Clinical Evaluation of Endoscopic Bronchial Occlusion with Silicone Spigots for the Management of Persistent Pulmonary Air Leaks

Shinji Sasada, Kazuyo Tamura, Ya-shu Chang, Norio Okamoto, Yuka Matsuura, Motohiro Tamiya, Hidekazu Suzuki, Nobuko Uehara, Masashi Kobayashi, Tomonori Hirashima and Ichiro Kawase

Abstract

Objective The aim of this study was to evaluate the clinical effectiveness of endoscopic bronchial occlusion (EBO) with endobronchial Watanabe spigots (EWSs), a type of silicone bronchial blocker, for managing prolonged pulmonary air leaks.

Patients and Methods Between October 2002 and April 2010, 24 patients with surgically incurable pulmonary air leaks underwent EBO with EWSs. The spigot was grasped with forceps and inserted into the affected bronchus by using a flexible bronchoscope through an endotracheal or a tracheostomy tube.

Results In each patient, at least one EWS (mean=2.8) was placed for air leaks due to pneumothorax (n=15), empyema (n=8), or postsurgical complications (n=1). Twelve patients (50%) had complete resolution of the air leaks and seven (29.2%) had a reduction in air leaks, but five (20.8%) showed no improvement. Twenty-three patients required thoracic drainage tubes, which were successfully removed after EBO in 15 patients (65.2%). Of the 24 patients, four experienced severe respiratory failure requiring mechanical ventilation but were successfully treated. Complications were spigot migration, atelectasis, pneumonia, and lung abscess, but none caused significant mortality.

Conclusion EBO with EWSs seems to be a reasonable and manageable treatment option for patients with prolonged pulmonary air leaks, including those with severe respiratory failure requiring mechanical ventilation.

Key words: endobronchial Watanabe spigot, endoscopic bronchial occlusion, interventional bronchoscopy

Introduction

Bronchopleural and alveolopleural fistulas with persistent air leaks can cause significant morbidity and increased risk of mortality. These fistulas are usually managed by chest drainage and occasionally by pleurodesis; intractable cases require surgical decortication, direct closure, thoracoplasty, or omental or muscle transposition (1). However, surgery is often inappropriate for patients with respiratory failure because of the underlying pulmonary pathology.

Treatment of prolonged air leaks with sclerosing agents such as fibrin glue, gelatin sponge, and cyanoacrylate produces only short-term effects (2, 3). Other endoscopic approaches include inserting endovascular metallic coils into the affected airway (4, 5), inserting a tracheobronchial...
stent (6), and placing endobronchial valves (7-9). The results of these nonsurgical approaches are promising, and the US Food and Drug Administration has approved the humanitarian use of bronchial valves to treat selected postsurgical patients with prolonged air leaks (10). Persistent air leaks sometimes follow a complicated course of severe pneumonia or acute respiratory distress syndrome (ARDS) (8). In patients with severe respiratory failure, endoscopic approaches may be the only option available after all the conventional treatments have failed (11).

Watanabe et al (12, 13) developed the endobronchial Watanabe spigot (EWS) and reported its effectiveness in reducing air leaks by endoscopic bronchial occlusion (EBO). EWSs are easy to insert and remove with a flexible bronchoscope and simple grasping forceps, and do not require a specific delivery device, loader system, or guide wires, which are required to place endobronchial valves. The aim of this study was to evaluate the clinical effectiveness of EBO with EWSs for managing prolonged pulmonary air leaks.

**Patients and Methods**

**Patients**

We conducted a single-center retrospective analysis of patients who presented with surgically incurable pulmonary air leaks at the Osaka Prefectural Medical Center for Respiratory and Allergic Diseases between October 2002 and April 2010. The institutional review board approved the study design. All patients gave their written informed consent after receiving a detailed description of the procedure.

**EWS**

An EWS (Novatech, Cedex, France) is a cork-shaped silicone bronchial blocker originally developed by Watanabe et al (12, 13). Its diameter is designed to be the same as that of the subsegmental bronchi (Fig. 1). Its surface is covered with small studs and projections on the top and bottom for easy grasping with forceps.

