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Clinical Performance and Safety of the Metic™ Airway Balloon Catheter in Airway Interventions: A Multicentre Retrospective Study

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ABSTRACT

Background: Balloon dilation has emerged as a minimally invasive alternative to surgical reconstruction, offering restoration of airway patency with reduced procedural morbidity. This study evaluated the real-world safety and performance of the Metic™ Airway Balloon Catheter in patients undergoing endoscopic airway dilation.

Methods: This retrospective, single-arm, multicentre study included patients who underwent endoscopic airway dilation using the Metic™ Airway Balloon Catheter across three tertiary care centres in India. Clinical data were retrospectively collected from hospital medical records. Primary performance outcomes included improvement in airway stenosis and airway patency assessed using the Cotton–Myer grading system. Safety outcomes included the incidence of procedure-related adverse events (AEs), serious adverse events (SAEs), complications, recurrence, and hospital stay.

Results: A total of 144 patients with tracheal stenosis were included. The mean age was 31.47 ± 17.97 years, and 75.0% were male. The most frequently used balloon catheter size was 10 × 40 mm (41.7%). Procedure-related AEs occurred in 7 patients (4.9%), including blood-tinged sputum (2.1%), superficial laceration (2.1%), and transient cough (0.7%). No SAEs occurred, and all patients were discharged after a mean hospital stay of 3.14 ± 3.82 days. Complete follow-up was achieved in all patients through 6 months. No recurrence, post-discharge complications, or new AEs were reported during follow-up. Airway patency improved progressively, with 57.6% of patients demonstrating Cotton–Myer Grade I stenosis at 3 months and all patients (100%) achieving Grade I stenosis by 6 months.

Conclusions: Metic™ Airway Balloon Catheter was safe and effective for managing benign tracheal stenosis, providing sustained airway patency without recurrence or serious device-related complications over 6 months.

Keywords: *Airway stenosis; Tracheal stenosis; Balloon dilation; Bronchoscopy; Airway balloon catheter.*

INTRODUCTION

Airway stenosis (AS) is a condition characterized by the narrowing of the respiratory tract, affecting the supraglottic, glottic, subglottic, or tracheal regions [1]. It can arise from a variety of etiologies, including iatrogenic injury, trauma, idiopathic causes, and congenital abnormalities [2]. The management of airway stenosis includes endoscopic interventions, open surgical reconstruction, and adjunctive therapies. Endoscopic procedures are minimally invasive and offer the advantage of preserving swallowing and vocal function. However, their relatively high recurrence rates often require repeated interventions.

Consequently, open surgical reconstruction remains the gold standard for the treatment of complex or recurrent airway stenosis [3]. However, many patients are not suitable candidates for surgery because of poor general health, impaired pulmonary function, anatomical limitations, or technical challenges. Airway stent placement is another commonly used treatment option but is associated with complications such as stent migration, granulation tissue formation, and restenosis [4].

Advances in interventional pulmonology have led to the increasing use of bronchoscopic balloon dilatation as a minimally invasive treatment for benign airway stenosis [5]. Bronchoscopically or fluoroscopically guided balloon dilation is widely accepted as an initial therapeutic option because it is associated with lower morbidity and mortality than corrective surgery. The procedure restores airway patency by applying controlled radial force to uniformly expand the stenotic airway while minimizing mucosal injury and preserving airway architecture [6 7 8]. Consequently, balloon catheter technology has emerged as a safe and effective endoscopic approach for the management of benign airway stenosis. Its minimally invasive nature, favourable safety profile, and ability to facilitate faster recovery have contributed to its increasing use in appropriately selected patients [9].

The Metic™ Airway Dilation Catheter (Meril Life Sciences Pvt Ltd) is a balloon-based medical device designed for the endoscopic dilation of benign airway strictures. The catheter enables controlled radial expansion of the stenotic airway while minimizing mucosal trauma, thereby facilitating restoration of airway patency. It is available in a range of balloon diameters and lengths to accommodate both pediatric and adult patients and is intended for use during bronchoscopic airway dilation procedures [10].

