Prognostic factors after therapeutic bronchoscopy for tracheo- or broncho-oesophageal fistulas: results from the EpiGETIF registry

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Shareable abstract (@ERSpublications)
This study confirms the poor prognosis associated with malignant fistula treated with therapeutic bronchoscopy. Some simple prognostic factors (PS, combination with OS) have been identified and may help selection of candidates for this treatment. https://bit.ly/3BZ5LJR

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Abstract

Introduction Treatment of malignant tracheo- or broncho-oesophageal fistulas (TOF) using therapeutic bronchoscopy (TB) is not standardised and its outcomes are poorly described. This study aimed to analyse the characteristics of patients treated with TB for a TOF and to identify prognostic factors.

Methods We analysed data from 96 patients undergoing TB for TOF entered in the EpiGETIF registry between January 2019 and December 2022.

Results The mean age was 61.4 years. Median survival after TB was 2.40 months (95% CI 1.81–3.32). Histology was mainly represented by oesophageal (72%) and lung (23%) cancers and did not influence prognosis (p=0.15), whereas smoking did (2.17 *versus* 3.32 months for nonsmokers, p=0.04). Patients with poor *performance status* (Eastern Cooperative Oncology Group >2) had shorter survival (1.99 *versus* 3.02 months, p=0.04). 69% of patients had already received oncologic treatment, with no difference in survival (3.02 *versus* 2.21 months for treatment-naive patients, p=0.14). Neither the localisation (trachea 61.5%, left main bronchus 34.4%, other 4.1%) nor the size of the fistulas (23% <5 mm, 20% 5–10 mm, 54% >10 mm) impacted survival (p=0.91 and p=0.83, respectively). An airway stent (AS) was placed in 92.7% of patients, mainly self-expanding metallic stents (45%). Patients treated with both an oesophageal stent and AS had a better prognosis than patients treated with an AS alone (2.88 *versus* 1.77 months, respectively, p=0.02).

Conclusion Survival of patients treated with TB for a TOF is very poor, and is impacted by smoking, performance status and the presence of an oesophageal stent.

Introduction

Tracheo- or broncho-oesophageal fistulas (regrouped as TOF here) can be acquired or congenital [1]. Malignant acquired TOF account for more than 50% of fistulas [2], complicating 5 to 15% of oesophageal

cancers but <1% of bronchogenic cancers [3, 4]. It is often a consequence of tumour necrosis induced by systemic or radiation therapies and leads to a deep alteration in quality of life, due to repeated aspiration pneumonias [5–7], and prognosis [7–10]. Diagnosis is suspected on computed tomography scan and confirmed by bronchoscopy and/or oesophagoscopy. Oesophageal stent (OS) usually leads to short-term improvement [10], but little is known about symptomatic improvement and survival after airway stenting (AS). In addition, the best therapeutic sequence is not clear. In the only prospective observational study on the topic, including 112 patients, HERTH *et al.* [11] reported the superiority of double stenting on overall survival. Some studies suggested that OS and/or AS may improve dyspnoea, dysphagia and quality of life [10–12], while another found no difference when compared to conventional palliative measures in terms of quality of life [13]. Therefore, uncertainty persists regarding optimal management of TOF and patient selection for invasive, endoscopic approaches.

A prospective registry, EpiGETIF, was created by the GETIF (Groupe d'Endoscopie Thoracique et Interventionnel Francophone) in 2019. It is a web-based, multicentre (36 centres) clinical database with the purpose of prospectively collecting data on various interventional pulmonology topics, including therapeutic bronchoscopy (TB) for malignant indications. [14]. The aims of our study were to analyse data from this registry on early symptomatic improvement and survival in patients with TOF treated with TB, and to identify prognostic factors that could be used to better select candidates for this palliative but invasive treatment.

Materials and methods

Population

Data from all patients undergoing a rigid bronchoscopy for a TOF between January 2019 and December 2022 and prospectively included in the EpiGETIF registry, whether AS was performed or not, were analysed.

Data acquisition

Data were entered into the web-based registry using predefined items (detailed in a previous article [14]). Demographic characteristics at inclusion were collected at the time of TB and not at diagnosis of TOF and included: age, sex, performance status using the Eastern Cooperative Oncology Group scale (ECOG), smoking status, comorbidities, histology and previous treatment. The predefined arbitrary size options to describe the fistulas were <5 mm, 5–10 mm and >10 mm and more precise data could not be obtained. Pre- and post-procedure cough (graded none, mild, moderate or severe), haemoptysis (graded none, mild, moderate, or severe) and Borg scale of dyspnoea (0–10) were collected on admission and within 48 h post-procedure, respectively. Survival data were recovered retrospectively for all patients, and survival was calculated from the day of the TB.

