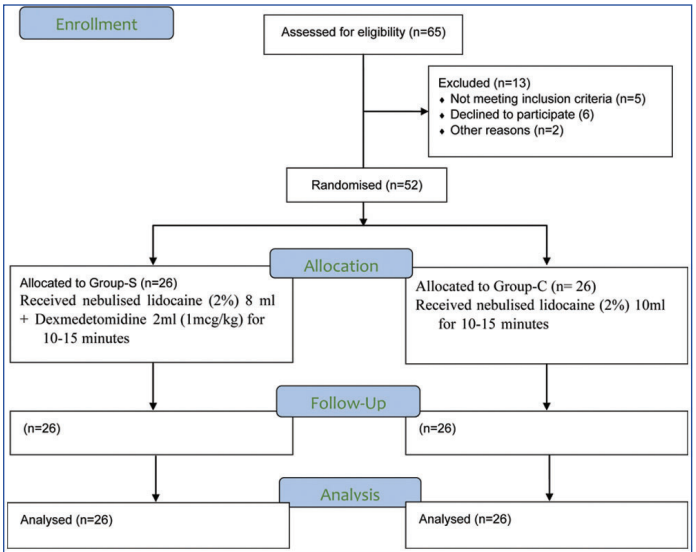
The randomised double-blinded controlled study was conducted in the Department of Anaesthesiology and Pulmonary Medicine at Sher-i-Kashmir Institute of Medical Sciences, Srinagar, Jammu and Kashmir, India from 2020 to 2022. After obtaining approval from the Institutional Ethics Committee (IEC/SKIMS#RP 045/2022, dated 11/05/22), written informed consent was obtained from all patients.

Sample size calculation: Using G*Power software (version 3.0.10; Franz Faul, Kiel, Germany), it was estimated that the least number of patients required in each group with 80% power, an effect size of 0.4, and a 5% significance level is 26. Since the authors have to compare two groups in the present study, a total of 52 patients were included.

Inclusion and Exclusion criteria: A total of 52 patients aged between 18 to 70 years with American Society of Anaesthesiologists (ASA) physical status I-III scheduled for EBUS were included. Exclusion criteria were a Heart Rate (HR) less than 60 bpm, hypersensitivity to the study drug, and a Body Mass Index (BMI) greater than 30 kg/m^2.

Study Procedure

All procedures were performed by the same team. Patients were kept fasting for eight hours before the procedure. None of the patients received any premedication. Upon arrival in the procedure room, standard monitoring, including Non Invasive Blood Pressure (NIBP), Oxygen saturation (SpO_2), and Electrocardiogram (ECG), were instituted. A 20-gauge i.v. cannula was secured, and Ringer's lactate fluid was administered at a rate of 100 mL/hr. Patients undergoing EBUS were randomised in a one-to-one ratio using a computer-generated randomisation table created with Microsoft excel software and were allocated to either Group S or Group C [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trial (CONSORT) flow diagram.

Group C: Received nebulised lidocaine (2%) 10 mL for 10-15 minutes in a sitting position.

Group S: Received nebulised lidocaine (2%) 8 mL + Dexmedetomidine 2 mL (1 mcg/kg) for 10-15 minutes in a sitting position [6].

Patients were nebulised by an anaesthesiologist who was not involved in any subsequent research to ensure double-blinding. Another anaesthesiologist carried out procedure and documented the observations. Dryness of the posterior pharynx and heaviness in the tongue served as indicators of adequate local anaesthesia. After positioning the patient supine, 10% xylocaine was sprayed onto the posterior pharyngeal wall in both groups. Supplementary oxygen was given via a nasal cannula at a rate of 4-6 litres per minute. An End-tidal Carbon Dioxide ($EtCO_2$) cannula was placed near the nasal cannula. A transtracheal block with 2-4 mL of 2% xylocaine was done in all patients. Heart rate, NIBP, and SpO_2 were recorded before the procedure and every five minutes thereafter until completion. Procedures lasting over 30 minutes were excluded from the study. A bolus of midazolam at 0.03 mg/kg was given to achieve a Ramsay sedation score of 3 to 4. Bronchoscopes were introduced transorally after putting mouth gag. Agitation or limb movements were considered inadequate sedation and were supplemented with additional boluses of midazolam. Upon visualisation of the glottis, 2-3 mL of 2% lidocaine was delivered via the working channel of the bronchoscope for cough suppression, with an additional 2 mL delivered upon visualisation of the carina.

