Journal of Cardiothoracic and Vascular Anesthesia 36 (2022) 3008–3014

Contents lists available at ScienceDirect

Journal of Cardiothoracic and Vascular Anesthesia

journal homepage: www.jcvaonline.com

Original Article

Prospective Observational Trial of a Nonocclusive Dilatation Balloon in the Management of Tracheal Stenosis

Ross Hofmeyr, MMed(Anaes), FCA(SA), FAWM[*,1],
Jessica McGuire, MBChB, FCORL, MMed[†],
Kenneth Park, BSc, MSc[‡], Matthew Proxenos, BSc, MSc[‡],
Shazia Peer, MBChB, FCORL, MMed[§], Markus Lehmann[‡],
Darlene Lubbe, MBChB, MMed, FCORL[§]

[*]*Associate Department of Anaesthesia and Perioperative Medicine, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa*
[†]*Department of Otolaryngology, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa*
[‡]*(formerly) DISA Medinotec, Johannesburg, South Africa*
[§]*Department of Otolaryngology, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa*

Objectives: Tracheal stenosis is a debilitating condition that often presents as an emergency and is challenging to treat. Dilatation may avoid tracheostomy or costly tracheal resection and reconstruction. Traditional dilators cause complete occlusion, preventing oxygenation and ventilation, limiting the safe duration of dilatation, and increasing the risk of hypoxic injury or barotrauma. The study authors here assessed an innovative nonocclusive tracheal dilatation balloon, which may improve patient safety by allowing continuous gas exchange.
Design: A prospective observational study of 20 discrete dilatation procedures performed in 13 patients under general anesthesia. The primary outcomes were the ability to ventilate during dilatation and the preservation of peripheral oxygen saturation. Secondary outcomes included a measured reduction in stenosis, improvement in Cotton-Myer grading, and procedure-related adverse events.
Setting: At a single university (academic) hospital.
Participants: Consenting adult patients with acquired tracheal stenosis.
Interventions: Access to the airway was maintained by a rigid bronchoscope or supraglottic airway device, as deemed appropriate. Continuous conventional ventilation was provided during 3-minute balloon dilatations.
Measurements and Main Results: Heart rate, airway pressure, end-tidal carbon dioxide partial pressure, and peripheral oxygen saturation were measured, and adverse events were recorded. Ventilation was satisfactory in all patients. Peripheral saturation remained greater than 94% in 19 of the 20 (95%) procedures. Stenosis internal diameter and grading were improved. Two patients had minor reversible adverse events (coughing and laryngospasm), which did not prevent completion of the procedure.
Conclusions: The authors report the first human trial of the device, in which continuous conventional ventilation could be provided during all tracheal balloon dilatation procedures. Larger trials are needed to confirm improved patient safety and comparative efficacy.

Key Words: airway management; balloon dilatation; oxygenation; tracheal stenosis; ventilation

This work was supported by departmental funding. Study devices were provided at no cost by the manufacturer (DISA Medinotec, Cape Town, South Africa) for enrolled patients and for compassionate use in those not meeting inclusion criteria.

Preliminary findings of this work have been presented at Euroanaesthesia 2018, Copenhagen, Denmark, and in part at the World Airway Management Meeting in November 2019, Amsterdam, The Netherlands.

[1]*Address correspondence to* Ross Hofmeyr, Department of Anaesthesia and Perioperative Medicine, D23, New Main Building, Groote Schuur Hospital, Groote Schuur Drive, Observatory, Cape Town, South Africa, 7925.

E-mail address: ross.hofmeyr@uct.ac.za (R. Hofmeyr).

https://doi.org/10.1053/j.jvca.2022.02.004

Introduction

TRACHEAL STENOSIS is a debilitating condition that is difficult to treat, requires multidisciplinary management, and yet often presents with severe respiratory compromise requiring urgent intervention. Emergency tracheostomy may be lifesaving but impacts future definitive management by tracheal resection and reconstruction (TRR).[1,2] Although considered the gold standard for the management of tracheal stenosis, TRR requires a high level of resources and still is associated with a significant rate of failure and restenosis.[1-5] Dilatation can allow time for a careful assessment and informed interdisciplinary decision-making, or may be curative, circumventing TRR. The avoidance of tracheostomy also has a significant impact on the quality of life of the patient.[6]

Tracheal dilatation is performed using solid bougies, rigid bronchoscopes, or dilatation balloons.[1,7-14] Shear forces caused by bougies or rigid bronchoscopes may cause additional trauma, increasing the risk of restenosis.[15] Traditional solid or balloon dilators also cause complete occlusion, preventing ventilation and oxygenation, limiting the safe duration of dilatation, and increasing the risk of hypoxic injury or barotrauma. The study authors postulated that nonocclusive dilation might reduce the procedural risk, improve the ease and safety of dilatation, and make the procedure less fraught for the general anesthesiologistconfronted with these cases when they present as emergencies.

