

A non-surgical option in large bronchopleural fistulas: Bronchoscopic conical stent application

Büyük bronkoplevral fistüllerde cerrahi dışı bir seçenek: Bronkoskopik konik stent uygulaması

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ABSTRACT

Background: This study aims to compare the results of the open surgical approach versus endobronchial conical stent application in the treatment of extensive fistulas.

Methods: Between December 2004 and April 2016, a total of 36 patients (34 males, 2 females; mean age 59.6±8.1 years; range, 40 to 72 years) with a bronchopleural fistula of ≥8 mm in diameter and underwent either conventional open surgery with stump-supported intercostal muscle flap or endobronchial ultra-flex expandable stenting were retrospectively analyzed. The demographic and clinical characteristics of the patients, operative data including the length of hospital stay, thoracic drainage time, and early mortality, and survival data were recorded.

Results: The mean hospitalization time was 17.4±4.5 days for the bronchoscopic group and 22.5±6.7 days for the invasive surgery group (p=0.026). The median time to removal of thoracic drains was 15 (range, 10 to 30) days for the bronchoscopic group and 26 (range, 14 to 55) days for the surgical group (p=0.027). Early mortality rates of both approaches were in favor of the bronchoscopic approach ($\chi^2=7.058$; p=0.008). Two-year survival rate was 76.47% (n=13) in the bronchoscopic group and 70% (n=7) in the surgical group. There was no statistically significant difference in the survival rates between the two groups ($\chi^2=0.132$; p=0.716).

Conclusion: Our study results suggest that bronchoscopic approach can be the first choice in the treatment algorithm of fistulas with a diameter of ≥8 mm presenting with empyema in selected cases.

Keywords: Bronchopleural fistula, conic stent, pneumonectomy, rigid bronchoscopy.

ÖZ

Amaç: Bu çalışmada, büyük fistüllerin tedavisinde açık cerrahi yaklaşımı ve endobronşiyal konik stent uygulamasının sonuçları karşılaştırıldı.

Çalışma planı: Aralık 2004 - Nisan 2016 tarihleri arasında, ≥8 mm çapında bronkoplevral fistülü olan ve güdüğün interkostal kas flebi ile desteklendiği konvansiyonel açık cerrahi veya endobronşiyal ultra-fleks genişleyebilen stentleme yapılan toplam 36 hasta (34 erkek, 2 kadın; ort. yaş 59.6±8.1 yıl; dağılım, 40-72 yıl) retrospektif olarak değerlendirildi. Hastaların demografik ve klinik özellikleri, hastanede yatış süresi, toraks dren süresi ve erken mortalite dahil üzere ameliyat verileri ve sağkalım verileri kaydedildi.

Bulgular: Ortalama hastanede yatış süresi, bronkoskopi grubu için 17.4±4.5 gün ve invaziv cerrahi grubu için 22.5±6.7 gün idi (p=0.026). Toraks drenlerinin çıkarılmasına kadar geçen medyan süre bronkoskopi grubu için 15 (dağılım, 10-30) gün ve invaziv cerrahi grubu için 26 (dağılım, 14-55) gün idi (p=0.027). İki yaklaşımın erken mortalite oranı, bronkoskopik yaklaşım lehine idi ($\chi^2=7.058$; p=0.008). İki yıllık sağkalım oranı, bronkoskopi grubunda %76.47 (n=13) ve cerrahi grubunda %70 (n=7) idi. İki grup arasında sağkalım oranları açısından istatistiksel olarak anlamlı bir fark yoktu ($\chi^2=0.132$; p=0.716).

Sonuç: Çalışma sonuçlarımız, bronkoskopik yaklaşımın, belirli hastalarda ampiyemin eşlik ettiği ≥8 mm çapındaki fistüllerin tedavii algoritmasında ilk seçenek olabileceğini göstermektedir.

Anahtar sözcükler: Bronkoplevral fistül, konik stent, pnömonektomi, rijit bronkoskopi.

