The Utility of a Multi-orifice Epidural Catheter when Using the “Spray-as-You-Go” Technique for Topical Airway Anesthesia during Flexible Bronchoscopy, a randomised trial

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Abstract

Background

Lidocaine administered through the working channel of a flexible bronchoscope can provide effective local anesthesia but cannot achieve good distribution in the airway. This study was undertaken to determine whether lidocaine delivered via a multi-orifice epidural catheter (three orifices/openings) is superior to conventional method and if a better distribution and decreased the cough reflex can be achieved.

Methods

The patients (N=100; 50 in each group) were randomized to receive either topical airway anesthesia by the “spray-as-you-go” technique via conventional application (group C) through the working channel of the bronchoscope or via a triple-orifice epidural catheter (group E). The primary outcome measurement was the cough severity, which was documented using a 4-point scale. Bronchoscopists and nurses assessed the coughing.

Results

There was a significant difference in the median cough severity scores between the two groups (group C: 3 vs group E: 2, $P = 0.004$). The median visual analogue scale (VAS) scores for the cough, were significantly higher in group C than those in group E (bronchoscopist: 3 vs 2 $P = 0.002$; nurse: 3 vs 2, $P < 0.001$). The incidence of cough was significantly higher in group C in the trachea, left and right bronchi. The highest respiratory rate was higher in group C than in group E ($P < 0.01$). Eight patients in group C and two patients in group E had an oxygen saturation below 90% during flexible bronchoscopy (FB) ($P = 0.046$). More patients in group C required extra topical anesthesia than in group E ($P < 0.001$). The total lidocaine consumption was also higher in group C than that in group E ($P < 0.001$).

Conclusions

Endotracheal topical anesthesia via the multi-orifice epidural catheter (three holes/openings) during flexible bronchoscopy using the “spray-as-you-go” technique was appeared to be superior to the conventional method.

Trial registration

Chinese Clinical Trial Register(Registration number #ChiCTR1800014690;Date of Registration on January 29th,2018)<http://www.chictr.org.cn/showproj.aspx?proj=24835>

Background

During bronchoscopy, topical anesthesia, analgesia, and sedation are recommended to increase patient tolerance for the procedure and enhance patient satisfaction.[1, 2] Although most patients cannot recall the FB because of sedatives and narcotics, the cough reflex may cause adverse hemodynamic responses for the patient and less than ideal working conditions for bronchoscopists.[3, 4] Therefore, appropriate sedation and analgesia should be provided, and the patient should also receive an effective application of a topical anesthetic.

Lidocaine is the most common local anesthetic used during FB.[5] Several previous studies have reported that a local anesthetic administered into the trachea by a “spray-as-you-go” technique is safe and tolerable, and provides effective local anesthesia.[6-9] However, lidocaine is typically administered directly through the working channel of the bronchoscope,[10] which may result in ineffective distribution of the local anesthetic. To address this point, Xue et al.[11] reported that awake, fiberoptic orotracheal intubation using a single-orifice epidural catheter allowed effective delivery of topical anesthetic. To date, there are few studies have focused on the use of epidural catheters in the administration of topical airway anesthesia during FB.

We hypothesized that lidocaine delivered via a triple orifice epidural catheter was superior to the conventional method of using only the bronchoscopy port via syringe to reduce of the cough reflex of the patients during FB. The primary outcome measured in this study was the severity of cough. Secondary outcomes included the VAS score for cough, total amounts of propofol and lidocaine administration, frequency of propofol and topical anesthesia administration, and PACU stay time.

Methods

Study Recruitment

This randomized controlled study was approved by the Ethics Committee of the First Affiliated Hospital of Wenzhou Medical University, and registered in the China Clinical Trial Register (ChiCTR1800014690). Written informed consent was obtained from all enrolled patients.

Patients

ASA I-III patients, aged 18-65 years and undergoing selective FB for diagnosis between February and April 2018, were included. Patients unable to cooperate, with a known allergy to local anesthetic, asthma, pregnancy, major cardiac disorders, renal or liver dysfunction, pre-existing neurological deficits, and psychiatric illness were excluded. Patients undergoing endobronchial ultrasoundguided transbronchial needle aspiration endobronchial ultrasonography (EBUS-TBNA) and transbronchial needle aspiration (TBNA) were also excluded because the procedure times exceeded the effective duration of single dose of lidocaine anesthesia.

