Original Article

Comparison of spray catheter with "spray-as-you-go" technique for airway anesthesia during flexible bronchoscopy – A randomized trial

Kavitha Venkatnarayan[1], Uma Devaraj[1], Uma Maheswari Krishnaswamy[1], Priya Ramachandran[1], Tinku Thomas[2], George D'Souza[1]

[1]Department of Pulmonary Medicine, St. John's National Academy of Health Sciences, Bengaluru, Karnataka, India, [2]Department of Biostatistics, St. John's National Academy of Health Sciences, Bengaluru, Karnataka, India

ABSTRACT

Background: Administration of local airway anesthesia is the principal determinant of procedural comfort during flexible bronchoscopy. However, the ideal method of administration is still unknown. In this study, we compared lignocaine administration using a spray catheter (SC) with "spray-as-you-go" technique. **Methods:** Patients undergoing bronchoscopy were randomized to receive airway anesthesia with 2% lignocaine through the SC (SC group) or "spray-as-you-go" technique through the working channel (WC group). The primary outcome parameter was cough count, and the secondary outcome parameters compared were need for sedation, operator-rated procedural satisfaction and cough, and patient-rated comfort on a Visual Analog Scale (VAS). **Results:** One hundred and thirty patients were randomized with comparable baseline parameters. The median (interquartile range [IQR]) cough count was 28 (19, 37) in the WC group and 15 (9, 23) in the SC group ($P < 0.001$). Requirement for sedation was lower in the SC group (5 vs. 18; $P = 0.003$). The mean (standard deviation [SD]) VAS score for operator-rated satisfaction was 66.5 (16.8) in the WC group and 80.6 (14.2) in the SC group; $P < 0.001$. The median (IQR) VAS score for operator-rated cough was 35 (23, 44) in the WC group and 18 (11, 28) in the SC group; $P < 0.001$. However, there was no difference in the patient-rated comfort VAS (mean [SD] of 66.4 [14.5] in the WC group and 69.9 [13.0] in the SC group; $P = 0.07$). **Conclusion:** Lignocaine instillation using the SC during bronchoscopy reduced cough, need for sedation, and improved operator satisfaction.

KEY WORDS: Anesthesia, bronchoscopy, lignocaine, spray catheter

Address for correspondence: Dr. Kavitha Venkatnarayan, 3rd Floor, Oncology Block, St. John's Medical College, Sarjapur Road, Bengaluru - 560 034, Karnataka, India. E-mail: kaviaiims@gmail.com

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INTRODUCTION

Flexible bronchoscopy is commonly performed in the practice of pulmonary medicine for various diagnostic and therapeutic indications.[1] Coughing due to glottic irritation or irritation of airway mucosa remains a major problem and leads to both patient and operator discontent.[2] Although sedation has been suggested to improve patient tolerance and satisfaction, bronchoscopy is preferentially performed without sedation in many centers in India and has been shown to be safe and well tolerated.[1,3,4] Hence, procedure

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tolerance depends on the administration of local anesthesia to a great extent.

The usual practice followed for airway anesthesia is the "spray-as-you-go" technique in which lignocaine solution is injected through the working channel (WC) of the bronchoscope. However, this technique has the distinctive limitation of nonuniform drug deposition and potential stimulation of the cough reflex. This has necessitated the need to look at alternative and more effective methods of local anesthetic delivery. Studies on nebulized lignocaine have failed to show any significant benefit.[5] The spray catheter (SC) (Olympus, model PW-6C-1, Tokyo, Japan) is a reusable catheter that can be inserted through the WC of the bronchoscope to administer lignocaine. After injection through the proximal end of the catheter, the drug is aerosolized at the distal end to produce a uniform circumferential spray. It is postulated that this technique maximizes the effectiveness of local anesthetic delivery due to even drug deposition over a wider area.

A pilot study using the SC during convex probe endobronchial ultrasound (CP-EBUS) found a decreased number of coughing episodes compared to the standard WC injection of local anesthesia.[2]

In this study, we hypothesized that the instillation of lignocaine using the SC would provide better airway anesthesia than the "spray-as-you-go" technique.

