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ORIGINAL RESEARCH

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Stenting versus balloon dilatation in patients with tracheal benign stenosis: The STROBE trial

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Abstract

Background: It is well known that benign tracheal stenosis represents an obstacle to open surgery, and that its treatment could be challenging. Two endoscopic techniques have so far been adopted to restore tracheal patency: balloon dilatation (BA) through laryngoscopy, and tracheal stenting (ST) with rigid bronchoscopy. The main objective of this study was to compare the efficacy of BA and ST to treat benign tracheal stenosis not eligible for surgery. We also compared the rate of adverse events in the two treatment groups.

Methods: A retrospective, observational cohort study was carried out at the University Hospital of Modena (Italy) from November 2012 to November 2017 in two separate departments. Patients were considered to be "stabilized" (primary outcome) if they did not report significant respiratory symptoms, or restenosis in the long-term (2 years) following the endoscopic procedure.

Results: Sixty-six patients were included in the study (33 in the BA and 33 in the ST group, respectively). Unadjusted Kaplan–Meier estimates showed a greater therapeutic effect of ST compared to BA at 2 years (hazard ratio = 3.9 95%CI [1.5–9.8], $p = .01$). After adjusting for confounders, stratified analyses showed that this effect was significant in patients with complex stenosis, idiopathic etiology, and degree of stenosis >70%. Compared with BA, ST showed a higher rate of adverse events ($p = .01$).

Conclusions: Compared to BA, ST seems to be more effective in achieving stabilization of tracheal patency in complex benign tracheal stenosis, although burdened with a significantly higher number of adverse effects. These findings warrant future prospective study for confirmation.

Level of evidence: 3.

Alessandro Marchioni and Dario Andrisani have contributed equally to the manuscript and both should be considered the first author.

KEYWORDS
balloon dilatation, benign tracheal stenosis, rigid bronchoscopy, tracheal stenting

1 | INTRODUCTION

Benign tracheal stenosis represents a major therapeutic challenge whose optimal treatment remains unknown. Although surgery can be considered the treatment of choice, resection-anastomosis is often limited by the patient's condition, and the technical limits inherent to laryngotracheal surgery.[1]

In recent years, the role of endoscopic treatment of airway stenosis has been progressively increasing due to its limited invasiveness, even though this approach is burdened by frequent relapses.[2] Stanley Shapshay first described in 1987 the endoscopic technique that combines laser resection with rigid bronchoscopy dilation in the treatment of tracheal and subglottic scarring stenosis.[3] Lately, the endoscopic treatment of tracheal stenosis has evolved with the introduction of different techniques whose success is still debated.[4–6] Therefore, no data are currently available to help physicians choosing the most appropriate intervention depending on the clinical and anatomical characteristics of the stenosis. As such, each center uses the endoscopic treatment based on the operator's experience. In particular, two endoscopic techniques are frequently adopted to restore the tracheal patency: laryngoscopy with balloon dilatation (BA), and tracheal stenting (ST) with rigid bronchoscopy. However, the comparison between the two techniques on long-term results has never been evaluated. Furthermore, lasers therapy is often used in the treatment of pathogenic airway processes, but it is still unclear whether the potential tissue laser-injury can accelerate stenosis recurrence.

Tracheal narrowing can be the result of an underlying heterogeneous mechanisms that involving mechanical (traumatic or iatrogenic), autoimmune, or idiopathic causes. Surgical resection per se in patients with autoimmune disease is rarely performed due to the concern of anastomotic complications.[7,8] The identification of the etiology of stenosis could be a critical factor for the long-term success of endoscopic treatment, although currently only a few studies have investigated the relationship between causes of tracheal stenosis and relapse after endoscopic surgery.

Because there is no definitive or proven consensus about the endoluminal treatment of benign tracheal stenosis,[9] the purpose of this study is to compare the effectiveness of the two main endoscopic intervention methods (i.e., BA and stent placement) on the treatment of benign tracheal not eligible for open surgery.

2 | MATERIALS AND METHODS

2.1 | Design

This retrospective, observational cohort study was carried out in two operative settings (Diagnostic and Interventional Bronchoscopy Unit—Unit A, and Otolaryngology Unit—Unit B) at the University Hospital of Modena (Italy). These units follow different routinely applied protocols to treat tracheal benign stenosis. Endoscopic treatment through mechanical dilatation via rigid bronchoscopy and subsequent stent placing (ST) is performed in Unit A, whereas BA via direct laryngoscopy is used in Unit B.

