



A novel method for the bronchial occlusion of prolonged air leakage using customized endobronchial plugs

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Background: The management of prolonged air leakage (PAL) is a significant clinical challenge, particularly for patients who are unfit for surgical treatment. The use of endoscopic interventions with occlusive devices has been reported previously; however, local availability and cost may represent potential hurdles, especially in developing countries. In this study, we presented a conical endobronchial plug of our design and evaluated the efficacy of making use of that in the treatment of PAL as a novel method.

Methods: This retrospective study included a total of 23 patients with PAL who were not suitable for surgery and underwent bronchial occlusion using customized plugs. The responsible bronchi were identified by the balloon occlusion test or by end-tidal carbon dioxide detection. In each case, the plug was grasped at the knot of the tip with forceps and then inserted into the target bronchus with a flexible bronchoscope.

Results: Of the 23 patients with intractable pneumothorax, 1 to 3 plugs (median =1) were successfully inserted into the affected bronchi of each patient for bronchial occlusion. Air leakage showed complete cessation in 13 patients (56.5%) and reduction in seven patients (30.4%). A total of 20 patients (87.0%) experienced successful removal of the drainage tube following plug occlusion or presented with additional pleurodesis. Complications included expectoration of the plug (n=1) and fever (n=1); no other severe complications were observed.

Conclusions: Bronchial occlusion using customized endobronchial plugs appears to be an effective and simple option for the management of PAL in patients who are not suitable for surgery, especially in developing countries, as the customized plug is a cost-effective alternative.

Keywords: Prolonged air leakage (PAL); bronchoscopy; bronchial occlusion; customized plug

Submitted Jul 11, 2023. Accepted for publication Oct 20, 2023. Published online Dec 12, 2023.

doi: 10.21037/jtd-23-1053

View this article at: <https://dx.doi.org/10.21037/jtd-23-1053>

Introduction

Refractory pneumothorax includes recurrent pneumothorax and prolonged air leakage (PAL). PAL is defined as persistent air leakage for more than seven days (1) and is indicated by abnormal communication between the pleural space and lung parenchyma or airways. PAL can be caused by alveolar-pleural fistulas (APFs) or bronchopleural fistulas (BPFs) and is associated with prolonged hospitalization and significant morbidity; thus, PAL represents a significant clinical challenge for both clinicians and patients (2,3).

Surgery is currently considered to be the recommended treatment for the management of PAL (4,5). However, surgical management is not without risk for patients in poor condition or with limited cardiopulmonary function; these patients are known as the suboptimal surgical candidates. Existing guidelines recommend medical pleurodesis as an alternative treatment in patients with PAL who are not suitable candidates for surgery (4,5). However, medical pleurodesis may not be suitable or effective for patients with extremely vigorous air leaks that prevent the visceral and parietal pleura from coming into contact. With the development of bronchoscopic techniques, endoscopic interventions have been increasingly used as options for the management of PAL in patients who are unfit for surgery (6). Bronchial occlusion can help control air leakage, involving biocompatibility sealants and closure devices. Silicone plugs have been confirmed to be highly effective for managing PAL as endobronchial blockers (7-9). A key step after identifying the suspect airway is the placement of silicone plugs. Several approaches have been reported to facilitate insertion of such plugs into the target bronchus (10-12). However, it is still difficult to insert the plugs into the

angulated bronchi such as the apical segment of the right upper lobe. In addition, the commercially produced endobronchial Watanabe spigot (EWS) is not available in China. Therefore, we designed a conical silicone plug for the treatment of PAL. In this study, we evaluated the efficacy of bronchial occlusion when applying the customized silicone plugs for the management of PAL. We present this article in accordance with the STROBE reporting checklist (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1053/rc>).

Methods

Patients

This was a retrospective study conducted in the Second Affiliated Hospital of Fujian Medical University between August 2012 and December 2021. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of the Second Affiliated Hospital of Fujian Medical University (FYFE2021-51) and individual consent for this retrospective analysis was waived.

