

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20261121>

Original Research Article

## Nebulized lignocaine versus saline in non-sedated flexible bronchoscopy: a double-blind randomized controlled trial

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**Received:** 13 March 2026

**Accepted:** 08 April 2026

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### ABSTRACT

**Background:** Flexible bronchoscopy performed without sedation can cause patient discomfort, coughing, and anxiety, potentially affecting procedural quality. Nebulized lignocaine has been proposed as an adjunct to standard topical anesthesia to improve tolerance, but evidence remains inconsistent.

**Methods:** In this double-blind, randomized, placebo-controlled trial, 150 adult patients undergoing diagnostic non-sedated flexible bronchoscopy were randomized to receive pre-procedure nebulization with 4 ml 2% lignocaine (n=73) or 4 ml 0.9% saline (n=77), in addition to standard topical anesthesia. Primary outcomes included operator- and patient-rated cough scores assessed by visual analogue scale (VAS). Secondary outcomes included cumulative lignocaine dose, procedural characteristics, complications, and willingness to undergo repeat bronchoscopy. Statistical significance was set at  $p < 0.05$ .

**Results:** Operator- and patient-rated cough scores were comparable between groups ( $3.04 \pm 0.79$  versus  $3.12 \pm 0.84$ ,  $p = 0.53$ ;  $2.91 \pm 0.76$  versus  $2.98 \pm 0.81$ ,  $p = 0.57$ ). Cumulative lignocaine dose was significantly higher in the lignocaine group but did not exceed upper safety limit. ( $12.2 \pm 1.4$  ml versus  $12.7 \pm 1.2$  ml,  $p < 0.020$ ). So pre procedural nebulized lignocaine does not produce additional benefit and may be safely omitted during routine flexible bronchoscopy. Procedural timings, complications, and willingness to repeat bronchoscopy did not differ significantly. No adverse events or signs of lignocaine toxicity were observed in either group.

**Conclusions:** Pre-procedural nebulized lignocaine did not improve cough suppression, procedural comfort, or willingness for repeat bronchoscopy as compared to normal saline. Although it reduced total lignocaine exposure, routine use as an adjunct to standard topical anesthesia provides limited additional benefit and may be safely omitted, particularly in resource-limited settings.

**Keywords:** Flexible bronchoscopy, Nebulized lignocaine, Non-sedated, Topical anesthesia, Cough

### INTRODUCTION

Flexible bronchoscopy is widely used for diagnostic and therapeutic evaluation of airway disease, allowing direct visualization of the tracheobronchial tree and facilitating procedures such as bronchoalveolar lavage, endobronchial biopsy, transbronchial lung biopsy, and transbronchial needle aspiration.<sup>1</sup> Despite its widespread use,

bronchoscopy is frequently associated with patient discomfort, coughing, and anxiety, which may adversely affect procedural quality and patient cooperation. Traditionally, these concerns are addressed with intravenous conscious sedation; however, sedation may not always be feasible or desirable due to patient comorbidities, risk of respiratory depression, limited anesthetic support, or the need for rapid outpatient

turnover, particularly in resource-limited settings.<sup>2</sup> As a result, flexible bronchoscopy without sedation remains common practice in many regions, including India.<sup>3,4</sup>

In the absence of sedation, adequate topical airway anesthesia becomes essential for ensuring patient comfort and procedural success. Lignocaine (lidocaine) is the most commonly used local anesthetic for airway anesthesia during bronchoscopy because of its rapid onset of action, effectiveness in suppressing airway reflexes, and favorable safety profile. Nevertheless, lignocaine is not devoid of risk; systemic absorption may result in dose-related adverse effects, including central nervous system and cardiovascular toxicity. Plasma lignocaine concentrations have been shown to correlate with the cumulative administered dose, emphasizing the importance of using the lowest effective dose to achieve adequate anesthesia.<sup>5,6</sup>

