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Research Article

Clinical Observation of Modified Implantation of ASD Closure Device to Treat BPFs

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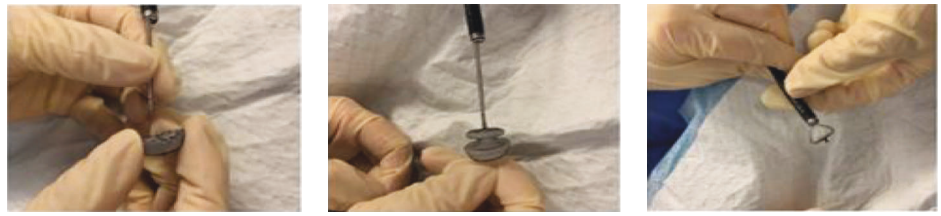
Objectives. The aim of the paper is to explore the clinical efficacy and prognosis of the modified implantation of atrial septal defect (ASD) closure device to treat bronchopleural fistulas (BPFs). *Methods*. This paper has reviewed the results of 13 BPF patients implanted with a modified ASD closure device in Shaw Hospital Affiliated with the Medical College of Zhejiang University from October 2018 to November 2021. Anesthesia was selected based on the patient's condition. Different sizes of ASD closures were selected based on the characteristics of fistulas. The modified implantation of the ASD closure device was applied to treat BPFs. The closure effects, closure time, and Borg score were observed at 4 weeks, 8 weeks, and 12 weeks after the surgery. *Results*. All 13 BPF patients were successfully implanted with the ASD closure device, and the immediate clinical remission rate was 100%. Follow-up at 4 weeks after the surgery showed that 2 cases were automatically discharged within a few days and 4 cases had closed fistula at 1 day after the surgery; follow-up at 8 weeks after the surgery showed that 1 case with fistula closure was observed at 55 days after the surgery; follow-up at 12 weeks after the surgery showed that 1 case with fistula closure was observed at 82 days after the surgery. T/*P* values ($T = 7.90, 5.99, 7.44$, $P < 0.05$) of paired *t*-tests before surgery and 4 weeks, 8 weeks, and 12 weeks after the surgery were rated by the Borg scale. The data were statistically different, and the clinical symptoms improved significantly. As of publication, the follow-up at 12 weeks after the surgery showed that the clinical remission rate was 9/11, namely, 81.8%, 3 of 11 cases had relieved clinical symptoms but still needed continuous drainage, and 2 cases had fistula closure. The median time of thoracic extubation was 63 (3,120) days. No patients died from surgical complications or BPF recurrence during the prognosis and the follow-up period. *Conclusions*. The modified implantation method has a high success rate and clinical remission rate, quick and early fistula closure, and simple and noninvasive operation, without the need for a dedicated delivery sheath and rigid endoscopy. Moreover, it has accurate positioning, reliable closure efficiency, and prognosis, and can be completed under local anesthesia. This reduces the operation time, difficulty, and risks of anesthesia.

1. Introduction

BPF is an abnormal sinus tract among the trunk, pulmonary lobe, or segmental bronchial tract and the pleural cavity. Although it is relatively rare, BPF has a life-threatening postoperative complication. Its postoperative morbidity after total pneumonectomy is 2~20%; postoperative morbidity after lobectomia pulmonalis is 0.5~3%, and its mortality is 16~71% [1]. BPF recurrence rate after surgical repair is as high as 23.6% [2]. In clinical work, we found that patients generally have contraindications. Interventional treatment such as a stent, plugging agent, or closure can effectively control BPF-related symptoms [3].

