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Endoscopic treatment of nonmalignant tracheoesophageal and bronchoesophageal fistula: results and prognostic factors for its success

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Abstract

Background Nonmalignant esophago-respiratory fistulas (ERF) are frightening clinical situations, involving surgery with high morbi-mortality rate. We described the endoscopic management of benign ERF. The aim of the study was to describe outcomes of endoscopic treatment of nonmalignant ERF and to analyze factors associated with its success.

Methods This is a retrospective study involving patients managed for benign ERF in our center between 2012 and 2016. The ERFs were classified into three groups of sizes: (I) punctiform, (II) medium, and (III) large. The primary aim was to document the endoscopic success (= fistula's healing after 6 months). The secondary objectives were characteristics of endoscopic treatment, the functional success and death, and identifying factors associated with success and death.

Results 22 patients were included. The etiologies of ERF were surgery in 12 patients, esophageal dilatation in 3, invasive ventilation in 3, radiation therapy in 2, and tracheostomy in 2. Ninety-three procedures were performed (mean of number: 4.2 ± 4.5/patient). Twenty-one patients had stent placement, eight over-the-scope clips (OTSC), and seven a combined therapy. The endoscopic success rate was 45.5% ($n = 10$; 67% in punctiform, 50% in medium, and 14% in large ERF), and the functional success was 55% ($n = 12$). Serious adverse events occurred in 9 patients (40.9%). Six patients died (27%). The persistence of the orifice after 6 months of endoscopic treatment was associated with failure (OR 44; IC95: 3.38–573.4; $p = 0.004$ multivariate analysis). The orifice's size was associated with mortality [71% of death if large fistulas ($p = 0.001$) univariate analysis].

Conclusion Endoscopic treatment of ERF leads to 45.5% of successful endoscopic closure and 55.5% of functional success, depending on fistula's orifice size. After 6 months without healing, the chances for success dramatically decrease.

Keywords Tracheoesophageal fistula · SEMS · Esophageal stenting · Endotherapy · Post-surgical complications · Radiation therapy · Esophagectomy

Acquired esophago-respiratory fistulas (ERF) are rare but frightening clinical situations, most of them resulting from locally advanced malignancy. In such cases, the treatment is palliative, mostly applying partially covered metallic stent [1, 2], but the prognosis remains very poor mainly related to tumor progression.

ERF occurring in a benign setting is a challenging clinical issue that affects the patients' quality of life and leads to significant pulmonary morbidity and mortality. The etiologies of ERF include complications of invasive ventilation [3, 4], anastomotic complications after esophageal surgery [5, 6], trauma such as foreign bodies [4], or caustic ingestion [7].

The most commonly performed surgical treatment in nonmalignant ERF consists of soft tissue interposition flaps or 2-layer technique for esophagus closure and concomitant resection and reconstruction of the trachea, with more than 90% of efficacy [4]. However, surgery may be

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impossible or not suitable in a few patients because of their poor general condition or previous thoracic surgery. Moreover, despite these good outcomes, surgery is associated with a significant morbidity, greater than 50% [4]. In the literature, the modalities of surgical treatment are more precisely described than endoscopic treatment [4, 8]. Indeed, only few endoscopic studies are available and limited to case reports and small series mixing malignant and benign etiologies [9]. Consequently, the outcomes and the therapeutic modalities are still unclear in ERF that underwent an endoscopic management.

Thus, we conducted this study to expose our experience in managing ERF in our tertiary center, trying to propose a therapeutic strategy.

Patients and methods

Study design

This was a retrospective analysis of consecutive patients referred for benign esophago-respiratory fistulas (ERF) and managed endoscopically in a tertiary-care referral academic center (Hospital North, Marseille, France). A retrospective review of our database was carried out from July 2012 to December 2016 to identify patients with ERF treated endoscopically.

The inclusion criteria were as follows: (i) ERF treated by endoscopy, (ii) fluoroscopic confirmation of the fistula during the endoscopy, (iii) benign etiology of the fistula, and (iv) age over 18 years old. Exclusion criteria were (i) age < 18 years old, (ii) patient referred to our unit before July 2012, (iii) malignant ERF, (iv) esophago-pleural fistula, and (v) incomplete data in medical file. The diagnosis of ERF was based on the presence of bronchography at esophageal contrast injection under X-rays, during the upper GI endoscopy.