METHODS

The study was an investigator-initiated, open-label, randomized trial conducted in a tertiary care teaching hospital. The study was conducted between August 2018 and April 2019. Ethical approval was obtained from the institutional ethics committee (Ref No. 192/2018), and the trial was registered in the Clinical Trials Registry-India (trial registration: CTRI/2018/08/015300). Written informed consent was obtained from all participants.

Patients aged above 18 years scheduled for bronchoscopy were screened. In order to ensure uniformity, only patients undergoing bronchoalveolar lavage were included in this study. Patients undergoing bronchoscopy through tracheostomy or in the intensive care unit, those in whom bronchoscopy was performed under general anesthesia, and those in whom a pediatric bronchoscope was used were excluded.

Patients were randomized to receive anesthesia by the usual "spray-as-you-go" technique through the bronchoscope (WC group) or using the SC (SC group) in a 1:1 ratio using variable block randomization. Allocation concealment was ensured using sealed opaque envelopes.

All the patients had an intravenous access secured before the procedure. Baseline hemodynamic parameters including pulse rate, blood pressure, and oxygen saturation were recorded and monitored throughout the procedure for all patients. Lignocaine jelly 2% was applied in the nostril through which the scope was introduced. Two actuations of 15% w/w lignocaine (15 mg lidocaine) were sprayed over the oropharynx. Sedation was avoided forthright, but intravenous midazolam or fentanyl was administered as per the discretion of the operator and recorded. Oxygen supplementation was provided using nasal cannula whenever indicated.

Patients randomized to the "WC group" received 2 ml of 2% lignocaine (21.3 mg lignocaine/ml) instilled at the cord, 1 ml each in the trachea and carina and 1 ml in each main bronchus. Patients randomized to the "SC group" received the same volume of lignocaine in the same areas through the SC [Figure 1]. Apart from this, additional lignocaine instillation was decided by the operator.

An independent observer counted the number of coughing episodes (each cough counted separately) throughout the procedure manually. The time taken from visualization of the vocal cords to reach the carina (cord-to-carina time [CTC]) and the total time taken for the procedure were recorded. After the procedure, the operator was asked to rate cough during the procedure and overall procedural satisfaction on a 100-mm Visual Analog Scale (VAS) (0 - no cough, 100 - worst cough; 0 - extremely unsatisfactory, 100 - very satisfactory). Similarly the patient was also asked to rate overall comfort during the procedure (0 - extremely uncomfortable, 100 - very comfortable).

The primary outcome parameter was cough count, and the secondary outcome parameters included operator-rated cough, operator-rated procedure satisfaction, and patient-rated comfort during the procedure measured using VAS scale. The total dose of lignocaine used, need for sedation, CTC time, total duration of the procedure, and changes in vital parameters were compared between the groups.

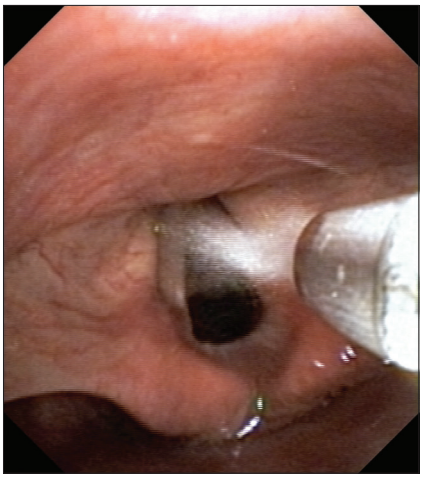

Figure 1: Local anesthetic being sprayed at the vocal cord using spray catheter

The sample size was calculated based on the outcome parameter assessed in the pilot study.[2] The sample size required to observe a difference of one cough count between the two groups with standard deviation (SD) of 2 and a power of 80% and Type I error of 0.05 was 64 in each group.

Categorical variables were compared between the groups by Chi-square test and continuous variables by independent sample *t*-test or Mann–Whitney *U*-test as appropriate. Stata 15.0 statistical software (Stata Corp. 2017. Stata Statistical Software: Release 15. College Station, TX, USA: Stata Corp LLC) was used for analysis. All statistical tests were two tailed, and $P \leq 0.05$ was considered statistically significant.