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Bronchopleural fistula (BPF) is one of the most complicated clinical situations in the field of thoracic surgery. It accounts for 20% of all empyema cases and occurs when the tracheobronchial structure binds to the pleural space with the fistula tract.^[1] It is most frequently seen after major pulmonary resections, particularly after pneumonectomy.^[2] Bronchopleural fistula can occur in the early (≤ 7 days) and late (>30 days) postoperative period.^[3] Early cases are usually due to inadequacy in the surgical technique or risks such as having a pulmonary infection, immunosuppression, smoking, chemotherapy, and radiotherapy before the operation.^[4] Rethoracotomy and primary repair and support of the bronchial stump with the tissues such as omentum and intercostal muscle are considered the standard approach in the early period cases.^[5] In these cases, empyema is often unexpected.

The late BPF seen after 30 days is often more complicated and usually accompanied by empyema. There is no established treatment algorithm for these cases. For BPF and associated empyema, the treatment depends on the general condition of the case, timing, and the size of the fistula. Drainage and antibiotics for empyema are the sine qua non for successful results, but need to be accompanied fistula closure techniques. Surgical options are based on primary repair or the support of the stump with aforementioned tissues via thoracotomy, trans-sternal, or trans-pericardial approaches. Bronchoscopic procedures are less invasive alternatives.^[6-8]

The diameter of the fistula is critical for determining the proper bronchoscopic application. Methyl-2-cyanoacrylate type-fibrin glue applications are successful in BPFs of 3 to 5 mm in diameter; however, they fail for BPFs of ≥ 8 mm.^[9] Bronchoscopic closure by an Amplatzer™ (St. Jude Medical, MN, USA) vascular plug for fistulas with a diameter of ≥ 8 mm was previously suggested;^[10] however, the failure of this method was reported in the literature.

It is evident that thoracic surgeons need new bronchoscopic treatment options for wider BPFs. In the present study, we aimed to compare the results of the open surgical approach versus endobronchial conical stent application in the treatment of extensive fistulas in patients with a BPF of ≥ 8 mm and associated empyema.

PATIENTS AND METHODS

This retrospective study included medical data of a total of 36 patients (34 males, 2 females; mean

age 59.6 ± 8.1 years; range, 40 to 72 years) with late BPFs who underwent either bronchoscopic approach or invasive surgical approach from three Thoracic Surgery clinic between December 2004 and April 2016. Due to the limited number of BPFs after surgery, we created an invasive surgery group which consisted of patients who fulfilled the inclusion criteria of the study as the control group. The primary repair of the stump with posterolateral thoracotomy and the support of the stump with the intercostal muscle flap were used in all patients in the invasive surgery group. Patients with a fistula diameter of less than 8 mm were excluded from the study. In addition, patients with poor general status and/or requiring mechanical ventilation were excluded. Those who underwent different bronchoscopic methods and whose empyema could not be drained by tube thoracostomy were also excluded. Other exclusion criteria were as follows: diabetes mellitus, rheumatic diseases, and chronic lung diseases such as tuberculosis and interstitial lung disease. The study flow chart is shown in Figure 1. A written informed consent was obtained from each patient. The study protocol was approved by the Ethics Committee of Yıldırım Beyazıt University, Faculty of Medicine (25.12.2018-2018/72). The study was conducted in accordance with the principles of the Declaration of Helsinki.

We analyzed pathological and surgical data. The invasive surgery group and the bronchoscopic group were compared in terms of drainage termination, length of hospitalization, early mortality, and two-year survival. Cancer-related death-censored survival was also evaluated. Fistula diameters were measured on computed tomography. For each patient, tube thoracostomy provided pleural drainage. Evaluation of the records and the entry of data was performed by an independent surgeon to avoid bias.

Bronchoscopic technique

Empyema was confirmed by thoracentesis and the samples were sent to culture analysis. Concomitantly, empirical antibiotic treatment was started (intravenous [IV] piperacillin/tazobactam 4.5 g [totaling 18 g: 16 g piperacillin/2 g tazobactam] q6h + IV meropenem 1 g q8h).^[11] Antibiotic therapy was, then, tailored according to the culture results. We employed two tube thoracotomies, one from the midclavicular second intercostal space and one from the anterior axillary line of the fifth intercostal space to drain empyema (Figure 2). Continuous pleural lavage and normal saline were administered from the first and removed from the latter. The diagnosis of BPF was made based on chest X-ray and computed tomography