The data collected were (i) patient demographics including sex, age at diagnosis, body mass index, albumin at diagnosis, history of previous radiation therapy, and clinical presentation; (ii) ERF characterization: etiology, ERF location, and orifice size, and type and number of treatments applied. The size of the fistula's orifice in GI endoscopy was divided in three comprehensive groups: I—"punctiform" if the diameter was less than the diameter of a closed biopsy forceps, II—"medium" if the size was larger but without visibility of tracheo-bronchial tree, and III—"large" if bronchial tree was seen throughout the fistula's orifice with the endoscope (Fig. 1). The baseline date for analysis was defined as the date of the first fluoroscopic ERF diagnosis during endoscopy.

IRB approval

According to the French law, it was not necessary or possible to obtain approval from an ethics committee (Comité de protection des personnes CCP) for this type of retrospective and noninterventional study before January 2017.

Global endoscopic management strategy

The strategy of management was decided depending on the characteristics of the fistulas and anatomical findings. Thus, in situation of recent fistula and small orifice with smooth and nonfibrotic edges, Over-the-scope clip (OTSc, Overco, Tubingen, Germany) placement was attempted. If OTSc placement was unsatisfying or technically not feasible, because of a large orifice (> 10–15 mm) or fibrotic edges, an esophageal fully covered self-expandable metallic stent (FC-SEMS) was inserted. Different types of FC-SEMS were used, depending on operator's experience and on the new devices available over the period of inclusion. In case of stricture associated to the fistula, the FC-SEMS was used to treat both the leakage and the stricture. Monopolar coagulation of the orifice's edges or endoclip placement for closure could also be applied. Several modalities of treatment could be associated in a combined approach. At the end of the procedure, a contrast injection under fluoroscopic control was always performed, to check for the absence of persisting leakage.

The esophageal stent was removed after 6 weeks to avoid ingrowth, to re-evaluate the fistula, and eventually to perform an additional treatment in case of persistence of leakage.

Study objectives

The aim of this study was to retrospectively report and analyze the cases of benign acquired ERF managed in our tertiary center and to analyze the factors associated with its success.

The primary endpoint was to document the efficacy of the endoscopic treatment for healing ERF (considered as successful endoscopic closure). This successful endoscopic closure was defined as the closure of the fistula confirmed by the contrast injection under X-ray during endoscopy after stent removal as well as the absence of recurrence after 6 months of follow-up with the patients eating orally.

The secondary endpoints were to document the overall mortality rate and the functional success, which was defined by the ability to recover normal oral intake without any ERF symptom (pneumonia or post eating cough) with or without the persistence of an orifice. We also intended to identify