RESULTS

One hundred and thirty-four patients were screened for the study. Four patients were excluded and 130 patients were randomized. The recruitment of patients is depicted in the CONSORT diagram [Figure 2]. No patients were excluded after randomization.

Baseline characteristics including age, gender distribution, and hemodynamic parameters were comparable between the groups [Table 1]. Bronchoscopies were performed using Fujinon EB-530H or Olympus BF1T150 videobronchoscopes. Majority of the patients were male, with a mean (SD) age of 48.3 (16.3) years. All the bronchoscopies were performed through the nasal route.

The cough count was significantly lower in the SC group, with a median (interquartile range [IQR]) cough count of 28 (19, 37) in the WC group and 15 (9, 23) in the SC group ($P < 0.001$) [Table 2]. Sedation was used in 17.6% of the total study population with 18 (27.7%) patients in the WC group and only 5 (7.7%) patients in the SC group requiring sedation ($P = 0.003$). The mean (SD) time taken from cord to carina was lower in the WC group (57.5 [11.7]) and 60.3 (9.15) seconds in the SC group ($P = 0.04$). However, the total duration of procedure was similar in both the groups. The lignocaine dose used was significantly lower in the SC group (mean [SD] of 314.5 [36.2] mg in the WC group and 299.1 [23.0] mg in the SC group; $P = 0.005$).

Operator-rated procedural satisfaction VAS was significantly better and operator-rated cough VAS lower in the SC group. The mean (SD) VAS score for operator-rated satisfaction was 66.5 (16.8) in the WC group and 80.6 (14.2) in the SC group, respectively; $P < 0.001$. The median (IQR) VAS score for operator-rated cough was 35 (23, 44) in the WC group and 18 (11, 28) in the SC group; $P < 0.001$. However, there was no difference in the patient-rated comfort VAS between the two groups (mean [SD] of 66.4 [14.5] in the WC group and 69.9 [13.0] in the SC