Statistical analysis

Quantitative data were presented using descriptive statistics, including the number of observations and the mean±SD. Categorical variables were described by their number and percentage. Missing data were reported for each variable. Bivariate analyses were performed to investigate factors associated with survival using the Kaplan–Meier method. For each analysis, the number of missing observations, the number of events, the median survival time (and their 95% confidence intervals (CI)) were reported. Multivariate analysis of survival factors was performed using a Cox regression model, starting with all variables with a p-value of <0.20 in the univariate analysis and applying a stepwise backward selection procedure. All tests were two-tailed and a p-value <0.05 was considered significant. The proportional hazards assumption was evaluated for each variable (using Schoenfeld residuals and log–log plots). All analyses were performed using R software (version 4.2.2). Overall survival was studied using the R packages "survival" and "surviminer". Responders regarding cough and dyspnoea were defined arbitrarily for cough by a change of one grade or more; and for dyspnoea by an improvement of 1 point or more, following the defined minimal clinically important difference (MCID).

Ethical considerations

EpiGETIF is a database created by the GETIF with the Conseil National Professionnel of pulmonology [14–16], according to the 2019–2017 governmental decree of 9 January 2019 relating to the missions of CNPs (https://splf.fr/epigetif/). Informed consent was obtained in accordance with French guidelines set by the National Commission for Data Protection and Liberties (CNIL number: 2048574).

Results

Demographic and clinical characteristics

A total of 96 patients were included. 17 of the 36 participating centres included at least one patient undergoing TB for TOF. Table 1 shows patients' baseline characteristics, and table 2 shows the treatment

TABLE 1 Characteristics of patients treated with therapeutic bronchoscopy for a broncho- or tracheo-oesophageal fistula (all patients n=96)

Sex	
Female	23 (24.0)
Male	73 (76.0)
Age years	
<50	10 (10.4)
50–65	50 (52.1)
>65	36 (37.5)
BMI classification	
Missing	33 (34.3)
Underweight	28 (29.2)
Obesity/overweight	8 (8.3)
Normal	27 (28.1)
PS (ECOG)	
Missing	2 (2.1)
ECOG ⩽2	43 (44.8)
ECOG >2	51 (53.1)
Smoking	
Missing	1 (1.0)
No	31 (32.3)
Yes	64 (66.7)
Histological type	
Missing	4 (4.2)
NSCLC adenocarcinoma	10 (10.4)
NSCLC squamous	12 (12.5)
Extra-thoracic	70 (72.9)
Oesophagus	63 (65.6)
Other	7 (7.3)
Previous systemic oncologic treatment	
No	31 (32.3)
Yes	65 (67.7)
Dyspnoea (Borg scale) before TB	
Missing	1 (1.0)
0 (none) to 3 (moderate)	34 (35.4)
4 (moderate to severe) to 6	29 (30.2)
7 (very severe) to 10 (maximal)	32 (33.3)
Oxygenotherapy L·min^{-1}	
Missing	3 (3.1)
None	52 (54.2)
1 to 4 L	23 (24.0)
5 to 10 L	2 (2.1)
>10 L	4 (4.2)
Mechanical ventilation	12 (12.5)
Cough before TB	
Missing	7 (7.3)
None/minimal	31 (32.2)
Moderate/severe	58 (60.4)

Data are presented as n (%). BMI: body mass index; PS: performance status; ECOG: Eastern Cooperative Oncology Group; NSCLC: nonsmall cell lung cancer; TB: therapeutic bronchoscopy.

previously received. Most patients were male (76%) and over 50 years old (89.6%). The majority were treated for a TOF complicating an oesophageal cancer (65.6%). 53% of patients had an ECOG >2. 68% of the population had received prior systemic or radiation therapy, 35.4% of which receiving two lines or more. One third of patients reported severe dyspnoea (Borg scale>6). 43% of patients needed oxygen support, 4.2% requiring an oxygen flow rate >10 L·min^{-1} and 12.5% mechanical ventilation. Moderate to severe cough was present in 60.4% of patients.