Procedures of Unit A have been performed in the operating room with a Dumon rigid bronchoscope (Efer Medical, La Ciotat, Cedex, France) under general anesthesia. A silicone stent (NOVATECH Dumon Stents, Boston Medical Products, Inc., Westborough, MA) sized 16–14–16 mm for females and 18–16–18 mm for males is placed after mechanical dilatation. Stent was planned to be maintained for 1 year and subsequently removed.

Procedures in Unit B are performed under general anesthesia. The patient's larynx is exposed using a rigid laryngoscope, and endoscopy is undertaken to assess the area of tracheal stenosis. In some circumstance, a long-acting corticosteroid is injected in the submucosa surrounding the stenotic area. Furthermore, CO_2 laser (4 W in a continuous mode) excision of the scarred surface can be performed if indicated. The stenotic area is then serially dilatated with balloon (CRE™ Balloon Dilatation Catheters, Boston Scientific) sized 14 mm for females and 16 mm for males. Office based tracheoscopy controls are planned 60 days after the procedure and the intervention is repeated if signs of stenosis are detected or symptoms are reported. If needed, another dilation is performed after further 60 days.

This study was approved by Local Ethics Committee (Prot. AOU 0025966/19) and registered on clinicaltrial.gov (trial registration number: NCT04674995). Consent to publish data was acquired from participants.

2.2 | Population and measures

We collected clinical, endoscopic, and radiological data of patients with benign tracheal stenosis admitted in the two units from November 2012 to November 2017. Inclusion criteria were as follows: age >18 years, no indication for resection-anastomosis surgery, Cotton Myer ≥ grade II, available follow-up of at least 3 years after endoscopic surgery, no previous tracheal surgery. Exclusion criteria were as follows: age >80, presence of subglottic stenosis, stent intolerance which required removal in the first year after endoscopic approach, performance status >2, end-stage chronic pulmonary disease, life-threatening stenosis with urgent endoscopic treatments, any neoplastic stenosis of the airways, tracheal benign stenosis caused by excessive dynamic airway collapse (EDAC), tracheobronchomalacia (TBM).

Chart review, medical record, and archival data analysis were performed at each unit. The following variables were collected in an electronic database: demographic data, Charlson Index for comorbidity

assessment, adverse events, need for re-intervention, type, extension and etiology of tracheal stenosis, Cotton Meyer grade at the time of intervention, laser appliance, use of steroids. According to their morphological aspects, stenoses were classified into two groups: simple and complex. Simple stenosis was defined as a lesion of the tracheal wall mucosa without tracheomalacia or cartilaginous involvement, with a longitudinal luminal occlusion <1 cm. Complex tracheal stenosis was defined as tracheal stricture with longitudinal tracheal involvement >1 cm, plus various degrees of cartilage involvement, in some cases also associated with malacia.

The etiology of tracheal stenosis was defined based on rheumatologic evaluation, history of intubation/tracheostomy and airway trauma. Patients for whom a full workup was unrevealing for etiology, were categorized as having an idiopathic stenosis.

Patients included in this study were divided into two groups: (1) patients undergoing endoscopic treatment through laryngoscope followed by BA, and (2) patients undergoing endoscopic treatment through rigid bronchoscope followed by stent placement (ST).

2.3 | Outcomes

Our primary purpose was to compare the clinical efficacy of the two therapeutical techniques on tracheal stenosis over time. We considered patients to be "stabilized" (as compared to "not stabilized") if they did not report any significant respiratory symptoms, or if they need re-intervention, or presented evidence of restenosis. This last variable was assessed during an endoscopic examination 2 years after an initial time period of 12 months from the date of the procedure (Figure S1). The time period elapsed before starting the follow-up was chosen either because: (1) BA required several interventions to achieve an ideal tracheal patency in the year apart, or (2) effectiveness on tracheal patency with the maintenance of the tracheal prosthesis in ST was evaluated over the same period.

The secondary aim of the study was to compare the adverse events rate in the two treatment groups.

All patients were followed with fiberoptic bronchoscopy at 1, 3, 6, and 12 months after initial treatment. The trachea was subsequently endoscopically examined at 1, 6, 24, and 48 months from then. Restenosis was defined as the presence of any type of stenosis associated with recurrent respiratory symptoms or evidence of stenosis >1 Cotton-Myers grade with or without symptoms.

