

# The Cricothyroid versus Spray-As-You-Go Method for Topical Anesthesia during Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA): The CRISPEN Randomized Clinical Trial

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## ABSTRACT

**Background:** Guidelines for flexible bronchoscopy in adults recommend both Cricothyroid and Spray-as-you-go method as the acceptable techniques for lignocaine administration. No studies have compared these two methods for topical anesthesia during endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA). **Objectives:** Co-primary outcomes were the comparison of cough count and operator-rated overall procedure satisfaction on a Visual Analog Scale (VAS) between the groups. The secondary outcomes were cumulative lignocaine dose, time from bronchoscope introduction to crossing the vocal cords, procedure duration, and complications between the groups. **Methods:** Consecutive participants (age >18 years) undergoing EBUS-TBNA were randomized (1:1) to either cricothyroid or spray-as-you-go methods for lignocaine administration. **Results:** Three hundred and sixty-five participants were randomized (183: Cricothyroid and 182: Spray-as-you-go). Cough count till reaching carina (median [interquartile range]) was significantly lower (cricothyroid, 1 [0–2] vs. spray-as-you-go, 4 [2–6],  $P < 0.001$ ) and operator rated overall procedure satisfaction, on VAS (mean  $\pm$  standard deviation) (cricothyroid,  $7.96 \pm 1.48$  vs. spray-as-you-go,  $7.29 \pm 1.48$ ,  $P < 0.001$ ) significantly greater in the cricothyroid group. Cumulative lignocaine dose ( $163.28 \pm 31.50$  mg vs.  $177.0 \pm 30.12$  mg,  $P < 0.0001$ ) and time from bronchoscope introduction to crossing the vocal cords ( $20.80 \pm 11.21$  s vs.  $38.08 \pm 15.26$  s,  $P < 0.001$ ) was significantly lower in the cricothyroid group. Procedure duration was similar in both the groups. Minor complications occurred in three patients in cricothyroid and six patients in the spray-as-you-go group ( $P = 0.31$ ). **Conclusions:** Cricothyroid lignocaine administration is associated with less cough and superior operator-rated procedure satisfaction during EBUS-TBNA, at a lower cumulative lignocaine dose administered. **Trial Registration:** www.clinicaltrials.gov NCT02981264

**KEY WORDS:** Anesthesia, bronchoscopy, cricothyroid, endobronchial ultrasound, lignocaine

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## INTRODUCTION

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a minimally invasive modality for obtaining the tissue samples from the mediastinal lymph nodes and mediastinal masses.<sup>[1]</sup> Although general anesthesia can be used during the procedure, EBUS-TBNA is widely performed using moderate sedation and topical anesthesia.<sup>[2]</sup> Topical anesthesia administration is a cardinal aspect of the procedure and impacts patient comfort. Lignocaine is the most commonly used drug for topical anesthesia during bronchoscopy and EBUS-TBNA.<sup>[3,4]</sup>

The available methods for lignocaine delivery for anesthetizing the vocal cords and the trachea are, (a) “spray as you go” through bronchoscope channel, (b) using a spray catheter via the bronchoscope working channel, and (c) direct intratracheal administration of lignocaine by puncturing the cricothyroid membrane, the cricothyroid method. The available guidelines on bronchoscopy recommend either the cricothyroid or the “spray-as-you-go” method as acceptable modalities.<sup>[5,6]</sup> A recent randomized controlled trial (RCT) found the cricothyroid method is associated with less cough and provides superior operator-rated procedure satisfaction, at a lower cumulative lignocaine dose in patients undergoing flexible bronchoscopy, when compared with the “spray-as-you-go” method.<sup>[7]</sup> As compared with a conventional flexible bronchoscope, the distal end diameter of the EBUS bronchoscope is greater. In addition, there is a frequent contact of the EBUS bronchoscope with the airway wall for lymph node visualization as well as during needle puncture to aspirate mediastinal lesions. Therefore, adequate topical airway anesthesia during EBUS-TBNA is essential to optimize patient comfort and enable the operator to perform a complete procedure with a minimal cough.

No studies have compared the cricothyroid method with the spray-as-you-go method for lignocaine administration during EBUS-TBNA. We performed a RCT to compare these two methods for topical anesthesia administration during EBUS-TBNA.

## METHODS

### Study design

The CRISPEN (CRicothyroid vs SPray lignocaine in ENdobronchial ultrasound guided TBNA) trial was an investigator-initiated, prospective, randomized, clinical trial. It was conducted in a large tertiary care referral center in North India between May 2017 and February 2018. The study protocol was approved by the Institutional Ethics Committee (IEC-593/05.01.2017, RP-4/2017), and written informed consent was obtained from all participants. Subjects and operator were not blinded due to the inherently different nature of the interventions in the two arms.