Characteristics of the TOF and techniques used

The bronchoscopic characteristics of the fistulas and interventions are detailed in table 3. The trachea was the most common location of the fistulas (61.5%), followed by the left main bronchus (34.4%). The right

TABLE 2 Characteristics of treatments received by patients previously treated and undergoing interventional bronchoscopy for broncho- or tracheo-oesophageal fistula (all patients n=96)

Number of lines of previous treatments received	
Missing	16 (16.7)
Nil	31 (32.3)
One	31 (32.3)
Two	8 (8.3)
Three or more	10 (10.4)
Type of previous treatment received	
Missing	1 (1.0)
Nil	31 (32.3)
Radiotherapy associated with chemotherapy	35 (36.4)
Chemotherapy	19 (19.8)
Chemotherapy associated with immunotherapy	5 (5.2)
Oesophageal surgery with or without chemotherapy	4 (4.2)
Targeted therapy (EGFR tyrosine kinase inhibitor)	1 (1.0)

Data are presented as n (%).

main bronchus was the sole location in only one patient (1%), and three patients had both main bronchi involved (3.1%). More than half were larger than 10 mm (55.9%). In 61 cases (63.5%), the TOF was associated with central airway obstruction, defined as a >50% stenosis of the trachea and/or main bronchi. The obstruction was extrinsic, intrinsic or mixed in 13.1%, 16.4% and 67.2% of cases, respectively. Among patients with central airway obstruction, 33 underwent a debulking procedure, including 11 (33.3%) where thermal techniques were used. An AS was inserted in 93.8% of cases. Fully covered self-expandable metallic stents (SEMS, 45.1%) and silicone stents (43.7%) were used almost equally. An associated oesophageal stent was used in 52 patients (54.7%), before, after or during the same procedure as AS in 24 (47.1%), 17 (33.3%) and 10 (19.6%) patients, respectively. The early complication rate of TB was 12.6% (95% CI 6.7–21.0%), dominated by stent migration (n=6) in the 48 h following the procedure. No late (>48 h) AS migration was reported in our cohort.

Primary end-point

The median overall survival was 2.4 months (95% CI 1.8–3.3). The main variables tested for their impact on survival are presented in table 4. An ECOG >2 and smoking status were associated with shorter median survival (figure 1a and b). Age, histology, fistula size or location on bronchoscopy, and the tools used during the procedures were not associated with survival. Survival in previously treated patients was 2.2 months compared with 3.0 months in treatment-naive patients, although the difference was not statistically significant (p=0.19, figure 1c). There was a significant difference in survival between patients who had an OS in addition to the AS and patients with AS alone with a median survival of 2.8 months compared to 1.7 months (p=0.03, figure 1d). The insertion sequence did not influence prognosis, despite a trend towards a poorer survival when the OS was inserted before AS, with a 2.2-month median survival *versus* 3.2 months when inserted concomitantly and 4.3 months when OS was inserted after AS (p=0.17).

Secondary end-points

Dyspnoea improved immediately after the procedure, with a median reduction of 2 points on the Borg scale (n=58). Most patients (43 out of 58, 74.1%) responded better than the established 1 point MCID [17] for the Borg scale. These "responders" tended to have a poorer prognosis, with a median survival of 1.9 months *versus* 5.4 months for "non-responders" (p=0.11). Cough improved in 71.1% of patients (n=32 out of 45). Also, patients with the highest baseline dyspnoea (Borg 6–10) tended to have lower survival, with a 1.8-month median survival compared to 4.3 months for patients with a baseline Borg score of 0 to 2 (p=0.13).

Discussion

In this prospectively collected cohort of patients undergoing TB for TOF, survival appears very poor, with a median survival of 2.4 months, and is consistent with other studies [7–10]. In addition to another study that showed no difference compared with palliative measures in terms of quality of life [13], our results question the benefit of this treatment. In this context, the objective of our study was to help patient selection for TB. ECOG emerges as a clear, and expected, prognostic factor while age is not. Physiological age might be a better predictor of benefit from TB in this context and abstention in patients with ECOG >2

TABLE 3 Bronchoscopic characteristics and interventions (all patients n=96)