2.4 | Statistical analysis

Sample size calculation was performed assuming an estimated relapse rate of 50% for patients in the BA group[9] with an estimated 20% reduction in ST (explorative analysis in 20 patients). Assuming $\alpha = .05$, power 80% and an enrollment ratio of 1:1 (according to the overall number of patients referred at each unit), a sample size of 66 patients was calculated to perform analysis on the primary outcome.

Baseline and clinical characteristics in the BA and ST groups, and in the stabilized and not stabilized categories were compared. Continuous variables were expressed as median and interquartile ranges (IQR) and compared by Mann–Whitney test. Categorical variables were expressed as numbers and percentages (%) and compared by χ^2 test or Fisher exact test across the integrated and the standard treatment groups.

Time to relapse by groups, starting 12-month after the initial procedures, was compared using unweighted Kaplan–Meier curves and univariable and multivariable Cox regression analysis with baseline fixed covariates. The treatment effect was reported by means of unadjusted and adjusted hazard ratio (HR) with 95%CI. Two key confounders (age and Cotton Meyer grade) were identified as the most likely causes of treatment group assignment and outcome risk. To test the hypothesis that the difference between treatment groups might vary according to the etiology (idiopathic), the type (complex) and the degree of stenosis (>70% of the lumen reduction), we formally included an interaction term in the Cox regression model. Results were then showed after categorizing the population in two strata using categorical separation for dichotomous variables (idiopathic vs. non-idiopathic and complex vs. noncomplex), and the overall median value for continuous variables (% of lumen occlusion). The impact of BA or ST on prespecified secondary outcomes was carried out through Fisher exact test. A two-sided test of less than .05 was considered to be significant.

Statistics was obtained using SPSS version 25.0 (IBM Corp., New York, NY) and Graphpad prism version 8.0 (Graphpad Software, Inc., La Jolla, CA) unless otherwise indicated.

3 | RESULTS

3.1 | Population

Seven-hundred and sixteen patients diagnosed with tracheal stenosis were referred to Units A and B over the considered time period. Out of the total number, 134 (18.7%) presented benign tracheal stenosis with >50% of lumen reduction on the CT scan at the time of diagnosis. Among the 87 eligible patients, 66 were included (see Figure 1).

Table 1 shows the general and clinical characteristics (etiology, type, and extension of stenosis) of the population in study. The patients included in the BA group were younger and showed a lower prevalence of Cotton Meyer III grade stenosis than in the ST group, whereas there was no difference in terms of etiology and type of tracheal stenosis. Table 1 shows the same characteristics in the two study groups and according to the predefined outcome in the long-term. Within the BA group, the "stabilized" patients (58%) were younger (51 vs. 58 years, $p = .002$), reported more frequent simple stenosis (53% vs. 14%, $p = .03$) and a lower number of laser sessions (1 vs. 11, $p < .001$), and did not present any autoimmune etiology as compared to the "non-stabilized" ones. In the ST group, patients "stabilized" (85%) only reported a lower rate of autoimmune stenosis than in the "not stabilized" category (4% vs. 80%, $p = .001$). With regard to