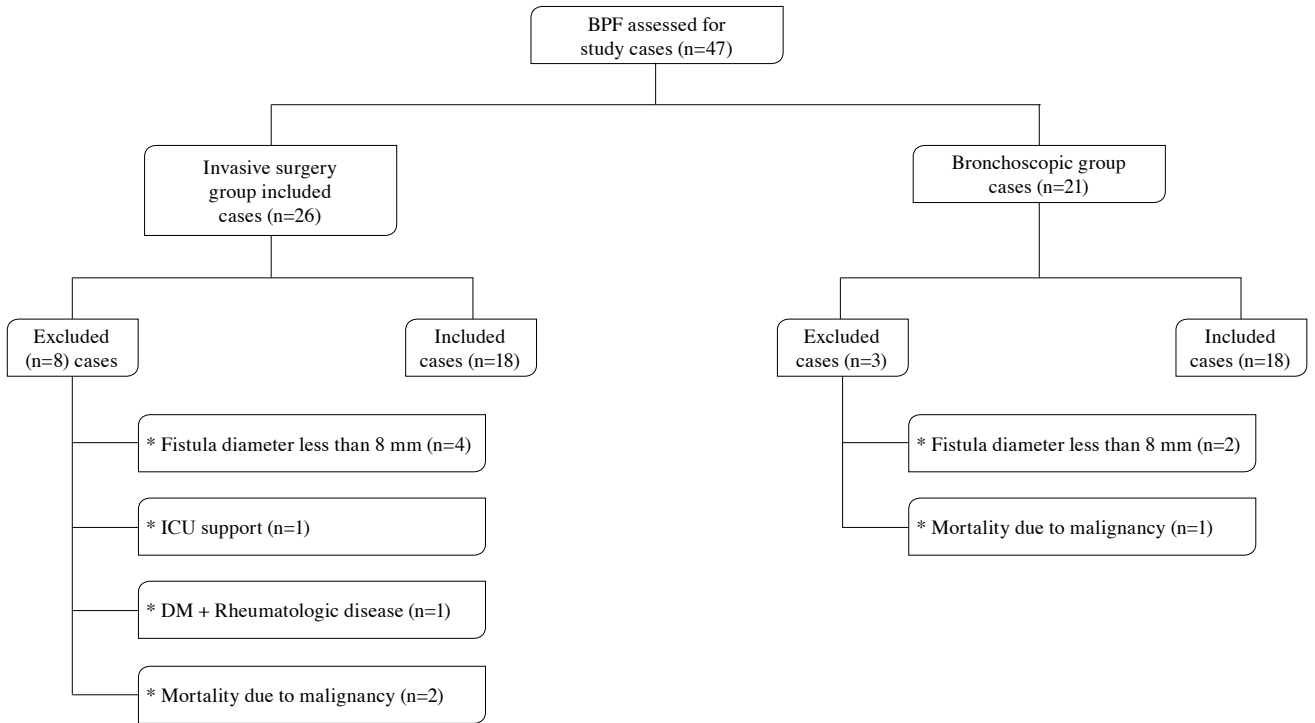


Figure 1. Study flowchart.

BPF: Bronchopleural fistula; ICU: Intensive care unit; DM: Diabetes mellitus.

and confirmed through fiberoptic bronchoscopy. We chose the appropriate stent after measuring fistula, trachea, and main bronchial diameter via three-dimensional virtual bronchoscopy. Next, a rigid bronchoscopy in the supine position under general anesthesia was performed in the operating room. A conical stent was applied to endobronchial space proximal to the fistula tract. The main goal of this approach was to cover the area starting from 2 cm above the carina to 1 cm distal of the main bronchus. We applied an endobronchial ultra-flexible, self-expandable custom-made, nitinol stent (Aerstent® Trachea Bronchus Nitinol Stent; Leufen Medical GmbH, Berlin, Germany) (Figure 3). The place of the stent was confirmed by scope. Airflow was directed to the intact lung, after the tracheal side of the BPF was closed with the stent. Particular care was taken to prevent the air leak, contamination by bronchial secretions, or empyema content. All patients were monitored for two hours during recovery. Daily postoperative chest X-ray, complete blood count, and C-reactive protein results were obtained. All patients in the bronchoscopic group were treated with an antitussive medication for seven days (Oxolamine phosphate 150 mg t.i.d.) to prevent the displacement of the stent. Three criteria were used to terminate

thoracotomies and discontinue antibiotics including clinical recovery, resolving of empyema, and three negative pleural cultures.