All the included participants had PAL and had been administered with intercostal drainage for more than seven days. These patients were unsuitable for surgical management due to their poor overall clinical condition. We excluded the patients with the following conditions: (I) patients were allergic to silicone material; (II) patients had uncontrolled acute lung infection or severe chronic infection at the target bronchi; (III) patients with compromised cardiopulmonary function unable to tolerate the bronchoscopic procedure. Bronchoscopic treatment for bronchial occlusion was performed on each patient using the customized silicone plugs. Written informed consent was obtained from all patients.

Customized silicone plugs

The silicone plugs were manufactured from a mandibular prosthesis (Kangning Medical Device, Shanghai, China). Plug size was designed to be slightly larger than the diameter of the target bronchus measured on high-resolution computerized tomography (HRCT). Then, we used scissors to trim the silicone material to a conical shape with rough surface to facilitate insertion into the airway. A knot (length =1 cm) was tied at the tip of the silicone plug using 1-0 suture thread to manipulate orientation. In

Highlight box

Key findings

- Bronchial occlusion with customized endobronchial plugs represents an effective and simple option for the management of prolonged air leakage (PAL) in patients who are not fit for surgery.

What is known and what is new?

- Endoscopic interventions have been used as options for the management of PAL in patients who are unfit for surgery.
- This study focuses on the safety and efficacy of using customized endobronchial plugs for bronchial occlusion of PAL treatment.

What is the implication, and what should change now?

- The new customized plug is a cost-effective alternative in the management of PAL, especially for developing countries.

