Novel bronchofiberscopic catheter spray device allows effective anesthetic spray and sputum suctioning

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Summary

Study objectives: To evaluate how serum lidocaine concentrations (SLC) rise when lidocaine is administered by a Bronchofiberscopic Catheter Spray Device (BCSD), and to demonstrate the effect on the aspiration speed of a substitute for sputum when a catheter spray remains in the channel of the bronchofiberscope (BF).

Methods: This is a prospective randomized clinical study. After lidocaine ultrasonic nebulizer, the BF was inserted orally. During the procedure patients received 4\% lidocaine by two methods. In Group 1, 11 patients received lidocaine by bronchofiberscopic (BF) injection. In Group 2, 15 patients received lidocaine by spraying from the $\varnothing$ 1.06 mm catheter through the BF channel. SLC were measured at 40 min from onset of nebulization. Separately, we examined how effectively sputum was aspirated through the BF channel with a catheter.

Results: Total lidocaine dose (TLD) is the total dose used for nebulization and for the BF injection or spray. The TLD for Groups 1 and 2 were 698.2 $\pm$ 162.1 mg (mean $\pm$ SD) and 498.7 $\pm$ 103.8 mg, respectively ($P = 0.03$). The SLC for Groups 1 and 2 were 1.28 $\pm$ 0.72 and 1.48 $\pm$ 0.70 mg/l, respectively ($P = 0.49$).

Conclusions: Using BCSD allows easier in administration of lidocaine and is not associated with a significant increase in SLC in comparison with BF injection. Although sputum aspiration using the BF inserted with our catheter was somewhat slow, we did not feel inconvenient so much. Compared to the conventional method, using BCSD may be preferable for patients and bronchoscopists.

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Introduction

In many institutions, bronchofiberscopic (BF) examination is now performed under local anesthesia. During BF examination, lidocaine is additionally administered into the trachea and bronchus by injection through the bronchofiberscope (BF) channel with a syringe.\textsuperscript{1,2} In this paper, we refer to this type of administration of lidocaine as “BF injection”. The BF injection itself induces coughing and
is associated with uneven anesthesia in the trachea and bronchus, and it is troublesome to do on a repeated basis. Thus, we developed a system allowing lidocaine to be easily sprayed repeatedly in the bronchus. In this paper we introduced a novel Bronchofiberscopic Catheter Spray Device (BCSD) to alleviate patient discomfort. We demonstrated the utility and safety of the BCSD in clinical application.

Materials and methods

Instruments

Figure 1 shows the BCSD and its schematic drawing. The BCSD consists of a gas–liquid mixing barrel, stopcock with lever, and an attached catheter. The barrel is a 5 ml disposable syringe containing lidocaine. The mouth of the barrel is closed by a cap that has an inductive tube for oxygen gas. Inside the barrel, there is a thin tube with a pinhole to take in lidocaine, and this thin tube goes out to the tip of the barrel. A 1 m teflon catheter tube (1.06, 0.56 mm inside diameter) is connected to the barrel. The pressure of oxygen gas was adjusted to 4 atm in clinical practice; the device withstands up to 8 atm. Simple operation of a stopcock lever allows ease in dosing of the lidocaine.

The spray device ejects 4% lidocaine at a maximal rate of 0.05 ml/s at 4 atm (Fig. 2).

Patients

This examination is a prospective randomized clinical study. Twenty-six patients (male; 20, female; 6) requiring diagnostic bronchofiberscopy for biopsy, treatment, observation, etc., gave consent to participation in this study. All patients were medically stable without cardiac, kidney or liver disease.

The total lidocaine dose (TLD) is the sum of the lidocaine used in the nebulization and lidocaine either injected or sprayed into the trachea and bronchus. Venous blood samples were taken for
measurement of serum lidocaine concentrations (SLC) by fluorescence polarization immunoassay at 40 min after the beginning of nebulization. Further Loukides et al.\textsuperscript{4} reported that the peak plasma concentration of lidocaine occurs within 20–30 min after the beginning of local anesthesia based on measurements at frequent intervals (before, 5, 10, 20, 30, 45, 60, 90, 120 min after initiation of anesthesia). We decided to measure SLC 40 min after administration, as this time point that of the expected was near peak concentration (20–30 min).