ASD closure was reported to treat BPFs in 2008 [4–6], which requires fluoroscopic positioning, rigid endoscopy, and intravenous general anesthesia. Fluorescein angiography can draw the outline of fistula anatomic structure, diameter, length, and deep structure, as well as the relative position of ASD closure to stump and fistula after operation [7]; rigid endoscopy provides a temporary channel for



(a) (b) (c)

Figure 1: Installation of ASD closure at the top of the bronchoscope.

bronchoscopy and dedicated delivery sheath to pass through rima glottidis simultaneously [8]; intravenous general anesthesia can provide better operation conditions and reduce surgical accidents caused by the patient's failure to cooperate. However, when recovering from intravenous general anesthesia, the patient may have temporary increases in BP and HR. Such side effects are generally controllable. But serious side effects may lead to terrible cardiovascular and cerebrovascular accidents, such as cerebral hemorrhage and myocardial ischemia [9]. The efficacy and prognosis of closure surgery are reliable, but the risk of rigid endoscopy and intravenous general anesthesia limits the feasibility of interventional treatment [5, 6]. To reduce the difficulty of closure surgery and anesthesia risks, improve the feasibility of the surgery, simplify cumbersome steps, and overcome the high requirements of rigid endoscopy in traditional closure surgery, our hospital modified the implantation of ASD closure by hiding the dedicated delivery sheath in the bronchoscope working channel in 2018. This method reduces the diameter of operating equipment passing through the rima glottidis and does not require rigid endoscopy, intravenous general anesthesia, or dedicated delivery sheath. Moreover, it uses bronchoscope direct vision instead of fluorescein angiography for fistula evaluation. To explore the application of this modified implantation, this paper analyzed the clinical data of 13 BPF patients treated with modified implantation of ASD closure from October 2018 to November 2021.

2. Data and Methods

2.1. General Data. 13 BPF patients treated with modified implantation of ASD closure from October 2018 to November 2021 were reviewed, including 12 males and 1 female aged 40–73 years old. They were all patients with a previous history of pulmonectomy and had signed informed consent prior to the surgery.

2.2. Clinical Instruments and Materials. BF-1T260 with an external diameter of 6.0 mm and a 2.8 mm working channel (OLYMPUS, Japan) was selected as the bronchoscope, and different types of ASD closures (Shandong Weixin Medical Device Co., Ltd.) were selected based on the characteristics of the fistulas. ASD closure is woven by a shape-memory alloy-nickel-titanium alloy wire. It has a double-disc structure (12–56 mm), which was connected through the waist (4–38 mm) with PE-coated film.

2.3. Preoperative Preparation. (1) Fasting for 8 hours before surgery; (2) preoperative tests are carried out before planned surgery, including routine blood tests, blood biochemistry, preoperative immunization, urine routine, ECG, cardiac ultrasound, and chest CT; (3) preoperative supportive treatment includes anti-infection, nutritional support, and closed thoracic drainage.

2.4. Anesthesia. Choose the following anesthesia method based on the patient's condition:

(1) Local anesthesia combined with compound sedation and analgesia: atomization inhalation of 2% lidocaine 10 ml (about 15 min), intravenous infusion of midazolam 2.5 mg, intravenous infusion of sufentanil 0.025 mg.

(2) Intravenous general anesthesia: venous channels were established and ECG, heart rate, blood pressure, SPO2, and ETCO2 were monitored. Patients intravenously received 0.02–0.04 mg/kg midazolam, 0.3–0.5 μg/kg sufentanil, 1.0–2.0 mg/kg propofol, and 0.12–0.15 mg/kg cis-atracurium in turn. The anesthesia machine was connected by a three-way tube. During surgery, propofol 4–6 mg/(kg·h) was infused continuously by a pump, with an intermittent intravenous injection to deliver anesthetic as needed. Spontaneous breathing was maintained after the recovery of muscle relaxation, and intermittent assisted respiration was maintained till the end of the surgery.

2.5. Operation Process. In the supine position, the patient was administered general anesthesia or local anesthesia. A tracheoscope was inserted to determine the location, diameter, and structure of BPFs. Different sizes of ASD closures were selected based on the characteristics of the fistulas. A guide wire passed through the working channel via the biopsy hole and connected with the ASD closure which has a special nut structure at the bottom of the inner disc. The ASD closure device was tested for release and folding. After the device is confirmed to meet the requirements, a bronchoscope with the ASD closure device at its top was inserted into the fistula. The guide wire was pushed to release the far-sided disk. After the bronchoscope and guide wire were kept relatively fixed, the far-sided disk was pushed and pulled to make it cling to the internal wall of the fistula

Table 1: General conditions of patients.