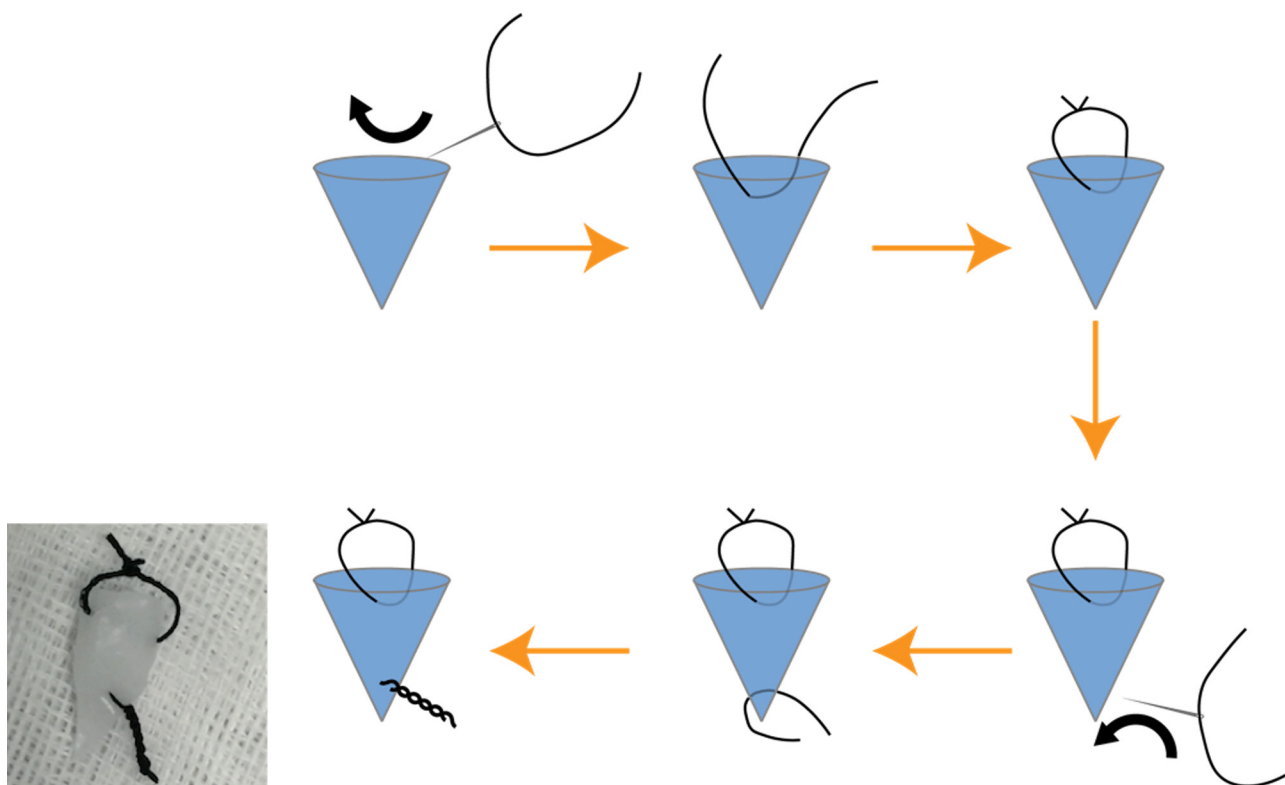


Figure 1 Illustration of the silicone plug used in the study. The customized silicone plug is cone-shaped, with a knot at the tip and a thread loop at the broad end.

addition, a thread loop was placed at the back end of the plug for convenient removal (*Figure 1*).

Bronchoscopic procedure and plug placement

All patients underwent flexible bronchoscopy under local anesthesia with 2% lidocaine and mild sedation with intravenous midazolam. The bronchi responsible for feeding the air leakage were identified by the balloon occlusion test or by end-tidal carbon dioxide (EtCO₂) detection. Technical details have been described in our previous publication (1). In brief, for balloon occlusion detection, the target bronchi were defined as those exhibiting a reduction or disappearance of air leakage through the chest tube after being occluded by an inflated balloon. If the balloon occlusion test failed to determine the responsible bronchi, then multiple leaks were considered. The affected bronchi were then determined by EtCO₂ detection. When the EtCO₂ value of a specific bronchus was approximately 5 mmHg lower than that of the main bronchus on the side of the pneumothorax, then this would be defined as the

responsible bronchus.

After identifying the responsible bronchus, a grasping forceps was passed through the working channel of a flexible bronchoscope to grasp the knot at the tip of the plug (*Figure 2*). Subsequently, guided by the bronchoscope, the grasping forceps held the plug to reach the target bronchus by adjusting the angle and direction. While maintaining the bronchoscope at the bronchial opening, the plug was inserted into the target bronchus with the assistance of the forceps. Once the plug blocked the target bronchus, the bronchoscope was used to press the back end of the plug further into the bronchus while simultaneously retracting the forceps. Finally, the forceps were reintroduced to impact against the back end of the plug to ensure a tight seal (*Figure 3*). In cases where local anesthesia was administered, patients were instructed to cough after the plug placement to ensure its stability and prevent potential migration. After the procedure, oral codeine was prescribed for the first 3 days to suppress coughing and prevent expectoration. For multiple leaks, we used multiple plugs, or a single large plug, to occlude the affected bronchi. The plugs were

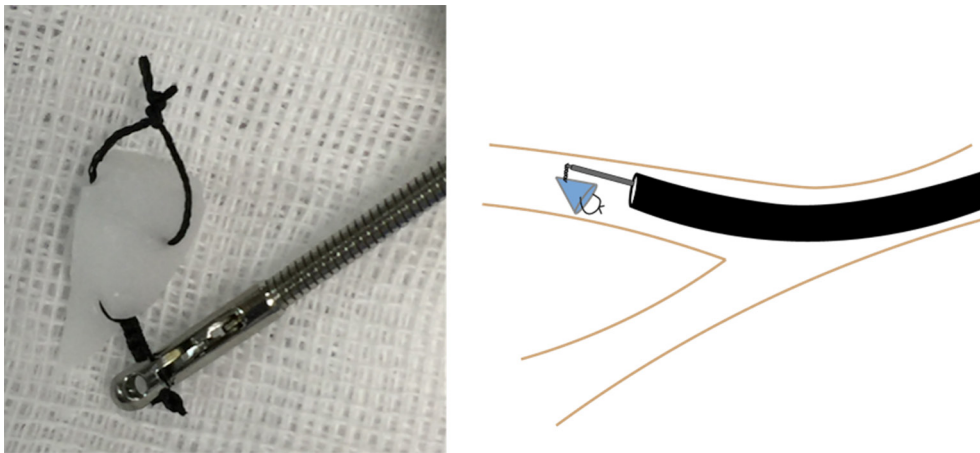


Figure 2 The novel method for the placement of endobronchial plug into the bronchus. The plug is held at the knot of the tip with grasping forceps to manipulate its orientation and route in the bronchus via the bronchoscope.