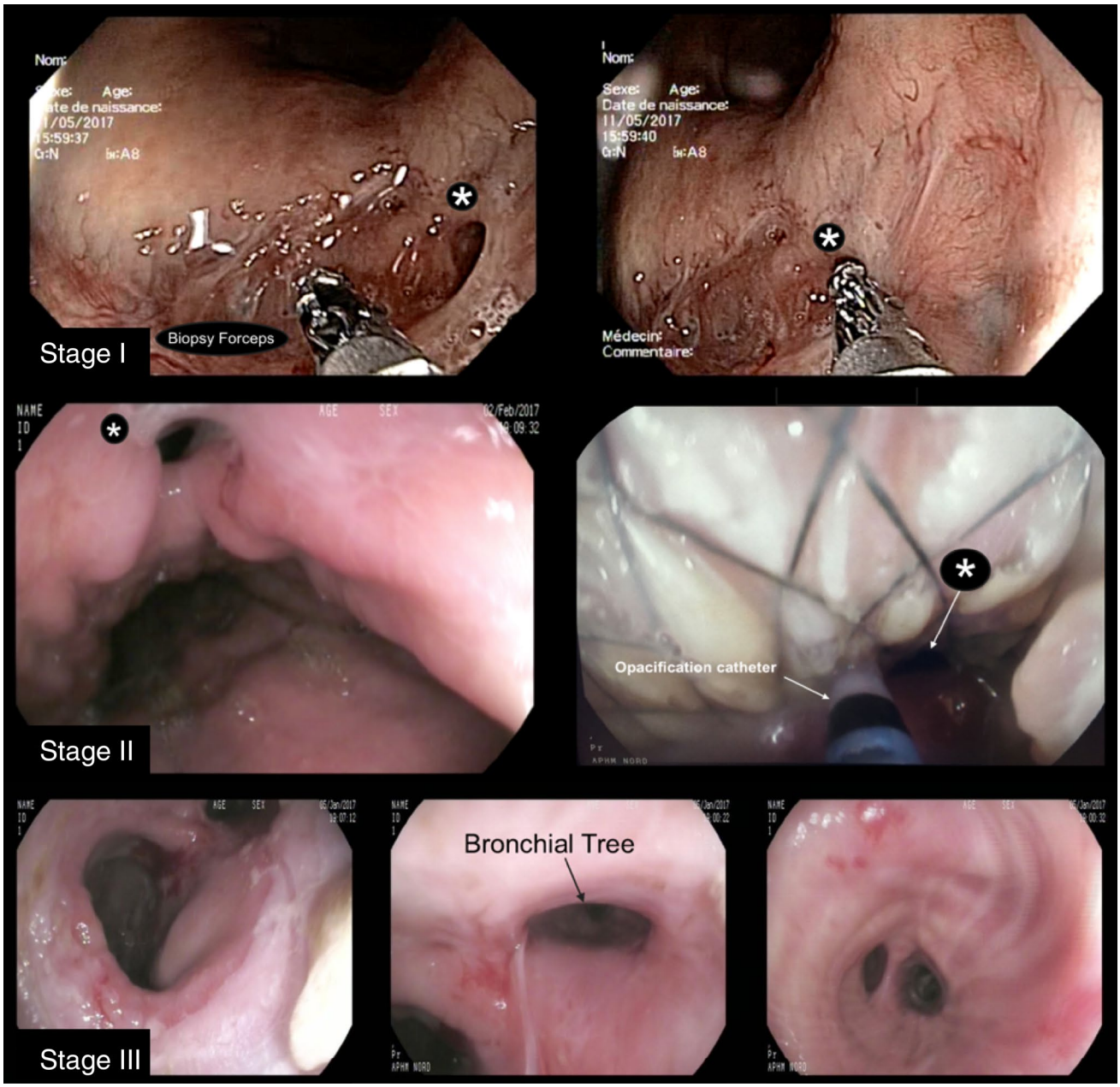

Fig. 1 Endoscopic classification of the eso-respiratory fistulas. Stage I ERF: Punctiform orifice which can be covered by the biopsy forceps or straight catheter. Stage II ERF: Medium orifice which cannot be covered by a straight catheter (or biopsy forceps) but without bronchial visibility. Stage III ERF: Large orifice with direct bronchial visibility

factors associated with endoscopic success and serious adverse events including death, ERF surgery, or the need for urgent endoscopy (complications related).

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 20.0 (Inc., IL., USA). Continuous variables were presented as mean ± standard deviation or as median with the first and third quartile. Categorical variables are presented as numbers and percentages. The relationship between categorical variables was assessed using the Chi-square test of Pearson or Fisher exact test if the theoretical numbers were below 5. The connection between a qualitative and a quantitative variable was evaluated using the Student's *t* test or the Anova test. Survival curve was made using Kaplan Meier model with log rank test. The variables that had a p value < 0.20 in univariate analysis and those that

had clinical relevance have been introduced in the multivariate analysis. The logistic regression model was used to identify independent predictive factors influencing the response to endoscopic treatment. For all tests, statistical significance is set at $p < 0.05$.

Results

Study population

Thirty-nine patients were confirmed with an esophago-respiratory fistula in our database. Seventeen were excluded (malignant fistula $n = 12$, age < 18 years old $n = 1$, missing data $n = 1$, treatment before July 2012 $n = 2$, esophago-pleural fistula $n = 1$). Finally, a total of 22 patients with benign ERF endoscopically treated were considered for analysis: thirteen men and nine women, with a mean age at diagnosis of 58 years old [20–75] (Figs. 2, 3).