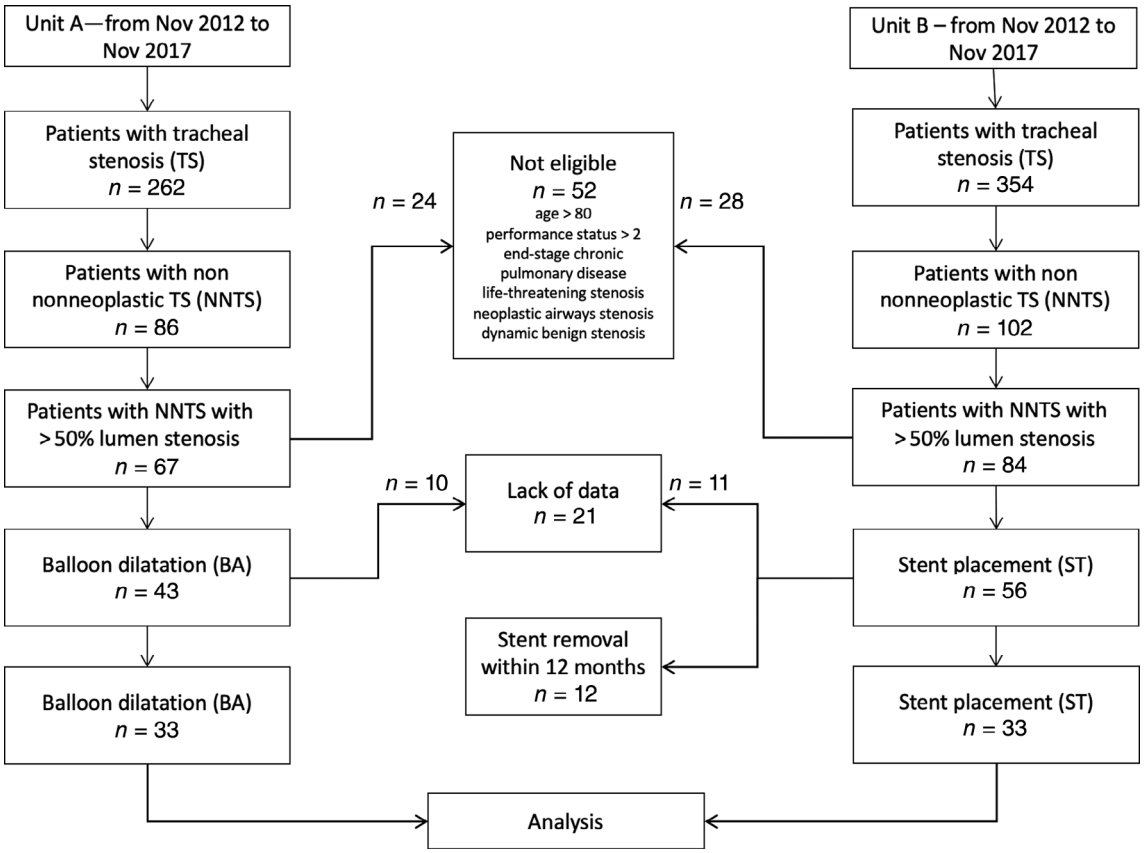

FIGURE 1 Study flowchart. Screened and enrolled patients according to study design

the complex stenosis, success rate was 71% (20/28), and 47% (9/19) in the ST and BA group, respectively ($p = .01$).

3.2 | Outcomes

On the long-term follow-up (2-year), unadjusted Kaplan–Meier estimates showed the beneficial effect of ST compared to BA on tracheal stenosis (HR = 3.9 95%CI [1.5–9.8], $p = .01$) (Figure 2A). Moreover, the same beneficial effect following ST was found when referring to the stratified analysis (Figure 2B–D) according to either etiology (idiopathic or non-idiopathic), type (complex or noncomplex), and degree of stenosis (>70% or <70%).

After controlling for the key identified confounders (see Section 2), results were almost superimposable, whereas stratified analyses showed that difference varied by etiology, type, and degree of stenosis (Table 2).

Finally, BA showed a statistically significant ($p = .01$) lower rate of adverse events (Table 3).

4 | DISCUSSION

This study shows that stent placement (ST) and subsequent removal (1 year later) has a better effect on long-term (2-year) stabilization of tracheal patency after endoscopic treatment for benign tracheal stenosis than BA technique. The different success rate between the two endoscopic treatments is significant in patients with idiopathic etiology, complex stenosis, a tracheal lumen >70%. Notwithstanding, ST is burdened with a significant rate increase of side effects compared with BA. Finally, we have shown that the use of laser in the BA group and autoimmune stenosis, are both associated with a risk of endoscopic treatment failure.

Actually, there is no definitive consensus on the endoscopic management of tracheal stenosis not eligible for surgery. Significant concerns about stent placement are patient tolerance and the risk of increasing the length of tracheal stenosis, which may complicate any future surgical approach to cure.[10] Despite this, previous studies reported that only simple web-like stenosis can be treated endoscopically using mechanical dilatation, with a success rate ranging from 60% to 95%, whereas complex stenosis with cartilaginous involvement are more likely to obtain effective stabilization of tracheal lumen by stenting.[11–14] In our study, success rate to treat simple stenosis did not show any difference between BA and ST group, thus suggesting that tracheal dilation without prosthetic implantation should be the treatment of choice with this type of stenosis. Conversely, a very high relapse rate (>90% of cases) has been reported in complex tracheal stenosis treated with BA only, therefore indicating that stent placement may be the best solution in most of these cases.[15]