No.	Gender/ age	Pulmonary surgery site	Fistula location	Histopathology	Time of fistula occurrence (day)	Fistula diameter (mm)
1	F/73	Right lower lung	Right lower lung	Adenocarcinoma	240	10
2	M/64	Right lower lung	Right lower lung	Squamous cell carcinoma	20	8
3	M/66	Left lung	Left main lung	Squamous cell carcinoma	9	8
4	M/71	Left upper lung	Left upper lung	Non-small-cell carcinoma	40	8
5	M/70	Right lung	Right main lung	Non-small-cell carcinoma	60	10
6	M/56	Right middle bottom lung	Right middle lung	Squamous cell carcinoma	30	6
7	M/44	Left upper lung	Left upper lung	Granulomatous	50	5
8	M/40	Left upper lung	Left upper lung	Tuberculosis	60	5, 3, 2, 2
9	M/66	Right middle, upper lung posterior segment	Right middle lung	Adenocarcinoma	11	5
10	M/71	Left upper lung	Left upper lung	Adenocarcinoma	21	7
11	M/67	Right lower lung	Right lower lung	Squamous cell carcinoma	30	5, 5
12	M/73	Right middle bottom lung	Right middle lung	Squamous cell carcinoma	120	7
13	M/40	Right upper lung	Right upper rear lung	Tuberculosis	1	5, 3