ERFs were consecutive to surgery (anastomotic fistulas) in twelve patients (54.5%), repeated esophageal dilatation in three (13.6%), invasive ventilation in three (13.6%), radiation therapy in two (9.1%), and post-tracheostomy in two (9.1%). Eleven patients (50%) had undergone previous thoracic radiation therapy at the diagnosis. Among the patients with postoperative fistulas ($n = 13$), five (38.5%) underwent Akiyama procedure, three (23.1%) Lewis Santy procedure, two (15.4%) retrosternal colon transplant, and one (7.7%) an esophageal reparation procedure after an endoscopic perforation. Two patients had late recurrences of ERF after a surgical repairing, more than 3 years ago. The baseline characteristics of the patients are summarized in Table 1.

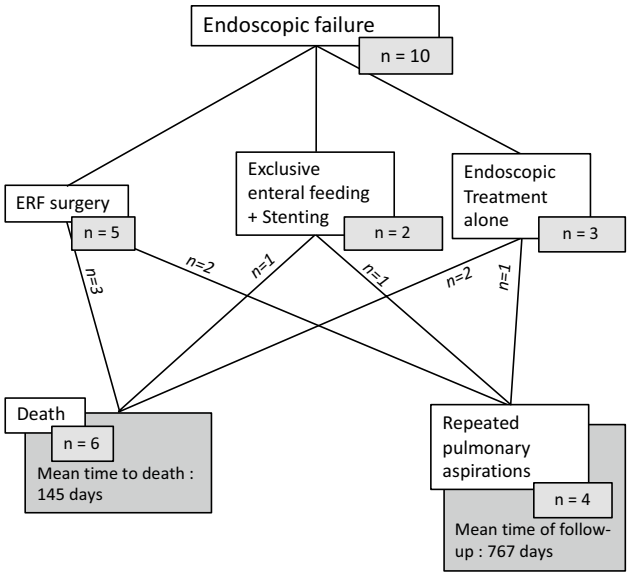

Fig. 3 Outcomes of patients with failure of endoscopic treatment

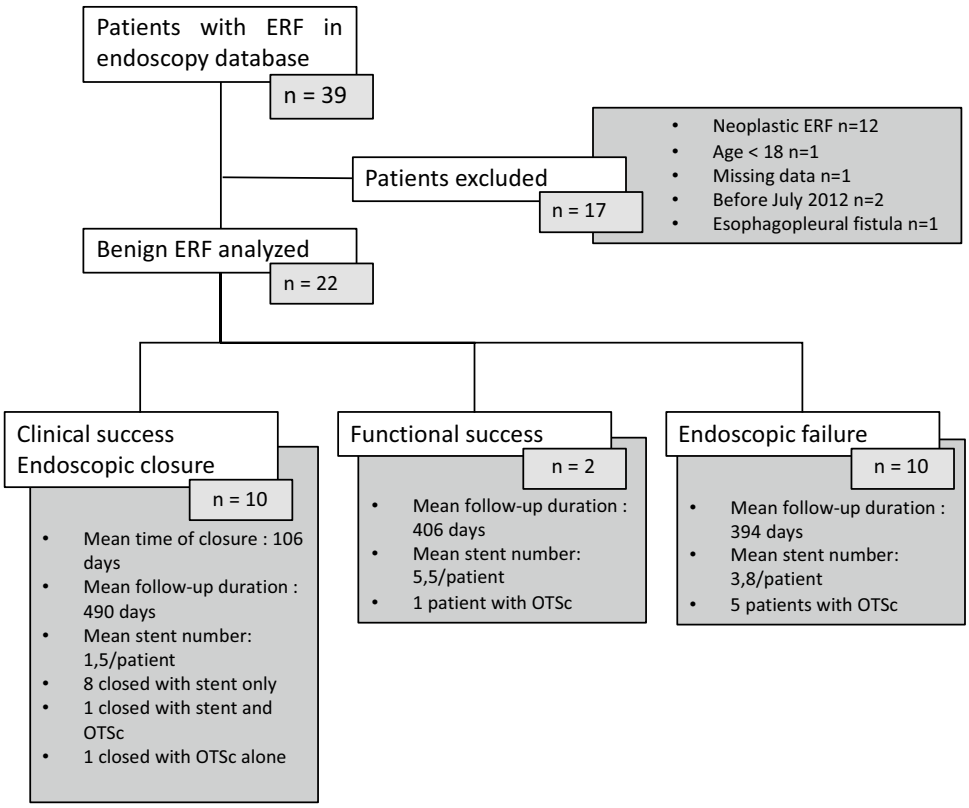

Fig. 2 Flow chart and results of endoscopic treatment of eso-respiratory fistulas