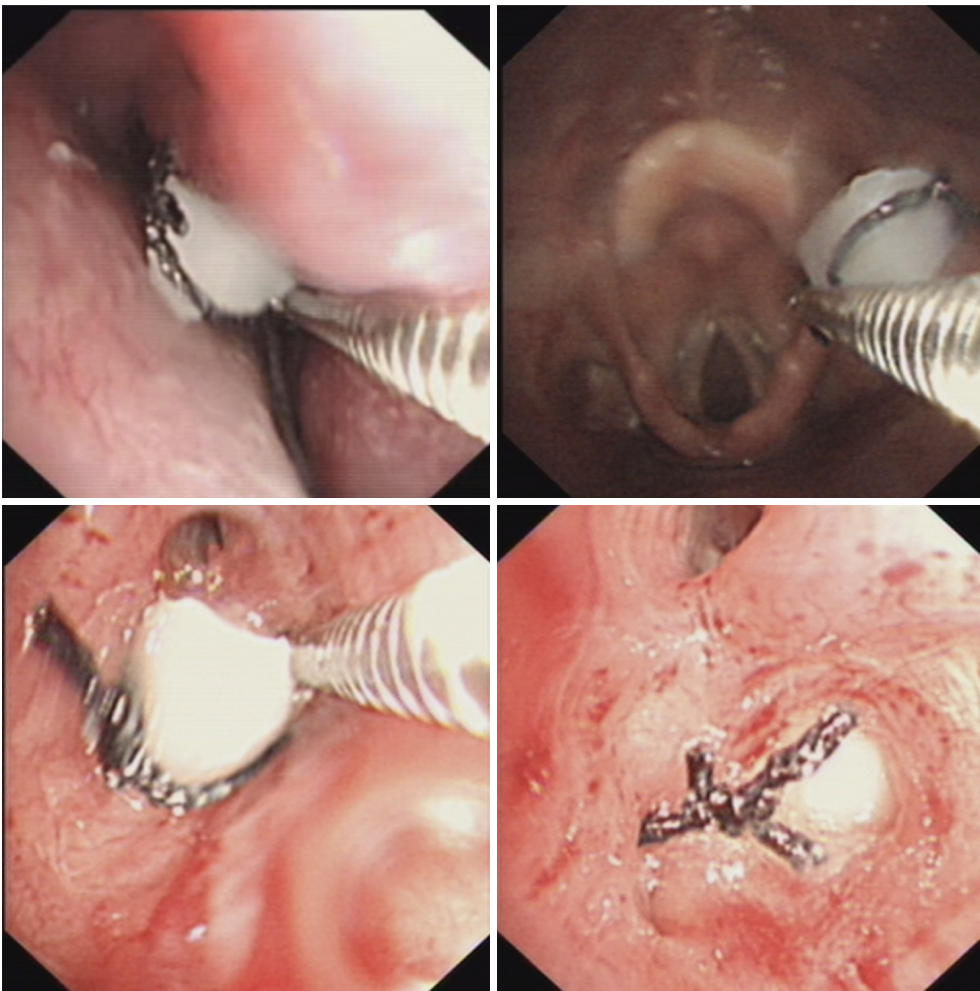


Figure 3 Customized silicone plug insertion into the right upper lobe posterior segment via the transnasal bronchoscopy.

Table 1 Patient characteristics

Demographics	Values
Number of participations	23
Age (years)	62 [24–81]
Sex (male/female)	23/0
Location of air leakage	
Right side	15
Left side	8
Duration of chest drainage (days)	28 [12–133]
Degree of collapsed lung (%)	20 [10–85]
Underlying diseases of pulmonary	
Chronic obstructive pulmonary disease	19
Pneumoconiosis	6
Old pulmonary tuberculosis	4
Bronchiectasis	1
Bronchiolitis obliterans	1

Data are presented as n or median [range].