Figure 2. An endobronchial ultra-flex expandable custom-made stent.

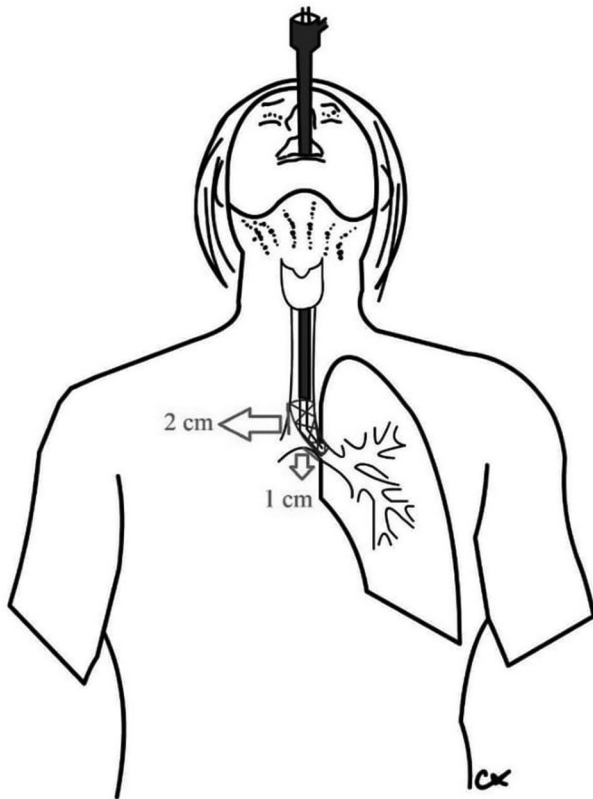


Figure 3. Localization of bronchoscopic stent application.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 21.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were presented in mean \pm standard deviation (SD), median (min-max) or number and frequency, where applicable for normally or non-normal distributed data. The Student t-test and chi-square test (Fisher's exact test) were used, when appropriate. The propensity score matching procedure was applied to test the effects of the probable confounders in respect of baseline characteristics (i.e., age, sex, perioperative treatment variables, BPF development time, fistula diameters, and right pneumonectomy ratio). The chi-square test was used for survival analysis. A *p* value of <0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference in the baseline demographic and clinical characteristics between the groups (Table 1). All patients included in the study had pneumonectomy. Right pneumonectomy was performed in five of the patients in the invasive surgery group and six of the patients in the bronchoscopic group ($p=0.716$).

The median fistula diameter of the patients treated with the bronchoscopic approach was

Table 1. Preoperative data

	Bronchoscopic approach group		Invasive surgery group		χ^2	<i>p</i>
	n	%	n	%		
Preoperative chemotherapy						
-	14	77.78	13	72.22	0.148	0.700
+	4	22.22	5	27.78		
Total	18	100.00	18	100.00		
Preoperative radiotherapy						
-	11	61.11	13	72.22	0.125	0.724
+	7	38.89	5	27.78		
Total	18	100.00	18	100.00		
Postoperative chemotherapy						
-	18	100.00	18	100.00		
+	0	0.00	0	0.00		
Total	18	100.00	18	100.00		
Postoperative radiotherapy						
-	1	5.56	14	77.78	16.457	<0.001
+	17	94.44	4	22.22		
Total	18	100.00	18	100.00		

11 (range, 8 to 26) mm. For the patients treated with the surgical approach, the median fistula diameter was 12.6 (range, 8 to 28) mm ($p=0.654$). The propensity score matching procedure revealed similar results between the surgically and bronchoscopically treated groups.