Topical airway anesthesia during flexible bronchoscopy typically targets the nasal passages, oropharynx, vocal cords, and trachea. Commonly employed methods include lignocaine gel for nasal anesthesia, lignocaine spray for pharyngeal anesthesia, and intratracheal administration via the spray-as-you-go technique or cricothyroid injection. Nebulized lignocaine represents a non-invasive alternative capable of anesthetizing multiple airway regions simultaneously and is relatively easy to administer. Owing to these advantages, nebulized lignocaine has attracted interest as a potential adjunct to standard topical anesthesia, particularly in non-sedated bronchoscopy.<sup>7</sup>

However, evidence regarding the clinical benefit of nebulized lignocaine remains inconsistent. Earlier studies suggested improved patient tolerance and reduced cough with nebulized lignocaine administration, whereas later randomized controlled trials have produced conflicting results. Some investigations demonstrated reductions in cough severity, sedative requirements, or total lignocaine dose, while others failed to show significant improvement in patient comfort or operator satisfaction when nebulized lignocaine was added to standard lignocaine spray protocols.<sup>8,9</sup> Importantly, several of these studies were conducted under moderate sedation, utilized varying lignocaine concentrations, or employed heterogeneous outcome measures, thereby limiting their applicability to awake bronchoscopy settings.<sup>10</sup>

Current evidence does not support the routine use of nebulized lignocaine in addition to pharyngeal lignocaine spray for all patients undergoing flexible bronchoscopy. Nevertheless, in real-world clinical practice—particularly in high-volume centers performing non-sedated bronchoscopy—the potential role of nebulized lignocaine as a lignocaine-sparing strategy or as a means of improving patient tolerance remains uncertain. Furthermore, there is a relative paucity of well-designed, double-blind randomized controlled trials specifically evaluating nebulized lignocaine in non-sedated flexible bronchoscopy, especially from the Indian subcontinent.<sup>4,11</sup>

In view of these gaps in evidence, the present study was designed to compare pre-procedure nebulization with lignocaine versus saline in patients undergoing non-sedated flexible bronchoscopy. The primary outcomes focused on cough severity and procedural tolerance, while secondary outcomes included cumulative lignocaine dose, safety parameters, and patient willingness to undergo repeat procedures. By employing a double-blind randomized controlled design, this study aims to generate robust pharmacological evidence to guide the rational use of lignocaine during non-sedated flexible bronchoscopy.

## METHODS

### *Study setting*

The study was carried out in the department of Pulmonary Medicine and Pharmacology, Dr. R.P.G.M.C. Kangra at Tanda, a multispecialty tertiary healthcare facility located in the Kangra valley of Himachal Pradesh in India.

### *Study design*

The study was a prospective, randomized, double-blind, placebo-controlled interventional trial.

### *Study duration*

The study was conducted over a period of one year from 21 August 2024 to 20 August 2025 after receiving ethical approval from institute ethical committee.

### *Sample size*

Considering the time-bound nature of the study, all eligible patients presenting during the study period were enrolled, resulting in a total sample size of 150 participants.

### *Study population*

Adult patients aged  $\geq 18$  years undergoing flexible bronchoscopy for the first time were screened for eligibility.

### *Inclusion criteria*

Patients aged  $\geq 18$  years of either gender who were planned for diagnostic flexible bronchoscopy for the first time, hemodynamically stable, and willing to provide written informed consent included in the study.

### *Exclusion criteria*

Patients were excluded if they refused to provide informed consent, were pregnant, had baseline hypoxemia ( $SpO_2 < 90\%$  on room air), underwent bronchoscopy via the oral route, endotracheal tube, or tracheostomy, had a plan for upfront intravenous sedation, had a known hypersensitivity to lignocaine, or had abnormal baseline hemodynamic parameters, including systolic blood

pressure >180 mmHg or <100 mmHg, heart rate >100 beats/min or <50 beats/min, or the presence of cardiac arrhythmia.

**Randomization and blinding**

Participants were randomized into two groups using a simple random sampling (chit) method. Identical folded chits labeled group A or group B were placed in a container, and each participant randomly selected one chit.

