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【 ORIGINAL ARTICLE 】

Clinical Evaluation of Endoscopic Bronchial Occlusion with an Endobronchial Watanabe Spigot for the Management of Intractable Pneumothorax, Pyothorax with Bronchial Fistula, and Postoperative Air Leakage

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Abstract:

Objective The present study aimed to evaluate the clinical effectiveness of endoscopic bronchial occlusion (EBO) with endobronchial Watanabe spigots (EWSs) for the management of prolonged pulmonary air leaks, such as intractable pneumothorax, pyothorax with bronchial fistula, and postoperative air leakage.

Methods This was a retrospective study. Between April 2005 and March 2018, we recruited 21 patients with intractable pneumothorax (10 cases), pyothorax with bronchial fistula (7 cases), and postsurgical pulmonary fistula (4 cases) in whom appropriate drainage for 2 weeks had been unsuccessful and who were unsuitable for surgery. An EWS was inserted using a flexible bronchoscope via an endotracheal or a tracheostomy tube.

Results The mean number of sessions with EWS procedures was 1.94, and the mean number of inserted EWS per patient was 6.5. In addition to EWS procedures, pleural washing and pleural adhesion therapy were performed in all cases with pyothorax, whereas pleural adhesion therapy was performed in three patients with pneumothorax. The successful treatment rate was 85.7%. Reduction of air leakage was observed in 19/21 patients. The mean duration of reduction of air leaks was 4.1 days (median, 1; range, 0-24 days) following EWS procedures. The mean duration from tube insertion to chest tube removal was 43.4 days (median, 29; range, 16-105 days). Complications included spigot migration and infection (aspergillosis); no complications caused significant mortality.

Conclusion Performing EBO using an EWS appears to be a reasonable option for the management of intractable pneumothorax, pyothorax with pulmonary fistula, and postoperative air leakage.

Key words: endobronchial Watanabe spigot, intractable pneumothorax, pyothorax with bronchial fistula, postoperative air leakage

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Introduction

A bronchopleural fistula with a persistent air leak is an abnormal pathway between the bronchus and pleural space. Fistulas are commonly related to underlying pulmonary diseases including chronic obstructive disease, bullous emphysema, interstitial lung disease, and infectious pulmonary diseases, such as pulmonary abscess or pyothorax. Furthermore, this condition can occur postoperatively and is associated with substantial morbidity and mortality (1). Surgical closure of the defect is considered the definitive approach for controlling the air leak, but some patients with fistula often exhibit severe complications or a poor performance status; therefore, these patients are suboptimal candidates for surgery. Therefore, in recent decades, there has been an ac-

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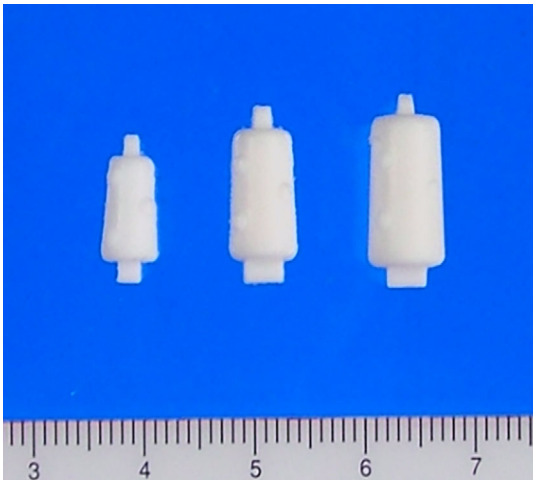

Figure. Endobronchial Watanabe spigots (EWS), a silicone-made bronchial filler. Three sizes of EWS [diameter: 5 mm (S), 6 mm (M), and 7 mm (L)] are available. EWSs are spigot-shaped, with studs on the surface and graspable parts at both ends.

tive interest in the development of effective treatment options for bronchopleural fistulas with persistent air leaks.

Watanabe et al. developed the endobronchial Watanabe spigot (EWS) and reported its effectiveness in reducing air leakage by endoscopic bronchial occlusion (EBO) (2, 3). A flexible bronchoscope is used to easily insert and remove the EWS. However, original research on this device is limited (4), so its clinical effectiveness remains unclear.

Therefore, we investigated the efficacy and safety of performing EBO using an EWS for the management of prolonged pulmonary air leaks in our institute.

