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ORIGINAL ARTICLE

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Stent and Resection Anastomosis in Patients with Complex Tracheal Stenosis: The Stars Retrospective Multicenter Trial

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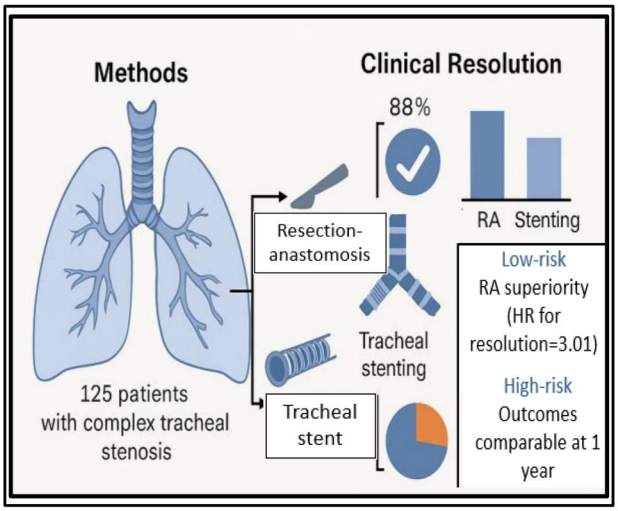
Graphical abstract

Stent and Resection Anastomosis in patients with complex tracheal Stenosis: the STARS retrospective multicenter trial

Summary

Complex tracheal stenosis poses significant treatment challenges.

This observational, international, retrospective cohort study on patients with complex benign tracheal stenoses evaluated the outcomes of two primary interventions: tracheal resection-anastomosis and tracheal stenting



Legend: RA: resection and anastomosis

Abstract

Objectives: Complex tracheal stenosis poses significant treatment challenges, especially in patients deemed inoperable due to anatomical or clinical factors. This study aimed to assess the outcomes of 2 primary interventions—tracheal resection-anastomosis and tracheal stenting—in an observational, international, retrospective cohort.

Methods: Multicenter study conducted on adult patients with benign complex tracheal stenosis who underwent either tracheal resection or silicone stent placement between 2009 and 2023, and who had at least 24 months of follow-up after resection-anastomosis or 12 months of follow-up after stent removal. Complete clinical resolution, defined as the absence of symptoms and no need for reintervention 1 year after treatment, was the primary outcome. Secondary analyses assessed the impact of treatment modality and patient risk profile on outcomes.

Results: Clinical resolution was achieved in 110 of 125 patients. Resection-anastomosis was associated with significantly higher hazard risk of resolution compared to stenting (adjusted HR = 2.0; 95% CI, 1.26-3.33; $P = .003$). In low-risk patients, surgery was notably superior (crude resolution HR = 3.01; 95% CI, 1.37-7.93, $P = .004$), while outcomes were not significantly different between the two treatments in high-risk patients with cardiorespiratory comorbidities or extended stenosis. Approximately 70% of patients treated with stenting remained symptom-free after 1 year.

Conclusions: Resection-anastomosis remains the preferred treatment for operable complex tracheal stenosis, offering the highest likelihood of long-term resolution. However, in high-risk or inoperable patients, endoscopic stenting provides a valuable alternative with acceptable outcomes. A tailored, multidisciplinary approach is essential to optimize treatment selection and avoid unnecessary tracheotomies.

Keywords: complex tracheal stenosis; tracheal resection and anastomosis; airway stenting; benign airway obstruction; multidisciplinary management; retrospective multicenter study; interventional pulmonology; otorhinolaryngology.