Table 1 Patients characteristic and results of endoscopic treatment

	All patients	No closure	Successful endoscopic closure	*p* value
Number of patients $n=22$		$n=12$	$n=10$	
Gender				
Male/female	22	6/6	7/3	0.342
Etiology				
Post-surgery	13	7	6	0.665
Post-dilatation	3	0	3	0.062
Post-radiation	2	2	0	0.138
Post-invasive ventilation	5	3	2	0.534
Clinical presentation at diagnosis				
Tracheotomy at the diagnosis of ERF	4	4	0	0.027
Previous thoracic radiation ($n=11$)	11	6	5	0.67
Esophageal stenosis ($n=7$)	7	2	5	0.17
Sepsis at diagnosis	18	10	8	0.269
Pulmonary complication at diagnosis	16	10	6	0.056
Pulmonary location				
Trachea	17	10	7	0.127
Right bronchus	3	2	1	0.534
Left bronchus	2	0	2	0.138
Orifice size—Stage of the fistula				
Punctiform (Stage I)	9	3	6	0.193
Medium (Stage II)	6	3	3	1
Large (Stage III)	7	6	1	0.17
Recurrence of fistula	5	4	1	0.193
Timing of closure				
Resolution at 3 months	7	0	7	0.001
Resolution at 6 months	8	0	8	$<10^{-3}$
No resolution at 6 months	14	12	2	$<10^{-3}$
Endoscopic treatment				
Mean number of esophageal stents	2.9 (±3)	3.6 (±3.9)	2.3 (±2.7)	0.069
Mean number of OTSc	0.8 (±1.4)	1.2 (±1.8)	0.4 (±0.7)	0.082
At least one esophageal stent	20	11	9	0.892
At least one OTSc	8	6	2	0.146

The fistulas were clinically suspected following aspiration pneumonia in ten patients (45.5%) and immediate post-prandial cough in five of them (22.7%), whereas four patients had dysphagia as only symptom and two presented with mediastinitis. Only one patient was asymptomatic and ERF was diagnosed during an endoscopy after esophageal dilatation for stenosis. Sixteen patients (72.7%) presented with pulmonary complications linked to the fistula: ten patients (45.5%) had aspiration pneumonia, three (13.6%) had a pleural effusion, two patients had recurrent COPD exacerbation, and one patient has a difficult invasive ventilation due to a wide orifice fistula. Eighteen of them (81.8%) had severe sepsis at the time of diagnosis.

Regarding the location of the ERF, there were mainly eso-tracheal fistulas ($n=17/22$; 77%). In three cases, there was a communication with the right bronchi (13.6%), and in two others with the left bronchi (9.1%). Six patients had an esophageal stricture associated and two had a tracheal stenosis.

The primary (esophageal) orifice of the ERF was single in seventeen cases, whereas there were multiple orifices in five other patients (22.7%). Nine patients had a small orifice (stage I), six had a medium one (stage II), and seven had a large orifice (stage III). The aspect of the mucosa surrounding the fistula's orifice was normal in eleven patients, inflammatory in seven, fibrotic in three, and necrotic in one.

Overall characteristics of the endoscopic treatment

Between July 2012 and February 2017, a total of 93 procedures were performed on the 22 patients. The median number of endoscopies was 2 per patient (range 1–19).

FC-SEMS stenting was the main therapeutic modality with a mean of 3.9 ± 3.4 stents per patient (median 2, range 0–13), among whom twenty patients (90.9%) had at least one SEMS. Seventeen OTSc were placed (mean 0.8 ± 1.4; median 0; range 0–6). Two patients had tracheal stent placement, one in combination with esophageal stents. The features of the endoscopic treatments are detailed in Table 1. The mean time of follow-up was 13.8 ± 14 months.