Randomization

One hundred patients undergoing diagnostic FB were randomly allocated into two groups according to a computerized random number generator (Figure1). group C patients received topical lidocaine through the working channel of the bronchoscope, whereas group E patients received topical lidocaine via a triple-orifice epidural catheter.

Study Protocol

All patients were fasted from solids for eight hours before the procedure, and from liquids for two hours before the operation. Intravenous (IV) access was established before the procedure. Proper inspection of the anesthesia machine was performed preoperatively. Standard monitoring was instituted before the induction of anesthesia, including ECG, noninvasive blood pressure (BP), and oxygen saturation (SpO₂). Prior to the procedure all the patients received oral and nasal lidocaine at a volume of 2 mL 2% lidocaine (100mg/5mL, 31710302, Tianyao Pharma. Co. Ltd, China). Thereafter the patient received midazolam 1 mg and sufentanil 10 ug IV for sedation. Anesthesia induction was achieved with 0.1 mg/kg etomidate (10 mg/10mL, 20171116, NhwaPharma.Corporation, China.) followed by 1 mg/kg propofol (200 mg/20mL, 16LF8047, Fresenius Kabi Deutschland GmbH D-61346 Bad Homburg v.d.H. Germany) IV. All patients were intubated nasotracheally, and maintained spontaneous breathing.

While advancing the flexible bronchoscope in the airway, 2% lidocaine was delivered using the “spray-as-you-go” technique through the bronchoscope by the conventional method (direct application via syringe), or by a triple-orifice epidural catheter. The epidural catheter (20-gauge, Haisheng Medical Equipment co. LTD. China) used in this study was designed with three orifices oriented in a helicoidal distribution along the long axis of the catheter in the distal 10 mm segment (Figure 2,3). Lidocaine 2% 3 ml was administered supraglottically, and three aliquots of 5 ml of lidocaine 2% were applied to the trachea as well as the right and left main stem bronchi, consecutively. The bronchoscopist waited for one minute after applying the topical anesthesia to the glottis before passing the bronchoscope through the vocal cords. Extra lidocaine aliquots were instilled at the discretion of the respiratory physician for cough suppression. Additional propofol 0.4 mg/kg was added at the discretion of the anesthetist to blunt any patient reflexive responses. Whenever the oxygen saturation dropped below than 90%, the patients received supplemental manual ventilation via the nasotracheal tube to maintain an oxygen saturation above 90%. Additionally, the heart rate and blood pressure were kept within $\pm 20\%$ of the baseline values. After the procedure, the patients were transferred to the post-anesthesia care unit (PACU) and evaluated using the post-anesthesia outpatient discharge criteria (PADC), which were modified by the Department of Anesthesiology, the First Affiliated Hospital Medical University and to be stricter than the previous post-anesthesia discharge scoring system (Table 1).[12] The criterion used for patient discharge was a PADC score of >8 and the nurse recorded the recovery time of each patient in the PACU.[12]

All the airway anesthesia was conducted by one bronchoscopist. The respiratory physicians and nurses who participated in the bronchoscopy were the same clinical team members. They were blinded to the groups and came into the operating room after airway anesthesia. At the end of the procedure, they independently assessed the cough using the visual analog scale (VAS) during FB. We included 6 nurses

and 3 respiratory physicians and have explained the VAS for cough before the study. The anesthesiologist was responsible for the general anesthesia and airway management throughout the procedure and assessed cough severity via “4-point” scale. Another study assistant was responsible for recording data.

Outcome Measures

The primary outcome of this study was cough severity. Cough severity was assessed by the anesthesiologist using a 4-point scale (1=no cough; 2=slightly cough; 3=moderate cough; 4=severe cough).[11 13] Coughing during the procedure was considered slight if ≤ 2 coughs occurred in sequence, moderate if 3 to 5 coughs occurred in sequence, and severe if more than 5 coughs occurred in sequence. [11, 13]

The secondary outcomes were as follows. The bronchoscopists and the assisting nurses independently evaluated the cough intensity during FB using a visual analogue scale (VAS), where 0 represented no cough and 10 represented incessant cough. The numbers of patient coughs during the bronchoscope placement in the glottis, trachea, left and right bronchi were recorded for each group. The highest respiratory rate (H-RR), heart rate (H-HR), and blood pressure (H-SBP, H-DBP), as well as the lowest oxygen saturation (L-SpO₂) during the procedure were documented. The duration and type of diagnostic procedures were recorded for each patient at the end of FB. The patients were followed up by telephone concerning the extent of coughing and level of satisfaction (recall, pain, and discomfort) two hours after the procedure. Any adverse events, such as nausea and vomiting, arrhythmia, hypoxemia, bronchospasm, and local anesthetic toxicity, were recorded.