INTRODUCTION

Benign laryngotracheal stenosis (LTS) is a debilitating condition that can result from various etiologies, including mechanical trauma, autoimmune disorders, and infections. In some cases, no identifiable cause is found despite extensive evaluation, leading to a diagnosis of idiopathic tracheal stenosis, which predominantly affects middle-aged women.[1] Laryngotracheal stenosis is thought to result from aberrant wound-healing responses, in which dysregulated fibroblast activity and reduced sensitivity to anti-fibrotic signaling promote hypertrophic scarring and progressive airway narrowing.[2] Although the different etiologies behind LTS may have distinct immunological derangements and outcomes, the surgical procedure (ie, endoscopic vs tracheal sleeve resection) choice is based on the distinction between simple and complex tracheal stenosis (CTS). Simple tracheal web-like stenosis affects only the tracheal mucosa, and can be treated endoscopically by balloon or mechanical dilatation with a healing rate ranging from 60% to 95%.[3,4] A tracheal stenosis is defined as complex when it presents cartilage involvement or a longitudinal extension of at least 10 mm.[5,6] The endoscopic approach alone for CTS is generally unsuccessful in stabilizing the airway, and, therefore, tracheal sleeve resection is the first and definitive treatment. However, for anatomical features or comorbidities, not all patients with CTS are operable.[7] In such patients suffering from CTS, airway stent placement is more effective than balloon dilatation in achieving stabilization of tracheal patency and may be a valid treatment option in selected patients.[8]

However, there is no definitive consensus on the management of tracheal stenosis, and treatment modalities mostly depend on the experience of the different referral centers. Few studies analyzed factors associated with the complete resolution of CTS with a multidisciplinary approach, including different treatments, such as surgery and stenting.

The primary aim of this study was to evaluate the clinical success rate of two main treatments—resection and anastomosis (RA) stenting—in patients with complex tracheal stenosis. A secondary objective was to identify patient- and disease-related factors associated with long-term clinical resolution.

METHODS

Study design and setting

We conducted a retrospective, multicenter, international cohort study across six tertiary referral centers with expertise in the management of complex tracheal stenosis (CTS). Participating institutions included Otorhinolaryngology (ear, nose, and throat [ENT]) Units in Brescia, Reggio Emilia (Santa Maria Nuova Hospital), Genoa, and Modena, as well as Interventional Pulmonology (IP) Units at the University Hospital of Modena (Italy) and Amsterdam University Medical Center (The Netherlands). The study period extended from March 2009 to November 2023. The protocol was approved by the local ethics committee (Protocol AOU 0013040/19 and 276/2019/OSS/AOUMO), and the study was conducted in accordance with the Declaration of Helsinki. Collection and storage of data from included patients is consistent with requirements outlined in the WMA Declaration of Taipei.

Patients' informed consent was waived since, despite every reasonable organizational effort, it was not possible to contact the enrolled individuals, as they are either deceased or unreachable.

Study population

Eligible participants were adult patients (≥18 years) diagnosed with benign CTS, defined as 50% reduction in tracheal lumen with longitudinal extension ≥10 mm and cartilage involvement. Complex tracheal stenosis was confirmed via endoscopy and radiologic imaging. All included patients underwent either tracheal RA or silicone stent placement (Novatech SA, La Ciotat, France), kept in place for at least 1 year as their primary treatment strategy. To ensure homogeneity and minimize selection bias, we included only patients who had at least 24 months of follow-up after RA or

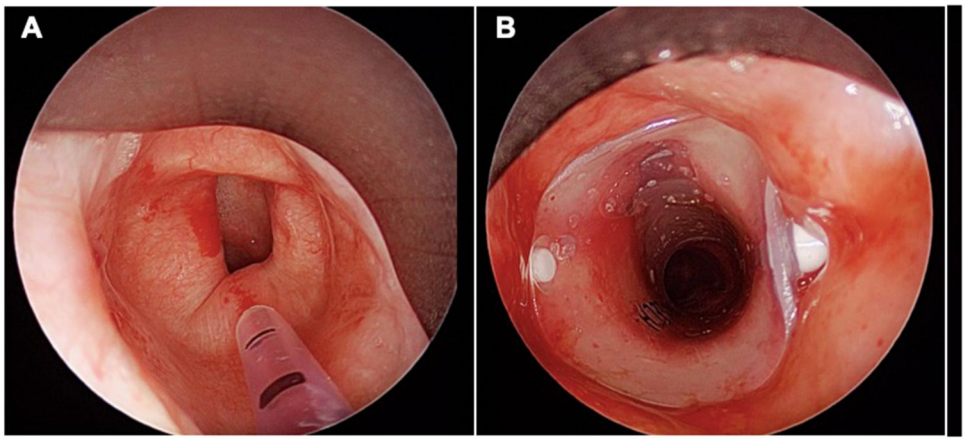


Figure 1. Complex Tracheal Stenosis Cotton-Myer 3 Before (Panel A) and After (Panel B) Silicon Stent Placement