TABLE 1 Demographic and clinical characteristics of the general population and on the basis of treatment

	Cohort									
	Overall				BA ($n = 33$)			ST ($n = 33$)		
Variable	Total ($n = 66$)	BA ($n = 33$)	ST ($n = 33$)	p value	Stabilized ($n = 19$)	Not stabilized ($n = 14$)	p value	Stabilized ($n = 28$)	Not stabilized ($n = 5$)	p value
Age, score (IQR)	68 (52–76)	56 (47–69)	75 (57–80)	.002	51 (45–63)	58 (55–69)	.002	75 (57–80)	73 (71–77)	n.s. (.4)
Male, *n* (%)	37 (56)	17 (52)	20 (61)	n.s. (.6)	7 (37)	10 (61)	n.s. (.1)	18 (64)	2 (40)	n.s. (.4)
Charlson index, score (IQR)	3 (1–5)	2 (1–4)	3 (1–5)	n.s. (.2)	1 (1–3)	4 (3–5)	n.s. (.2)	5 (3–6)	5.5 (5–7)	n.s (.4)
Type of stenosis										
Simple, *n* (%)	20 (30)	12 (36)	8 (24)	n.s (.4)	10 (53)	2 (14)	.03	8 (29)	0 (0)	n.s (.3)
Complex, *n* (%)	46 (70)	21 (64)	25 (76)	n.s. (.4)	9 (47)	12 (86)	.03	20 (71)	5 (100)	n.s (.3)
Degree of stenosis, % (IQR)	70 (50–80)	67 (50–79)	73 (60–85)	n.s. (.1)	64 (50–76)	70 (55–78)	n.s. (.1)	75 (55–80)	60 (50–73)	n.s. (.6)
Cotton Meyer grade										
Grade II, *n* (%)	27 (40)	18 (55)	9 (27)	.04	12 (63)	6 (43)	n.s. (.3)	8 (29)	1 (20)	n.s. (.9)
Grade III, *n* (%)	39 (60)	15 (45)	24 (73)	.04	7 (37)	8 (67)	n.s. (.3)	20 (71)	4 (80)	n.s. (.9)
Etiology										
Idiopathic, *n* (%)	31 (47)	15 (45)	16 (49)	n.s. (.8)	10 (53)	5 (36)	n.s. (.5)	15 (54)	1 (20)	n.s. (.3)
Autoimmune, *n* (%)	10 (15)	5 (15)	5 (15)	n.s. (.9)	0 (0)	5 (36)	.01	1 (4)	4 (80)	.001
Iatrogenic, *n* (%)	25 (38)	13 (39)	12 (36)	n.s. (.8)	9 (47)	4 (29)	n.s. (.3)	12 (43)	0 (0)	n.s. (.2)
Laser treatment, *n* (%)	12 (18)	12 (36)	–	–	1 (8)	11 (55)	<.001	–	–	–
Steroid treatment, *n* (%)	14 (21)	14 (42)	–	–	6 (32)	8 (57)	n.s. (.2)	–	–	–

Note: The data are presented as a numerical and percentage value for dichotomic variables and as median and interquartile ranges for continuous variables. The statistical significance was set for $p < .05$.
Abbreviations: BA, balloon dilatation; IQR, interquartile ranges; ST, tracheal stenting.