Overall, serious adverse events linked to esophageal stents occurred in 9 patients (40.9%) distributed in gastrointestinal bleeding due to mucosal erosion (4 patients, 18.2%), stent migration (4 patients, 18.2%), thoracic spondylodiscitis (2 patients, 9.1%), food impaction (1 patient, 4.5%), stent mucosal impaction (1 patient, 4.5%), and major chest pain (1 patient, 4.5%). During the follow-up, six (27.3%) patients died of pulmonary complications from the fistula. The adverse events rate tended to be higher in patients who had undergone prior esophageal surgery: 53% (7/13) versus 22% (2/9).

Efficacy of endoscopic management

Successful endoscopic closure as defined (no more orifice, no stent, and no recurrence at 6 months) was reached in 45.5% of the cases ($n = 10$), in a mean time of 3 ± 3.9 months. In these patients, a mean of 1.5 ± 0.8 esophageal stents and 0.2 ± 0.4 OTS Clips were used. OTSc was attempted in eight patients but with success in only two (25%, $p = 0.146$). Twelve patients (55%) had a functional success as defined: ten whose fistulas were healed and two who are still undergoing iterative covered SEM stenting because of a persisting orifice. All the patients with clinical and functional success were still alive at the end of the follow-up.

Among the 10 patients with failure, five (22.7%) underwent surgery, six finally died (27.2%) among whom three after surgery, two patients had repeated aspiration pneumonias, and two patients had exclusive intravenous alimentation for persisting fistula despite the SEMS.

Factors associated with success and death

In univariate analysis, the only factor associated with no successful endoscopic closure was the presence of a tracheotomy at diagnosis ($p = 0.027$). There was a nonsignificant trend towards endoscopic successful closure associated with the size of the orifice. Radiation therapy was not associated with a lower rate of ERF's closure ($n = 5/11$; $p = 0.67$), but the time for fistula's healing trended to be longer in case of previous radiation therapy (44 ± 13.3 days without radiation therapy vs. 167 ± 143.7 days with $p = 0.092$). The data regarding the other factors linked to endoscopic successful closure that were analyzed are summarized in Table 1.

In multivariate analysis, the absence of fistula closure after 6 months of endoscopic treatment was associated with final failure (OR 44; IC95: 3.38–573.4; $p = 0.004$).

The death rate was significantly associated with the size of the fistula orifice, since there was no death in the group with punctiform fistula (0/9, $p = 0.017$), against 71.4% of mortality in the group of large orifices (5/7, $p = 0.001$).

Discussion

Surgical treatment of benign ERF is widely described than endoscopic treatment. Indication for surgery is retained for post-intubation perforations and for cervical esophageal fistulas with cervical approach [4, 10]. This approach is used in more than 95% of cases of surgical repair of ERF located in upper and middle esophagus [4]. The other option, which consists of thoracic approach with thoracotomy, is more difficult and morbid, explaining that endoscopic treatment may be preferred in case of distal ERF. Several additional reasons lead to the promotion of endoscopic management, such as complex history of prior thoracic surgeries, patients in poor clinical conditions, or if patients refuse surgery.

Definitely, for nonmalignant ERF, healing the fistula has to be the main therapeutic objective. With 22 patients included, our series offers the largest sample documentation of the endoscopic management in an exclusively nonmalignant homogeneous ERF population, demonstrating endoscopic successful closure and functional efficacy of 45 and 55%, respectively. To date, data about the endoscopic management were missing. One single series described a population of 35 ERF, including malignant ($n = 25$) and nonmalignant ($n = 11$) etiologies, surprisingly showing a very high rate of success (80%), given the complexity of such pathology [9]. However, they considered patients with definitive stent in place as cured and they did not mention follow-up time or potential recurrences. Other reports are limited to case reports or limited case series [11–13].

In another hand, functional efficacy was difficult to achieve, even with covered stent, mainly because their diameter was insufficient to seal the orifice completely. Swinnen et al. [14] described the use of partially covered SEMS for the treatment of benign upper GI leaks and perforations, with a long stenting duration (83 days). This method led to the development of a growing tissue around the stent flanges avoiding migration and liquid flow from above. The stent was either left in place or removed applying the "stent in stent" technique. Thus, this approach may be interesting in case of failure after 6 months of endoscopic treatment, in order to address pulmonary aspiration-related complications and decrease the death rate.