All patients, after premedication (atropine sulfate 0.5 mg, i.m.), received ultrasonic nebulization of 4 ml of 4% lidocaine. Just prior to insertion of the BF, 2 ml of 4% lidocaine was sprayed additionally to the pharyngo-larynx with a Jackson’s type atomizer. Patients were randomly divided into 2 groups; Group 1 included patients undergoing bronchofiberscopy by BF injection, and Group 2 included patients undergoing bronchofiberscopy by the new method using BCSD. Group 1 comprised 11 patients: 8 males, 3 females, aged 48–82 years old (67.1 ± 16.8, mean ± SD). Group 2 comprised 15 patients: 12 males, 3 females, aged 25–78 years old (62.7 ± 11.4). The BF with a 2.00 mm channel for forceps or suction (Olympus BF type 240, Japan) was inserted orally. In Group 1, we injected 1 ml of 4% lidocaine solution at the vocal cord, trachea, carina, right upper bronchus, right basal bronchus, left main bronchus, left upper bronchus and left lower bronchus. For patients coughing, we add lidocaine after each cough. In Group 2, we sprayed 4% lidocaine solution on the vocal cord, trachea, right main bronchus and left main bronchus using the spray catheter of ø 1.06 mm. Because we can achieve satisfactory local anesthesia administration, we rarely need to lidocaine for observation only.

Sputum aspiration performance study

During the BF examination it is necessary to aspirate sputum whenever needed. When the BF is loaded for BCSD, sputum must be aspirated through the opening between the channel and the inserted spray catheter. Therefore we studied the aspiration ability of a viscous starch test material (STM) as a substitute for sputum.

The STM had coefficient of viscosity higher than that of sputum. It was prepared from 4 g of starch and 150 ml of water. Starch and water were mixed, heated until semi-transparent, and cooled to 22°C. We used an Olympus BF type 240 with a 2.00 mm channel and three different catheter sizes of spray catheter: ø 1.06, 1.25 and 1.90 mm (commercial spray catheter: PW-6C-1, Olympus Optical Co., Ltd., Japan). Each catheter tube protruding 1 mm from the BF tip was tested under same conditions. The aspiration pressure was ~500 mmHg, and the time required to aspirate 25 ml of STM was measured.

Student’s unpaired t-test and Pearson’s correlation coefficient was used for statistical analysis. Results were considered statistically significant at $P<0.05$.

Results

Clinical study

Table 1 shows TLD and SLC for patients of Group 1 and Group 2. The TLD of Group 1 ranged from 460 to 1000 mg with a mean of 698.2 ± 162.1 mg. The TLD of Group 2 ranged from 340 to 680 mg with a mean of 498.7 ± 103.8 mg. The TLD of Group 2 was significantly less than that of Group 1 ($P = 0.03$). The SLC of Group 1 ranged from 0.6 to 2.7 mg/l with a mean of 1.28 ± 0.72 mg/l. The SLC of Group 2 ranged from 0.6 to 2.7 mg/l with a mean of 1.48 ± 0.70 mg/l. There was no significant difference in SLC between the two groups ($P = 0.49$).

Figure 3 demonstrates the relationship of TLD to SLC. In Group 2, TLD was highly correlated with SLC (correlation coefficient: $r = 0.81$, $P<0.01$). However, in Group 1, there was no correlation between TLD and SLC (correlation coefficient: $r = 0.59$, $P > 0.05$). No overdosage reactions of lidocaine were observed in either group.

Total examination times from the nebulization in Group 1 and Group 2 were 30–60 min (40.5 ± 8.8)

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<tr>
<th>Table 1</th>
<th>TLD and SLC of Group 1 and Group 2.</th>
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<td>Mean TLD (mg)</td>
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<td>Group 1 (n = 11)</td>
<td>698.2 ± 162.1 (460–1000)</td>
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<tr>
<td>Group 2 (n = 15)</td>
<td>498.7 ± 103.8 (340–680)</td>
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Values given as mean ± SD.
and 30–60 min (40.3 ± 9.2), respectively. There was no significant difference between the two groups.

Sputum aspiration performance study

Table 2 shows the results of the aspiration studies. The time required to aspirate 100 ml of water using the BF without a catheter was 10 s. The times to aspirate using the BF loaded with ∅1.06, 1.25 and 1.90 mm catheters were 22, 27 and 220 s, respectively. When Olympus’s catheter (∅1.90 mm) was loaded, aspiration took a very long time compared with our catheter (∅1.06 mm). The time for aspiration of 2 ml of STM using the BF without a catheter was 1.2 s. The time for aspiration using BF with catheters of ∅1.06 or 1.25 mm were 3.6 and 6.0 s, respectively. However, in the extremely narrow slit of the channel with ∅1.90 mm (PW-6C-1) it took more than 50 s. The BF loaded with Olympus’s catheter cannot aspirate sputum at bedside.