Measurements: Demographic characteristics and procedure time were noted in all cases. Haemodynamic parameters were monitored at T0 (before the start of the procedure) and every five minutes until the end of the procedure. The cough score was assessed during bronchoscopy (Mild <2 coughs, Moderate 3-5 coughs, Severe >5 coughs) [9]. The primary endpoint was to evaluate cough suppression with nebulised Dexmedetomidine. Secondary outcomes like condition of the vocal cords, limb movements during the procedure, and sedation scores were noted. Additional doses of midazolam needed were recorded for both groups. Cough suppression and the midazolam-sparing effect were taken as indicators of Dexmedetomidine efficacy. The bronchoscopist (immediately after the procedure) and patients (after 24 hours) were interviewed regarding their satisfaction and assessed on a Numeric Rating Scale (NRS) from 0 to 100 (0 indicating incessant coughing and maximum discomfort, 100 indicating no coughing and no discomfort) [10]. Complications like hypoxia (SpO_2 <85%), bradycardia (HR <50 bpm), tachycardia (HR >120 bpm), and prolonged sedation, if any, were noted. Haemodynamic stability and any complications were considered as indicators of the safety of nebulised Dexmedetomidine.

STATISTICAL ANALYSIS

After recording and entering the data into a Microsoft excel spreadsheet, it was exported to the data editor of Statistical Package for Social Sciences (SPSS) version 20.0 (SPSS Inc., Chicago, Illinois, USA). The categorical data were summarised as frequencies and percentages, while the continuous variables were expressed as Mean±Standard Deviation (SD). The data were displayed graphically using line and bar graphs. For comparing continuous variables, either the Mann-Whitney U-test or the Student's independent t-test was used, depending on practicality. To compare categorical variables, the Chi-square test was utilised. P-values below 0.05 were considered statistically significant.

RESULTS

The demographic parameters of the groups were comparable with respect to age, weight, sex, ASA status, and duration of the procedure [Table/Fig-2]. The authors observed that SpO_2 was comparable between the groups at all times, with no statistically significant difference. The haemodynamic variables {HR, Mean Arterial Pressure (MAP)} were comparable at T0 between the groups. From T1 to T30, there was a statistically significant increase in heart rate, systolic and diastolic blood pressure in Group S compared to Group C [Table/Fig-3]. The authors

Parameters	Group C n=26	Group S n=26	p-value (Chi-square test)
Age (y)	46.3±14.01	44.5±14.35	0.823
M/F	12/14	9/17	0.397
Weight (kg)	61.6±8.27	63.5±10.06	0.455
Duration of Procedure (min)	20.53±8.70	21.67±7.56	0.224
ASA status II/I (n %)	21/5 18.8 (19.2)	20/6 76.9 (23.1)	0.734

[Table/Fig-2]: Demographic characteristics of two groups. Data presented as mean±SD and n%. SD: Standard deviation. N: number. %: percentage.

Time interval	HR (b/min)		p-value (Chi-square test)	MAP (mmHg)		p-value (Chi-square test)
	Group C	Group S		Group C	Group S	
T0	84.65 6.71	86.50 8.92	0.701	95.39 5.64	97.545.67	<0.001*
T1	93.23 5.55	83.73 5.11	<0.001*	103.3 6.62	94.386.97	<0.001*
T5	95.96 5.85	84.12 5.54	<0.001*	104.3 6.88	94.55 5.64	<0.001*
T10	94.42 4.96	84.77 4.92	<0.001*	103.4 6.24	95.34 5.73	<0.001*
T15	95.77 5.38	83.54 5.54	<0.001*	103.2 8.55	94.33 6.54	<0.001*
T20	94.15 5.14	83.31 4.47	<0.001*	103.1 6.90	94.04 6.10	<0.001*
T25	93.68 4.43	82.73 5.22	<0.001*	101.4 7.01	93.04 6.37	<0.001*
T30	93.27 5.39	82.85 5.83	<0.001*	101.6 6.71	93.45 6.37	<0.001*

[Table/Fig-3]: Comparison of haemodynamics between the two groups at different time intervals. Data presented as mean±SD and n%.
SD: Standard deviation; N: number; %: percentage; p<0.001* statistically highly significant

observed that the incidence of coughing was significantly higher in Group C compared to Group S (73.1% vs. 46.2%). The majority of patients in Group C had moderate coughing, accounting for 42.3%, while in Group S, the majority had mild coughing status (34.6%). There was no incidence of severe coughing in Group S compared to 11.5% of patients with severe cough in Group C [Table/Fig-4].