### Subjects

Consecutive participants who were planned to undergo EBUS-TBNA were screened for inclusion into the study. Participants aged 18 years or older were included if they had an indication for EBUS-TBNA, were hemodynamically stable (systolic blood pressure  $\geq 100$  and  $\leq 180$  mm Hg) and were willing to participate in the trial. The exclusion criteria were as follows: (1) refusal of consent; (2) previously documented hypersensitivity to lignocaine; (3) EBUS performed under general anesthesia, (4) pregnancy, (5) hypoxemia (oxygen saturation  $< 92\%$  while breathing oxygen at  $FiO_2$  of  $\geq 0.3$ ), (6) use of an artificial airway (endotracheal or tracheostomy tube), (7) midline neck mass or thyroid enlargement, (8) symptomatic central airway obstruction, (9) active hemoptysis, and (10) a known bleeding disorder.

### Randomization

Participants willing to participate in the study and those meeting the study inclusion criteria were randomized (1: 1 ratio) to the cricothyroid or the spray-as-you-go group. The sequence for randomization was computer generated. Group allocation was concealed (inside sealed envelopes) and was only revealed by an assisting nurse once the patient had been taken inside the EBUS-TBNA preparation area.

### Protocol

Baseline demographic information was recorded for all participants. Participants were asked to report fasting (nil oral for solids 6 h before the procedure). Standard hemodynamic monitoring included monitoring of oxygen saturation, heart rate, and noninvasive blood pressure throughout the procedure. Intravenous access was routinely secured, and low flow supplemental oxygen (1–2 L/min) was administered via nasal cannula to all participants. For patients with cardiac diseases, electrocardiographic monitoring was also done. Participants in both the groups were prepared similarly, except for the route of lignocaine administration (cricothyroid vs “spray-as-you-go” technique). Nebulized lignocaine was not administered. Two operators (SM and KM) performed all the procedures in both groups. EBUS-TBNA was performed under moderate sedation using a combination of intravenous midazolam and fentanyl. Initially, midazolam 0.015 mg/kg, and fentanyl 1.0 mcg/kg were given. The dose was escalated, targeting a sedation level where the subject was sedated and verbal contact was possible at all times. Sedation administration was performed by an experienced bronchoscopy nurse who was unaware of the group allocation. Baseline preparation in both study groups included the administration of four sprays of 10% lignocaine (40 mg equivalent) to the oropharynx. Lignocaine solution (2%) was used for both cricothyroid and spray-as-you-go administration.

In the cricothyroid group, the neck of the participant was extended by placing a shoulder roll, and the cricothyroid membrane was identified using palpation of anatomic

landmarks. After aseptic preparation of the injection site, the cricothyroid puncture was performed using a 22G intravenous cannula. A syringe (containing 5 mL of 2% lignocaine solution, lignocaine equivalent 100 mg) was attached to it. As soon as the feeling of loss of resistance was felt, the metallic needle of the cannula was immediately withdrawn. The plastic sheath was left in place. After aspiration of air, lignocaine solution was quickly injected intratracheally. The subject was encouraged to cough once or twice to facilitate the spread of the injected solution, and the operator waited for 2 min before the bronchoscope introduction. EBUS-TBNA was subsequently performed (Olympus BF-UC180F Convex Probe Bronchoscope [Olympus Corporation, Japan]) through oral route using a bite block. Following the negotiation of the vocal cords and trachea, two aliquots of 1.5 mL (2% lignocaine) (lignocaine equivalent 60 mg) were administered, one each in either of the main bronchi.

In the spray-as-you-go group, six aliquots (1.5 mL each) of 2% lignocaine solution (lignocaine equivalent 180 mg) were administered: 2 at the vocal cords, 2 in the trachea, and one each in either of the main bronchi. Following the application of the two aliquots to the vocal cords, the bronchoscopist removed the EBUS bronchoscope. The operator waited for 2 min to allow lignocaine action before negotiating the vocal cords. Spray-as-you-go administration was performed through the working channel of the EBUS bronchoscope. A separate spray catheter was not used.

The administration of additional lignocaine aliquots was allowed at the discretion of the operator in both the groups. The total dose of lignocaine administered was recorded. A dedicated assistant noted the cough count from bronchoscope introduction until reaching the carina and the overall procedure duration. A log of the cumulative lignocaine dose administered was also maintained. A single cough or a rapid cluster of coughs in continuity for a short period without any intervening inspiratory pause between the cluster was counted as a single cough. In case there was an intervening inspiratory pause between the coughs, they were counted as separate coughs. We did not use an electronic cough recorder device.