Although balloon dilation has demonstrated favourable clinical outcomes in the treatment of airway stenosis, continued evaluation of device performance under routine clinical conditions is essential. These studies complement pre-market clinical evidence by assessing device performance across diverse patient populations, clinical settings, and operator experience, while also identifying uncommon or delayed adverse events (AEs). The present study is designed to evaluate the safety and clinical performance of the Metic™ Airway Balloon Catheter in patients undergoing endoscopic airway dilation as part of routine clinical practice. The study will assess procedural success, improvement in airway patency, device-related and procedure-related AEs, and other relevant clinical outcomes to further establish the safety profile and performance of the device in a real-world setting.

METHODOLOGY:

Study Design and Population

This retrospective, single-arm, multi-centre, open-label, observational study conducted across various centers in India. The study population comprised all consecutive patients who underwent endoscopic airway dilation using the Metic™ Airway Balloon Catheter as part of routine clinical practice at the participating centers during the study period and had complete medical records available for retrospective review were included in the study. The device was used to dilate airway strictures involving the trachea, subglottic region, and upper bronchi with the aim of restoring airway patency while minimizing mucosal trauma. Patients who were not treated with the Metic™ Airway Balloon Catheter or had incomplete clinical or procedural records that precluded assessment of the study endpoints were excluded.

Study endpoints

The primary endpoints were primary airway patency at 1 month, defined as the interval from the initial balloon dilation procedure to recurrence of restenosis-related symptoms without the need for repeat dilation, and procedure-related complications assessed at 1, 3, and 6 months, including mucosal laceration, airway perforation, pneumothorax, pneumomediastinum, bronchospasm, pain, and procedural discomfort. The secondary endpoints included primary airway patency at 3 and 6 months, reduction in the degree of airway stenosis, improvement in Cotton–Myer stenosis grading (Grade I: 0–50%, Grade II: 51–70%, Grade III: 71–99%, Grade IV: 100% obstruction), and AEs such as nausea, vomiting, and sore throat during the 6-month follow-up period.

Device specification

The Metic™ Airway Balloon Catheter (Meril Life Sciences Pvt. Ltd.) is a sterile, single-use, single-lumen catheter equipped with a high-pressure balloon positioned near its distal tip. The device includes a removable stylet to facilitate the advancement and accurate positioning of the catheter within the stenotic airway. The stylet must be removed prior to balloon inflation. A Luer connector at the proximal end allows for stylet insertion and the injection of sterile water to inflate the balloon to the desired pressure. The Metic™ Airway Balloon Catheter is indicated for the endoscopic dilation of airway strictures, including those involving the trachea and upper bronchi, to restore airway patency while minimizing mucosal trauma [10] (**Figure 1 & 2**).