The pleural fluid culture results of the patients receiving empiric antibiotics showed no growth in six patients, while there was *Staphylococcus aureus* (*S. aureus*) growth in five of 12 patients, *Pseudomonas aeruginosa* (*P. aeruginosa*) growth in four patients, and *Streptococcus pneumoniae* (*S. pneumoniae*) in three patients in the bronchoscopic group. Twelve patients were manually closed with the bronchial stapler and six patients with prolene suture as in the previous surgical procedure. In the invasive surgery group, 10 of 18 patients had positive pleural fluid cultures, namely *S. pneumoniae* in four, *P. aeruginosa* in two, and *S. aureus* in two patients. Two patients had a mixed flora. In the surgical treatment group, the bronchial stump was closed with the stapler in 18 patients. However, the suture closure technique “continuous or not” was unable to be retrieved from the medical records.

The mean length of hospitalization was 17.4 ± 4.5 days in the bronchoscopic group and 22.5 ± 6.7 days in the invasive surgical group, indicating

a statistically significant difference ($p=0.026$). In the bronchoscopic group, three patients were discharged with the Heimlich valve, and their thoracic drains were removed on Day 7 after discharge (i.e., in the first outpatient control). In the invasive surgical group, six patients were discharged with the Heimlich valve. The median time to the removal of drains was 15 (range, 10 to 30) days in the bronchoscopic group and 26 (range, 14 to 55) days in the invasive surgery group, indicating statistically significantly shorter time in the bronchoscopic group ($p=0.026$) (Table 2).

No patient experienced problems related to stent displacement during hospitalization. However, a repeated procedure to correct stent malposition was required in four patients during follow-up. No stent-related complications or septic complications were observed. In the bronchoscopy group, one patient died in the early postoperative period. In this patient, rigid bronchoscopy-related tracheobronchial injury resulted in fatal bilateral pneumothorax. In the invasive surgery group, eight patients died in the early postoperative period. Two of the patients died from progression of pneumonia and sepsis. Four patients died due to surgical complications, and two from cardiac pathologies (atrial fibrillation and myocardial infarction in each).

Four of 18 patients in the bronchoscopy group and three of 10 patients in the invasive surgery group

Table 2. Baseline and postoperative data

Parameters	Mean±SD	Median	Min-Max	t	p
Age (year)					
Control invasive surgery group	57.7±8.8			1.372	0.175
Study bronchoscopic approach group	61.4±7.2				
Overall	59.6±8.1				
BPF development time (months)					
Control invasive surgery group		9.00	2-49		
Study bronchoscopic approach group		11.50	3-144		
Overall		10	2-144		
Hospitalization time (days)					
Control invasive surgery group	22.5±6.7			2.365	0.026
Study bronchoscopic approach group	17.4±4.5				
Overall	19.3±5.9				
Termination of thorax drainage (days)					
Control invasive surgery group		26.00*	14 -55*	2.230	0.027
Study bronchoscopic approach group		15.00*	10-30*		
Overall		19*	10-55*		

SD: Standard deviation; Min: Minimum; Max: Maximum.

Table 3. Mortality and survival rates

Parameters	Positive		Negative		χ^2	p
	n	%	n	%		
Mortality						
Control invasive surgery group	8	44.44	10	55.56	7.058	0.008
Study bronchoscopic approach group	1	5.56	17	94.44		
Two-years survival						
Control invasive surgery group	7	70.00	3	30.00	0.132	0.716
Study	13	76.47	4	23.53		

were lost to follow-up. The two-year survival rate was 76.47% (n=13) in the bronchoscopic group and 70.00% (n=7) in the invasive surgery group. Eventually, the bronchoscopic group had a postoperative early mortality rate of 5.56% (n=1), while this rate was 44.44% (n=8) in the invasive surgery group (Table 3). There was no statistically significant difference in the two-year survival rates between the groups, although the early postoperative mortality rates were in favor of the bronchoscopic group ($\chi^2=0.132$; p=0.716 and $\chi^2=7.058$; p=0.008, respectively).

DISCUSSION

Empyema due to BPF formation cause mortality (up to 50%) and morbidity after pneumonectomy.^[12] There is still no established treatment algorithm for late-stage BPFs. Invasive surgical approaches are more frequently performed with reported poor outcomes. The most common methods are re-amputation and suturation or resection of the bronchial stump with via rethoracotomy, trans-sternal, or trans-pericardial approaches.^[13,14] Bronchial stump with the impaired feeding due to empyema can be supported by vascular tissue grafts such as intercostal muscle, omentum, latissimus dorsi, or serratus anterior. Given the history of pneumonectomy, the existence of empyema, and poor general condition, such an invasive approach is bound to cause additional complications. Therefore, we propose bronchoscopic stenting to cover the fistula tract in this patient population.