Group A (control group) included nebulization with 4 ml of 0.9% normal saline.

Group B (intervention group) included nebulization with 4 ml of 2% lignocaine.

The nebulizing solutions were prepared and administered by a nursing staff member not involved in the bronchoscopy or outcome assessment. Both the patient and the bronchoscopist were blinded to group allocation. Solutions were administered using identical nebulizer setups to maintain blinding.

**Study procedure (intervention)**

All participants were advised to fast for at least four hours prior to the procedure. Baseline demographic details and vital parameters, including blood pressure, heart rate, respiratory rate, and oxygen saturation, were recorded. A lignocaine hypersensitivity test was performed in all participants prior to nebulization.

Nebulization was administered over 10 minutes using a compressed air nebulizer mask (made of medical-grade PVC apex care): group A received 4 ml of 0.9% normal saline, and group B received 4 ml of 2% lignocaine.

No intravenous sedatives were administered to any participant. Following nebulization, flexible bronchoscopy (Olympus BF-1TH190; Olympus Medical Systems Corp., Japan) was used for the procedure. Standard topical anesthesia was provided to both groups which including, five sprays (10 mg per spray) of 10% lignocaine to the pharynx and 5 ml of 2% lignocaine jelly applied to both nostrils. Additionally, a 1% lignocaine solution was administered using the “spray-as-you-go” technique during bronchoscope insertion and navigation. Vital parameters were continuously monitored throughout the procedure. Procedural timings, including time to cross the vocal cords and total procedure duration, were recorded.

**Outcome measures**

*Primary outcome*

Primary outcome included operator-rated cough score during the procedure, assessed using a visual analogue

scale (VAS), and patient-rated cough score assessed two hours after the procedure using VAS.

*Secondary outcomes*

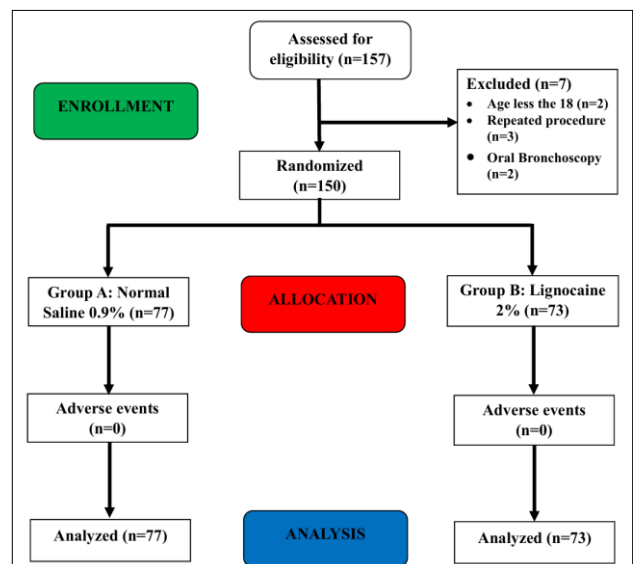
Secondary outcomes included cumulative dose of lignocaine administered, proportion of patients receiving lignocaine dose >8.2 mg/kg, patient willingness to undergo repeat bronchoscopy, time to cross the vocal cords, and procedure-related complications, if any.

**Statistical analysis**

All collected data were entered into Microsoft Excel and subsequently analyzed using Epi-Info statistical software. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean±standard deviation or median (interquartile range), depending on data distribution. Comparative analyses between groups were performed using the Chi-square test or Fisher’s exact test for categorical variables, depending on cell distribution. For continuous variables, the independent student’s t-test was employed to assess differences across groups. A p value of less than 0.05 was considered statistically significant for all analyses.

**RESULTS**

A total of 157 patients were assessed for eligibility. seven patients were excluded (age <18 years, n=2; repeat bronchoscopy, n=3). The remaining 150 patients were randomized, with 77 allocated to the normal saline group (group A) and 73 to the lignocaine nebulization group (group B). All randomized participants completed the study and were included in the final analysis. No procedure-related adverse events were reported in either group. as shown in Figure 1.