Location of fistula	n=96
Trachea	59 (61.5)
Left main stem bronchus	33 (34.4)
Both main bronchi	3 (3.1)
Right main stem bronchus	1 (1.0)
Size of fistula mm	n=96
Missing	3 (3.1)
⩽10 mm	41 (42.7)
>10 mm	52 (54.2)
Concomitant central airway obstruction	n=96
No	35 (36.5)
Yes	61 (63.5)
Location of obstruction	n=61
Missing	1 (1.6)
Trachea	34 (55.7)
Left main bronchus	18 (29.5)
Other	8 (13.1)
Airway stenting	n=96
Yes	90 (93.8)
No	6 (6.3)
Type of airway stent	n=90
Missing	19 (21.1)
Fully covered self-expanding	32 (35.6)
Self-expanding, not covered	1 (1.1)
Self-expanding, partially covered	7 (7.8)
Silicone	31 (34.4)
Shape of airway stent	n=90
Missing	15 (16.7)
Y	32 (35.6)
Straight	43 (47.9)
Oesophageal stent	n=96
Missing	1 (1.0)
Yes	52 (54.2)
No	43 (44.8)
Complications	n=96
Missing	1 (1.0)
No	83 (86.5)
Yes	12 (12.5)
Type of complications	n=15
Missing	3 (20)
Stent migration	6 (40)
Tracheal wound	1 (6.7)
Haemoptysis	1 (6.7)
Laryngeal oedema	1 (6.7)

Data are presented as n (%).

may be legitimate. This abstention appears particularly reasonable in the absence of concomitant malignant central airway obstruction (MCAO) since the early benefit in terms of dyspnoea and cough becomes unlikely. The median decrease in dyspnoea based on the Borg scale is indeed less significant in this study (2 points) compared to what is observed after TB for MCAO (4.1 points [14]).

TOF are more likely to occur in patients previously treated with systemic and/or radiation therapy [3–8]. Our findings support this idea, 68.8% of our patients having been previously treated. More than half of them received radiation therapy. Our study surprisingly only shows a trend towards a better survival in treatment-naive patients, with a median survival of 3.0 *versus* 2.2 months in patients who already received treatments, unlike in MCAO situations where it is usually a strong prognostic factor [18]. This might only be due to a lack of power. It could also be that the presence of a fistula at diagnosis is a marker of a more aggressive or more advanced disease. Herth *et al.* [11] found concomitant chemo- or radiation treatment to be an independent positive prognostic factor. We analysed survival depending on the number of lines and type of treatments received, but the very low number of patients in each of these subgroups preclude us

TABLE 4 Impact of the characteristics of the patient, the underlying disease, the fistula and treatments received on survival

Variable	Median survival months (95% CI)	p-value
Sex	n=94	p=0.23
Female (n=22)	2.0 (1.5–4.0)	
Male (n=72)	2.7 (2.0–3.7)	
ECOG (pre-procedure)	n=92	p=0.04#
⩽2 (n=42)	3.0 (2.4–5.2)	
>2 (n=50)	1.9 (1.5–3.1)	
Age years	n=94	p=0.58
<50 (n=10)	3.2 (1.4, NA)	
50–65 (n=49)	2.4 (1.8–3.7)	
>65 (n=35)	2.2 (1.4–4.5)	
Smoking status	n=93	p=0.04#
Never (n=29)	3.3 (2.2–5.8)	
Former or active (n=64)	2.2 (1.6–3.0)	
Body mass index kg·m^{-2}	n=63	p=0.38
⩽18.5 (n=28)	3.0 (2.0–4.3)	
>18.5 (n=35)	1.7 (1.4–3.3)	
Previous treatment	n=94	p=0.19
No (n=31)	3.0 (2.0–4.5)	p=0.35
Yes (n=63)	2.2 (1.6–3.1)	
1 line (n=31)	1.5 (0.5–4.9)	
>1 line (n=32)	2.4 (2.0–4.0)	
Baseline dyspnoea (Borg scale)	n=93	p=0.13
0–2 (n=18)	4.3 (3.3–6.9)	
3–4 (n=25)	2.2 (1.5–4.7)	
5–6 (n=18)	1.7 (1.4–5.2)	
7–10 (n=32)	1.8 (1.2–3.3)	
Histology	n=90	p=0.68
NSCLC adenocarcinoma (n=9)	2.7 (2.2, NA)	
NSCLC squamous (n=11)	1.8 (1.0, NA)	
Extra-thoracic (n=70)	2.7 (2.0–3.7)	
Size of fistula mm	n=91	p=0.83
<5 (n=21)	2.0 (1.3–5.2)	
5–10 (n=19)	1.8 (1.0–4.3)	
>10 (n=51)	3.0 (2.3–4.5)	
Oesophageal stent	n=94	p=0.03#
No (n=42)		p=0.17
Yes (n=52)	1.7 (1.2–3.1)	
Before (n=24)	2.8 (2.2–4.5)	
Concomitant (n=10)	2.2 (1.5–4.9)	
After (n=17)	3.2 (1.8, NA)	
NA (n=1)	4.3 (2.7–8.7)	

ECOG: Eastern Cooperative Oncology Group; NSCLC: nonsmall cell lung cancer; NA: not available. #: statistically significant.

from drawing any conclusion. Despite these results, we suggest that heavily pre-treated patients for whom no promising systemic or local treatment can be initiated after TB are poor candidates for TB, especially in the case of a poor ECOG score and absence of concomitant MCAO. In EpiGETIF, only previous treatments received are entered in the database, but not subsequent treatment(s), and it might have been interesting to know the profile and proportion of patients that could receive one.