**Determination of the affected bronchi**

A chest drainage system was used to assess the air leaks. A balloon occlusion test was performed to identify the affected region by passing a balloon catheter (B5-2C; Olympus, Tokyo, Japan) through the working channel of a standard flexible bronchoscope (≥2.8 mm i.d.). The balloon was then inflated to achieve complete occlusion in the lobar, segmental, and subsegmental bronchi. The affected airway was identified by reduction or elimination of the air leak through the chest tube 15-20 s after the occlusion. When air leak reduction by bronchial occlusion could not be achieved, lung inflation on fluoroscopic images was used to identify the affected bronchi.

**EWS insertion**

The EWS was inserted through an endotracheal or a tracheostomy tube under local anesthesia with moderate sedation to allow spontaneous breathing. In patients with severe respiratory failure requiring mechanical ventilation, the procedure was performed through the inserted tracheostomy tube. The grasping forceps (FB-15C-1; Olympus, Tokyo, Japan) were initially passed through the working channel of a bronchoscope; the EWS was held with the grasping forceps, inserted into the affected airway, and released. After EWS insertion, the patient was allowed to recover from anesthesia according to the standard hospital practices. Vital signs and oxygen saturation were closely monitored. Chest radiography was often used to assess lung re-inflation.

**Results**

In total, 24 patients (4 women and 20 men) had at least one EWS (mean=2.8; range=1-8) inserted to manage prolonged pulmonary air leaks (Table 1). Their median age was 67 years (range=48-82 years). Their primary comorbidities

<table>
<thead>
<tr>
<th>Table 1. Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects (n)</td>
</tr>
<tr>
<td>Median age (years, range)</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Comorbidities</td>
</tr>
<tr>
<td>COPD</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Lung cancer</td>
</tr>
<tr>
<td>Pneumonia</td>
</tr>
<tr>
<td>Interstitial pneumonitis</td>
</tr>
<tr>
<td>Bronchiectasis</td>
</tr>
<tr>
<td>Aspergillosis</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Data are presented as the number (%).</td>
</tr>
</tbody>
</table>

COPD: chronic obstructive pulmonary disease.
were chronic obstructive pulmonary disease (n=7), rheumatoid arthritis (n=5), tuberculosis (n=4), lung cancer (n=2), pneumonia (n=2), interstitial pneumonitis (n=1), bronchiectasis (n=1), aspergillosis (n=1), and diabetes mellitus (n=1). The air leaks were caused secondarily to pneumothorax (n=15), empyema (n=8), and postsurgical complications (n=1). Four patients (tuberculosis, n=2; pneumonia, n=1; empyema, n=1) had severe respiratory failure requiring mechanical ventilation; three of these patients had concurrent ARDS.

A balloon occlusion test was performed in 23 patients to identify the affected bronchi, and 10 patients showed apparent improvement of the air leaks. A patient with empyema who underwent open-window thoracotomy showed bubbles at the affected segmental bronchus during bronchosscopic observation; therefore, a balloon occlusion test was unnecessary. EWSs were placed in the right upper lobe (n=7), right middle lobe (n=1), right lower lobe (n=1), left upper lobe (n=9), left lower lobe (n=4), right middle and right lower lobes (n=1), and right upper and left upper lobes (n=1).

Of the 24 patients, 12 (50%) achieved complete resolution of the air leaks and seven (29.2%) experienced a reduction in the air leaks; however, five patients (20.8%) showed no improvement. Twenty-three patients required chest tubes as part of their clinical management, but the tubes were removed after EBO in 15 patients (65.2%). The four patients with severe respiratory failure requiring mechanical ventilation were successfully treated. The median time from chest tube insertion to EBO was 31 days (range=9-157 days), and the median time from EWS insertion to chest tube removal was 18 days (range=8-90 days).

Figure 2 shows representative chest radiographs of a 64-year-old man with a history of diabetes mellitus who developed ARDS due to bilateral Streptococcus pneumoniae infection accompanied by bilateral pneumothorax. This patient had severe respiratory failure requiring mechanical ventilation. A bronchopleural fistula remained despite the use of bilateral chest tubes (Fig. 2A), but air leaks were reduced after the placement of six EWSs, and the chest tubes were successfully removed (Fig. 2B). The patient was discharged five months after the procedure and did not require home oxygen therapy.