**Figure 1: Consort flowchart showing enrolment, allocation and analysis.**

The mean age of participants was 61.8±13.8 years in group A and 62.5±12.7 years in group B (p=0.747). Male patients predominated in both groups. Body mass index distribution and baseline vital parameters did not differ significantly between the groups, as shown in Table 1.

**Table 1: Baseline demographic characteristics of study participants.**

Characteristics	Group A (normal saline) n=77	Group B (Lignocaine) n=73	P value
<b>Age (years)</b>			
Mean±SD	61.8±13.8	62.5±12.7	0.747
<b>Sex, n (%)</b>			
Male	60 (77.9)	56 (76.7)	0.570
Female	17 (22.1)	17 (23.3)	
<b>BMI (kg/m<sup>2</sup>), n (%)</b>			
Underweight (<18.5)	11 (14.3)	8 (10.9)	0.530
Normal (18.5–24.9)	55 (71.4)	56 (76.8)	
Overweight (25–29.9)	10 (12.9)	9 (12.3)	
Obese (≥30)	1 (1.4)	0 (0.0)	

Baseline oxygen saturation, respiratory rate, and blood pressure were comparable between groups. Procedural timings, including time to cross the vocal cords and total procedure duration, showed no statistically significant difference, as shown in Table 2.

**Table 2: Comparison of procedural parameters between groups.**

Parameter	Group A (normal saline) n=77, mean±SD	Group B (Lignocaine) n=73, mean±SD	P value
<b>SpO<sub>2</sub> (%)</b>	96.6±1.7	96.0±1.8	0.36
<b>Respiratory rate (breaths/min)</b>	18.3±2.1	18.1±2.0	0.28
<b>Time to cross vocal cords (min)</b>	0.90±0.30	1.05±0.40	0.39
<b>Total procedure duration (min)</b>	7.1±1.9	6.9±2.0	0.53

There was no statistically significant difference between the two groups in terms of cough severity during and after non-sedated flexible bronchoscopy. The operator-rated cough score assessed intra-procedurally was comparable between the normal saline group and the nebulized lignocaine group, with no statistically significant difference observed. Similarly, the patient-rated cough score measured two hours after the procedure using the

Visual analogue scale did not differ statistically significant between the two groups. The total cumulative dose of lignocaine administered during bronchoscopy was statistically significant higher in the nebulized lignocaine group compared to the saline group but not exceed the lignocaine upper safety limit. With regard to willingness to undergo repeat bronchoscopy, the majority of patients (n=124, 82.7%) were unwilling, while 26 patients (17.3%) expressed willingness to repeat the procedure; this distribution was comparable between the two groups and did not achieve statistical significance. No major adverse events or features suggestive of lignocaine toxicity were observed in either group, as shown in Table 3.

**Table 3: Comparison of primary and secondary outcome measures.**

Parameter	Group A (normal saline) n=77, mean±SD	Group B (Lignocaine) n=73, mean±SD	P value
<b>Operator-rated cough score (VAS)</b>	3.12±0.84	3.04±0.79	0.53
<b>Patient-rated cough score (VAS),</b>	2.98±0.81	2.91±0.76	0.57
<b>Total lignocaine dose (ml)</b>	12.2±1.4	12.7±1.2	<0.020
<b>Willingness to repeat procedure, n (%)</b>			
Yes	17 (22.1)	9 (12.3)	0.140
No	60 (77.9)	64 (87.7)	

## DISCUSSION

Flexible bronchoscopy without sedation continues to be widely practiced in resource-limited settings due to concerns related to patient comorbidities, risk of respiratory depression, and limited anesthetic support.<sup>1,2</sup> In such circumstances, effective topical airway anesthesia is critical to ensure procedural success while maintaining patient safety. This randomized double-blind trial evaluated whether nebulized lignocaine provides additional benefit over nebulized saline in non-sedated flexible bronchoscopy.