The 'Trachealator' airway balloon (DISA Medinotec, Johannesburg, South Africa) is designed for a single-use dilatation (Fig 1). Consisting of 6-to-8 polyamide subunit balloons, it forms a ring with an open central space when inflated (Fig 2). The resultant radial force combines dilatation with an open passage for continuous ventilation, which also should reduce the risk of barotrauma. The semi-compliant device is available in outer diameters of 6-to-18 mm, which allows pressure-to-lumen diameter correlation at up to the rated burst pressure of 12 atmospheres.[16] Effective ventilation and oxygenation during dilatation with this device previously have been described in an animal model.[17,18] This study was the first description of the use of this device in humans. The study hypothesis was that a nonocclusive balloon would allow for continuous oxygenation and ventilation during the procedure. Coprimary outcomes were the ability to ventilate during dilatation (defined as the presence of square waveform capnography) and the preservation of peripheral plethysmographic oxygen saturation (SpO_2 $\geq$90%). Secondary outcomes included an improvement in stenosis diameter (endoscopically estimated pre- and postdilatation), improvement in Cotton-Myer stenosis grading, and procedure-related adverse events.

Methods

Institutional and ethics approval were obtained from the Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town for this prospective, observational, interventional study, undertaken after written informed consent (HREC 382/2016). As a first-in-man study, the authors elected to include 20 individual balloon dilatation procedures in adult patients presenting to their multidisciplinary tracheal intervention group at a regional specialist and tertiary academic hospital in Cape Town, South Africa. The inclusion criteria included an age older than 18, symptomatic airway narrowing with endoscopic evidence of subglottic or

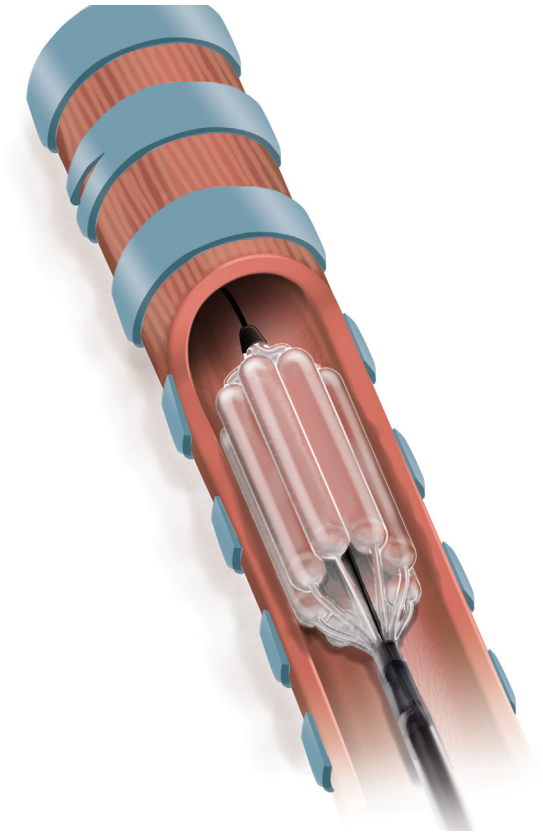

Fig 1. A diagram showing nonocclusive balloon deployed over guidewire in trachea.

Fig 2. The 18- mm Trachealator® nonocclusive airway balloon showing inflated subunit balloons creating central space for conventional ventilation.

tracheal stenosis, and the ability to give informed consent. Patients with specific contraindications to balloon dilatation or with known refractory stenosis were excluded. The trial was registered with ClinicalTrials.gov (NCT02796326).