Sample Size

The sample size was calculated using the Power Sample Size Program (PASS11.0). In the preliminary study, the cough severity scores of group C and group E were 2.50 ± 0.26 and 2.30 ± 0.21 , respectively. The minimum sample size required was 44 patients per group for a power of 0.9 with a two-tailed significance level of 0.05 ($\beta = 0.1$ and $\alpha = 0.05$). Assuming a dropout rate of 10%, the final sample size was set at 50 patients in each group.

Statistical analysis

Analysis was performed using SPSS software version 19.0 (SPSS Inc, Chicago, IL, USA). The Shapiro-Wilk test was used to a test for normal distribution. The normally distributed data were presented as the mean with standard deviation, and the non-normally distributed data were presented as a median with an interquartile range. Categorical variables were expressed as a number with the percentage. The height, weight, BMI, HR, SBP, and SDP at the baseline, H-HR, H-SBP, and H-SDP during the procedure; the duration of the procedure; and the PACU stay time were compared using Student's unpaired t-tests. The ASA physical classification, VAS scores, cough severity, RR and SpO₂ at baseline, H-RR and L-SpO₂ during the procedure, as well as the total consumption of lidocaine and propofol were compared using Mann-Whitney U-tests for intergroup differences. The correlation between the judgements of the bronchoscopist

and the assistant nurse was compared using Spearman correlation analysis. The sex, adverse effects, and frequency requirements for propofol and lidocaine were compared by χ^2 test. A $P < 0.05$ was considered statistically significant.

Results

There were no differences in the patient characteristics between the groups with respect to age, height, weight, and ASA physical status (Table 2). The median patient cough severity scores in group C was significantly higher than that in group E (group C:3 vs group E:2; $P = 0.004$, Table 3). Correspondingly, the VAS scores of the coughs assessed by the bronchoscopist and nurse were both significantly lower in group E than in group C ($P = 0.002$ and $P < 0.001$, respectively). There was no difference in the scoring between the bronchoscopist and nurse for the two groups (Spearman's correlation coefficient = 0.754, $P < 0.001$). Additionally, the cough incidence (number of patients coughed at each site in each group/50*100%) was higher in group C than in group E with regard to the trachea, and the left and right bronchi ($P = 0.005$, $P = 0.035$, and $P = 0.029$, respectively, Figure 4).

The requirement for propofol and the total consumption of propofol in the two groups were similar ($P = 0.539$ and $P = 0.492$). However, more patients in group C required extra topical anesthesia than the patients in group E ($P < 0.001$). The total lidocaine consumption was higher in group C than that in group E ($P < 0.001$). No significant intergroup difference was observed in the type or duration of the procedure ($P = 0.431$). There was also no significant difference between the groups in regard to H-HR, H-BP, and L-SpO₂, despite the significant difference in H-RR (group C:22 vs. group E:19, $P = 0.007$). Eight patients in group C and two patients in group E had an oxygen saturation below 90% during FB ($P = 0.046$). There was no significant difference in PACU stay time between the two groups ($P = 0.093$). No patient could recall any cough, discomfort or pain during FB. There were no FB-related complications, such as local anesthetic toxicity, arrhythmia, bronchospasm, or pneumothorax.

Discussion

This randomized controlled trial was conducted to compare the efficacy of endotracheal topical anesthesia via a triple-orifice epidural catheter with that of anesthesia delivered via the conventional method in patients undergoing FB. We found that the patients who had lidocaine delivered through the triple-orifice epidural catheter had significant blunting of their coughs, and a decreased requirement for and total consumption of local anesthesia, compared to the patients who had lidocaine delivered via conventional method.