Regarding therapeutic modalities, most of the patients underwent covered SEMS placement (91%). Interestingly,

OTSc did not appear as a good therapeutic option, since only 25% of the patients had success, and it was always associated with the presence of a SEMS. We hypothesized that a recurrence occurred in most of the cases because of a secondary necrosis of the tissue grasped by the clip inducing its release and a reopening of the fistula. Consequently, we believe OTS clipping has to be avoided for treating ERF, and that esophageal SEMS are the cornerstone of the endoscopic treatment. The only issue with the stenting is the occurrence of related adverse events, especially migration. However, our migration rate was not dramatically high (18%) for fully covered SEMS and might be decreased thanks to the newly designed stents such as Double type of Beta stents (Taewoong Medical, Seoul, Korea), dedicated to fistula management.

Regarding the factors influencing the prognosis, the main findings were that the absence of healing after 6 months of endoscopic treatment was significantly associated with a final failure healing in univariate and in multivariate analysis. We also showed a significant impact of the orifice's size, with no mortality in punctiform group and more than 70% of mortality for the patients who had fistula with direct visibility (group III) of the bronchial tree. All the deaths were due to pulmonary complications, despite the SEMS. Because of the reduced sample size, we could not identify other factors, but some results remain interesting. Thus, dilatation-related ERF tended to have a better prognosis (100% of closure $p = 0.062$). There was no difference in terms of fistula's healing with regard to previous radiation therapy, even if patients without previous radiation therapy seemed to heal more quickly (44 days vs. 167 days $p = 0.092$). This is consistent to what we demonstrated previously for anastomotic leakages after esophageal surgery for cancer [15]. In the literature, the role of radiation therapy is controversial since two studies showed an increased mortality after this treatment [16, 17], whereas some reports do not confirm any impact [18, 19].

Basically, with 45% of fistula closure the result of endoscopic management is not satisfying; however, a few key points may be underlined with direct impact on clinical practice. First, fistulas with punctiform and medium orifices had better chances to heal than large ones (67 and 50% vs. 14%, respectively), so an endoscopic treatment using mainly SEMS must be attempted. Second, if the fistula has not closed after 6 months of management, partially covered stent (to achieve functional success) or surgery must be discussed, depending on patient's clinical condition (Fig. 4). The retrospective results of this study have led us to reconsider ERF surgery for large ERFs, even in patients with comorbidities.

In conclusion, nonmalignant ERF is a challenging issue that can be managed by endoscopy in selected cases with punctiform or medium orifices. We need to improve technique and tools to be able to close larger fistulas.

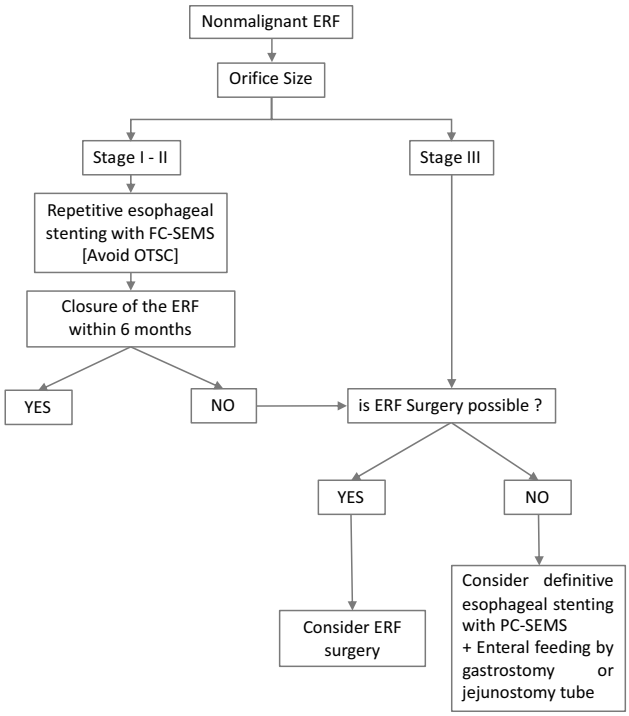

Fig. 4 Proposition of a treatment algorithm for nonmalignant ERF

Compliance with ethical standards

Disclosures Dr Marc Barthet is consultant in endoscopy for Boston Scientifics. Drs Antoine Debourdeau, Jean-Michel Gonzalez, Hervé Dutau, and Alban Benezech have no conflicts of interest or financial ties to disclose.

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