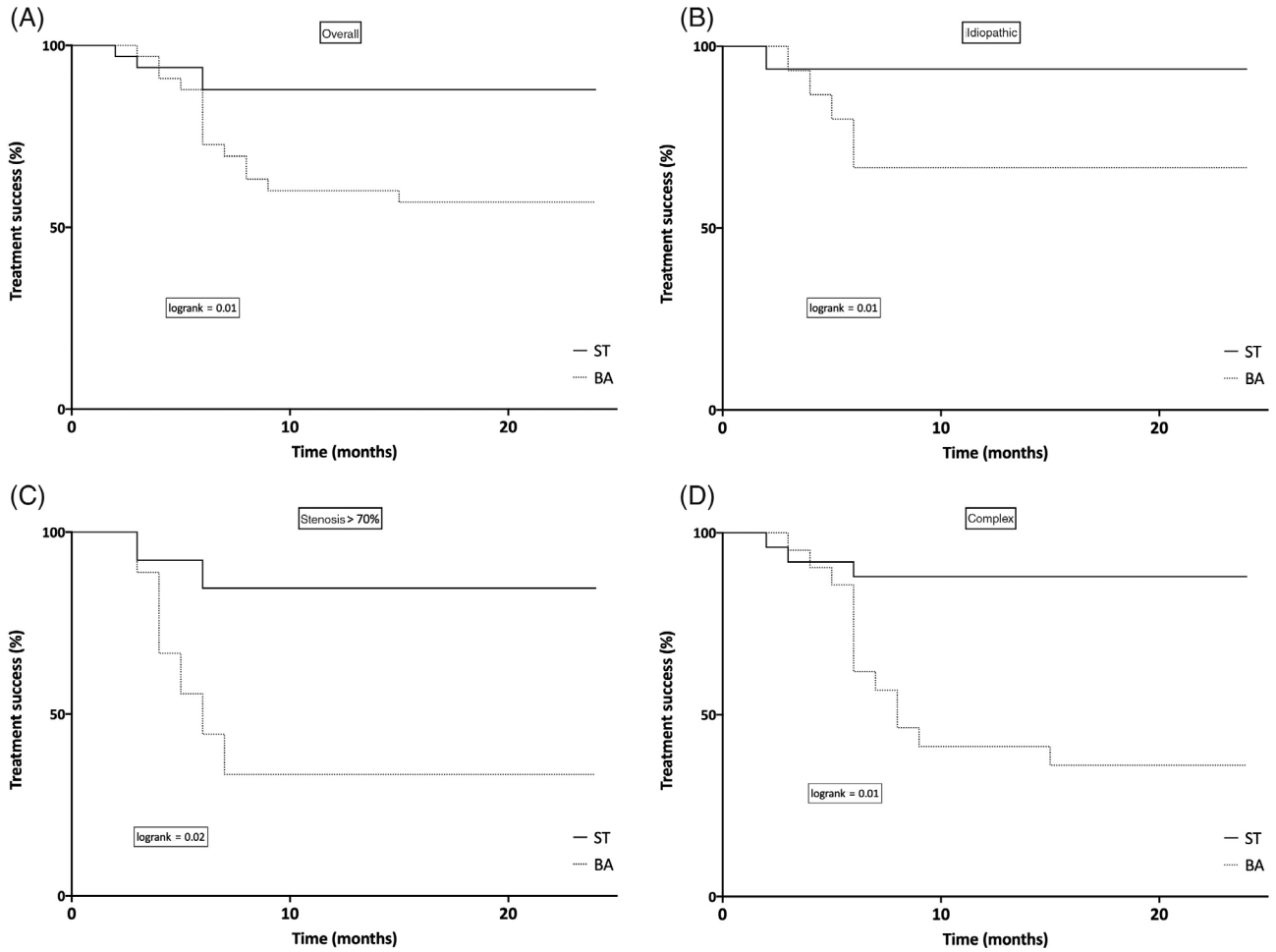

FIGURE 2 Treatment efficacy. Kaplan–Mayer curves showing treatment efficacy by groups in the long-term (2 years), in the whole population (A), in patients with idiopathic stenosis (B), in patients with complex stenosis (C), and in patients with degree of tracheal stenosis >70% (D). BA, balloon dilatation; ST, tracheal stenting

Brichet et al. reported a low success rate (17.6%) in the management of complex stenosis with stent placement, however endoprostheses were left in place for only 6 months[16] at difference with our study. More recently, Galluccio et al. treated 33 patients with complex stenosis with BA + ST and reported 69% success rate; however, mean duration of stenting (18 months) was longer.[11] A similar success rate in similar patients was also reported in the study by Dalar et al., with a mean duration of stenting time of 11.9 months.[13]

Timing of stent removal seems to be crucial for endoscopic treatment success in the long-term; indeed, a stented tracheal stenosis can progressively mature and stiffen over a longer time, thus resulting in definitive stabilization of patency. In an earlier study, tracheal stent has been removed after 18 months, and 17 out of 21 patients did not show any relapse of stenosis 259 days later.[17]

In our study, patient selection and timing of stent removal could have contributed to the high success rate in the treatment of complex stenosis in ST group. Notably, the exclusion of patients who required stent removal due to intolerance in the 12 months following endoscopic treatment certainly have influenced the study primary outcome among ST patients. However, data available in literature and clinical experience suggest that the long-term efficacy with stent placement can only be achieved when the prosthesis has remained in place for the necessary time (i.e., >1 year) to stabilize trachea.