In the current study, the two-year survival rate after treatment with the bronchoscopic approach was similar to the surgical procedure. Of 18 patients treated with bronchoscopy, only one had non-tumor related mortality. All other deaths were attributable to primary malignancy. In the invasive surgery group, mortality was observed in three of 10 patients, and all were related to local recurrence. Altogether, there was no statistically significant difference between the

two approaches in terms of two-year survival, and this finding suggests that a less invasive approach is feasible.

Early mortality was observed in only one patient in the bronchoscopic group, and this complication was not a septic complication due to the fistula. The patient had a right pneumonectomy 12 years ago, when he was 50 years old. Desaturation occurred on the first postoperative day after the stent application, and subcutaneous emphysema and pneumothorax developed in both lungs, and eventually the patient died. Tracheobronchial injury is a rare, but expected complication of rigid bronchoscopy. Caputi *et al.*,^[15] in a series of 11,000 cases, reported the mortality rate associated with rigid bronchoscopy as 0.019%. However, due to a low number of patients and only one related death, it is not possible to make an accurate statistical evaluation in our study. Nonetheless, it should be kept in mind that post-pneumonectomy bronchoscopy is more risky than a standard procedure.^[12,15,16]

In our study, the early mortality rate in the invasive surgery group was 16-times higher than in the bronchoscopic group (p=0.008). The significant difference in the early mortality rates between the two groups is consistent with the literature.^[17] Besides, we found that the bronchoscopic approach was superior in terms of length of hospitalization (p=0.026). The shorter hospital stay can be expected due to the less invasive bronchoscopic procedure than open repair. Gharagozloo *et al.*^[18] also reported a mean length of hospitalization of 12.9 days with open repair of BPFs and pleural irrigation treatment in post-pneumonic empyema, consistent with our findings. Still, unfortunately, the actual determinant of the length of hospitalization is the clearance of the infection.

In the literature, various bronchoscopic approaches have been described so far. These include fibrin glue,

cyano-acrylate, decalcified bone tissues, hour-glass shaped stent, and Amplatzer™ vascular plug to the fistula.^[7,19-22] Success with tissue glues or other closing materials can be achieved for BPFs with a diameter of 3 to 5 mm.^[5,23,24] However, the number of patients in these reports is relatively low, and none of them have empyema. The success rate of tissue glue-based approaches decreases toward 8 mm, and they are not considered a viable choice for broader BPFs.^[9,10]

The BPF diameter can theoretically reach 30 mm, nearly the size of the main bronchus.^[25] Fistulas over 8 mm in diameter create a cut-off value for the fistula size, due to the increasing failure rates reported in the literature. In general, BPFs with a diameter over 8 mm are complicated with empyema. That is why we believe bronchoscopic stenting would be of value, by preventing contamination by the empyema content. In an extensive series of 35 patients, Varoli et al.^[5] reported that the bronchoscopic approach, using polidocanol - hydroxy polyethoxy dodecane was successful in 23 patients. In another study, the same group also claimed that an Amplatzer™ plug could be used for BPFs up to 12 mm.^[21] However, another

study showed contradictory results.^[10] In our cohort, the largest fistula diameter was 26 mm. Yet, we had favorable outcomes without serious complications. Based on these findings, we believe that our technique can be employed even in larger BPFs. From our point of view, this technique can overcome the limitations of bronchoscopic approaches in BPFs with larger diameters (Figure 4).