The present study demonstrates that nebulized lignocaine did not significantly reduce cough severity, as assessed by both operator-rated and patient-rated visual analogue scale scores. These findings suggest that when standard topical anesthesia techniques—such as pharyngeal lignocaine spray, nasal lignocaine jelly, and spray-as-you-go lignocaine—are adequately applied, the addition of nebulized lignocaine does not confer meaningful improvement in cough suppression. Similar observations have been reported studies by Islamitabar et al and Soliman et al, in previous randomized that failed to show significant

advantages of nebulized lignocaine over conventional topical anesthesia methods.<sup>12,13</sup> The lack of benefit may be attributable to sufficient airway anesthesia achieved through established techniques, leaving little scope for incremental improvement with nebulization.

Importantly, although cough scores were comparable, the cumulative lignocaine dose was significantly lower in patients receiving nebulized lignocaine. This cumulative lignocaine dose has relevant pharmacological implications, as systemic lignocaine toxicity is dose-dependent and plasma concentrations correlate with total administered dose.<sup>14</sup> Prior studies have raised concerns regarding inadvertent lignocaine overdose during bronchoscopy, particularly in elderly patients and those with cardiovascular comorbidities.<sup>15</sup> While no adverse events were observed in the present study, the reduction in total lignocaine exposure suggests that normal saline may enhance procedural safety margins without compromising procedural outcomes.

Patient willingness to undergo repeat bronchoscopy was low in both groups, with no statistically significant difference between them. This finding highlights the inherently uncomfortable nature of non-sedated bronchoscopy and indicates that cough suppression alone may not sufficiently influence patient acceptance of repeat procedures. Similar low repeat willingness has been documented in studies evaluating awake bronchoscopy, emphasizing the multifactorial determinants of patient tolerance, including anxiety, procedural discomfort, and individual pain perception.<sup>16</sup>

Procedural feasibility was comparable between the two groups, with no significant differences in time to cross the vocal cords or total procedure duration. The absence of procedure-related complications further confirms the safety of both nebulization strategies when used alongside standard topical anesthesia protocols.

### **Strengths and limitations**

This study has several strengths that enhance the reliability of its findings. It was a randomized, double-blind, controlled trial that minimized bias through uniform nebulization and standardized airway anesthesia protocols. The study was conducted in a real-world, non-sedated bronchoscopy setting, making the results clinically relevant. Both patient-reported and operator-reported outcomes were assessed, and safety was confirmed, with no adverse events observed. Importantly, to the best of our knowledge, this is the first randomized controlled study of nebulized lignocaine conducted in the sub-Himalayan region, adding valuable regional data to the existing literature.

However, the study has certain limitations. These include its single-center design, a moderate sample size, lack of assessment of serum lignocaine levels, absence of a sedated

comparison group, and unmeasured operator-related variability.

Overall, the study demonstrates that nebulized lignocaine is safe but offers limited additional benefit during unsedated bronchoscopy. Therefore, the findings should be interpreted in light of these limitations.

### **CONCLUSION**

In this randomized, double-blind, placebo-controlled trial of non-sedated flexible bronchoscopy, pre-procedural nebulized (4 ml) 2% lignocaine did not confer any clinically meaningful advantage over normal saline in terms of cough severity, procedural comfort, or willingness to undergo repeat bronchoscopy. Operator- and patient-rated cough scores, procedural characteristics, and complication rates were comparable between groups. Although cumulative lignocaine use differed statistically, it remained clinically insignificant and within safe limits, with no adverse events observed. Overall, when standard topical anesthesia is adequately administered, routine use of nebulized lignocaine offers no additional benefit and may be safely omitted, particularly in resource-limited settings.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Minhas A, Sood A, Dadhwal DS, Sawaraj S. Nebulized lignocaine versus saline in non-sedated flexible bronchoscopy: a double-blind randomized controlled trial. *Int J Basic Clin Pharmacol* 2026;15:538-43.