Patients underwent general anesthesia with manual and intermittent mechanical ventilation. Initially, the anesthesia management followed the institutional regimen for patients with obstructive airway lesions undergoing rigid bronchoscopy, which included an absence of premedication, inhalation induction with sevoflurane in oxygen, and the maintenance of anesthesia with spontaneous ventilation. This frequently was supplemented with nebulized lidocaine and/or intravenous dexmedetomidine by slow infusions, after a loading dose of 1 μg/kg. However, experience with the new device led to a change in technique to total intravenous anesthesia (TIVA) by titrated target-controlled infusions of propofol and remifentanil, and endoscopically-guided dilatation through a supraglottic airway device (SAD), with manual or pressure-controlled ventilation. A high fraction of inspired oxygen was used routinely to maintain preoxygenation as a protection against inadvertent airway compromise.

Flexible endoscopic airway assessment and measurements were performed by the surgeon-anesthesiologist team. The length of the stenosis segment(s), distance from vocal cords and carina, Cotton-Myer (CM) grade,[9] and estimated narrowest internal diameter of the stenosis were recorded before each intervention. Access was maintained by a rigid bronchoscope or SAD, as deemed appropriate by the team. When using a SAD, a guidewire passed through the bronchoscope facilitated the subsequent smooth introduction of the balloon under endoscopic vision (Fig 3; Supplemental Video 1). The balloon size was selected at the discretion of the surgeon during bronchoscopy at the beginning of the case, taking into account the nature of the stenosis and the diameter of the native trachea. Continuous manually-controlled or mechanical pressure-controlled ventilation was provided during 3-minute dilatations, using the nonocclusive balloon. Typical balloon inflation pressure was 8-to-10 atmospheres, using a saline-filled inflation device with an integrated pressure gauge.

Data Processing

Data regarding patient characteristics were limited to age, sex, presenting complaint, and level and nature of the stenosis. In addition to routine anesthesia monitoring, heart rate, airway pressure, end-tidal carbon dioxide partial pressure, and peripheral oxygen saturation were measured continuously and documented at 1-minute intervals, and adverse events were recorded on a standardized case report form. Data then were transcribed into electronic format.

Statistical Analysis

Oximetry, capnography, airway pressure, and stenosis measurement data were assessed with descriptive statistics (mean and standard deviation or median and interquartile range [IQR], as appropriate), and continuous data were compared using the Wilcoxon signed rank test. Analysis was performed using MedCalc (MedCalc Statistical Software version 19.1.6, Ostend, Belgium).

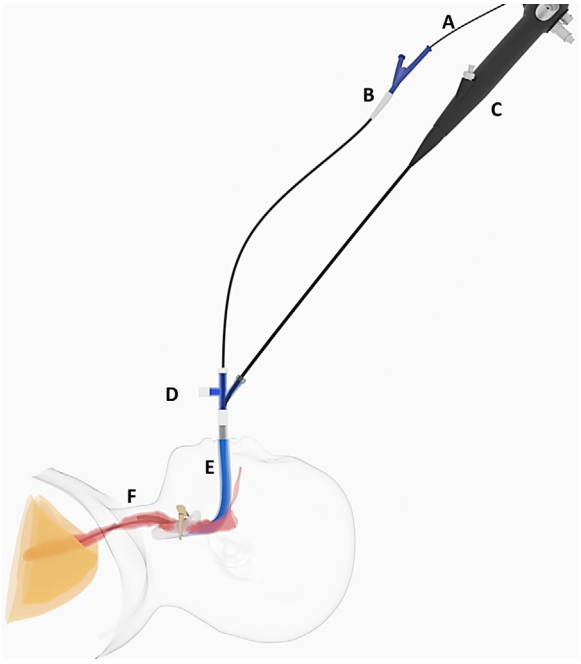

Fig 3. An overview of the endoscopic-guided technique, showing the nonocclusive balloon (B) passed over guidewire (A) being positioned within the stenosis (F) under vision through the flexible endoscope (C). Continuous conventional ventilation is provided using a multiport adaptor (D) connected to the supraglottic airway device (E).

Results

Twenty discrete dilatation procedures were performed in 13 patients from October 2016 to June 2017. The mean (standard deviation) patient age was 39 (15.2) years. Seventeen of the procedures were performed in female patients (85%). The level of the stenosis was subglottic (<20 mm below the vocal cords) in 7 of 20 (35%) patients, tracheal in 12 of 20 (60%) patients, and tracheobronchial in 1 (5%) patient. Individual data for each procedure are presented in Table 1.