Table 2 Results of bronchial occlusion using customized plugs

Variables	Values
Number of plugs inserted per patient	2 [1–3]
Position of plugs placement	
RUL	7
RML	5
RLL	3
LUL	7
LLL	1
Diameter of plugs used (mm)	5.5 (3–10)
Number of bronchial occlusion procedure	1 [1–3]
Successful removal of the drainage tube	20 (87.0)
Status of air leaks after bronchial occlusion	
Cessation	13 (56.5)
Reduction	7 (30.4)
No change	3 (13.0)
Duration of air leak stopped (days)	5.9 (0–21)
Recurrence	3 (13.0)

Data are presented as median [range], n, mean (range) or n (%). RUL, right upper lobe; RML, right middle lobe; RLL, right lower lobe; LUL, left upper lobe; LLL, left lower lobe.

removed by grasping the loop at the back end when the physician deemed this to be clinically feasible.

Outcomes measurement

After the bronchoscopic procedure, all patients were continuously observed for 7 days. When the air leakage was not completely resolved after bronchial occlusion, we implemented additional treatment by performing chemical pleurodesis with interleukin-2 infusion. When no bubbling was detected in the water seal chest drain system for at least 3 days, the drainage tube was then clamped for a minimum of 1 day. After the lung recruitment was confirmed through chest X-ray or chest CT, the drainage tube was removed.

Statistical analysis

We used descriptive statistics, such as the mean, median, range, and percentage, to summarize patient demographics and outcomes. The data analysis was conducted using IBM® SPSS® Software version 22.0.

Results

A total of 23 male patients, with a median age of 62 years (range, 24–81 years), underwent bronchial occlusion using the customized silicone plugs (*Table 1*). The location of PAL was on the right in 15 cases and on the left in 8 cases. Each patient had at least one of the following underlying diseases: chronic obstructive disease (n=19), pneumoconiosis (n=6), old pulmonary tuberculosis (n=4), bronchiectasis (n=1) and bronchiolitis obliterans (n=1). Prior to bronchoscopic treatment, the median degree of collapsed lung was 20% (range, 10% to 85%), and the median duration of chest drainage was 28 days (range, 12–133 days).

The outcomes of the plug procedures are listed in *Table 2* and *Table S1*. Bronchial occlusion was performed 1 to 3 (median =1) times per patient. The median number of plugs inserted for bronchial occlusion was 2 (range, 1–3), and the mean diameter of the plugs used was 5.5 mm, with a range of 3 to 10 mm. Based on the localization of the responsible bronchi, the plugs were placed in the right upper (n=7), right middle (n=5), right lower (n=3), left upper (n=7), and left lower lobe (n=1). All plugs were successfully inserted into the target bronchi (success rate: 100%), although 60.9% (14/23) of the target bronchi were located in the upper lobe. Only one patient experienced expectoration of the plugs and required a repeat insertion.

Following bronchial occlusion with the plugs, drainage tubes were successfully removed in 20 (87.0%) of the 23 patients. In our study, after using bronchial occlusion alone, 13 patients (56.5%) observed complete cessation of air leakage without the need for pleurodesis, while seven patients (30.4%) experienced a reduction in bubbles in the water-sealed chamber and required additional pleurodesis as a combined therapy to achieve complete resolution of pneumothorax. The mean duration of time over which the air leakage stopped was 5.9 days, including the immediate disappearance of air leakage after the insertion of the plugs in three cases.

The plugs were removed in nine out of the 23 patients who achieved complete resolution of air leakage; the median duration of placement was 63 days (range, 14–151 days). The other patients retained the plugs in their bronchi without any obvious discomfort over a 1-year period of follow-up. One patient experienced fever on day 3 following bronchial occlusion and was cured by antibiotic therapy without plug removal. Three patients experienced pneumothorax recurrence, and successfully managed air leakage through intercostal drainage. No severe treatment-related complications were observed during follow-up.