Interestingly, neither the size nor the location of the TOF influenced survival in our study. Regarding the influence of the location, Herth *et al.* showed that involvement of the trachea, left main bronchus or carina had a better prognosis because it is anatomically closer to the oesophagus, with probably lower tumour burden. Only four patients in our cohort had other anatomical presentations (one isolated right main bronchus, three with both main bronchi), preventing confirmation of this finding. Most AS used in our study (54.9%) were covered or partially covered SEMS. They are more likely used in this context (silicone being preferred in cases of MCAO in France [14–16]) because they are more flexible and offer a better

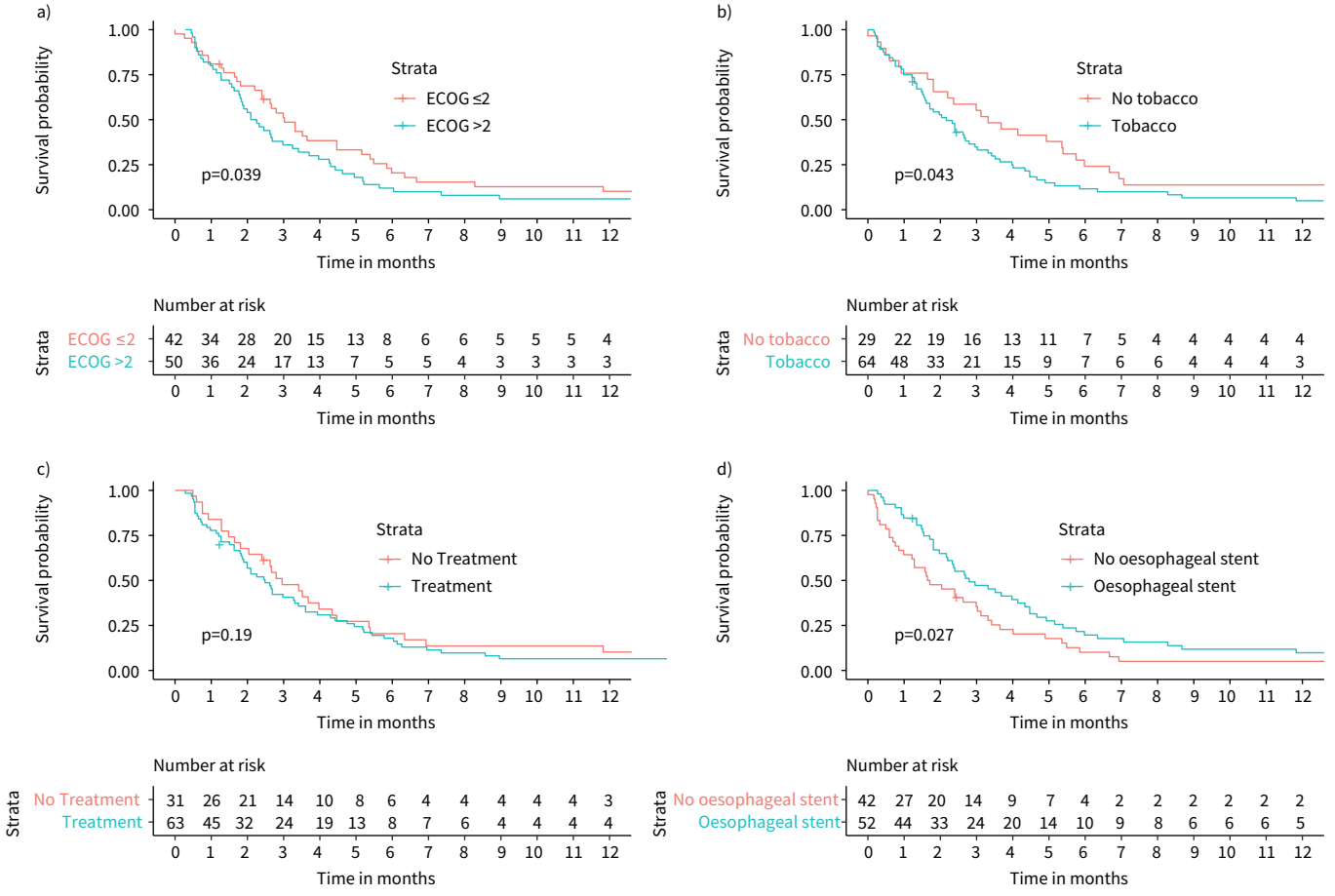

FIGURE 1 Overall survival after therapeutic bronchoscopy for the management of trachea-broncho-oesophageal fistula depending on: a) performance status (ECOG); b) smoking status; c) prior reception of treatments; d) combined use of an oesophageal stent (OS). ECOG: Eastern Cooperative Oncology Group.

congruence with airways [19]. In our cohort, the main complication was early stent migration with acute respiratory distress and urgent repeat bronchoscopy, common with fully covered SEMS which do not anchor to the airway mucosa as much as silicone or partially covered SEMS do.

In this cohort, patients with the highest baseline dyspnoea (Borg 6–10) tended to have shorter survival, with a median survival of 1.8 months *versus* 4.3 months for patients with baseline Borg score 0–2. Also, "responders" regarding dyspnoea tended to have poorer survival (p=0.11). This is probably simply a marker of higher tumour burden and is consistent with data in MCAO issued from both the AQuIRE and EpiGETIF registries, where baseline dyspnoea and degree of obstruction are predictive factors for improvement [20].

The strongest prognostic factor in our study is the presence of an OS. The literature is poor regarding the best strategy regarding double stenting and the best sequence to use, with most series being very limited (n<20) [21, 22]. To our knowledge, only one study (n=13) demonstrated additional symptomatic improvement after placement of an AS or OS compared with the clinical evaluation after placement of a first OS or AS using a staged approach [17]. The retrospective nature of the study has logically selected patients who were insufficiently controlled by the first stent alone. This is however consistent with our results, which show a better survival for patients who received double stenting, compared to AS alone (p=0.03). The registry did not include patients treated with OS alone, and the outcomes of this strategy are not evaluated here. The GETIF usually suggests (whenever an endoscopic management has been indicated), when technically feasible, an OS as a first option, eventually followed by AS in case of persistent aspiration pneumonias. The trend towards a shorter survival when the OS was placed before AS supports the idea that this strategy was used for this population. This work cannot confirm this expert