Satisfactory ventilation (as determined by the presence of square waveform capnography) was achieved during balloon dilatation in all patients throughout the study. Mean (range) end-tidal PCO_2 for all patients was 4.8 (3.3-8.5) kPa. Mean (range) peak airway pressures were 19 (11-29) cmH_2O during balloon inflation. The highest instantaneous airway pressures ranged from 17-to-50 cmH_2O. In only 2 patients did this pressure exceed 36 cmH_2O (Table 1). In 1 patient, a peak airway pressure of 50 cmH_2O was recorded, which occurred during a bout of coughing during endoscopy before insertion of the balloon. There were no recorded instances of barotrauma or lung injury.

Peripheral saturation remained above 94% in 95% (19/20) of the procedures. The median saturation nadir was 99%. In 1 patient, with a background of severe respiratory disease, a saturation nadir of 82% was recorded. It should be noted that this

Table 1
Summary of Case Records.

Stenosis Level	Airway Technique	SpO_2 (%)			$EtCO_2$, kPa		Peak Airway Pressure, cmH_2O		Cotton-Myer Grade		Stenosis Diameter, mm)	
		Nadir	Median	Max	Mean	Peak	Mean	Max	Pre-	Post-	Pre-	Post-
Tr	RB	100	100	100	5.6	6.9	17	22	4	1	0	12
Tr	RB	99	100	100	6.0	8.5	23	26	1	1	12	14
SG	RB	97	98	98	3.8	6.0	13	28	1	1	6	14.5
Tr	TT	82	93	98	4.8	5.4	28	45	4	2	1	6
Tr	SL	98	99	99	4.7	7.5	15	18	2	1	6	13
Tr	ETT	99	100	100	5.0	7.7	24	36	3	1	7	12
Tr	TT	99	99	99	3.7	5.0	18	26	2	1	10	14
Tr	RB	100	100	100	3.3	3.8	29	30	3	1	5	12
TrBr	TT	100	100	100	4.9	7.5	25	50	4	2	1	6
Tr	RB	100	100	100	3.3	3.8	29	30	3	1	5	12
Tr	SAD	98	99	99	5.5	6.4	11	17	3	1	4	14
Tr	SAD	94	98	99	5.3	5.6	18	30	2	1	5	12
SG	RB	99	100	100	3.8	4.6	21	23	3	1	3	12
SG	SAD	100	100	100	4.8	5.5	18	22	3	1	4	10
SG	SAD	99	100	100	5.2	6.1	12	17	3	1	4	16
Tr	SAD	98	100	100	5.7	6.4	14	18	2	2	4	12
Tr	SAD	97	100	100	6.0	6.9	12	35	2	1	7	15
SG	SAD	100	100	100	4.5	5.0	17	22	3	1	4	10
SG	SAD	100	100	100	5.4	6.0	18	25	3	1	5	14
SG	SAD	99	100	100	4.2	5.2	16	20	2	1	7	12
Mean or median		99	100	100	4.8	6.0	19	27	3	1	5	12
SD or IQR		98-100	99-100	99-100	0.9	1.3	5.7	8.9	2-3	1-1	4-6	12-14

Abbreviations: ETT, endotracheal tube; IQR, interquartile range; RB, rigid bronchoscope; SAD, supraglottic airway device; SD, standard deviation; SG, subglottic; SL, suspension laryngoscopy; Tr, Tracheal; TrBr, tracheobronchial; TT, tracheostomy tube.

saturation was present at the commencement of the procedure because of the recent complete occlusion of 1 main bronchus, and the patient recovered well after dilatation (median SpO_2 93%, peak 98%). No other difficulties with oxygenation were experienced. (It should be noted that the time to desaturation below 90% was proposed initially as an outcome measure but was discarded when it became apparent that this did not occur.)

Surgical outcomes were satisfactory. Median (IQR) stenosis diameter increased from 5 (4-6) to 12 (12-14) mm ($p < 0.001$), and the median Cotton-Myer grade improved from 3-to-1 (representing 71%-99% to >50% stenosis). Ten (50%) patients underwent a single procedure, with the remaining patients each undergoing 2 or 3 dilatations. For patients who required >1 dilatation procedure during the study period, the median (IQR [range]) time between treatments was 31 (15-34 [13-90]) days. No patients required postoperative ventilation, nor were any new tracheostomies required.

Two patients had minor reversible adverse events (coughing and laryngospasm), which did not prevent the completion of the procedure. This occurred in the early phase of the study when dilatation was performed using rigid bronchoscopy with spontaneous ventilation. In 6 out of 20 procedures (30%), there was a minor degree of mucosal oozing and/or bleeding after dilatation, which ceased spontaneously and could be cleared by suction via the bronchoscope.