The main limitation of our study is its relatively small sample size with a retrospective design. In addition, the surgery group was later formed. In our study, the patients of invasive surgery group were followed postoperatively in the intensive care unit. However, admission to the intensive care unit and requirement of mechanical ventilation may cause additional problems. The patients were followed without any mechanical ventilator support in the bronchoscopic group postoperatively. Therefore, an ideal comparison is not possible. In an attempt to strengthen the statistical analysis, we used propensity score matching. Overall, our results are compatible with the literature regarding BPFs. The main strength of this study is its originality. In the present study,

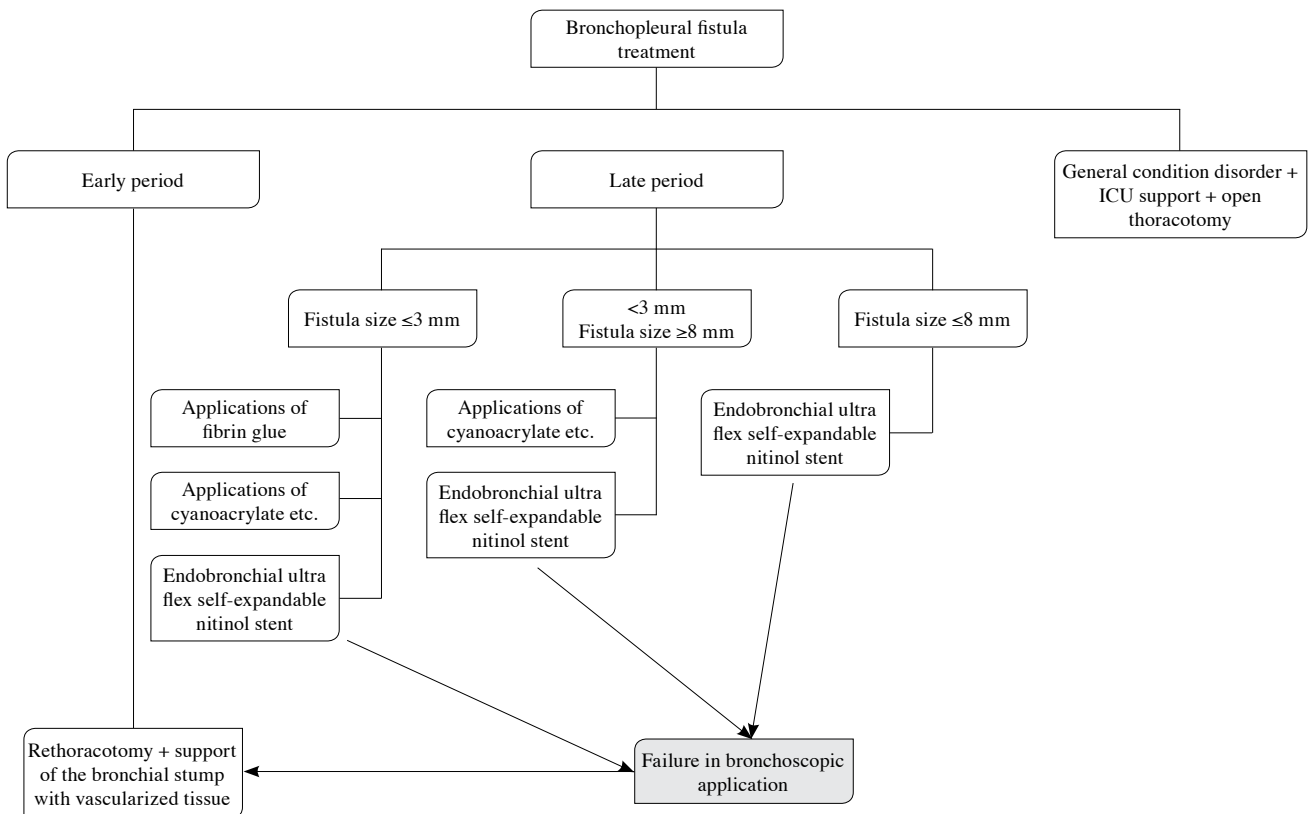


Figure 4. Treatment algorithm for bronchopleural fistulas.

ICU: Intensive care unit;

we propose a new treatment approach in late BPFs larger than 8 mm. Our non-invasive method can be easily applied by every clinician experienced in rigid bronchoscopy. Nonetheless, further large-scale, prospective, randomized-controlled studies are needed to confirm these findings and to re-appreciate the power of our technique.

In conclusion, bronchoscopic approach can be the first choice in the treatment algorithm of BPFs with a diameter of ≥ 8 mm presenting with empyema in selected cases. We believe that it may be widely adopted by the clinicians in the near future as the first-line treatment.

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