Discussion

Even after lidocaine nebulization, the traditional BF injection produces coughing and discomfort, and its anesthetic effect is uneven.\textsuperscript{1,2} It is also troublesome to perform the bronchofiberscopy. On the other hand, patients experienced no discomfort when spraying lidocaine.

In the past such spray catheter devices have not allowed effective aspiration of sputum. The spray device (Olympus PW-6C-1) has an external catheter diameter of 1.9 mm, which is too large for effective aspiration through the slit between the channel and the catheter. Using a PW-6C-1 for additional local anesthesia, we would have to remove the catheter from the channel at every aspiration.

We previously reported a method in which a Jackson’s atomizer was used as a gas–liquid mixer.\textsuperscript{3} Although there are other reports\textsuperscript{5–8} of topical anesthesia of the nasal cavity, pharynx and larynx by sprays, there has been few reported uses of a catheter inserted in the channel. Our BCSD is constructed from a syringe barrel equipped with a pin-holed tube, a thin long catheter and an oxygen gas inductive tube. In addition, while anesthetizing by our device, the patient’s SaO\textsubscript{2} did not deteriorate (data not shown). The patients did not cough, and were not discomforted by anesthetizing at any time. We do not have to pull out our catheter during observation because there is sufficient aspiration of sputa through the channel. After observation, we sprayed lidocaine one time using our device, pull out the device, then insert the biopsy or needle aspiration tool. It is very rare for us to re-insert our anesthetic catheter during biopsy or aspiration biopsy. The BCSD is simple and easy for operation and allows the aspiration of

<table>
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<th>Table 2</th>
<th>The time to absorb samples of water and the STM.</th>
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<td>Catheter diameter (mm)</td>
<td>No device catheter</td>
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<tr>
<td>Time to aspirate water 100 ml (s)</td>
<td>10</td>
</tr>
<tr>
<td>Time to aspirate STM 2 ml (s)</td>
<td>1.2</td>
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∅: catheter dimension outside diameter.
sputum while keeping the spray catheter in the BF channel.

Lidocaine administration by ultrasonic nebulization has been reported to be safe.9,10 In contrast, there is a report that ultrasonic nebulization of lidocaine is similar to intravenous administration in pharmacokinetics.11 We thus evaluated how SLC rises when administered by BF injection or by catheter spray. In our study the TLD of the spray group (498.7 ± 103.8 mg) was significantly less than that of the injection group (698.2 ± 162.1 mg). However, the SLCs of both groups were almost the same: 1.48 ± 0.70 mg/l (spray group) versus 1.28 ± 0.72 mg/l (injection group). The average of SLC for both groups was considerably lower than the level (5 mg/l) at which side effects of lidocaine are reported to appear.12 Clinically, no adverse reactions were observed. TLD was highly correlated to SLC in the spray group (r = 0.81), but the relationship between them was indistinct in the injection group (r = 0.59). In BF injection we must immediately aspirate the excess of lidocaine after injection, and its range of local anesthesia is narrow. On the other hand, our BCSD can put a wide area under local anesthesia with only a small amount of lidocaine due to the good absorption rate. The higher correlation coefficient suggests a more predictable dose-response curve and thus dosing parameters for safety can be more easily predicted with the spray technique.

During bronchofiberscopy it is necessary to aspirate sputum. Our experiment demonstrated that the aspiration speed of a starch preparation depends on the spray catheter diameter. The time for aspiration of 2 ml of STM using BF with our device was 3.6 s, while that with the Olympus PW-6C-1 spray system was more than 50 s. Clinically, sputum cannot be aspirated with a PW-6C-1 inserted in the channel. In contrast, we can easily aspirate sputum samples when using our spray catheter of size  1.06 mm.

Our BCSD and Olympus’s PW-6C-1 cost less than 3000 Japanese yen and 18,000 Japanese yen, respectively. Our current BCSD model has a simple structure and is almost handmade. We can expect greater reduction in cost if we mass-produce the device.

In conclusion, using BCSD we can perform BF without coughing and discomfort. We can easily aspirate the sputum while using BCSD, and we can adequately predict SLC from TLD and reduce the risk of side effects because TLD is highly correlated to SLC in this spray technique. We can achieve effective SLC in safe and wide ranging anesthesia without aspirating excess lidocaine. Thus, we believe that this simple and inexpensive device is useful for administration of lidocaine during bronchofiberscopy. The spray technique using our device is easily performed by the physician and well tolerated by the patient.

References