Materials and Methods

We conducted a single-center retrospective analysis of patients who had been treated with EBO using an EWS at Miyazaki Prefectural Miyazaki Hospital between 2005 and March 2018. The study design was approved by our institutional review board. Informed consent was obtained from all patients after providing a detailed description of the procedures.

Indications for performing EBO using an EWS were as follows: a) cases of intractable pneumothorax and pyothorax with bronchial fistula in patients whose condition was not improved by appropriate drainage for two weeks and who were unsuitable for surgery because of complications or their respiratory status; and b) cases of postoperative air leakage in patients whose condition was not improved by appropriate drainage and who were unsuitable for surgery because of complications or their respiratory status.

Preparation and anesthesia

As a basic rule, bronchial occlusion is performed using a bronchofiberscope with a sliding tube intubated under local anesthesia. As spraying anesthesia in the posterior pharyngeal/laryngeal and local tracheal/bronchial regions delivered via the channel of the bronchofiberscope, 10 mL of 1% Xylocaine (lidocaine hydrochloride) is used. EWS placement was performed under local anesthesia with sedation (midazolam or propofol) to facilitate spontaneous breathing. In patients with severe respiratory failure requiring mechanical ventilation, the procedure was performed via an inserted endotracheal tube. In certain cases, the procedure was performed under general anesthesia.

Determination of the affected bronchi

The balloon test was performed to identify the affected region by confirming air leakage from the drain using a continuous low-pressure suction device with a balloon catheter (B5-2C; OLYMPUS, Tokyo, Japan). The possible responsible bronchus was blocked in the order of lobe bronchus, segmental bronchus, and subsegmental bronchus with a balloon catheter for approximately 30-60 seconds; the bronchus where the air leakage disappeared or was significantly reduced was determined to be the responsible bronchus.

In cases wherein air leak reduction by bronchial occlusion was not achieved, the responsible bronchus was determined by evaluating the clinical findings, such as chest X-ray or chest CT findings, and the change in the air leakage due to body position. In addition, the injection of dye was used to determine the affected bronchus.

EWS insertion

An EWS (Novatech, La Ciotat, France) is a silicone-made spigot-shaped bronchial filler (Figure). To fill the affected bronchus with an EWS, the central end of the spigot was held using grasping forceps (FG-14P; OLYMPUS) that had been passed via the channel of a bronchoscope in advance. The EWS was then tightly wedged into the responsible bronchus during the insertion of the bronchoscope. In cases of multiple responsible bronchi, multiple EWSs were used to fill each affected bronchus.

Additional therapies

Pleural adhesion was performed using OK432 (Picibanil: Chugai Pharmaceutical, Tokyo, Japan). Bronchial injection of fibrin glue was performed according to the method described previously (5). In brief, after EBO with EWS, fibrin glue was injected from the side of the EWS using a catheter.

Results

Patients' characteristics

The baseline characteristics of all patients are summarized in Table 1. The patient population included 18 men and 3 women, with a mean age of 67 (range 51-82) years old. The causes of air leaks in the 21 patients were intractable pneumothorax (10 cases), pyothorax with bronchial fistula (7 cases), and postoperative air leakage (4 cases).

Comorbidities noted in the patients were lung cancer (9

Table 1. Patients Characteristics of EWS Treatment.

Subjects (n)	21
Age [years; average (range)]	67 (51-82)
Sex (male/female)	18/3
Causes of air leaks	
Intractable pneumothorax	10
Pyothorax with bronchial fistula	7
Postoperative air leakage	4
Comorbidities	
Lung cancer	9
Interstitial pneumonia	7
COPD	3
Diabetes mellitus	3
RA/vascluaitis/ProstateCa/HD/ARDS	1/1/1/1
(One IP case was under mechanical ventilation)	

Data are presented as the number. EWS: endobronchial Watanabe spigot, COPD: chronic obstructive pulmonary disease, RA: rheumatoid arthritis, ProstateCa: prostatic cancer, HD: hemodialysis, ARDS: acute respiratory distress syndrome

Table 2. EWS Procedures.