Two device-related events occurred. In 1 instance, the balloon developed a slow leak during inflation, likely due to impingement on the tip of the rigid bronchoscope. On another occasion, inflation of the balloon in tight stenosis resulted in 1 of the subunits being forced into the central lumen, which did not compromise ventilation. Neither device-related adverse event resulted in patient harm or required the abandonment of the procedure.

Discussion

Dilatation of tracheal stenosis was performed with a novel nonocclusive balloon while maintaining continuous ventilation and preservation of arterial oxygen saturation (Fig 4). Although the study was neither designed nor powered to demonstrate surgical outcomes of dilatation with the balloon, the procedures were routinely effective.

Previous studies have demonstrated the utility of dilatation for the management of tracheal stenosis.[8,10,12,19-24] Although TRR continues to be considered the gold standard therapy, this major surgery is not without complications, and the recurrence of stenosis occurs in 4%-to-25% of patients.[1-4] Balloon dilatation (with or without adjuncts such as laser or cryotherapy) requires fewer operative resources, can be performed routinely without intensive care unit admission, and is curative in 40%-to-100% of patients.[7,12,15,25] Prior work using occlusive balloons, however, has demonstrated that complications can occur, including subcutaneous emphysema, pneumomediastinum, and tracheal rupture.[26-30] More than half (51 %) of patients undergoing occlusive balloon dilatations in 1 study suffered a tracheobronchial laceration.[27] Balloons should, therefore, be sized correctly for the patient and stenosis and undergo meticulous positioning and inflation.

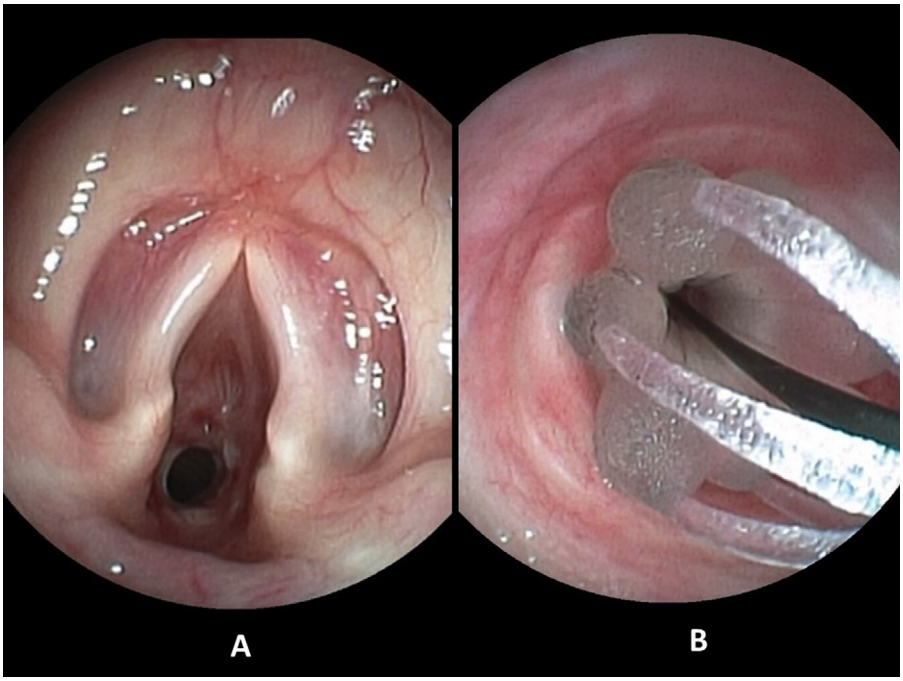

Fig 4. (A) Typical subglottic stenosis before dilatation and (B) with inflated nonocclusive balloon in situ, showing the central passage for ventilation.

Until the present time, balloon dilatation has been limited in utility and duration by the achievable safe apneic period in the individual patient.[31] This often is reduced by the underlying respiratory illness that led to the tracheal stenosis. Early cessation of dilatation due to desaturation and/or hypercarbia may reduce the efficacy of the treatment. In the authors' study, all patients' tracheas could be dilated for the 3-minute period required by the surgeon. This built upon and strengthened the findings of their earlier animal research showing the ability to continue with conventional ventilation for extended periods during nonocclusive balloon deployment.[17,18] Whether the duration of dilatation is linked to the efficacy of treatment, restenosis rate, or the requirement for repeat procedures, is unknown. However, effective ventilation and oxygenation to prevent hypocarbia and hypoxemia, and the reduction in risk of barotrauma due to the nonocclusive nature of the device, nonetheless confer an advantage that may result in an improvement in anesthesia safety.