Cough	Group C n (%)	Group S n (%)	p-value (Chi-square test)
No	7 (26.9)	14 (53.8)	0.012*
Mild	5 (19.2)	9 (34.6)	
Moderate	11 (42.3)	3 (11.5)	
Severe	3 (11.5)	0 (0.0)	
Total	26 (100)	26 (100)	

[Table/Fig-4]: Incidence and severity of coughing in two groups. Data presented as n%. n: number. %: percentage.
p<0.05* statistically significant

The authors observed that both groups were comparable with respect to vocal cords and limb movement. However, open vocal cords and no limb movements were predominant features in both groups [Table/Fig-5]. When the assessment of midazolam requirement in both groups was made, it was found that Group C had a significantly higher requirement for midazolam doses compared to Group S (53.8% vs. 19.2%). A single dose of midazolam was needed in 8 (30.8%) cases in Group C compared to 3 (11.5%) in Group S, and two doses of midazolam were needed in 6 (23.1%) cases in Group C compared to 2 (7.7%) cases in Group S

Parameters		Group C n (%)	Group S n (%)	p-value (Chi-square test)
Vocal cords	Open	25 (96.2)	26 (100)	1.000
	Closed	1 (3.8)	0 (0.0)	
Limb movement	None	23 (88.5)	24 (92.3)	0.638
	Severe	3 (11.5)	2 (7.7)	

[Table/Fig-5]: Condition of vocal cords and limb movement in two groups.
Data presented as n (%). n: number. %: percentage

[Table/Fig-6]. The difference was statistically significant (p=0.035). The elapsed time until recovery in Group S was comparable to Group C (10.34±1.11 vs. 11.35±1.21, p=0.345). Patient satisfaction 24 hours postoperatively and Bronchoscopist satisfaction immediately were significantly better in Group S compared to Group C [Table/Fig-7]. No drug- or procedure-related complications were observed in the two groups.

No. of doses	Group C n (%)	Group S n (%)	p-value (Chi-square test)
None	12 (46.2)	21 (80.8)	0.035*
One	8 (30.8)	3 (11.5)	
Two	6 (23.1)	2 (7.7)	
Total	26 (100)	26 (100)	

[Table/Fig-6]: Number of doses of Midazolam needed in two groups.
Data presented as n (%). n: number. %: percentage.
p<0.05* statistically significant

Satisfaction scores	Group C	Group S	p-value (Student's t-test
Patient	64±21.4	79.8±10.96	<0.001*
Bronchoscopist	69.4±21.28	84.6±11.74	<0.001*

[Table/Fig-7]: Comparison of the mean patient satisfaction score and Bronchoscopist satisfaction score between the two groups. Data presented as mean±SD.
p<0.001* statistically highly significant

DISCUSSION

Endobronchial Ultrasonography (EBUS) is a type of bronchoscopy in which the mediastinum, lung, and airway wall are seen using ultrasound technology. Various classes of drugs are used to provide sedation during bronchoscopy, including Benzodiazepines, Propofol, Alpha 2 agonists, Opioids, and Ketamine [11]. Sedation reduces patient anxiety, improves test tolerance, enhances comfort for both the bronchoscopist and the patient and ensures readiness to repeat the test if necessary.

A relatively recent medication being utilised as an Intensive Care Unit (ICU) sedative is dexmedetomidine [9]. This α2-adrenoceptor agonist has hypnotic and analgesic properties without inducing respiratory depression, unlike traditional sedative drugs [12]. Previous studies have used intravenous dexmedetomidine at various doses, an effective sedative agent [13,14]. However, with greater doses, intravenous dexmedetomidine may occasionally cause a drop in blood pressure and heart rate. The bioavailability of dexmedetomidine is 65% via inhalation through the nasal mucosa and 82% through the buccal mucosa compared to the intravenous route. Hence, adverse events such as hypotension, bradycardia, desaturation, and transient hypertension, though possible, are expected to be rare [15,16]. Gu W et al., and Antony T et al., in their studies, compared the acceptability and safety of nebulised dexmedetomidine to those of normal intravenous delivery in patients undergoing flexible bronchoscopy [7,17]. They observed that nebulised dexmedetomidine lidocaine inhalation was well-tolerated during bronchoscopy and was associated with a reduced incidence of severe coughing.