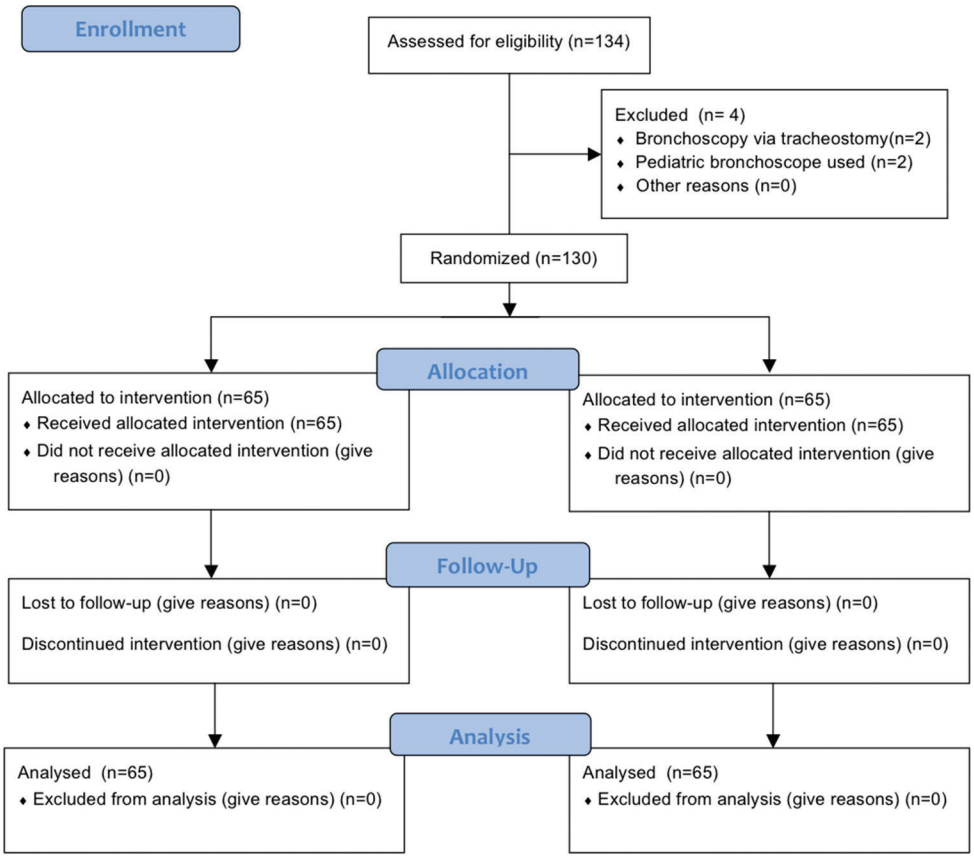

Figure 2: CONSORT diagram showing the recruitment of the study participants

Table 1: Baseline characteristics of the patients

	Group WC (*n*=65)	Group SC (*n*=65)	*P*
Age (years), mean±SD	46.9±16.1	49.7±16.4	0.32
Males, *n* (%)	49 (75.3)	39 (60)	0.06
Baseline PR (beats per min), mean±SD	94.7±16.4	96.8±14.7	0.62
Baseline SpO2 (%), mean±SD	97.2±2.0	97.1±2.3	0.99
Baseline SBP (mmHg), mean±SD	129.9±22.4	126.8±16.1	0.53
Baseline DBP (mmHg), mean±SD	79.1±13.7	76.9±10.7	0.43

SD: Standard deviation, PR: Pulse rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, WC: Working channel, SC: Spray catheter

Table 2: Comparison of outcome parameters between the two groups

	Group WC (*n*=65)	Group SC (*n*=65)	*P*
Sedation used in, *n* (%)	18 (27.7)	5 (7.7)	0.003
Lignocaine dose (mg), mean±SD	314.5±36.2	299.1±23.0	0.005
CTC (s), mean±SD	57.5±11.7	60.3±9.15	0.04
Total duration of procedure (min), mean±SD	7.1±1.1	6.93±9.1	0.38
Cough count, median (IQR)	28 (19-37)	15 (9-23)	<0.001
VAS operator satisfaction, mean±SD	66.5±16.8	80.6±14.2	<0.001
VAS operator cough, median (IQR)	35 (23-44)	18 (11-28)	<0.001
VAS patient comfort, mean±SD	66.4±14.5	69.9±13.0	0.07
Postprocedure PR (beats per min), mean±SD	106.4±15.9	109.3±18.5	0.39
Postprocedure SpO_2 (%), mean±SD	95.1±2.57	95.1±3.23	0.60
Postprocedure SBP (mmHg), mean±SD	132.6±25.0	132.5±19.6	0.71
Postprocedure DBP (mmHg), mean±SD	82.0±12.6	81.8±12.4	0.82
Complications (*n*)	1	0	

SD: Standard deviation, CTC: Cord-to-carina time, IQR: Interquartile range, VAS: Visual Analog Scale, PR: Pulse rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, WC: Working channel, SC: Spray catheter

group; $P = 0.07$). The change in hemodynamic parameters after the procedure was similar in both the groups. Only one patient in the WC group developed bronchospasm postprocedure requiring observation and treatment for 2 h. There were no other complications during or after the procedure in either of the groups.

DISCUSSION

The main objective in every flexible bronchoscopy is to attain airway visualization and perform diagnostic procedures unhindered by cough and patient discomfort, with utmost safety. The two main aspects that help in efficient performance of the procedure are sedation and local anesthesia. However, lack of standardization of these aspects has led to significant variability in the practice of bronchoscopy based on clinician preferences. This variability has been well reported in various bronchoscopy surveys.[4]

Although sedation is suggested by various guidelines for better patient comfort, the evidence for the same is weak and it is left open to the discretion of the operator.[3,4,6] As a result, there is a lot of heterogeneity in the sedation practices worldwide.[1,7,8] Sedation carries the risk of variability in response to the drugs administered and chances of oversedation, thus necessitating close monitoring for the level of sedation and consequent careful titration of drug dose. Hence, in many centers in India, bronchoscopies are performed without sedation under local anesthesia.