12 months of follow-up after stent removal. Patients were excluded if they underwent emergency intervention for life-threatening airway obstruction, had incomplete or missing clinical records, or had a malignant or mixed aetiology of tracheal stenosis. Treatment allocation was not randomized but reflected institutional expertise: RA was exclusively performed in ENT units, whereas stent placement was exclusively performed in IP centers. All endoscopic procedures were performed under general anaesthesia using rigid bronchoscopy (Efer-Medical, La Ciotat, Cedex, France), and all stents were silicone devices implanted according to standard protocols (**Figure 1**).

Data collection

Clinical data were retrospectively extracted from institutional electronic health records, operative reports, and archival documentation using a standardized electronic case report form shared across participating centers to ensure consistency and minimize information bias. Collected variables included demographic characteristics (such as age, sex, and body mass index), comorbidity burden as assessed by the Charlson Comorbidity Index, and functional status according to the Eastern Cooperative Oncology Group (ECOG) performance scale. Additional clinical information encompassed the aetiology of the stenosis, history of intubation or tracheostomy, number of tracheal rings involved, and the degree of luminal obstruction as assessed endoscopically. Treatment-related variables included the modality of intervention—RA or stent placement—and, in the case of stenting, the duration of stent permanence. In the stenting group, adjunctive endoscopic procedures such as balloon dilatation and mechanical debridement were frequently employed before stent placement, based on center-specific protocols. However, due to the retrospective design, a uniform quantitative record of these interventions was not available.

Outcomes

Patient severity was pre-defined by the presence of cardiorespiratory comorbidities, with high-risk patients defined as with stenosis longer than 3 cm and/or a major cardiorespiratory condition (eg, chronic obstructive pulmonary disease [COPD], chronic heart failure). To enhance the reliability of outcome classification, clinical endpoints were independently reviewed by 2 physicians at each participating center. In case of disagreement, consensus was reached through discussion.

The classification of patients into high- and low-risk categories was based on 2 key factors: (i) a tracheal stenosis length >3 cm and/or (ii) the presence of major cardiorespiratory comorbidities (eg, chronic obstructive pulmonary disease or chronic heart failure). This stratification was chosen in light of evidence showing that resections extending beyond 4-5 cm carry a higher risk of anastomotic complications, particularly in patients with limited cardiopulmonary reserve.[9] Furthermore, major comorbidities such as COPD are well-established risk factors for adverse surgical outcomes and often influence candidacy for tracheal resection.[10]

Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics, with continuous variables expressed as medians and interquartile ranges (IQRs) and categorical variables as frequencies and percentages. Variables included in the multivariable models were selected based on their clinical relevance and theoretical plausibility. We focused on factors such as age, sex, body mass index (BMI), comorbidities, and extent of stenosis, which are known to influence treatment outcomes. In light of the study's power limitations, we prioritized the inclusion of these key variables to avoid overfitting and ensure the model remains clinically meaningful. Logistic regression models were employed to calculate odds ratios (ORs) for resolution outcomes.

To assess the association between treatment (stenting vs resection) and outcome, Cox proportional hazards regression models were fitted. Effect modification by risk group was tested by adding a treatment $\times$ risk group interaction term. Hazard ratios (HRs) with 95% confidence intervals (CIs) were reported. Survival analyses were conducted using Kaplan-Meier curves for descriptive purposes.

Given the limited number of refractory cases ($n = 15$), no additional subgroup-specific regression models were fitted. Statistical significance was set at a 2-tailed $P < .05$.

Statistical analyses were performed using SPSS version 25.0 (IBM Corp.) and Graphpad prism version 9.0 (Graphpad Software, Inc.) unless otherwise indicated.