In the current study, Group C, receiving nebulised lidocaine, was associated with a significant increase in HR, SBP, DBP, and MAP during the procedure compared to Group S. This infers the fact, that the addition of 2 mL of dexmedetomidine (1 mcg/kg) to nebulised lidocaine (2%) improves the haemodynamic response of patients. Shafa A et al., conducted a study to compare the effects of nebulised dexmedetomidine and nebulised lidocaine on haemodynamic characteristics among paediatric patients undergoing bronchoscopy, in which they reported that premedication with nebulised dexmedetomidine was significantly associated with more stable haemodynamic parameters and a lower risk of side-

effects compared to nebulised lidocaine in children undergoing fibre-optic bronchoscopy [18].

Nebulised dexmedetomidine is likely to avoid reflex bronchospasm during FB because it also has the advantage of relaxing bronchial smooth muscle [8]. Dexmedetomidine's comparatively little impact on upper airway muscles significantly reduces respiratory depression during sedation [19]. The present study demonstrated that nebulised dexmedetomidine-lidocaine inhalation was well-tolerated during bronchoscopies under moderate sedation and was associated with a decreased incidence of coughing, early recovery, and a lower consumption of sedative drugs. The authors observed that the incidence of coughing was significantly higher in Group C compared to Group S [Table/Fig-4]. Similar findings were observed by Gu W et al., in their study. Saidie S et al., in their study on the efficacy of dexmedetomidine versus lidocaine in suppressing cough during anaesthetic emergencies, reported that dexmedetomidine was more effective than lidocaine in suppressing cough in patients undergoing anaesthesia, which concurs with the present study [7,20].

In a study by Lee JS et al., to determine if a single dose of dexmedetomidine might effectively suppress coughing while under anaesthesia, they reported that the dexmedetomidine group demonstrated a lower frequency of coughing during endotracheal extubation [21]. Similar to the present study, Mirkheshti A et al., and Gu W et al., in their studies, also observed an insignificant difference between the groups with respect to vocal cords and limb movement [Table/Fig-5] [7,22]. When the assessment of midazolam requirement in both groups was made, it was found that Group C had a significantly higher requirement for midazolam doses compared to Group S (53.8% vs 19.2%). This indicates that nebulised dexmedetomidine in combination with lidocaine significantly restricts the need for midazolam. Because of its sedative and analgesic properties, dexmedetomidine has been licensed in both Europe and the US. The effects are mediated by $\alpha 2$ adrenergic receptors located in the spinal cord's dorsal horn and locus coeruleus [23].

The present study demonstrated that patients were highly satisfied in Group S compared to Group C. The mean patient satisfaction score for Group S was 79.8±10.96 compared to 64±21.4 in Group C ($p<0.001$). Bronchoscopist satisfaction score on the ease of the procedure was also highly significant in Group S compared to Group C (84.6±11.74 vs. 69.4±21.28, 95% CI). Shafa A et al., in their study, also reported a significant difference between the three groups regarding the level of satisfaction of the bronchoscopist while performing fibre-optic bronchoscopy [18]; this level was higher in the first group (nebulised dexmedetomidine; 4.92±0.27) than in the second group (nebulised lidocaine; 4.16±0.62) and was also higher in the second group than in the third group (normal saline; 3.68±0.62) ($p<0.01$). The authors did not observe any significant side-effects like hypotension, bradycardia, excessive sedation, and signs of lidocaine toxicity.

Limitation(s)

The ease of bronchoscopy is subjective and could vary with different observers and proceduralists. To achieve desired results, nebulised dexmedetomidine or lidocaine needs to be administered for 20 to 30 minutes prior to starting the procedure. This longer time to the onset of action can sometimes be undesirable when there is a long list of surgeries or when the procedure needs to be started earlier. Intravenous sedatives, though used in both groups, can add as a confounding factor.

CONCLUSION(S)

The present study demonstrated that nebulised dexmedetomidine-lidocaine inhalation was well-tolerated during EBUS under mild sedation and was linked to a lower incidence of moderate to severe coughing, quicker recovery, optimal maintenance of vitals, and a lesser need for additional doses of midazolam and lidocaine. In view of its safety and efficacy, it can be safely used by the proceduralist in airway instrumentation procedures like FB and EBUS, alleviating the need for trained anaesthesiologists in limited resource settings and therefore, reducing procedure costs.

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