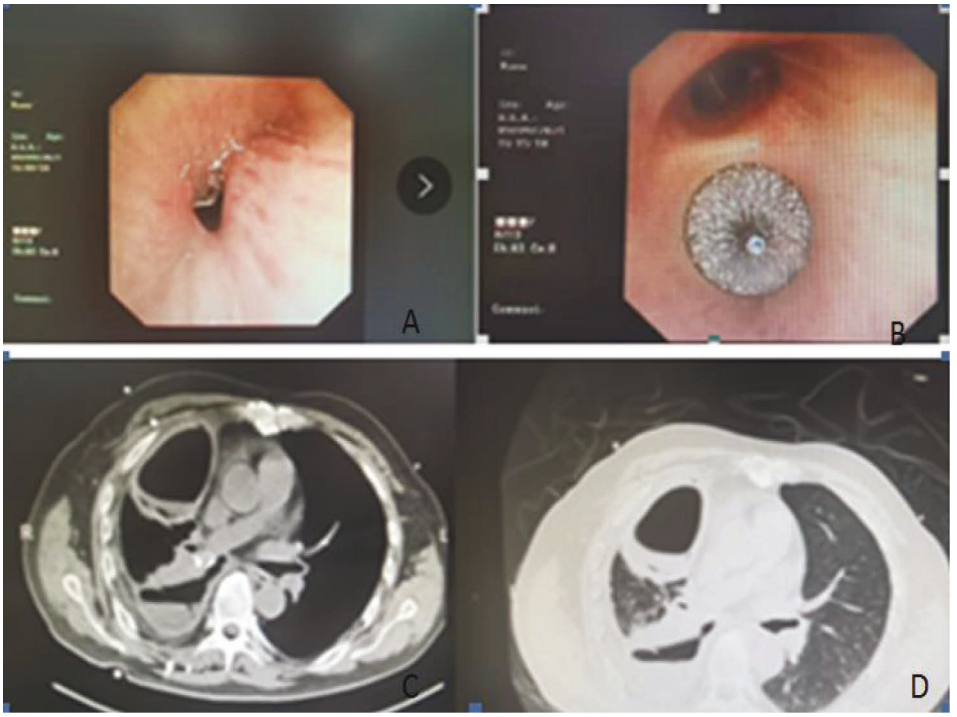
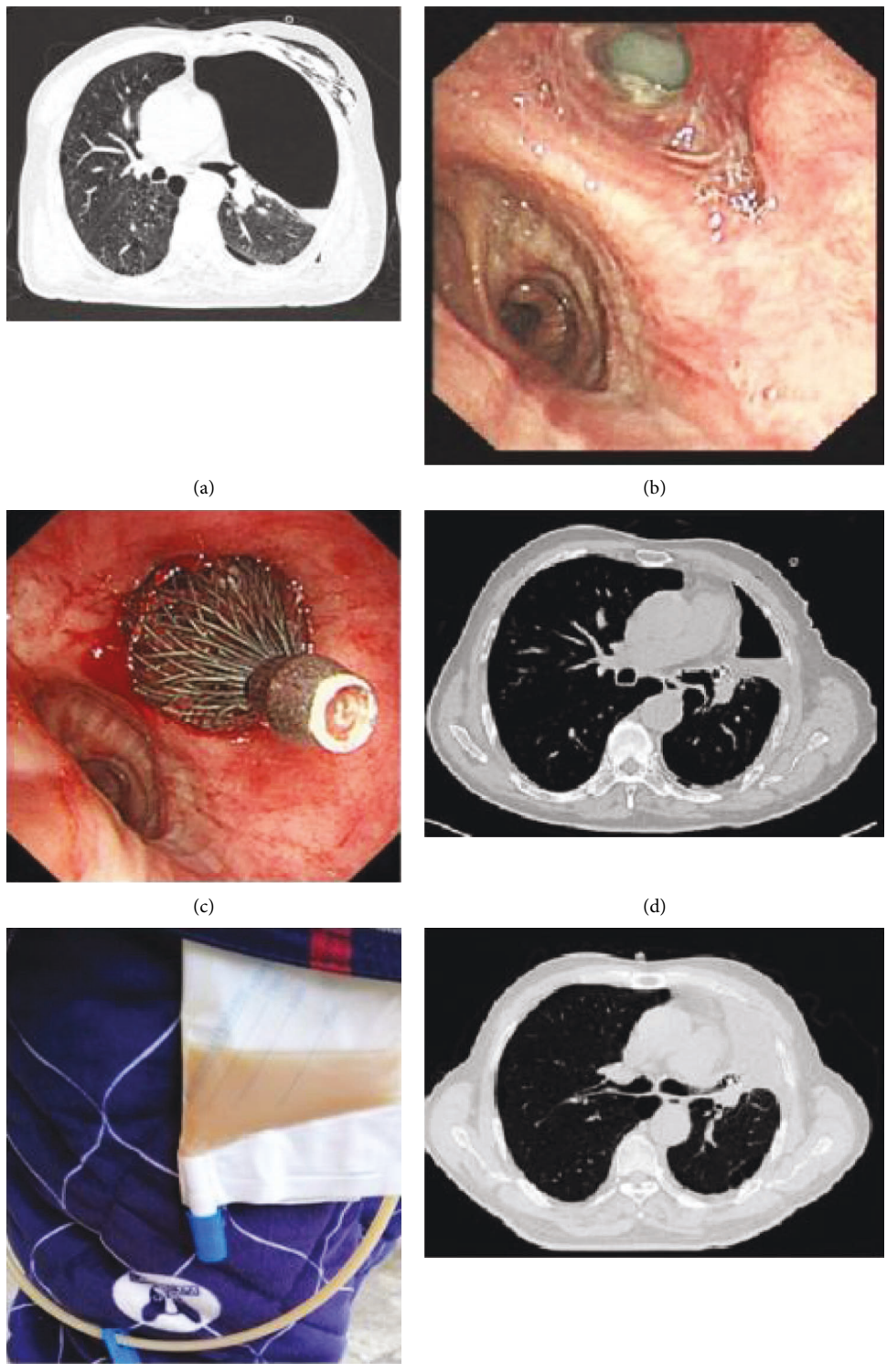


Figure 2: After implantation of the ASD closure device in the right middle lung lobe (Table 1 No.6).

after being fully unfolded. The near-sided disk was not released until the far-sided disk was confirmed to cling to the internal wall of the fistula. After the release, the guide wire was pulled to observe whether it was firm enough. Then, the guide wire was released by rotating the nut structure. And the patient was pushed to the postanesthesia care unit (PACU) after the surgery. Figure 1 shows the steps of installing the occluder and storing it at the head end of the working channel of the tracheoscope. Figure 1(a) shows the guide wire is extended and connected with the inner disc port of the occluder by a rotating nut structure. Figure 1(b) shows the successful connection between the guide wire and



(a) (b) (c) (d) (e) (f)

Figure 3: After implantation of the ASD closure device in the left upper lung lobe (Table 1 No.4).