An unexpected outcome was the shift in preferred anesthesia and airway management techniques over the study duration.[32,33] At the authors' institution, the originally favored approach to tracheal stenosis was rigid bronchoscopy performed by the otorhinolaryngology or cardiothoracic surgeon under inhalation anesthesia with spontaneous ventilation. For high and/or subglottic lesions, suspension laryngoscopy would be used, often combined with manual low-frequency supraglottic jet ventilation and intermittent apnea. (High-frequency jet ventilation is not available in South Africa). However, compassionate-use experience gained with the nonocclusive balloon treating patients not meeting the study authors' inclusion criteria (such as patients with a previous laryngectomy and tracheostomy),[34] combined with the use of an SAD for the endoscopic assessment of the airway, led to the development of the new technique (as described in the Methods and featured in Fig 3 and Supplemental Video 1).

In the context of tracheal stenosis, SADs provide easy ventilation and good airway control, simplify airway management, and avoid the problem of an absent 'landing zone' for a rigid bronchoscope or endotracheal tube when the stenosis lies close to the vocal cords. Although developed independently in the authors' institution, previous work has alluded to the utility of the technique, albeit with the use of occlusive balloons.[25] This subsequently has become the authors' standard approach.[33]

Effective and safe control of the airway with an SAD also facilitates the use of TIVA with target-controlled infusions of propofol and remifentanil. Despite initial concerns regarding apnea in patients with a threatened airway, experience gained throughout the study led to confidence that the airway is more reliably managed with a SAD and endoscopic-guided balloon dilatation than with rigid bronchoscopy. It is noteworthy that both patients who had transient adverse events (coughing and laryngospasm) were not receiving TIVA.

The authors' study was limited by the small number of patients recruited and procedures performed, the fact that assessments were unblinded, and the potential confounding factor of repeated procedures in 3 patients. In addition, there was potential bias in that the management teams were small, and only 2 centers were involved. However, this procedure is highly specialized and relies upon a keen understanding by everyone in the team of the exact details of their role. It was debated whether the study should include a total of 20 procedures (with some patients receiving repeat dilatations on separate occasions) or extend the study to include a total of 20 patients. Since the study examined the ability to ventilate and oxygenate during individual procedures, and not specifically long-term outcome, and considering the long duration between

procedures (median 31 days), the authors felt that the inclusion of patients returning for repeat dilatations did not introduce bias into the primary outcomes.

The single patient with a saturation nadir below the target of 90% was due to low baseline saturation rather than an inability to ventilate during the procedure. This patient was referred to the tracheal intervention team with multilevel stenosis (tracheal and bronchial) because of life-threatening endobronchial tuberculosis. The patient had failed weaning from ventilation on several occasions and had undergone a tracheostomy. Severe stenosis of the right main bronchus led to complete occlusion and desaturation in the intensive care unit. Because of the acute nature of the hypoxemia, the authors elected to perform a balloon dilatation despite the low starting arterial saturation of 82%. The endoscopic-guided dilatation through the tracheostomy tube was successful, with immediate improvement in saturations.

There were a limited number of device-related adverse events. The case of balloon leak did not cause harm, and the procedure could be completed. This patient had a Cotton-Myer grade-3 subglottic stenosis with an initial diameter of 3 mm. The slow leak occurred on the second dilatation with the balloon after it was repositioned. During inflation, it was noted to be expanding with partial impingement against the tip of the rigid bronchoscope. Dilatation was able to be completed by gradual adjustment of the pressure insufflator to keep the balloon inflated at a working pressure of 10 atm. The postdilatation assessment showed Cotton-Myer grade-1 stenosis with a diameter of 12 mm. In the patient in whom 1 of the subunits was forced into the central lumen, it was apparent that this did not limit ventilation, with gas flow continuing through the gaps between subunit balloons. The superstructure collapse may even prevent injury to the trachea when a stenosis is too fibrotic to dilate with a balloon. Subsequent to the authors' study, the manufacturer has modified the balloon to limit this occurrence.