The most important aspect of bronchoscopy that decides comfort during the procedure is the effective administration of local anesthesia. Various methods of administering lignocaine for airway anesthesia have been practiced including oropharyngeal spray, nebulization, transtracheal injection, local nerve block, and instillation through the WC – "spray as you go." However, the optimal method of anesthetic administration to maximize patient comfort still remains unknown. Apart from the quest for the optimal airway anesthesia technique, efforts to reduce the cumulative dose of lignocaine administered are ongoing. It has been found that 1% lignocaine is as effective as the traditionally used concentration of 2% lignocaine with a lower cumulative dose of the drug.[9,10] Despite continued use in certain centers, nebulized lignocaine has failed to show a significant benefit.[3-5] Transtracheal injection, which was earlier deemed invasive, has been found to be safe and provides better operator satisfaction and reduced cough at a lower dose of lignocaine as compared to the "spray-as-you-go" technique.[11] In view of the above data, methods to improve the effectiveness of local anesthesia during bronchoscopy to maximize patient and operator comfort are in order.

"Spray as you go" is the most commonly followed technique in which lignocaine is sprayed through the WC of the bronchoscope. The inherent problems with this technique are uneven drug deposition and possible stimulation of cough due to the instillation itself. Administration of the drug as a directed aerosol using a novel bronchofiberscopic catheter spray device was found to reduce the dose of lidocaine.[12] In a randomized, single-center, pilot study in forty patients undergoing CP-EBUS, the number of coughing episodes was significantly lower in the SC group. There was no difference between the groups with respect to the sedation requirement or the dose of lidocaine.[2]

In our study, we found that airway anesthesia using the SC significantly reduced cough and provided better operator-rated comfort during the procedure and reduced operator-rated cough. The median cough count in our study was much higher than that reported by Lee *et al*.[2] This is because they defined a coughing episode as "cough that required an intervention by the bronchoscopist to administer more sedation or lignocaine," whereas in our study, each cough was counted separately. Furthermore, CP-EBUS was performed under moderate sedation in their study which could also explain the reduced coughing episodes. Although the patient-rated comfort did not show a significant difference between the groups in our study, there was a trend toward significance. This may be due to the fact that patients may have a preconceived notion of discomfort and may not be able to appreciate distinct aspects of the procedure such as reduction in cough. A larger sample size may give a better idea regarding the

same. The total dose of lignocaine used was significantly lower in the SC group which is desirable given the adverse effects related to the drug.[13] Although the absolute mean difference of lignocaine dose was just 15 mg, the standardization of upfront lignocaine instillation in both the groups indicates that the SC group received lesser additional lignocaine instillations during the procedure. Whether lower doses of lignocaine are sufficient for upfront anesthesia also needs to be evaluated in the future. Whether the use of 1% lignocaine using the SC could further decrease the cumulative dose of drug administered also needs to be evaluated in future studies.

To the best of our knowledge, this is the first study to compare airway anesthesia using the SC to the "spray-as-you-go" technique during no sedation flexible bronchoscopy. Our study had a few limitations. It is a single-center study, and methodologically, blinding was not possible allowing a possibility of observer bias. Clinical importance of reduced cough count and lignocaine dose observed needs to be evaluated in a larger population. The results cannot be extrapolated to other bronchoscopic diagnostic procedures such as endobronchial biopsies, transbronchial needle aspiration, and transbronchial lung biopsies which were not included in the study. The results may also vary with the sedation practices used for bronchoscopy, especially in centers where deep sedation may be used. Serum concentrations of lignocaine could not be assessed which could have added more objectivity to the results. Coughing episodes were manually counted which could add an element of bias and variability. However, the same person did the cough count for all the procedures minimizing this variability to the extent possible. A cough recorder device could have reduced this margin of error.

CONCLUSIONS

We conclude that lignocaine instillation using the SC during flexible bronchoscopy reduces cough and need for sedation and improves operator satisfaction. Larger studies including various bronchoscopic procedures with objective cough recording using cough counters are required to validate the findings. Studies comparing various modalities of airway anesthesia such as "spray as you go," SC, and transtracheal injection using various concentrations of lignocaine are needed to find the ideal method or a combination of methods to provide optimal patient comfort.

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Conflicts of interest

There are no conflicts of interest.

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