The procedure-related complications included EWS migration (n=4), atelectasis (n=3), pneumonia (n=2), fever (n=2), and lung abscess (n=1). All events of EWS migration were identified by lower lobe air leaks; B6 (n=3) and B8 (n=1), and EWSs were replaced in the same bronchus. EWSs in four patients were removed because of complications (lung abscess or hypoxic atelectasis; n=2) or because of the patient’s request (n=2). One patient with severe respiratory failure requiring mechanical ventilation who experienced atelectasis of the left lower lobe showed improvement after the EWS was removed. The case of pulmonary abscess was successfully managed by EWS removal. Although the EWSs were permanently placed in 20 patients, we did not observe any late-phase complications or treatment-related deaths during the follow-up period.

**Discussion**

In this study, we show that EWS insertion is an effective modality for managing prolonged air leaks caused secondarily to pneumothorax, empyema, and postoperative complications, including in cases of co-existing respiratory conditions. Although many of the patients had significant underlying pulmonary conditions or other comorbidities, the air leaks were eliminated or reduced in 79.1% of 24 patients and the chest drains were successfully removed in 65.2% of 23 patients. To the best of our knowledge, few studies have reported EBO in patients with severe respiratory failure requiring mechanical ventilation. Based on our experience, the
less-invasive EWS procedure is useful for such high-risk patients.

In a study by Travaline et al. (8), the use of endobronchial one-way valves (Zephyr EBV; Emphasys Medical, Redwood City, CA) led to the complete resolution of persistent air leaks in 19 of 40 (47.5%) patients and reduced air leaks in 18 of 40 (45%) patients; these results are comparable to our findings. The management of patients with poor cardiopulmonary reserve and those at risk of further morbidity and mortality with surgical intervention always presents a challenge. Further, infectious complications are often a problem with surgical techniques. One-way endobronchial valves can be considered for treating persistent air leaks, including rapidly progressive cases (11).

In the present study, the most frequent EWS-related complication was migration of the spigot. To prevent migration, EWSs should be inserted to the maximum possible distance, and coughing should be minimized with the appropriate medication. In a few cases, we cut the EWS obliquely to halve its length and facilitate maximum insertion. This reduction in size does not appear to affect the functioning of the device. In addition, all of the cases of EWS migration occurred in the lower lobe: the greater breathing movement of the lower bronchus may be responsible for this complication. Medium-sized EWSs (6 mm diameter) were the most frequently used in this study. If the inserted EWS was smaller or larger than the diameter of the affected bronchus, it was removed and a different size was selected to ensure the optimal fit. In addition, factor XIII with fibrinogen was endobronchially administered after EBO to seal the aperture of the affected bronchus in some cases of EWS migration. One patient developed atelectasis, a known complication of bronchial occlusion, and severe respiratory failure after the insertion of eight EWSs, which were immediately removed.

We found no evidence to support the choice of permanent versus temporary EWS insertion; however, late-phase lung infection will influence this decision. In the study, the case of pulmonary abscess was successfully managed by EWS removal. Although severe infections were not observed in the 20 patients with permanent EWSs during the follow-up period, we recommend temporary placement to prevent complications in high-risk cases. An active infection should be treated before the placement of occlusive devices.

Based on our experience, sublobar occlusion sometimes produced only a temporary decrease in air leaks. In patients with advanced chronic obstructive lung disease, it is difficult to resolve air leaks by simple placement of an occlusive device, because collateral channels contribute to the persistence of air leaks in these patients (14). In some studies, collateral ventilation from the adjacent lobes through collateral channels could prevent target lobe atelectasis, which potentially limits the clinical response after endobronchial lung-volume reduction (15-17). A balloon occlusion test of the adjacent segments should be attempted to treat more than one segment or subsegment and maximize the effectiveness of EBO. In this study, repetitive balloon occlusion tests were performed in most patients and EWSs were inserted if necessary. Even if EWS insertion does not completely resolve air leaks, reducing the airflow will allow the bronchopleural fistula to heal.

In conclusion, EBO with EWSs seems to be a reasonable and manageable treatment option for persistent pulmonary air leaks unsuited for surgical treatment. This procedure can also be used in patients with severe respiratory failure requiring mechanical ventilation.

The authors state that they have no Conflict of Interest (COI).

Acknowledgement
The authors thank Yoichi Watanabe for technical advice for using EWSs. This work was supported by grants from the Osaka Medical Research Foundation for Incurable Diseases.

References


© 2011 The Japanese Society of Internal Medicine
http://www.naika.or.jp/imindex.html