An interesting observation in the authors' study was that the ability to perform dilatations in a controlled manner in patients with severe respiratory compromise led to a reduction in the requirement for tracheostomy. Indeed, no patient presenting as an emergency with tracheal stenosis during the study period underwent tracheostomy, as all were successfully dilated. This was in keeping with earlier reports of avoiding emergency tracheostomy by performing dilatation.[20] Prior tracheostomy can complicate later TRR and carries significant social implications for the patient.[1,12] Even if the initial dilatation is not curative, the avoidance of tracheostomy and allowing time to plan TRR may be of benefit. The relative cost-benefit analysis of tracheal dilatation (even if repeated procedures are required) versus resource-intensive TRR has not been studied in the African context, and should be the focus of further work. The long-term efficacy and overall safety of the nonocclusive balloon technique now is being assessed in a larger number of patients. The authors are collating cases in a registry in order to address this aim, but multicenter studies are required. Although the value of prospective observational trials has been elucidated,[35] surgical and safety outcomes with this device also ideally should be compared in a randomized controlled trial.

In conclusion, in this first clinical trial in humans using a nonocclusive balloon, the study authors were able to maintain continuous oxygenation and ventilation during dilatation for tracheal stenosis. There was a significant increase in the diameter of the stenosis after the procedure. The ability to perform endoscopic-guided dilatation through a SAD renders the procedure less invasive and improves airway control. Larger trials should be undertaken to confirm improved efficacy and patient safety.

Acknowledgments

The authors wish to acknowledge the support of the Department of Health, Western Cape Government, and Groote Schuur Hospital. They are grateful to Alexander Woulterson for the animation and computer-rendered images of the technique, and for the inputs of Prof Robert Dyer and Dr Kariem El-Boghdadly into manuscript preparation.

Conflict of Interest

KP, MP and ML were employed by the manufacturer at the time of the study and involved in development of the device. The other authors have no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1053/j.jvca.2022.02.004.

References

1 Grillo HC, Donahue DM, Mathisen DJ, et al. Postintubation tracheal stenosis. Treatment and results. J Cardiothorac Vasc Surg 1995;109:486–92;discussion 492-3.
2 Bagheri R, Majidi M, Khadivi E, et al. Outcome of surgical treatment for proximal long segment post intubation tracheal stenosis. J Cardiothorac Surg 2013;8:35.
3 Grillo HC, Mathisen DJ, Wain JC. Laryngotracheal resection and reconstruction for subglottic stenosis. Ann Thorac Surg 1992;53:54–63.
4 Auchincloss HG, Wright CD. Complications after tracheal resection and reconstruction: Prevention and treatment. J Thorac Dis 2016;8:S160–7.
5 Aydogmus U, Kis A, Ugurlu E, et al. Superior strategy in benign tracheal stenosis treatment: Surgery or endoscopy? Thorac Cardiovasc Surg 2021;69:756–63.
6 Park JH, Kim JH, Song HY, et al. Management of benign tracheal strictures caused by tracheostomy. Cardiovasc Intervent Radiol 2014;37:743–9.
7 National Inistutte for Health and Care Excellence (NICE). Interventional Procedures Guidance (IPG425): Endoscopic balloon dilatation for subglottic or tracheal stenosis. Available from: https://www.nice.org.uk/guidance/ipg425. Accessed 15 June 2021.
8 Bagwell CE, Talbert JL, Tepas JJ. Balloon dilatation of long-segment tracheal stenoses. J Pediatr Surg 1991;26:153–9.
9 Myer CM 3rd, O'Connor DM, Cotton RT. Proposed grading system for subglottic stenosis based on endotracheal tube sizes. Ann Otol Rhinol Laryngol 1994;103:319–23.
10 Noppen M, Schlesser M, Meysman M, et al. Bronchoscopic balloon dilatation in the combined management of postintubation stenosis of the trachea in adults. Chest 1997;112:1136–40.