No of EWS procedures (average; range)	1.94 (1-3)	
No of EWS (average; range)	6.5 (1-17)	
Size of inserted EWS (L/M/S)	31/74/21	
Position of EWS placement	RUL	8
	RML	2
	RLL	2
	LUL	3
	LLL	6

EWS: endobronchial Watanabe spigot, RUL: right upper lobe, RML: right middle lobe, RLL: right lower lobe, LUL: left upper lobe, LLL: left lower lobe

cases), interstitial pneumonia (7 cases), chronic obstructive pulmonary disease (COPD; 3 cases), diabetes mellitus (3 cases), rheumatoid arthritis (1 case), antineutrophil cytoplasmic antibodies-related vasculitis (1 case), prostatic carcinoma (1 case), hemodialysis (1 case), and acute respiratory distress syndrome (1 case). One patient with interstitial pneumonia was under mechanical ventilation.

Sedation for EWS treatment was achieved using propofol (13 procedures), midazolam (6 procedures), and midazolam and fentanyl (4 procedures); 13 procedures were performed under general anesthesia. To detect the affected bronchi, 17 patients (81%) were examined by balloon test, and the apparent reduction of air leaks was observed in 13 cases (13/17, 76.5%).

Table 2 summarizes the results of the EWS procedures. The mean number of sessions with an EWS procedure was 1.94 (range 1-3). The mean number of inserted EWS per patient was 6.5 (range 1-17). The medium-sized EWS was mainly used in our institute. EWSs were placed in the right upper lobe in eight cases, right middle lobe in two cases, right lower lobe in two cases, left upper lobe in three cases, and left lower lobe in six cases. In addition to the EWS procedures, several additional therapies were performed according to the primary diseases; for intractable pneumothorax, pleural adhesion therapy was performed in three cases, and bronchial injection of fibrin glue was performed in two patients; for pyothorax with bronchial fistula, pleural washing was performed in five cases, pleural washing and pleural adhesion was performed in one case, and pleural washing and window operation was performed in one patient; and for postoperative air leakage, bronchial injection of fibrin glue was performed in one patient.

Efficacy

The successful chest tube removal rate was 85.7% (18/21; Table 3). The successful treatment rates by primary disease are as follows: intractable pneumothorax, 80.0% (8/10); pyothorax with bronchial fistula, 100% (7/7); and postoperative air leakage, 75% (3/4).

These results included the combination of EWS and additional therapies. In intractable pneumothorax, 50.0% (5/10) were managed with EWS insertion alone, and a combination of EWS and pleural adhesions was effective in 30.0% (3/10) of the cases. In pyothorax with bronchial fistula, all patients were treated with EWS insertion and additional therapies, such as washing. In postoperative air leakage, EWS insertion alone was effective in 25.0% (1/4) of the cases, and a combination of EWS, bronchial injection of fibrin glue, and pleural adhesion was effective in 50.0% (2/4) of the cases.

Reduction of air leakage was observed in 19/21 (90.5%) patients. Reduction of air leakage was observed within a mean duration of 4.1 (median, 1; range, 0-24) days following EWS procedures. However, multiple sessions of EWS insertion were required in 11 cases, and we observed a reduction in air leakage within 2 days of the placement of the most recent EWS. The mean duration from tube insertion to chest tube removal was 43.4 (median, 29; range, 16-105) days.

Complications

The procedure-related complications were EWS migration in 5 cases and infection in 1 case; the infection was detected 4.5 years after EWS placement. However, no severe complications or treatment-related deaths were observed during the follow-up period.

Discussion

To our knowledge, this is the first report that provides details of EWS treatment, additional therapy, and timing of additional EWS placement and demonstrates our strategy of EBO using an EWS.

EWSs appear to be an effective treatment option for cases of pneumothorax, pyothorax with bronchial fistula, and postoperative air leakage. According to a previous report of 138 cases collected from the Japanese medical documentation database, the success rate was 74% (6). In our study, the success rate was 85.7%, which was nearly equivalent to that

Table 3. Efficacy of EWS Insertion and Reduction of Air Leakage.

Successful chest tube removal	18/21 (85.7%)
Reduction of air leaks (%)	
Stopped	6 (28.6)
Reduction	13 (61.9)
No change	2 (9.5)
Tube removal from tube insertion (average, median, range)	43.4 (29, 16-105)
Tube removal from EWS procedures (average, median, range)	24.9 (19, 0-86)

EWS: endobronchial Watanabe spigot

in the previous report. However, these data differ with respect to the underlying disease. Therefore, it is necessary to discuss the results according to underlying diseases.

In our study, all cases of intractable pneumothorax were considered to be secondary spontaneous pneumothorax (SSP). SSP is associated with a higher mortality than PSP (7). Although early surgery is the recommended choice of treatment for intractable SSP (7), the surgical mortality is high, especially in SSP with interstitial pneumonia (8).