RESULTS

Study population

The study included 125 patients with CTS, of whom 110 (88%) achieved resolution, while 15 (12%) were classified as refractory cases. Refractory cases were defined as those in which patients continued to experience symptoms or required additional interventions within the follow-up period despite the initial treatment, either RA or stenting. The median age was 56 years (IQR: 39-66.3), without a significant difference between resolved and refractory groups ($P = .28$). Body mass index was higher for refractory cases, although not statistically significant (32 vs 27 kg/m^2, $P = .33$). Males were fewer in the refractory group (40% vs 65.5%, $P = .08$). Clinical factors such as the Charlson index and ECOG performance were similar ($P = .97$ and $P = .84$, respectively).

Three patients initially treated with stenting ultimately underwent resection-anastomosis due to stent failure or recurrence.

Significant differences were observed in the number of involved tracheal rings, with refractory cases having fewer affected rings (median: 2 vs 5, $P = .001$). Treatment modalities also varied significantly, with tracheal RA being more common in resolved cases compared to refractory cases (80.9% vs 40%, $P = .002$). Conversely, stenting was more frequent in refractory cases than in resolved cases (40% vs 19.1%, $P = .002$; **Table 1**).

Baseline patients' characteristics according to high- vs low-risk groups are summarized in **Table S1**.

Factors associated with complete resolution

Univariable and multivariable analyses revealed that treatment modality was a strong predictor of clinical resolution. RA was associated with significantly higher odds of resolution compared to stenting (adjusted OR = 3.95; 95% CI, 1.11–14.8; $P = .03$, **Table 2**).

Survival and sensitivity analysis

In the Cox regression model RA treatment was independently associated with a higher hazard of complete resolution (crude HR = 2.0 95% CI, 1.26-3.33; $P = .003$, adjusted HR = 1.93. 95% CI, 1.15-2.82; $P = .006$) (**Table 3**). When a treatment × risk group interaction term was introduced, the effect of treatment differed significantly by severity strata (P for interaction = .04). Specifically, RA treatment conferred a greater benefit in the low-risk stratum (crude HR treat-low = 3.01; 95% CI, 1.37-7.93, $P = .004$, adjusted HR = 2.32; 95% CI, 1.1-8.69, $P = .01$), whereas the benefit was attenuated and non-significant in the high-risk stratum (HR treat-high = 1.6; 95% CI, 0.9-2.98, $P = 0.11$, adjusted HR = 1.21; 95% CI, 0.4-3.27, $P = 0.29$) (**Table 3**). Overall and stratum-specific Kaplan-Meier curves are presented for illustration in **Figure 2** (panels A and panels B and C, respectively).

DISCUSSION

Complex tracheal stenosis is defined by the presence of extensive scarring (>1 cm) associated with varying degrees of cartilage involvement.[11] This condition, regardless of the underlying aetiology, constitutes a challenge for its tendency to recur. Currently, tracheal RA is considered the treatment of choice in patients suffering from CTS.[12]

However, <10% of patients with tracheal stenosis are suitable for surgery, considering the high risks associated with the length of the resection, the extent of the stenosis, and patient-related factors such as comorbidities.[13] Our study shows an overall success rate of 88% considering both surgical and endoscopic techniques performed in different centers. At univariate analysis, post-intubation tracheal stenosis and RA are both favorably associated with CTS resolution, while BMI >30 and stenting are associated with unfavorable outcome. In multivariable analysis, treatment modality is independently associated with outcome.

Table 1. Demographic and Clinical Features of the Study Population According to Outcome

Variable	Total $n = 125$	Resolution $n = 110$	Refractory $n = 15$
Age, years (IQR)	56 (39–66.3)	56 (38–66)	56 (51–65.8)
BMI, kg/m^2, (IQR)	28 (24–31.4)	27 (23–30)	32 (27.8–35)
Male sex, *n* (%)	78 (62.4)	72 (65.5)	6 (40)
Charlson index, score (IQR)	2 (0–4)	2 (0–5)	1.5 (1–4)
Performance status, ECOG score, (IQR)	0 (0–1)	0 (0–1)	0 (0–0)
Previous treatment, *n* (%)	56 (44.8)	52 (47.3)	4 (26.7)
A-shape stenosis[a], *n* (%)	17 (24.6)	15 (27.3)	2 (14.3)
Tracheomalacia, *n* (%)	14 (11.2)	13 (11.8)	1 (6.7)
Tracheal rings involved, *n* (IQR)	4 (3–6)	5 (3–6)	2 (2–3)
Cartilage involvement, *n* (%)	93 (74.4)	80 (72.7)	13 (86.7)
Stenosis length			
1-2 cm, *n* (%)	81 (64.8)	70 (63.6)	11 (73.3)
≥ 3 cm, *n* (%)	44 (35.2)	40 (36.4)	4 (26.7)
Treatment			
Tracheal, resection *n* (%)	95 (76)	89 (80.9)	6 (40)
Stenting, *n* (%)	30 (24)	21 (19.1)	9 (60)