### Outcomes

Co-primary outcomes were the comparison of “Cough-count” from bronchoscope introduction till reaching carina and operator-rated overall procedure satisfaction on a Visual Analog scale (VAS) between the groups. The secondary outcome measures included cumulative lignocaine dose, time from bronchoscope introduction to crossing the vocal cords, duration of the procedure, and complications between the groups. The cough count and time to passing the vocal cords were noted from bronchoscope introduction (post cricothyroid injection) in the cricothyroid group and bronchoscope re-introduction (following vocal cord lignocaine aliquot administration) in the “Spray-as-you-go” group. The VAS for operator-rated overall procedure satisfaction was

anchored between “totally unsatisfactory (0 mm)” to “most satisfactory (100 mm).”

### Statistical analysis

Sample size calculation was performed to obtain a power of 90% with alpha 0.05 for a within-group mean difference of 0.5 in the VAS score for operator-rated overall procedure satisfaction. One hundred and sixty participants were required in each arm. Statistical analysis was performed using the STATA statistical software package (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). The categorical variables were presented as numbers and percentage. The continuous variables were presented as mean (standard deviation [SD]) for normally distributed data or median (range, interquartile range) for nonnormally distributed data. The categorical variables were compared using the Chi-squared test/Fisher’s exact test. The continuous variables were compared using the *t*-test (normally distributed data) or the Wilcoxon rank-sum test (nonnormally distributed data).

## RESULTS

Four hundred participants were screened for inclusion, and 365 were randomized (183 to cricothyroid and 182 to “Spray-as-you-go” groups, respectively). Thirty-five were excluded before randomization (10 did not meet inclusion criteria, 10 had high blood pressure, five declined to participate, 5 had low baseline oxygen saturation, and five were not randomized due to other reasons). The flow of patients in the study is depicted in the CONSORT diagram [Figure 1]. Baseline characteristics of the study participants are summarized in Table 1. The baseline characteristics were similar between the groups. All procedures were performed under moderate sedation, and the mean dose of sedatives used in both groups was also similar. The size of the lymph nodes sampled, the number of needle punctures, and the number of lymph node stations sampled were also similar between the groups.

The primary and secondary outcomes are summarized in Table 2. The cough count until reaching the carina was significantly lower (median [range], cricothyroid, 1 [0–2] and spray-as-you-go, 4 [2–6],  $P < 0.001$ ), and the operator-rated overall procedure satisfaction, VAS score (mean [SD], cricothyroid, 7.96 [1.48], and spray-as-you-go, 7.26 [1.48],  $P < 0.001$ ), significantly greater in the cricothyroid group. The cumulative lignocaine dose administered during the procedure (mg), mean (SD) (163.28 [31.50], cricothyroid vs. 177.0 [30.12], spray-as-you-go,  $P < 0.001$ ) was lower in the cricothyroid group. The time from EBUS bronchoscope introduction to crossing the vocal cords, (mean [SD] in seconds), was significantly less in the cricothyroid group (cricothyroid, 20.80 [11.21] and spray-as-you-go, 38.08 [15.26]). Three and six patients developed procedural complications in the cricothyroid and spray-as-you-go groups, respectively,  $P = 0.31$ . None of the complications was related to