Discussion

Several occlusive devices can be used in the bronchoscopic treatment of PAL, including endobronchial valves (EBVs), Amplatz devices, and spigots (6,13–15). Both EBVs and the Amplatz device require special placement equipment and technical expertise. Furthermore, these two occlusive devices are expensive and not widely available in developing countries. The EWS is the most widely used endobronchial spigot and most often, yields successful outcomes when being applied for the bronchial occlusion in the treatment of PAL. However, the EWS spigot is not licensed in China. Therefore, we developed a silicone plug made from commercial chin implants that could also be replaced by other implants with the same quality of silicone. The biocompatibility and safety of this material have been verified previously by implant surgery over the long term. Our customized plugs have several key features that allow them to be placed successfully in the target bronchus as effective endobronchial occlusive devices. First, as the knot at the tip is tightly grasped with forceps, the spigot can be rotated in any direction without dropout during the placement procedure. Second, the plug can be easily removed as necessary by bronchoscopic grasping forceps with the knot created at the bottom of the plug. Third,

the plug can be trimmed to a conical shape of any size so that it can be inserted into any distal airways. In addition, the cost of each plug is approximately 10 U.S. dollars, thus representing a highly affordable treatment option.

It is a significant challenge to insert an EWS spigot into the target bronchus via a bronchoscope, especially into the apical segment bronchus, by holding the graspable end of the EWS spigot with forceps (the conventional technique). The procedure used to insert the plug should be convenient and simple without the need of special devices. The technique used to place the customized plug described herein is a simple method that allows the plug to be inserted into the target bronchi at any angle without the aid of special instruments.

Unlike the previous methods used to maneuver the ends of the plugs, our new placement technique is characterized by grasping the knot at the tip of the plug for its insertion. This is more effective in terms of manipulating the direction at the tip of the plug. Using grasping forceps to adjust the orientation, the plug can be inserted into any bronchi in only a short period of time. We found that grasping the knot was more reliable than previously described techniques; furthermore, none of the plugs were dropped during the placement procedure. For patients who were unable to tolerate oral insertion of the bronchoscope, we successfully completed the placement procedure of the plug via transnasal bronchoscopy (*Figure 3*). In addition, the forceps that we used to grasp the knot were able to pass through the working channel (2.0 mm in diameter) of a thin bronchoscope, thus allowing simple insertion into the target bronchus. We also found that grasping the knot at the tip of the plug was associated with a shorter learning curve and a lower failure rate with regards to plug placement when compared with grasping the end of the plug (unpublished data). Junior bronchoscopists would also be easily able to master this technique after only simple training.

Previous studies reported that air leakage was stopped or reduced in 50% and 29.2% of patients, respectively, when EWS spigots were applied for the management of PAL (7). The success rate for drainage tube removal was from 72.7% to 86%, respectively, when using EWS alone or combined with pleural adhesions (7–9). In our study, the proportion of patients achieving complete cessation or a reduction in air leakage was 56.5% and 30.4%, respectively. Overall, 87.0% of patients achieved complete resolution of PAL when customized plugs were combined with pleurodesis. The efficacy of the customized plugs used in our case series was like that described in previous reports.

The complications associated with bronchial occlusion when using the EWS spigot included dyspnea (3.4%), pneumonia (3.4%) and fever (1.7%) (15). In our series of patients who were fitted with customized plugs as occlusive devices, there was only one case of fever with a short duration; there were no severe complications. The plugs were made of silicone material acquired from a mandibular prosthesis; this material has been confirmed to be safe for patients as a permanent implant. In the present study, the silicone plugs were placed in the airways of 14 patients for more than 1 year. None of these patients experienced any significant discomfort. Generally, the plug as a foreign body, should be removed from the bronchi after the resolution of air leakage. However, a previous study reported one patient in which the EWS spigot was retained in the airway without significant complications for more than 3 years (9). Based on the excellent biocompatibility and tolerance of this silicone material, we consider that it is acceptable to place our plugs over a long period of time with careful follow-up.

There are several limitations in our study that need to be considered. First, this was a retrospective study with a limited number of participants in a single center, and all patients were male. Multicenter and prospective clinical trials involving a larger sample size are required. Second, we did not record the operation time used to insert each plug. In future research, it would be worth to record operation time during the bronchoscopic process. Third, the proportion of cases with BPF among the enrolled patients was low; different causes of air leaks may affect the outcomes of treatment.

Conclusions

In conclusion, our study demonstrates that bronchial occlusion with customized endobronchial plugs represents an effective and simple option for the management of PAL in patients who are not good candidates for surgery. In countries where EWS is not available, especially in developing countries, our new customized plug represents a cost-effective alternative.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the

STROBE reporting checklist. Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1053/rc>

Data Sharing Statement: Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1053/dss>

Peer Review File: Available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1053/prf>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <https://jtd.amegroups.com/article/view/10.21037/jtd-23-1053/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of the Second Affiliated Hospital of Fujian Medical University (FYFE2021-51) and individual consent for this retrospective analysis was waived.