Table 2: Efficacy of postoperative follow-up.

	4 weeks	8 weeks	12 weeks
CR	4	5	6
CCR	2	3	2
PR	4	2	1
NR	1	1	2
Number of cases	11*	11	11
Clinical remission rate**	90.9%	90.9%	81.8%

Note. * 2 cases were discharged a few days after the surgery; ** Clinical remission rate = (CR + CCR + PR)/number of cases.

the inner disc of the occluder. Figure 1(c) shows the occluder is stored at the head end of the working channel of the tracheoscope.

2.6. Indications and Contraindications

Indications: (1) fistula diameter >5 mm; (2) the anatomy of the fistula is similar to ASD [10];

Contraindications: (1) fistula periphery has or is near the large vessel [11]; (2) the fistula is located at the bronchus below the pulmonary segment; (3) incomplete lung fissure or cribriform fistulas (many small fistulas) appears in the lung section after pulmonary wedge resection.

2.7. Observation Indicators. The fistula closure, length of fistula closure, thoracic extubation time, and Borg score of the patient were observed at 4 weeks, 8 weeks, and 12 weeks after the surgery [12].

2.8. Criteria of Fistula Closure Efficacy. Based on experience, Professor Wang Hongwu and his team formulated a criterion for evaluating the efficacy of fistula closure [13]. Cure (CR) denotes that the fistula is healed and clinical symptoms are completely relieved for 1 month; clinical remission (CCR) indicates that the fistula is not healed, but completely occluded by the stent, and symptoms such as coughing while drinking liquids or fever are completely relieved for more than 1 month; partial relief (PR) means that fistula is not closed, but partially occluded by the stent, and clinical symptoms are partially relieved; invalid (NR) represents that fistula is neither closed nor occluded by the stent, and clinical symptoms are not relieved.

2.9. Statistical Methods. SPSS26 is used for statistical analysis of patients' general conditions, operation minutes, Borg scores, etc. Categorical data results are expressed as constitutive ratios and the measurement results are expressed as $x \pm s$. A paired t-test is conducted before and after the surgery and $P < 0.05$ is considered statistically significant.

3. Results

3.1. Clinical Data. Basic information through Table 1, we know that there were 13 patients with BPFs, including 12 males (92.3%) and 1 female (7.7%), aged 61.62 ± 12.43. Different pulmonary surgery sites occurred in 13 cases (including 2 cases of pneumonectomy and 11 cases of lobectomy or segmentectomy). In the 13 cases, fistulas were located at different parts of the lungs, including 1 at the left mainstem bronchus, 1 at the right mainstem bronchus, 4 at the left upper lung lobe, 1 at the right upper lung lobe, 3 at the right middle lobe, and 3 at the right lower lobe. Among 13 patients with BPFs, there were 5 squamous cell carcinoma, 3 adenocarcinomas, 2 non-small-cell carcinomas, 2 tuberculosis, and 1 granulomatous. The median time for patients to develop postoperative fistulas was 30 days (15.5, 60) days, the total number of fistulas was 18, and the diameter of the fistula was 5.57 ± 2.44 mm. Figure 2 treatment picture information comes from NO.6 patient in Table 1. The patient had right mesobronchial lung cancer, and the fistula appeared 30 days after the operation. The diameter of the fistula was 6 mm. Figure 2(a) shows the fistula after tracheoscopy, and Figure 2(b) shows the fistula after successful closure. Figures 2(c) and 2(d) are preoperative chest CT images. Figure 3 treatment data are from NO.4 patient in Table 1. This patient had left upper lung cancer, and the fistula appeared 40 days after the operation. The diameter of the fistula was 8 mm. Figure 3(a) is the preoperative chest CT of the patient, Figure 3(b) is the fistula under the intraoperative tracheoscope, Figure 3(c) is the fistula after the successful placement of the occluder, Figures 3(d) and 3(f) are the postoperative chest CT Reexamination results, and Figure 3(e) is the postoperative drainage bag drainage of the patient.