Flexible bronchoscopy can cause coughing, shortness of breath, and throat irritation. It has been reported that the stress reaction during bronchoscopy may lead to dramatic changes in hemodynamics.[14] Cough control/suppression averted the contamination of the specimens with blood and bronchial secretions, resulting in a high diagnostic yield of the bronchoalveolar lavage fluid; and low the intrathoracic pressure during transbronchial biopsies, which may have led to a low risk of pneumothorax.[15] It was also

noteworthy that the cough reflex due to secondary airway irritation during topical anesthesia via the conventional methods was more intense, which aroused concern for the potential of cervical injury subsequent to exaggerated patient neck and back movements. Based on our results, the triple-orifice epidural catheter method is optimal, because compared to the conventional method, it induced less irritation and demonstrated an effective distribution of lidocaine, as well as cough suppression during FB. Deep sedation is required during the airway anesthesia because lidocaine takes time to act. Therefore, it is important to reduce the stimulation of the airway anesthesia. In the present study, all the patients underwent deep sedation of spontaneous breathing and the airway management was conducted via the nasopharyngeal cannula connected to the anesthetic machine. This method provides a more comfortable experience and make the patients quicker wake up during the procedure. It was noteworthy that each patient in our study could not recall any cough, discomfort and pain during the procedure.

We found that lidocaine (and its effect) was concentrated along the posterior wall of the trachea due to gravity, resulting in an uneven delivery of local anesthetic by the single-orifice epidural catheter or syringe. To achieve an accurate and uniform delivery of lidocaine, we finally used a triple-orifice epidural catheter in this study. Our results demonstrate that the total lidocaine consumption was lower when using the epidural catheter than when using the conventional method, which is in agreement with our hypothesis. In addition, the smaller diameters of the catheter orifices lead to less flow which may cause less irritation to the airway than the bolus injection from a syringe. It has also been found that the epidural catheter has the capacity to enter the secondary bronchi, which leads to a more effective topical anesthetic administration. This effect is consistent with our findings, in that the incidence of cough in the epidural catheter group was significantly lower than that in the conventional group in the trachea, as well as the left and right bronchi during the procedure. Additionally, the conventional method required more topical anesthesia than the triple-orifice epidural catheter method. Another advantage of the epidural catheter is that use of the suction port of the bronchoscope could continue to be used during the application of topical anesthesia to the airway, while not adversely disturbing the effective application of lidocaine. It has been reported that the pharmacokinetics of topical lidocaine during FB are complex and can be affected by several factors, such as the duration and frequency of suction.[16] Previous studies have demonstrated that lidocaine offers a considerable margin of safety as a local anesthetic agent.[17, 18] The triple-orifice epidural catheter may allow for a reduction in the amount of lidocaine applied because of its small diameter and an improved accuracy and uniformity in spraying. Nonetheless, a large number of patients in our study exceeded the recommended maximum dose of >8.2 mg/kg. However, no lidocaine-induced adverse events were identified in our study.

In the present study we used a combination of propofol and etomidate for induction of general anesthesia, which allowed spontaneous ventilation and stable hemodynamics during the procedure. This combination avoided the pain of injection and dose-related hemodynamic effects caused by propofol and the myoclonus caused by etomidate.[19] The consumption of sedatives was similar and resulted in comparable recovery times between two groups. It was noteworthy that each patient in our study could not recall any cough, discomfort and pain during the procedure, suggesting the superiority of this pharmacological combination.

The current study has limitations that should be considered. First, there was no blinding between the anesthesiologist and the patients in our study and this may be a source of bias. Second, we could not evaluate the patients' cough reflexes during FB because of the general anesthesia.

Conclusions

In conclusion, the results of our study suggest that endotracheal topical anesthesia via a triple-orifice epidural catheter appeared to be superior to the conventional method. However, further study is needed to determine the optimal dose of lidocaine.

List Of Abbreviations

FB, flexible bronchoscopy; VAS, visual analogue scale; EBUS, endobronchial ultrasonography; TBNA, transbronchial needle aspiration; BP, noninvasive blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; SpO₂, oxygen saturation.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the First Affiliated Hospital of Wenzhou Medical University, and registered in the Chinese Clinical Trial Register (ChiCTR1800014690).

<http://www.chictr.org.cn/showproj.aspx?proj=24835>. Before study entry, all subjects reviewed and signed an informed consent document explaining the study procedures and potential risks.

Consent for publication

Not applicable.

Competing interests

Yaoyao Cai, Dongmei Dong, Min Ye, Xiuling Jin, Fuli Liu and Limei Chen declare no competing interests.

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Availability of data and material

The datasets generated and analysed during the current study are available from the corresponding author on reasonable requests.

Authors' contributions

LC: Design the study, conduct the study, analyse the data and write the manuscript. YC: Conduct the study, analyse the data and write the manuscript. MY: Performed bronchoscopy. DD,XJ,FL: Conduct the study and record the data. All authors read and approved the final manuscript.