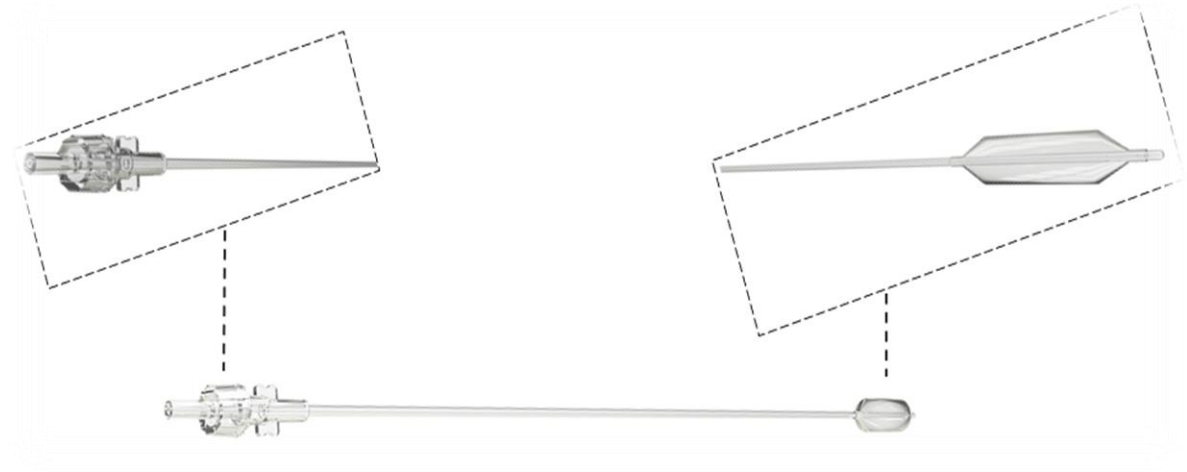

Figure 1: Schematic Illustration of the Metic™ Airway Dilation Catheter

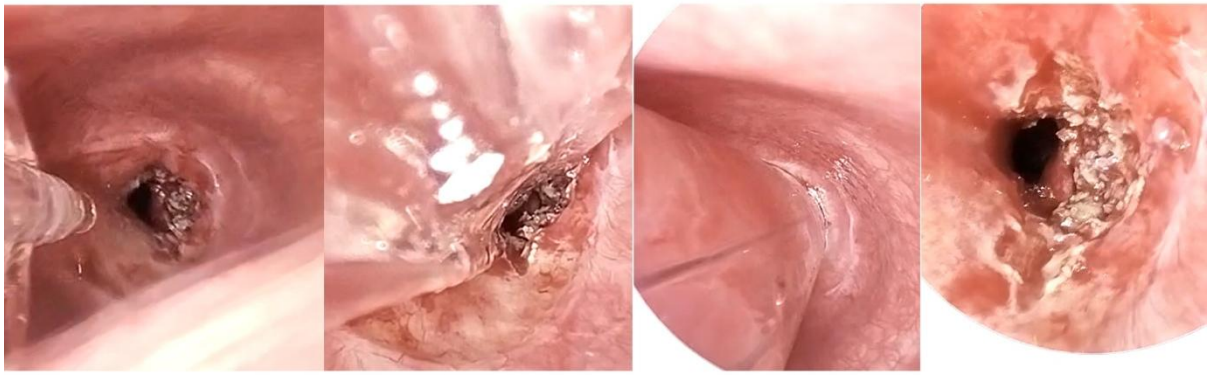

Figure 2: Endoscopic images showing tracheal stenosis before, during and after balloon dilation.

Data Collection

Clinical data were retrospectively extracted from patients' hospital medical records and documented in standardized Case Report Forms (CRFs). Data collected included baseline demographics, medical history, physical examination findings, current medications, procedural details, discharge summaries, clinical outcomes related to the primary and secondary study endpoints, and records of AEs and serious adverse events (SAEs).

Sample Size Calculation

The sample size was calculated based on a reference 6-month primary patency rate of 60% reported in a previous study [11]. Assuming a similar primary patency rate, with a two-sided significance level (α) of 0.05, 80% statistical power, and a 95% confidence interval with a half-width of 8.74%, the required sample size was estimated to be 120 patients using the Wilson score confidence interval method.

Statistical Analysis

Microsoft Excel and SPSS (version 27) were used for data entry, cleaning, and analysis. Continuous variables are presented as mean ± standard deviation (SD), and categorical variables are summarised as frequencies and percentages.

RESULTS:

Baseline Demographic and Clinical Characteristics

Of the 144 patient's majority of them were male (75.0%). The mean age was 31.47 ± 17.97 years, with nearly half of the patients (45.8%) aged 0–27 years, followed by 41.0% aged 28–54 years and 13.2% aged 55–82 years. The most frequently reported clinical history was tracheostomy stenosis (47.2%), followed by dyspnea (9.0%), airway scarring (5.6%). Baseline vital signs demonstrated a mean height of 158.61 ± 26.63 cm, weight of 57.59 ± 17.98 kg, body mass index of 22.46 ± 6.77 kg/m², heart rate of 78.35 ± 16.91 bpm, systolic blood pressure of 118.47 ± 11.54 mmHg, and diastolic blood pressure of 76.74 ± 7.56 mmHg. According to the Cotton–Myer classification, 75.0% of patients had Grade III stenosis, while 25.0% had Grade IV stenosis at baseline (**Table 1).**

Table 1. Baseline Demographic and clinical characteristics of the study population

Demographic	

Gender, n (%) Male Female	 108 (75) 36 (25)
Age (Years) Age Bifurcation, n (%) 0 – 27 28 – 54 55 – 82	**31.47 ± 17.97** 66 (45.83) 59 (40.97) 19 (13.19)
Medical History, n (%) Hypertension Diabetes Bronchial narrowing Airway scarring Dyspnea Stridor Tracheostomy stenosis Prior balloon dilations, stenting, or surgical resection bronchoscopy Other (Hyperthyroidism)	 5 (3.47) 3 (2.08) 6 (4.17) 8 (5.56) 13 (9.03) 7 (4.86) 68 (47.22) 8 (5.56) 5 (3.47) 1 (0.69)
Vital Signs, Mean ± SD Height (cm) Weight (Kg) BMI (Kg/m2) Heart Rate (bpm) Systolic BP (mmHg) Diastolic BP (mmHg)	 158.61 ± 26.63 57.59 ± 17.98 22.46 ± 6.77 78.35 ± 16.91 118.47 ± 11.54 76.74 ± 7.56
Cotton-Myer grade, n (%) Grade III: 71% to 99% Grade IV: 100%	 108 (75.00) 36 (25.00)