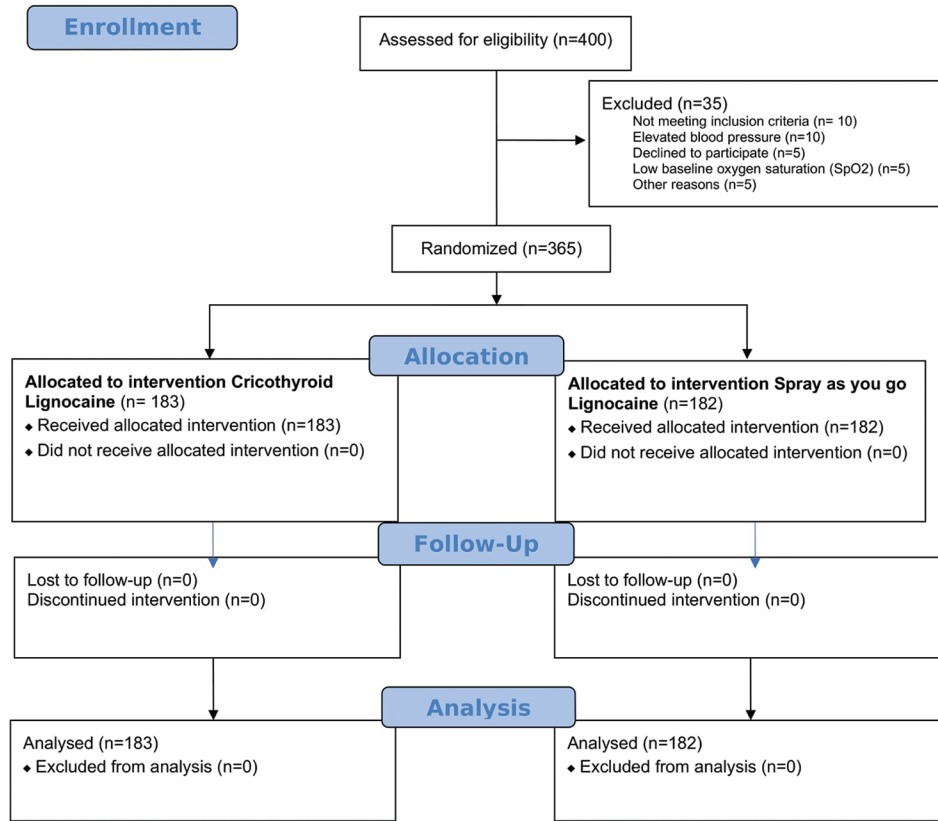


Figure 1: CONSORT diagram showing the flow of subjects in the CRISPEN randomized controlled trial

Table 1: Baseline characteristics of the participants in the CRISPEN RCT

Parameter	Cricothyroid group (n=183)	Spray-as-you-go group (n=182)
Age (years), median (IQR)	47 (33-60)	47 (30-59)
Males, n (%)	105 (57.4)	117 (64.3)
Weight (kg), median (IQR)	60 (36-80)	60 (50-60)
Oral route for EBUS scope introduction, n (%)*	181 (98.9)	178 (97.8)
Indication for EBUS-TBNA		
Sarcoidosis	51	43
Tuberculosis	69	59
Lung cancer	41	53
Others	22	27
Intravenous sedation, n (%)	183 (100)	182 (100)
Short axis lymph node size on EBUS (mm), median (IQR)	14.2 (10-19)	15 (11-20)
Number of sampled stations, median (IQR)	1 (1-2)	1 (1-2)
Number of needle passes, median (IQR)	5 (4-6)	5 (4-6)
Use of 21G aspiration needle, n (%)	150 (81.9)	156 (85.7)
Midazolam dose (mg), median (IQR)	1 (1-1)	1 (1-2)
Fentanyl dose (µg), median (IQR)	75 (75-75)	75 (75-75)

\*Two patients and four patients underwent nasal EBUS scope insertion in the cricothyroid and spray-as-you-go groups, respectively, due to issues with oral negotiation. IQR: Interquartile range, EBUS-TBNA: Endobronchial ultrasound-guided transbronchial needle aspiration

cricothyroid puncture, and there were no events of bleeding at the puncture site or local infection. The overall procedure duration was similar between the groups.

## DISCUSSION

We found the cricothyroid method for lignocaine delivery during EBUS-TBNA to be safe and associated with significantly less procedural cough and greater operator

satisfaction. The benefits of the cricothyroid approach were achieved at a considerably less cumulative lignocaine dose during the procedure.

The available guidelines on the technical aspects of EBUS-TBNA suggest either moderate or deep sedation as acceptable approaches for the procedure.<sup>[2]</sup> In a prospective RCT, no difference was found in the diagnostic yield of EBUS-TBNA performed under moderate or deep



**Table 2: Summary of primary and secondary outcomes of the CRISPEN RCT**

Parameter	Cricothyroid group (n=183)	Spray-as-you-go group (n=182)	P
Primary objectives			
Cough count from bronchoscope insertion till reaching carina, median (IQR)	1 (0-2)	4 (2-6)	<0.001
Operator-rated overall procedure satisfaction (VAS), mean (SD)	7.96 (1.48)	7.29 (1.48)	<0.001
Secondary objectives			
Cumulative lignocaine dose (mg), mean (SD)	163.28 (31.50)	177.0 (30.12)	<0.001
Time from bronchoscope introduction to crossing the vocal cords (s), mean (SD)	20.80 (11.21)	38.08 (15.26)	<0.001
Procedure duration (min); mean (SD)	14.36 (4.70)	14.84 (4.71)	0.34
Complications, n (%)	3 (1.64)*	6 (3.30)	0.31
Accelerated hypertension	2	5	
Excessive cough	1	1	