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: BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; IQR, interquartile ranges.

*$n = 69$.

Table 2. Raw and Independent Association Between Clinical Variables and Clinical Resolution of Tracheal Stenosis

Parameter	Univariable			Multivariable		
	OR	95% Confidence interval	*P* value	OR	95% Confidence interval	*P* value
Age	0.98	0.94-1.01	.28			
BMI > 30	0.25	0.08-0.79	.02			
Male, *n* (%)	0.35	0.11-1.05	.08			
Charlson index, score (IQR)	0.99	0.79-1.27	.97			
Performance status, ECOG score, (IQR)	1.08	0.57-2.54	.84			
Previous treatment, *n* (%)	2.47	0.79-9.33	.17			
A-shape stenosis, *n* (%)	2.25	0.53-15.6	.49			
Tracheomalacia, *n* (%)	1.88	0.33-35.4	.99			
Tracheal rings involved, *n* (IQR)	1.87	1.3-2.92	.002			
Cartilage involvement, *n* (%)	0.77	0.17-2.65	.35			
Stenosis length						
1-2 cm, *n* (%)	0.63	0.17-1.99	.57			
≥ 3 cm, *n* (%)	1.57	0.5-5.96	.57			
Treatment						
Tracheal resection *n* (%)	6.36	2.07-20.9	.001	3.95	1.11-14.8	.03
Stenting, *n* (%)	0.16	0.05-0.48	.001	0.25	0.07-0.89	.03

Association between clinical variables and clinical resolution of tracheal stenosis is shown through odds ratio (OR) and IQR.
Abbreviations: BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; IQR, interquartile ranges.

Table 3. Raw and Independent Association Between Treatment and Clinical Resolution of Tracheal Stenosis According to Patient Severity

	Unadjusted and adjusted relative hazard ratios for stenosis resolution			
	Unadjusted HR (95% CI)	*P* value	Adjusted[a] HR (95% CI)	*P* value
	Overall			
Stenting	1		1	
Resection	2 (1.26-3.33)	0.003	1.93 (1.15-2.82)	.006
Stratum high risk				
Stenting	1		1	
Resection	1.6 (0.9-2.98)	0.11	1.21 (0.4-3.27)	.29
	Stratum low risk			
Stenting	1		1	
Resection	3.01 (1.37-7.93)	0.004	2.32 (1.1-8.69)	.01

Association between treatment and clinical resolution of tracheal stenosis is shown through adjusted and unadjusted hazard ratio (OR) and IQR from fitting a Cox logistic regression model with interaction term (treatment × stratum).
[a]Adjustment was made for sex, age, BMI, and number of tracheal rings involved. The outcome for both strata was complete clinical resolution 1 year after treatment.
Abbreviation: HR, hazard ratio.

In particular, RA is associated with CTS resolution, while stenting is unfavorably associated with outcome. However, in the high-risk patients subgroup, surgery and stent placement show similar efficacy. The results of this study require careful analysis to understand its clinical impact and practical implications.