opinion but suggests that AS alone is not the best option. Another important limitation of this work relies in the fact that the reason why the OS was not inserted first is unknown, even though we believe it was likely because it was not technically feasible [17]. Herth *et al.* showed a slightly better survival in patients treated with a single OS or double OS/AS compared with single AS. Altogether, this study does not allow for additional knowledge regarding the best sequence, and we stick with the GETIF recommendations mentioned here. Another limitation of our study is due to the fact that the EpiGETIF registry only includes patients undergoing rigid bronchoscopy for malignant indication. All 36 participating centres perform most of their cases through a rigid bronchoscope, but in some rare cases, endotracheal tube or laryngeal mask might have been the only possible airway access to insert a self-expandable metallic stent, and these patients are not included in the analysis. Also, the type of AS used (silicone in 43.7% in our study) might limit the generalisation of these results, since other centres might use other airway accesses and thus exclusively expandable stents.

In conclusion, our study confirms the poor prognosis associated with the development of a malignant TOF treated with TB. Symptomatic improvement is less significant than what is reported after TB for MCAO. Some simple prognostic factors (ECOG, combination with OS) have been identified, while others need to be confirmed in other studies, in particular the nature and volume of previous treatments received and may help improve selection of candidates for this invasive but palliative treatment.

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Ethics statement: EpiGETIF is a database created by the GETIF (Groupe d'Endoscopie Thoracique et Interventionnel Francophone) with the Conseil National Professionnel (CNP) of pulmonology (14), according to the 2019-17 governmental decree of 9 January 2019 relating to the missions of CNPs (https://splf.fr/epigetif/). Informed consent was obtained in accordance with French guidelines set by the National Commission for Data Protection and Liberties (CNIL number: 2048574).

Author contributions: All authors contributed to the acquisition of data and approved the final version of the manuscript. N. Guibert designed the study. J. Edme and N. Guibert wrote the manuscript. B. Lepage and C. Zea Obando Ep Chateau performed the statistical analysis.

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