\*No patient had any local complication related to cricothyroid puncture. IQR: Interquartile range, SD: Standard deviation, VAS: Visual Analog Scale

sedation. However, fewer patients could complete the procedure in the moderate sedation group,  $P = 0.028$ .<sup>[6]</sup> EBUS-TBNA is widely performed under moderate sedation around the world. Topical anesthesia is an essential component for optimizing patient comfort when the procedure is performed under moderate sedation. Topical anesthesia for EBUS-TBNA has not received significant attention, and most of the data is extrapolated from available data in flexible bronchoscopy. This approach may not be appropriate as the EBUS bronchoscope has a diameter which is larger than the conventional flexible bronchoscope and it also requires a close mucosal contact to generate an adequate sonographic view of the lymph node for real-time sampling. Hence, there is a potential for more cough, which can compromise the procedure performance. Two previous studies have focused specifically on topical anaesthesia (lignocaine administration) during EBUS-TBNA. One study compared two concentrations of lignocaine (1% vs. 2%) administered using the spray as you go method (1% as efficient as 2%) and another compared lignocaine administration using a spray catheter versus direct administration through the bronchoscope channel (less cough using spray catheter).<sup>[3,9]</sup>

The findings of our study confirm the observations of superior topical anesthesia characteristics of direct intratracheal administration of lignocaine using the cricothyroid method for EBUS-TBNA similar to the recent data in flexible bronchoscopy.<sup>[7]</sup> Control of cough is a valid endpoint to assess the procedure comfort of an airway procedure. Madan *et al.* reported less cough and superior operator-rated procedure satisfaction during flexible diagnostic bronchoscopy using the cricothyroid method.<sup>[7]</sup> Studies using higher concentrations of lignocaine (4%) for cricothyroid administration in no-sedation bronchoscopy have also found that the time to reach carina is lower and cough is less with the cricothyroid method.<sup>[10]</sup> We used 2% lignocaine for transcricoid administration. A particular advantage of the cricothyroid method is significantly lower cumulative lignocaine dose. Minimization of lignocaine during bronchoscopy/EBUS-TBNA is vital since various cardiac and neurological toxic effects of lignocaine may be dose-related.<sup>[11]</sup> The cricothyroid puncture may be associated with local complications like an inadvertent

puncture of the vocal cords or local hematoma. However, no such complications were observed in our study.

The findings of this study may be generalizable to most other settings where EBUS-TBNA is performed under moderate sedation. The procedures were performed under sedation through the oral route. Although some operators use the nasal route for EBUS-TBNA, the results are unlikely to be different in that setting.<sup>[12]</sup> In an RCT, both nasal and oral routes have shown to be associated with a similar degree of patient comfort during EBUS-TBNA.<sup>[13]</sup> Operator training for performing cricothyroid puncture is essential as all procedures in our study were performed by two operators well versed with the method and expertise in EBUS-TBNA.

The strengths of our study include an adequately powered randomized trial design with analysis of clinically meaningful parameters. Our study has a few limitations. We did not use an electronic cough recorder. We did not record the total cough count. The reliability of manual total cough count recording is unclear as has a greater likelihood of erroneous results. Therefore, we used the cough count till carina, as it is easier to record manually and may represent the efficacy of glottic and tracheal anesthesia reliably. A sedation scale was not used to monitor the depth of anesthesia. We did not record a patient-centred outcome in this RCT, as patient rated assessments may be difficult to record in sedated patients. However, a greater willingness to return for a repeat procedure was demonstrated in our previous RCT in flexible bronchoscopy; therefore, the findings are unlikely to be different in EBUS-TBNA.<sup>[7]</sup> Pain due to cricothyroid puncture was not recorded, as there was no control group due to obvious ethical concerns. The use of ultrasound for localizing the cricothyroid membrane has been described that can minimize the inadvertent complications. In our study, the cricothyroid puncture was performed by experienced operators using anatomical landmarks.

The results of this study have important implications for practice. EBUS-TBNA is widely performed under topical anesthesia and sedation worldwide. Operators can quickly adopt this method in the clinical practice, and this may

translate into better patient outcomes for procedure comfort and safety.

## CONCLUSIONS

The findings of the CRISPEN RCT demonstrate that cricothyroid administration of lignocaine for topical anesthesia in EBUS-TBNA is safe and efficacious. The cricothyroid method is associated with significantly less cough and higher operator-rated procedure satisfaction. Interventional pulmonologists should familiarize themselves with this useful adjunctive modality of airway lignocaine administration and adopt this in the routine clinical practice.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

## Statement of ethics

- Participants have given their written informed consent
- The study protocol has been approved by the research institute's committee on human research.

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