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Tables

TABLE 1 Post-anesthesia of outpatient discharge criteria of the First Affiliated Hospital of Wenzhou Medical University.

observation	0	1	2
Vital signs	BP and HR both are above 40% of the preoperative level	BP and HR both are at 20% - 40% of the preoperative level	BP and HR both are beyond 20% of the preoperative level
Pain	VAS≤3	VAS≤3	None
Orientation	all of time, space, figure are abnormal	two of time, space, figure are normal	all of time, space, figure are normal
Dizziness	both in standing or sitting	in standing, not in sitting	Both standing and sitting are not
Walking (2 meter line)	cannot walk	gait instability	gait stability

TABLE 2 Baseline Characteristics of the Study Population. Values are expressed as mean(SD) or median(interquartile range) unless otherwise stated.

Characteristics	Group C (n=50)	Group E (n=50)	P Value
Age (y)	53(10.6)	50(12.7)	0.305
Male/Female	33/17	31/19	0.835
Height (cm)	166(7.3)	164(7.8)	0.192
Weight (kg)	61(10.8)	61(10.0)	0.992
BMI (kg/m ²)	22.3(0.5)	22.7(0.4)	0.440
ASA I/II/III	17/26/7	15/28/7	0.905
Physiologic parameters			
HR (beats/min)	81(13.4)	82(14.0)	0.783
SBP. (mmHg)	131(22.8)	131(19)	0.997
DBP (mmHg)	83(13.7)	83(11.9)	0.988
SpO ₂ (%)	100(99-100)	100(99-100)	0.697
RR (breaths/min)	13.5(12-16.25)	13(12-14.75)	0.394

TABLE 3 Outcomes of the Study. Values are expressed with median (interquartile range) or mean(SD) unless otherwise stated.

Outcomes	Group C(n=50)	Group E(n=50)	P value
Procedures performed, No.(%)			0.431
Bronchoalveolar lavage	12(24)	15(30)	
Endobronchial biopsy	8(16)	4(8)	
Airway inspection only	30(60)	31(62)	
Duration of procedure	16(7.5)	16(6.5)	0.908
Cough severity score	3(2-4)	2(2-3)	0.004
Cough VAS			
Bronchoscopist (VAS)	3(2-4)	2(0-2)	0.002
Nurse (VAS)	3(2-4)	2(0-2)	0.000
Spearman correlation		0.754	0.000
Requirements frequency of extra propofol, No.(%)			0.539
0	29(58%)	32(64%)	
1	21(42%)	18(32%)	
Requirements frequency of extra lidocaine, No.(%)			0.000
0	27(54%)	46(92%)	
1	23(46%)	4(8%)	
Propofol consumption, mg	65(59,76)	65(55,72)	0.492
Lidocaine consumption, mg	400(400,500)	400(400,400)	0.000
Physiologic parameters			
H-HR, beats/min	98(16.0)	97(13.8)	0.793
H-SBP (mmHg)	145(22.0)	144(20.8)	0.83
H-DBP (mmHg)	95(16.3)	91(13.5)	0.326
L-SpO ₂ (%)	97(93.75-98)	97(95-98)	0.231
H-RR (breaths/min)	22(18.75-23)	20(17-22)	0.007
PACU retention time (min)	49(14)	44(12)	0.093

Figures

Figure 1

Flow diagram. One hundred patients were randomized. Group C: topical airway anesthesia via conventional method; Group E: topical anesthesia via three-holed epidural catheter.

Figure 2

The topical airway anesthesia by the “spray-as-you-go” technique via a triple-orifice epidural catheter.

Figure 3

Spray image of the three-holed epidural catheter. The lidocaine was delivered into airway in three directions through the three-holed epidural catheter during manual bolus. 1=left bronchus; 2=right bronchus; 3= three-holed epidural catheter Δ : lidocaine column

Figure 4

The cough incidence between two groups. * $P < 0.05$ compared with group C. ** $P < 0.01$ compared with group C. The cough incidence = number of the patients coughing at the site in each group / 50 * 100%. The cough incidence was significantly difference in tracheal ($P = 0.005$), left ($P = 0.035$) and right bronchus ($P = 0.029$), and was similar in glottis ($P = 0.16$). Group C: topical airway anesthesia via conventional method; Group E: topical anesthesia via three-holed epidural catheter.

Supplementary Files

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- [CONSORT2010Checklist1.doc](#)