Notwithstanding the positive results with ST strategy, adverse events were reported to be higher than with BA. Indeed, stent-related complications are the greatest concern associated with ST, and could lead to further bronchoscopic treatment. The main adverse events reported in previous studies are: mucostasis (30%–50% of cases), stent migration (5%–41%), and development of tissue granulation (19%–33%).[18–20] The incidence of adverse events in our study was lower than in previous series. It is likely that selection of patients, excluding those with severe respiratory comorbidities and low performance status, might have contributed to this result. However, two patients in ST group (6%) showed edema and tracheomalacia once the stent was removed, then required a second ST. This adverse event highlighted the importance of evaluating inflammatory state and location stenosis at the tracheal level, to prevent/avoid stent-related risk of major complications. In particular, much more attention is needed in proximal tracheal stenosis, close to the cricoid ring in the subglottic area. Indeed, the wall of the subglottic region presents with a layer of

TABLE 2 Overall and stratified treatment efficacy

	Unadjusted and adjusted relative hazards of 24 months treatment success			
	Unadjusted HR (95%CI)	*p* value	Adjusted[a] HR (95%CI)	*p* value
All cases				
Balloon dilatation	1		1	
Stent placement	3.9 (1.5–9.8)	.01	3.6 (1.2–10)	.01
Stratum etiology idiopathic				
Balloon dilatation	1		1	
Stent placement	4.6 (1.2–21)	.03	3.9 (1.1–24)	.04
Stratum etiology non idiopathic				
Balloon dilatation	1		1	
Stent placement	2.1 (0.7–6.4)	.1	1.7 (0.5–8)	.2
Stratum complex				
Balloon dilatation	1		1	
Stent placement	6 (2.3–17)	.002	4.2 (1.9–11)	.01
Stratum noncomplex				
Balloon dilatation	1		1	
Stent placement	1.2 (0.3–12)	.7	1.1 (0.2–10)	.8
Stratum stenosis >70%				
Balloon dilatation	1		1	
Stent placement	5.5 (1.3–23.7)	.01	4.4 (1.2–19.2)	.03
Stratum stenosis <70%				
Balloon dilatation	1		1	
Stent placement	3.3 (1.4–9.2)	.01	2.9 (1.2–8.6)	.02

Note: Adjusted and unadjusted hazard ratios from fitting a standard Cox regression model. Data are presented for the overall population and after stratification for etiology, type, and extension of the stenosis.
Abbreviation: HR, hazard ratio.
[a]Adjusted for age and Cotton Meyer grade.

TABLE 3 Adverse event reported in the general population and on the basis of treatment

	Cohort			
Adverse event	Total ($n = 66$)	Balloon dilatation ($n = 33$)	Stent dilatation ($n = 33$)	*p* value
Secretions, *n* (%)	4 (6)	2 (6)	2 (6)	
Granulomas formation, *n* (%)	6 (9)	2 (6)	4 (12)	
Patient intolerance, *n* (%)	4 (6)	–	4 (12)	
Stent migration, *n* (%)	1 (2)	–	1 (3)	
Stent occlusion, *n* (%)	1 (2)	–	1 (3)	
Tracheal edema/malacia, *n* (%)	2 (3)	–	2 (6)	
Total, *n* (%)	18 (27)	4 (12)	14 (42)	.01

Note: The data are presented as a numerical and percentage value. The statistical significance was set for $p < .05$.

loose subepithelial connective tissue containing a dense capillary plexus supplied by the cricothyroid branch of the superior thyroidal artery.[21] This capillary plexus is particularly enhanced in acute stenosing laryngotracheobronchitis of children (pseudocroup) and in adult local vasculitis (i.e., granulomatosis with polyangiitis), both conditions presenting with edema and airway stenosis. Stent placement in this area could result in inflammation, vessels' enlargement, and increased blood flow, which may lead to edema and obstruction. Furthermore, studies in animal models have shown that a systemic inflammatory response with increased IL-8 expression in blood may occur after stent implantation, suggesting that stent-related radial and shear stress forces of the tracheal wall could have significant influence on the systemic inflammation, especially when mucosal inflammation is endoscopically evident.[22]