Multidisciplinary approach to CTS and outcome

Studies about the efficacy of a multidisciplinary approach to treat CTS are lacking. Ozdemir et al,[14] conducted a retrospective study on 42 patients affected by post-intubation tracheal stenosis, treated with surgery or endoscopically, showing that a multidisciplinary approach results in a satisfactory outcome in 90% of cases. However, this work differs from our study for several reasons. First, we enrolled only patients affected by CTS. Furthermore, we enrolled only patients treated with a stent who had at least 1 year of follow-up after its removal. Our study might then be more representative of the effectiveness of the stent in stabilizing the airway in the long term. Another noteworthy finding in our study concerns the factors associated with favourable outcomes in multidisciplinary management, such as iatrogenic post-intubation tracheal stenosis and tracheal resection. Complex post-intubation tracheal stenosis is generally associated with shorter lesions and only focal cartilage involvement; thus, these anatomical factors may have contributed to outcomes.[10] Finally, the overall success rate of RA is

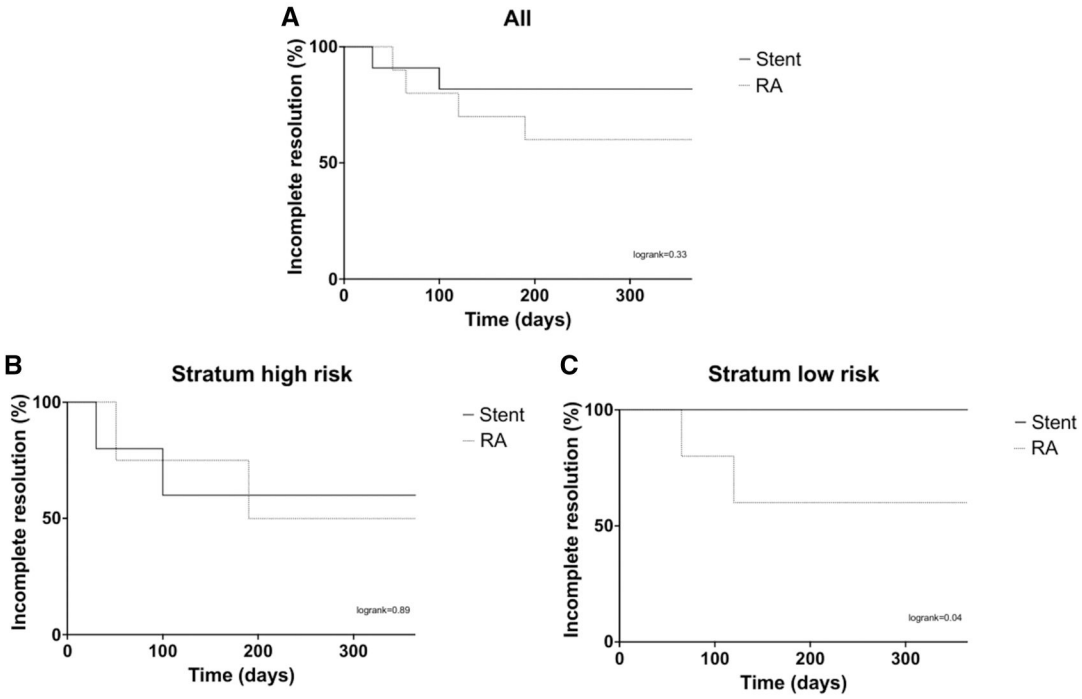


Figure 2. Kaplan-Meier Estimates Illustrates the Overall Population and Subgroups' Survival Rates

reported to be >90%. This aligns with the fact that it is one of the main factors associated with a favourable outcome.[15]

Treatments modalities and outcome in CTS

Our study confirms that tracheal RA is the treatment of choice in CTS. Univariable and multivariable analyses revealed that treatment modality was a strong predictor of clinical resolution, and tracheal resection was associated with significantly higher odds of resolution compared to stenting (adjusted OR = 3.95; 95% CI, 1.11-14.8; $P = .03$). Although refractory cases involved fewer tracheal rings, this counterintuitive finding likely reflects treatment allocation rather than anatomical complexity. In our cohort, longer stenoses were more often treated with RA—a modality linked to better outcomes—while shorter lesions were typically managed endoscopically. Thus, the association likely stems from RA's higher efficacy rather than stenosis length itself. These findings highlight the need to account for treatment modality, not just stenosis morphology, when predicting prognosis. However, not all patients are suitable for surgery and patient selection is paramount since diabetes mellitus, prior tracheostomy, stenosis location or resection extension >4-5 cm may lead to post-operative complications.[9] In inoperable patients with symptomatic CTS, endoscopic interventions with silicone stent placement may be an option to avoid definitive tracheotomy.[16] In our study, about 70% of patients treated with stenting showed a stable resolution at 1-year follow-up from removal. In a meta-analysis including retrospective, single-arm and single-center studies, silicon stent placement achieved a curative rate (defined as the number of patients who had their stent successfully removed without symptomatic relapse at 1-year follow-up) of 40.74%.[17] However, the curative rate was significantly lower when the stent was left in place <6 months compared with those kept for 6-12 months and over. These findings underline the crucial role of the appropriate timing of stent removal. In our study, all patients treated with a stent kept the prosthesis in the airways for about 1 year. Conversely, a prolonged stent dwell time may increase the risk of stent-related complications such as granulation tissue formation, migration and mucus retention.[18]