3.2. Postoperative Follow-Up Efficacy. According to the statistical data in Table 2, the follow-up after 4 weeks of the surgery showed that 2 patients died (nonsurgery caused) and 11 patients survived, including 4 CR, 2 CCR, 4 PR, and 1 NR, with the fistula closure rate of 36.4%, and the clinical remission rate of 90.9%. The follow-up after 8 weeks of the surgery showed that there were 5 CR, 3 CCR, 2 PR, and 1 NR, with a fistula closure rate of 45.5%, and a clinical remission rate of 90.9%. The follow-up after 12 weeks of the surgery showed that there were 6 CR, 2 CCR, 1 PR, and 2 NR, with a fistula closure rate of 54.5%, and a clinical remission rate of 81.8%, as well as 1 BPF recurrence.

According to relevant data in Table 3, we know that 12 received chest drains prior to the surgery and 13 received chest drains after the surgery. After the surgery, 8 patients stopped leaking air bubbles immediately (66.7%), and 4 patients leaked fewer bubbles than before (33.3%). 4 patients received thoracic extubation within 4 weeks, 5 of them within 8 weeks, and 6 patients were removed from the tube within 12 weeks. After 12 weeks, other 3 patients had the chest drain removed and 4 did not meet the criteria (Among the 4 patients, 2 had persistent fistulas and 2 were discharged a few days after the surgery). 8 cases had a closed fistula

Table 3: Surgery and follow-up.

No.	Preoperative thoracic drainage	Postoperative thoracic drainage	Bubbles stop overflowing after thoracic drainage	Length of fistula closure (day)	Thoracic extubation (day)	Extubation success	Follow-up period as of publication (month)	Survival	Anesthesia method	Operation time (min)	ASD closure waist diameter (mm)
1	Yes	Yes	Immediately	1	3	Yes	37.4	Yes	Local anesthesia	7	10
2	Yes	Yes	Immediately	1	82	Yes	35.1	Yes	Intravenous general anesthesia	23	8
3	Yes	Yes	Immediately	1	No extubation	No	0.1	No	Intravenous general anesthesia	25	12
4	Yes	Yes	Fewer	55	55	Yes	32.3	Yes	Intravenous general anesthesia	22	8
5	No	Yes	Free of bubbles	1	No extubation	No	16.8	Yes	Local anesthesia	20	10
6	Yes	Yes	Fewer	120	120	Yes	29.6	Yes	Intravenous general anesthesia	15	12
7	Yes	Yes	Fewer	195	195	Yes	21.8	Yes	Local anesthesia	17	8
8	Yes	Yes	Fewer	No closure	No extubation	No	12.8	Yes	Local anesthesia	14	8
9	Yes	Yes	Immediately	1	No extubation	No	0.2	No	Intravenous general anesthesia	16	6
10	Yes	Yes	Immediately *	No closure	540*	Yes	20.6	Yes	Intravenous general anesthesia	19	8
11	Yes	Yes	Immediately	1	1	Yes	28.4	Yes	Local anesthesia	10	8
12	Yes	Yes	Immediately	1	2	Yes	12.2	Yes	Local anesthesia	7	8
13	Yes	Yes	Immediately	1	14	Yes	15.8	Yes	Local anesthesia	23	6

Note. * Bubbles overflowed during thoracic drainage again 70 days after the surgery.

Table 4: Comparison of Borg scores before and after the surgery.

	Before surgery	4 weeks after the surgery	8 weeks after the surgery	12 weeks after the surgery
Borg score	5.15 + 2.23	0.73 + 0.90	0.82 + 1.78	0.3 + 0.48
Number of cases	13	11	11	11
t		7.9	5.99	7.44
P		<0.001	0.0001	<0.001

immediately after the surgical treatment. The longest time for the fistula to heal was 195 days. The success rate of extubation was 9/11, namely, 81.8%. The median time of extubation was 63 (3,120) days. As of publication, the follow-up period was 20.2 ± 12.2 months, with the longest of 37.4 months and the shortest of 0.1 months. During the follow-up period, 11 patients survived and 2 died of aggravated pulmonary abscess or empyema. As for anesthesia, 7 patients received local anesthesia and 6 had intravenous general anesthesia. The operation time was 16.8 ± 6.0 min, with the shortest of 7 min and the longest of 25 min. The waist diameter of the ASD closure device was 8.6 ± 1.9 mm, with the maximum and minimum diameters of 12 mm and 6 mm, respectively.