Procedural Characteristics and In-Hospital Outcomes

All 144 patients underwent balloon dilation for tracheal stenosis**.** The most frequently used device size was 10.00 × 40 mm (41.7%), followed by 9.00 × 24 mm and 12.00 × 40 mm (20.8% each), 14.00 × 40 mm (14.6%), 7.00 × 24 mm (1.4%), and 5.00 × 24 mm (0.7%). No pre-dilation balloon inflation pressure was applied prior to the procedure. Procedure-related AEs were reported in 7 patients (4.9%)**,** comprising blood-tinged sputum (2.1%)**,** superficial laceration (2.1%)**,** and transient cough following the procedure (0.7%)**.** No SAEs were observed during the procedure (**Table 2**).

Table 2: Procedural Characteristics and In-Hospital Outcomes (N = 144)

Variable	**Value**
Primary diagnosis/Indication, n (%) Tracheal stenosis	 144 (100.0)
Balloon catheter size, n (%) 5 × 24 mm 7 × 24 mm 9 × 24 mm 10 × 40 mm 12 × 40 mm 14 × 40 mm	 1 (0.7) 2 (1.4) 30 (20.8) 60 (41.7) 30 (20.8) 21 (14.6)
Pre-dilation balloon pressure (atm), mean ± SD	0

Procedure-related AEs, n (%) Blood-tinged sputum Superficial laceration Transient cough after procedure	7 (4.9) 3 (2.1) 3 (2.1) 1 (0.7)
Patients discharged, n (%)	144 (100.0)
Length of hospital stay (days), mean ± SD	3.14 ± 3.82

Safety and Performance Outcomes

All 144 patients (100%) completed the scheduled follow-up at 1, 3, and 6 months. At the 6-month assessment, 55.6% patients attended hospital visits, 44.4% completed follow-up through telephonic consultation. Reduction in airway stenosis was observed in all patients throughout the follow-up period, with no recurrence, complications, or new AEs reported after discharge. A total of seven (4.9%) procedure-related AEs were reported through discharge, comprising blood-tinged sputum (2.1%), superficial laceration (2.1%), and transient cough after the procedure (0.7%). All AEs were minor, and no SAEs were reported. Improvement in airway patency was reflected by the Cotton–Myer grading, with all patients initially presenting with Grade II stenosis at 1 month. By 3 months, 57.6% of patients had improved to Grade I, and by 6 months, all patients (100%) had achieved Grade I stenosis (**Figure 2**; **Table 3**).

Table 3. Safety Outcomes During Follow-up

Variable	1-Month Follow-up	3-Month Follow-up	6-Month Follow-up
Follow-up completed, n (%)	144 (100.0)	144 (100.0)	144 (100.0)
Type of follow-up, n (%) Hospital visit Telephonic follow-up	 144 (100.0) -	 144 (100.0) -	 80 (55.6) 64 (44.4)
Reduction in stenosis, n (%)	144 (100.0)	144 (100.0)	144 (100.0)
Recurrence, n (%)	0	0	0
Complications, n (%)	0	0	0
AEs since previous visit, n (%)	0	0	0
Cotton–Myer Grade, n (%) Grade I (0–50%) Grade II (51–70%)	 0 144 (100.0)	 83 (57.6) 61 (42.4)	 144 (100.0) 0
Procedure-related AEs through discharge, n (%)	7 (4.9) *	0	0
Blood-tinged sputum	3 (2.1)	–	–
Superficial laceration	3 (2.1)	–	–
Transient cough after procedure	1 (0.7)	–	–

*** same patients AE resolved on 1M FU**

DISCUSSION:

Airway dilation has become an established minimally invasive treatment for patients with laryngotracheal stenosis over the past few decades. Traditionally, dilation has been performed using rigid bronchoscopes, endotracheal tubes, and other mechanical dilators. However, these techniques may generate significant shearing forces that can injure both the stenotic segment and the adjacent healthy airway mucosa, potentially contributing to tissue trauma and restenosis. Balloon dilation offers a distinct advantage by applying controlled radial force to the stenotic segment, thereby minimizing mucosal injury while effectively restoring airway patency [12]. In the present multicentre, real-world, the Metic™ Airway Balloon Catheter demonstrated a favorable safety profile and excellent clinical performance in the management of benign tracheal stenosis.