Another goal of our study was to demonstrate the cause-effect relation between etiology of stenosis and the outcome of endoscopic treatment. Indeed, curability rate is significantly higher in ST group than in BA only in patients with idiopathic stenosis (Table 2). This condition is a rare fibrotic disease of unclear etiology that almost exclusively affects women, and mainly involves the subglottic area bounded inferiorly by the first two tracheal rings.[23] Autoimmune tracheal stenosis led to a lower probability to be successfully treated in both groups, suggesting that this type of lesion has a high relapse rate regardless of the endoscopic technique used, and may constitute one of the main issues in tracheal diseases. Tracheostomy as a late outcome due to treatment failure is more prevalent in autoimmune tracheal injury and in patients with tracheomalacia.[24]

Last, data resulting from the present study also showed that laser technique was less used in successfully treated patients of BA group than in ST, suggesting that in patients undergoing endoscopic dilatation the subsequent use of laser to obtain the excision of the scar area may be associated with relapse of stenosis. Lasers are often used in the treatment of pathogenic airway process, although several reports have described the occurrence of late tracheal stenosis.[25,26] In animal model, laryngotracheal laser-induced injury was due to mucosal and vascular changes which persist chronically, with an extensive reorganization of the connective tissue and the underlying cartilage.[27] Despite these observations, previous retrospective studies have not reported worse outcomes in patients undergoing endoscopic laser surgery compared to those who did not.[28] Taking as a whole the results that we observed comparing BA and ST modalities, we would suggest the following treatment approach in patients with benign tracheal stenosis without indication for open surgery.

Simple stenosis should be dilatated, and scar cutting may be performed with cold knife avoiding laser, whereas stent positioning is advisable only in case of relapses. Moreover, in patients with complex tracheal stenosis, the endoscopic therapy should be based on a multidisciplinary discussion considering the anatomical location of stenosis, the inflammatory state of the laryngeal-tracheal mucosa and the level of cartilage injury.

In patients with subglottic stenosis on the cricoid or supra-cricoid area, or with a stenosis showing signs of mucosal inflammation, dilation should be the first option for endoscopic treatment. Moreover, in complex tracheal stenosis with involvement of the sub-cricoid area (first-second tracheal ring), stent placement should be preferred first. However, ST could also be considered in case of frequent relapse after dilation.

Although present findings are intriguing, limitations to be emphasized still remain. First and most important, the retrospective design of the study and the limited sample size cannot lead us to draw a definitive conclusion. It is worth noticing that the allocation of patients to receive care by otolaryngology or interventional pulmonology was based on organizational reasons and was not related to the severity or type of stenosis. Second, enrollment criteria might have influenced the results between groups. In this line it should be noticed that patients in the ST group resulted significantly older as compared to BA. Third, for patients that had undergone stent placement, we decided to measure complications only after the first 12 months excluding those needing early stent removal for intolerance, to assess the real effectiveness of the technique that requires a sufficient amount of time to achieve tracheal stabilization. Furthermore, we have used the Myer Cotton scale to assess the grade of tracheal stenosis, although it is more suitable for subglottic stenosis. Moreover, we acknowledge that treating simple stenosis with ST might not be recommended as initial approach. However, the high rate of recurrence[13] and the need to further several re-interventions may have justified this strategy. We decided to include these cases in our retrospective analysis to generate reliable data regarding treatment success rate and adverse events between ST and BA technique also in this subset of stenosis. We believe that present study may help to open discussion in clarifying the role and the risk–benefit profile of different endoscopic therapies for benign tracheal stenosis for open surgery. Also, this may warrant future prospective studies to confirm data.

5 | CONCLUSION

This retrospective study suggests that ST placement and subsequent removal after 1 year seems to be more effective in achieving stabilization on tracheal patency in complex benign tracheal stenosis compared to BA technique. However, ST is burdened with a significantly higher number of adverse effects compared to BA, that limit widespread use of this technique. In non-operable complex stenosis, multidisciplinary evaluation with assessment of localization, inflammatory state of the mucosa and cartilage involvement of stenosis, is necessary to choose the first endoscopic approach technique with the best risk–benefit profile.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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