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Cite this article as: Lin H, Wang Y, Lu D, Hong W, Wu W, Song D, Zhang H, Zeng Y. A novel method for the bronchial occlusion of prolonged air leakage using customized endobronchial plugs. *J Thorac Dis* 2023;15(12):6419-6426. doi: 10.21037/jtd-23-1053

Table S1 Details of bronchial occlusion of prolonged air leakage using customized endobronchial plugs

Patient number	Age (years)	Sex	Underlying disease of pulmonary	Days of chest drainage	Degree of collapsed lung	Target of bronchial occlusion	Number of bronchial occlusion procedures	Number of plugs	Diameter of the plugs (mm)	Air leaks after bronchial occlusion	Pleurodesis	Removal of the drainage tube	Days of air leak stopped	Recurrence
1	55	M	COPD, OPT	12	15%	RB4, 5	1	2	6, 6	Cessation	No	Success	5	No
2	49	M	COPD, pneumoconiosis	15	20%	LB7, 8, 9, 10	1	3	6, 7, 7	Cessation	No	Success	3	No
3	58	M	COPD, pneumoconiosis, OPT	67	20%	RB5	2	1	7	Cessation	No	Success	1	No
4	81	M	COPD	21	30%	RB1	1	1	4	Reduction	Yes	Success	4	No
5	62	M	COPD	38	50%	LB1+3	2	1	5	No change	No	Failure	–	–
6	67	M	COPD, OPT	25	30%	RB4	2	1	5	Reduction	Yes	Success	21	No
7	39	M	Pneumoconiosis	23	20%	RB5	1	1	6	Cessation	No	Success	5	Yes
8	58	M	COPD	133	30%	LB1+3, 4, 5	1	3	3, 3, 4	Cessation	No	Success	8	No
9	62	M	COPD	44	20%	RB2	1	1	4	Cessation	No	Success	0*	No
10	62	M	Pneumoconiosis	20	20%	RB4	1	1	7	Cessation	No	Success	2	Yes
11	74	M	COPD	52	50%	LB1+3, 2, 4	2	3	6, 7, 7	Cessation	No	Success	3	No
12	65	M	COPD	29	30%	RB6, 7, 8	3	3	7, 6, 7	Cessation	No	Success	0*	No
13	64	M	COPD	22	35%	LB1+3, 4, 5	3	3	4, 6, 6	Cessation	No	Success	10	No
14	79	M	COPD	40	30%	RB8, 9	1	1	10	No change	Yes	Failure	–	–
15	69	M	COPD	21	15%	RB1, 3	1	1	5	Reduction	Yes	Success	6	No
16	72	M	COPD	30	20%	LB1+3, 2, 4	3	3	5, 4, 6	Cessation	No	Success	0*	No
17	60	M	COPD	28	15%	RB1, 3	1	1	5	No change	No	Failure	–	–
18	64	M	COPD, pneumoconiosis	76	30%	RB6	1	1	6	Reduction	Yes	Success	12	No
19	69	M	COPD, bronchiectasis	58	15%	LB1+3, 2	1	3	5, 5, 6	Reduction	Yes	Success	14	No
20	66	M	COPD, OPT	22	85%	LB1+3, 2	1	2	5, 6	Reduction	Yes	Success	1	No
21	56	M	COPD, pneumoconiosis	24	10%	RB1, 2, 3	1	3	4, 5, 5	Cessation	No	Success	7	Yes
22	24	M	BO	22	10%	RB1, 2	2	2	5, 5	Cessation	No	Success	10	No
23	52	M	Pneumoconiosis	47	30%	RB1, 3	1	2	4, 6	Reduction	Yes	Success	6	No

*, air leak stopped immediately after bronchial occlusion. M, male; COPD, chronic obstructive pulmonary disease; OPT, old pulmonary tuberculosis; RB, right bronchus; LB, left bronchus; BO, bronchiolitis obliterans.