11 Galluccio G, Lucantoni G, Battistoni P, et al. Interventional endoscopy in the management of benign tracheal stenoses: Definitive treatment at long-term follow-up. Eur J Cardiothorac Surg 2009;35:429–33;discussion 933-4.
12 Sinacori JT, Taliercio SJ, Duong E, et al. Modalities of treatment for laryngotracheal stenosis: The EVMS experience. Laryngoscope 2013;123:3131–6.
13 Guarisco JL, Yang CJ. Balloon dilation in the management of severe airway stenosis in children and adolescents. J Pediatr Surg 2013;48:1676–81.
14 Nouraei SA, Sandhu GS. Outcome of a multimodality approach to the management of idiopathic subglottic stenosis. Laryngoscope 2013;123:2474–84.
15 Glikson E, Abbass A, Carmel E, et al. Endoscopic management of benign laryngo-tracheal stenosis: Balloon vs. rigid dilatation. Isr Med Assoc J 2021;23:297–301.
16 Trachealator Airway Dilatation Balloon. 2022. Available at: https://www.disamedinotec.com/trachealator/. Accessed 5 January 2022.
17 Hofmeyr R, McGuire J, Marwick P, et al. Continuous ventilation during tracheal dilatation using a novel, non-occlusive tracheal balloon dilator in an ovine model. J Cardiothorac Vasc Anesth 2017;31:S84.
18 Hofmeyr R, McGuire J, Marwick P, et al. Assessment of continuous ventilation during tracheal dilatation using a novel, non-occlusive balloon in an ovine model. Southern Afr J Anaesth Analg 2020;26:245–9.
19 Nouraei SA, Singh A, Patel A, et al. Early endoscopic treatment of acute inflammatory airway lesions improves the outcome of postintubation airway stenosis. Laryngoscope 2006;116:1417–21.
20 Parker NP, Bandyopadhyay D, Misono S, et al. Endoscopic cold incision, balloon dilation, mitomycin C application, and steroid injection for adult laryngotracheal stenosis. Laryngoscope 2013;123:220–5.
21 Philippart AI, Long JA, Greenholz SK. Balloon dilatation of postoperative tracheal stenosis. J Pediatr Surg 1988;23:1178–9.
22 Hautmann H, Gamarra F, Pfeifer KJ, et al. Fiberoptic bronchoscopic balloon dilatation in malignant tracheobronchial disease. Chest 2001;120:43–9.
23 Nair S, Mohan S, Mandal G, et al. Tracheal stenosis: Our experience at a tertiary care centre in India with special regard to cause and management. Indian J Otolaryngol Head Neck Surg 2014;66:51–6.
24 Wright CD. Nonoperative endoscopic management of benign tracheobronchial disorders. Thorac Surg Clin 2018;28:243–7.
25 Vorasubin N, Vira D, Jamal N, et al. Airway management and endoscopic treatment of subglottic and tracheal stenosis: The laryngeal mask airway technique. Ann Otol Rhinol Laryngol 2014;123:293–8.
26 Heyes R, Cervantes SS, Matthaeus J, et al. Balloon dilation causing tracheal rupture: Endoscopic management and literature review. Laryngoscope 2016;126:2774–7.
27 Kim JH, Shin JH, Song HY, et al. Tracheobronchial laceration after balloon dilation for benign strictures: Incidence and clinical significance. Chest 2007;131:1114–7.
28 Daniel Knott P, Lorenz RR, Eliachar I, et al. Reconstruction of a tracheobronchial tree disruption with bovine pericardium. Interact Cardiovasc Thorac Surg 2004;3:554–6.
29 Strong EB, Randall DR, Cates DJ, et al. Analysis of reported balloon malfunctions and proposed rescue strategy for malfunction during airway dilation. Otolaryngol Head Neck Surg 2018;158:331–6.
30 Achkar J, Dowdal J, Fink D, et al. Balloon dilation complication during the treatment of subglottic stenosis: Background of the FDA class 1 recall for the 18 x 40-mm Acclarent Inspira AIR balloon dilation system. Ann Otol Rhinol Laryngol 2013;122:364–8.
31 Doyle DJ, Hantzakos AG. Anesthetic management of the narrowed airway. Otolaryngol Clin North Am 2019;52:1127–39.
32 Hofmeyr R, McGuire J, Park K, et al. Initial assessment and development of anaesthesia techniques for use of a novel, non-occlusive tracheal dilatation balloon allowing continuous oxygenation and ventilation (11AP05-9). Eur J Anaesthesiol 2017;34:273.
33 Hofmeyr R, Lubbe D. Innovation in endoscopic management of tracheal stenosis. Trends Anaesth Crit Care 2020;30:e165.
34 Hofmeyr R, McGuire J, Douglas-Jones P, et al. Multilevel dilatation of tracheal and bronchial stenosis using a non-occlusive tracheal dilatation balloon in a patient with sclerosing airway disease. J Cardiothorac Vasc Anesth 2017;31:S6–7.
35 Duggan LV, El-Boghdadly K. The importance of prospective observational studies in airway management: Yet only the first step. Anaesthesia 2021;76:1555–8.