According to the treatment information in Table 4, there were statistically significant differences between the Borg scores 4, 8, and 12 weeks after the surgery and before surgery ($P < 0.05$), indicating clinically meaningful improvement in symptoms and quality of life.

3.3. Postoperative Complications. After the surgery, the patient's cough, purulent sputum, chest tightness, and shortness of breath were significantly reduced, and the Borg score became much lower. Three patients had mild pharyngalgia and globus sensation within 1 week after the ASD closure device was implanted. It may be related to bronchoscopy. Therefore, the patients were given budesonide suspension (2 mg/time, twice/d) for oral inhalation (Pmiklingshu 1 mg/2 ml, AstraZeneca Pharmaceutical Co., LTD.) and their symptoms were thus relieved. After the surgery, pulmonary abscesses were reported by four patients, two of whom were discharged a few days after the surgery and one had fistula closure after debridement. Another one had fistula closure but required continuous chest drain. This may be caused by lung abscess combined with pulmonary Aspergillus.

4. Discussion

ASD closure for the treatment of BPFs requires fluoroscopic positioning, rigid endoscopy, and intravenous general anesthesia. Fluorescein angiography can draw the outline of fistula anatomic structure, diameter, length, and deep structure, as well as the relative position of the ASD closure to stump and fistula after operation; rigid endoscopy provides a temporary channel to ensure that bronchoscopy and dedicated delivery sheath pass through rima glottidis simultaneously [8]; intravenous general anesthesia can provide better operation conditions, reduce surgical accidents caused by the patient's failure to cooperate. However, rigid endoscopy requires a high level of operation, and there is a risk of respiratory tract contusion; intravenous general anesthesia increases surgical compliance and reduces fear, and large doses of anesthetics will lead to respiratory depression, delayed recovery, or symptoms of hypoxemia; Fluorescein angiography increases radiation exposure to the body and harms health and safety [7]. The average diameter of the widest cauda commissure of adult rima glottidis is 8 mm, and the diameters of a dedicated delivery sheath (diameter 2 mm) and tracheoscope (outer diameter 5.0 mm) are too large to pass through an adult's rima glottides [14]. If the diameter of operating equipment can be reduced, then passing through the rima glottidis will become easier, without the need for rigid endoscopy or intravenous general anesthesia. This can simplify the operation and reduce the risk of anesthesia.

Our hospital modified the implantation of ASD closure by discarding the dedicated delivery sheath and replacing it with the bronchoscope working channel, which reduces the diameter of operating equipment that passes through the rima glottidis. This operation requires no rigid endoscopy, and it can be completed under local anesthesia. In this way, the anesthesia intensity and risks as well as the operation time and difficulty can both be reduced. 7 cases were successfully implanted with the ASD closure device under local anesthesia, with a reduced operation time (16.8 ± 6.0 min) of only 7 min (Table 2 No.1) at a minimum.

The modified implantation of ASD closure has its limitations. The top of the bronchoscopy working channel (inner diameter 2.8 mm) can release and fold ASD closure, but it is not applicable to ASD closure devices with a diameter of more than 2.8 mm after folding. In addition, different brands of ASD closure devices may have different sizes of discs after folding, the surgeons should mind this during operation.

Our modified implantation of ASD closure device has a high success rate and clinical remission rate, quick and early fistula closure, and simple and noninvasive operation, without the need for dedicated delivery sheath or rigid endoscopy. It has accurate positioning, reliable closure efficiency, and prognosis and can be carried out under local anesthesia. With shorter operation time and lower risks of anesthesia, it is worth promoting as a minimally invasive, efficient, and safe method.

Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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