Significant improvement in airway patency was observed throughout the follow-up period, while procedure-related complications were infrequent and limited to minor AEs. Importantly, no SAEs, recurrence, or clinically significant complications were reported during the six-month follow-up, supporting the safety and effectiveness of the device in routine clinical practice.

Balloon dilation has become an established endoscopic treatment for benign airway stenosis because it provides controlled radial expansion of the stenotic segment while minimizing mucosal trauma. Compared with open surgical reconstruction, bronchoscopic balloon dilation is associated with lower procedural morbidity, shorter hospitalization, preservation of airway anatomy, and the possibility of repeat intervention when required [13] [14]. The findings of the present study are consistent with previous reports demonstrating favourable safety profiles and effective restoration of airway patency following bronchoscopic balloon dilation.

In this study All 144 patients underwent balloon dilation for tracheal stenosis of them Only 4.9% of patients experienced procedure-related AEs, all of which were minor and self-limiting. Blood-tinged sputum, superficial mucosal laceration, and transient cough are well-recognized events following airway dilation and generally resolve with conservative management. Importantly, no procedure-related SAEs occurred, supporting the safety profile of the Metic™ Airway Balloon Catheter.

These findings are consistent with those reported by Nosair et al., 2021 who retrospectively evaluated 40 patients with tracheal stenosis and achieved an initial procedural success rate of 95% without any major complications, severe discomfort, procedure-related mortality, or significant AEs [14]. Similarly, the retrospective study by Cho et al., involving 113 patients with tuberculous tracheobronchial strictures demonstrated that bronchoscopic balloon dilation was a safe and minimally invasive treatment, achieving a technical success rate of 73% with significant improvements in pulmonary function and no major safety concerns [15]. The low incidence of minor AEs and absence of serious complications observed in the present study further corroborate the established safety of balloon dilation reported in previous studies and support the use of the Metic™ Airway Balloon Catheter as a safe and effective option for the management of airway stenosis.

In the present study we observed a progressive improvement in Cotton–Myer stenosis grades during follow-up. Although all patients had Grade II stenosis one month after treatment, more than half improved to Grade I by three months, and all patients achieved Grade I stenosis at six months without evidence of restenosis. These findings suggest durable maintenance of airway patency following balloon dilation. Similar findings were reported by Roy et al., who demonstrated significant improvement in airway patency following balloon dilation in patients with mild-to-moderate (Cotton–Myer Grade I–II) idiopathic subglottic stenosis. The consistent improvement in stenosis severity across both studies supports the effectiveness of balloon dilation in restoring and maintaining airway patency over time [16].

Overall, the present study provides real-world evidence supporting the safety and clinical effectiveness of the Metic™ Airway Balloon Catheter for the management of benign tracheal stenosis and complements existing literature on bronchoscopic balloon dilation. However, this study has a few limitations. Its retrospective, single-arm design without a control group limits direct comparison with other treatment modalities and causal inference. Additionally, the relatively short follow-up period of 6 months may not fully capture long-term treatment durability or recurrence. Further prospective, controlled studies with longer follow-up are warranted to validate these findings.

CONCLUSION:

The present study demonstrated that the Metic™ Airway Balloon Catheter is a safe and effective device for the endoscopic management of benign tracheal stenosis. Balloon dilation resulted in progressive improvement in airway patency, with all patients achieving Cotton–Myer Grade I stenosis by 6 months and no recurrence observed during follow-up. Procedure-related AEs were infrequent, mild, and self-limiting, with no SAEs reported. These findings support the use of the Metic™ Airway Balloon Catheter as a minimally invasive treatment option that provides sustained airway patency while maintaining a favorable safety profile in routine clinical practice.

Conflicts of interest

KKS is an employee of Meril Life Sciences Pvt. Ltd., Vapi, India, the manufacturer of the medical device evaluated in this study. His involvement was restricted to providing technical input regarding the device, assistance with study methodology, and editorial support during manuscript preparation. He did not participate in clinical decision-making, data collection, or analysis. All other authors declare no conflicts of interest.

Data Availability Statement

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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