In addition, surgery is considered inappropriate because of a poor general condition in many SSP cases. In our study, all patients had intractable SSP with various complications and a poor general condition and were not suitable for surgery. For these patients, EWS treatment resulted in no mortality and the avoidance of surgery in many cases. Given these data, it can be said that EWS treatment is effective at treating intractable pneumothorax, but further investigations will be necessary, as the sample size in this study was very small.

Of note, EWS insertion alone was effective in 50.0% (5/10) of the cases, and a combination of EWS and pleural adhesions was effective in 30.0% (3/10) of the cases. Similarly, the success rates with EWS treatment alone has been previously reported to be 40-50% (3, 4). Using an EWS for intractable pneumothorax reportedly reduces and stops air leakage. Therefore, we propose that refractory pneumothorax be treated first with an EWS alone, and if the leak does not stop entirely, additional treatment should be considered when the leak decreases. Recently, there have been reports of suction devices that can be used to quantitatively measure air leaks (9); these devices may be used in further studies.

In pyothorax with bronchial fistula, treatment options are often limited, and such cases are associated with either or both significant morbidity or mortality. In our study, all cases were successfully treated with an EWS. Despite the lack of detailed data on the prognosis of pyothorax with bronchial fistula, accompanied by various complications, the results of our study support the effectiveness of a treatment strategy using an EWS. However, it is clear that treatment with an EWS alone cannot cure patients of pyothorax with bronchial fistula. The fistula acts as a major obstacle in treating those patients, as it makes adequate pleural washing difficult and inefficient. Thus, closing the fistula using an EWS would enable effective pleural washing. Therefore, when treating pyothorax with bronchial fistula, the combination of an EWS and appropriate pleural washing and drainage is extremely important.

For postoperative pulmonary fistulas, the success rate was 75%, and unnecessary surgery was avoided. EWS showed high efficacy for postoperative pulmonary fistulas, but originally they are a group of operable patients. Thus, the indications and timing require further research.

We reported a reduction of air leakage in 90.5% of the patients and successful chest tube removal in 85.6% of the patients. These results are compatible with those of previous reports (4, 10-12). It is often reported that air leakage does not immediately decrease following EWS treatment. Therefore, it is difficult to estimate the follow-up period required following initial treatment to determine whether or not additional treatment should be performed. We observed air leakage reduction within two days after the placement of the most recent EWS. In patients with advanced COPD, it is difficult to resolve air leaks by EWS placement alone because collateral channels contribute to persistent air leaks in such cases (13). In certain studies, collateral ventilation from the adjacent lobes via the collateral channels were able to prevent target lobe atelectasis, which potentially limits the clinical response following EWS placement. Based on our findings, we recommend a three-day observation period following EWS placement to determine the efficacy of the EBO procedure. If no reduction in air leak is observed after three days, a reattempt of EWS placement must be considered.

We experienced three cases of EWS placement with fibrin glue. Few case reports demonstrated that the combination of EWS and fibrin glue was effective (5). We speculate that fibrin glue may be effective by filling the gap between the EWS and the tracheal wall or by obstructing more peripheral bronchus. EBO in combination with an EWS and fibrin glue can be an effective choice as additional therapy. Further investigations regarding adequate additional therapy are warranted.

We experienced 1 case of pulmonary aspergillosis infection 4.5 years after EWS placement. Sato et al. reported a case of EWS placement with a long follow-up period (>6 years), concluding that EWSs could be placed long-term with careful and appropriate follow-up (14). However, Watanabe et al. reported that 4.8% of patients developed a related infection after EWS placement, although these procedure-related complications were not severe (15). These

findings support the prompt removal of an EWS in patients whose general condition has improved with a favorable long-term prognosis.

Several limitations associated with the present study warrant mention. First, the present study had a retrospective design, which has inherent limitations. Second, this was a single-center study conducted at a center that specializes in such procedures; therefore, duplicating our results may be challenging for less-experienced physicians. Third, the clinical indications of performing EBO using an EWS remain unclear.

In conclusion, performing EBO using an EWS appears to be a reasonable option for the management of intractable pneumothorax, pyothorax with bronchial fistula, and postoperative air leakage. Future studies, including a prospective study, are required to confirm these findings.

Author's disclosure of potential Conflicts of Interest (COI).
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