Implications in clinical practice

Consensus on which patients with CTS should be treated with stent placement or surgery is still lacking. Despite our study shows that RA achieved significantly better results compared to stenting, this advantage is lost in the high-risk population, consisting of patients with cardiorespiratory comorbidities (severe COPD or chronic heart failure) and/or stenosis length ≥3 cm (**Table 3**). These data are a novelty compared with previous studies on this subject and may suggest which subgroup of patients with CTS are suitable for stenting. These results emphasize the importance of a multidisciplinary discussion to select patient at risk for surgery but eligible for an endoscopic approach.

Study limitations

Although findings are intriguing, our study is burdened by several limitations. First, its retrospective design and the limited sample size do not allow us to draw a definitive conclusion. A key limitation is the nonrandomized treatment allocation, which reflected institutional expertise. This inherent selection bias may have influenced the observed treatment effects. We attempted to mitigate this limitation by performing multivariable logistic regression and stratified analyses, adjusting for key confounders,

including patient comorbidities and stenosis characteristics. Nonetheless, residual confounding cannot be entirely excluded.

Secondly, airway stenting in benign tracheal diseases is practiced in a few centers; thus, the results of this study may be influenced by the high level of experience in this field of the involved IP centers.

The limited number of refractory cases precluded the construction of adequately powered subgroup-specific models, and thus, the results of the multivariable analysis must be interpreted with caution.

The extended inclusion period may have introduced heterogeneity in indications and procedural experience. Besides, excluding patients with shorter follow-up may have introduced survival bias.

The exclusion of patients with missing clinical data may have introduced selection bias. However, due to the retrospective design and limited access to complete longitudinal records in some cases, multiple imputations were not feasible.

Finally, enrollment criteria might have influenced the result between groups. In particular, it is reasonable to assume that a considerable proportion of patients who received stent placement were deemed unsuitable for surgery. Therefore, based on this assumption, the analysis performed in the study may have underestimated the effectiveness of stenting in CTS treatment.

CONCLUSION

Surgical and endoscopic management of complex tracheal stenoses showed an overall clinical resolution in 88% of cases. Tracheal RA was associated with favourable outcomes in univariate and multivariate analysis, while stenting was associated with lower odds of resolution. However, in high-risk patients, endoscopy and surgery showed comparable results. Stent placement may be an option for patients with CTS burdened by significant comorbidities and judged to be at high risk for surgery by a multidisciplinary team.

AUTHOR CONTRIBUTIONS

Conceptualization: Dr A. Marchioni, Prof F. Mattioli. Data curation and analysis: Dr R. Tonelli, D. Puggioni, Dr M. Basso, Dr E. Serafini, Dr A. Moretti. Investigation: Dr L. Tabbì, Dr F. Livrieri, Dr JMA Daniels, Dr M. Filauro, Dr D. Lancini. Methodology: Dr A. Marchioni, Dr F. Mattioli. Supervision: Prof E. Clini, Prof G. Peretti, Prof. D. Marchioni, Prof C. Piazza. Writing—original draft: Dr S. Baroncini. Writing—review & editing: Dr A. Moretti, Dr A. Marchioni, and Dr R. Tonelli.

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CONFLICTS OF INTEREST

None declared.

DATA AVAILABILITY

The data underlying this article are available within the article and in its supplementary materials. Further details can be provided by the corresponding author upon reasonable request.

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