

# Assessment of continuous ventilation during tracheal dilatation using a novel, non-occlusive balloon in an ovine model

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**Introduction:** Balloon dilatation is frequently used in the management of tracheal stenosis. Traditional dilatation balloons cause complete occlusion of the tracheal lumen when deployed, limiting duration of dilatation due to development of hypoxia and increasing the risk of barotrauma. We assessed a novel, non-occlusive airway dilatation balloon to determine whether it would allow continuous oxygenation and ventilation.

**Methods:** This was a prospective, descriptive, interventional trial undertaken in the animal research laboratory using a healthy ovine model. Eight anaesthetised adult Dohne Merino sheep underwent placement and inflation of the study device in the trachea via an endotracheal tube with multiport adaptor. Airway pressures, ventilatory parameters, end-tidal capnography and peripheral oxygen saturations were monitored continuously and measured before insertion, before inflation and during balloon inflation.

**Results:** All subjects could be ventilated continuously. At no time during balloon deployment and inflation was there a loss of capnograph waveform or peripheral arterial desaturation. While there was a slight trend to increased pressures and decreased tidal volumes after balloon insertion and inflation, these changes were not clinically relevant. The median (range) at each time point were tidal volume of 565 (370–780), 560 (330–830) and 550 (320–830) ml, peak airway pressure of 11(9–22), 14 (11–17) and 14 (13–17) cmH<sub>2</sub>O, and plateau pressure of 9 (7–17), 11 (9–14) and 11 (9–14) cmH<sub>2</sub>O respectively.

**Conclusion:** Continuous oxygenation and ventilation through the study device during tracheal dilatation is possible, effective and practical.

**Keywords:** tracheal stenosis, tracheal dilatation, balloon dilatation, oxygenation, ventilation

\*An early version of this work was presented in abstract form at the 2017 European Association for Cardiothoracic Anaesthesia (EACTA) meeting in Berlin, Germany.<sup>1</sup>

## Introduction

Subglottic and tracheal stenosis pose multiple challenges to both surgeons and anaesthesiologists. Although common aetiologies differ in adults and children, post-intubation or iatrogenic stenosis is universally the leading acquired cause.<sup>2-4</sup> Often presenting as an emergency due to acute respiratory distress, it is difficult and costly to treat.<sup>5,6</sup> Definitive surgical correction requires tracheal resection and reconstruction, but if patients present with severe respiratory compromise, this may be delayed or avoided with dilatation.<sup>7-9</sup> This requires rigid bronchoscopes or solid bougies of increasing diameter, or the use of dilatation balloons.<sup>10</sup> Balloon dilatation is frequently effective and lower risk than reconstruction, but may require multiple procedures.<sup>11-13</sup> Traditional balloon dilators cause complete occlusion of the trachea, which prevents ongoing oxygenation and ventilation, limits the safe duration of dilatation, and increases the risk of barotrauma.<sup>14</sup> We investigated the performance of a novel, non-occlusive tracheal dilatation balloon in anaesthetised sheep, to assess whether continuous ventilation is possible with this device.

The 'Trachealator' balloon (DISA Medinotec, Cape Town, South Africa) is a single use device designed specifically for airway dilatation (Figure 1). It is intended to overcome the limitations

of occlusive balloons (listed above). The design incorporates a constellation of six to eight identical subunits. When inflated, each cylindrical polyamide subunit balloon inflates and exerts forces on the adjacent subunits, creating a self-supporting structure with an open central channel, allowing passage of ventilation gases. A central lumen that runs the length of the device from the inflation hub to the tip allows the balloon to be passed over a guidewire, or for the passage of a laser fibre. Insufflation and/or jet ventilation through this channel is feasible but has not yet been formally studied. The device is semi-compliant to allow controlled change in diameter for each specified size, and has a rated burst pressure of 14 atm. The subunit balloons run in parallel and require a relatively small volume of fluid (usually saline or diluted contrast medium) to effect inflation and deflation. This small displacement volume (1.7 ml compared to 9.4 ml for a comparator occlusive balloon of equal 16 mm external diameter) requires only 30–50% of the inflation/deflation times of conventional balloons.<sup>15</sup> Visual and radiopaque markers allow for precise endoscopic and fluoroscopic positioning.

Balloons of 6 to 18 mm diameters are available for adult and paediatric use, for use in both tracheal and bronchial strictures. (See Table I for available sizes).



Figure 1: 'Trachealator' balloon showing tip detail (left) and illustration of inflated balloon in trachea (right)

Table 1: Trachealator balloon sizes

Balloon diameter (mm)	Balloon length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)	Usable length (mm)	Shaft diameter (mm)	Guidewire compatibility
6.0	30	6	14	650	2.3	0.018"
7.0	30	6	14	650	2.3	0.018"
8.0	30	6	14	650	2.3	0.018"
9.0	30	6	14	650	2.3	0.018"
10.0	30	6	14	650	2.3	0.018"
12.0	40	6	14	650	2.3	0.018"
14.5	40	6	14	650	3.5	0.035"
16.0	40	6	14	650	3.5	0.035"
18.0	40	6	14	650	3.5	0.035"

## Methods

With institutional and animal research ethics approval (Reference SU-AUCD16-00058, Animal Research Ethics Committee, Stellenbosch University), eight anaesthetised adult female Dohne Merino sheep were included (mean weight 55 kg, range 42–63 kg). After premedication (intramuscular ketamine 5–10 mg.kg<sup>-1</sup>) and induction of anaesthesia (intravenous thiopental sodium 5–10 mg.kg<sup>-1</sup> and pancuronium bromide 0.10–0.15 mg.kg<sup>-1</sup>), each subject was placed in a dorsal recumbent position and intubated with a 9.0 mm internal diameter endotracheal tube (ETT). Anaesthesia was maintained with isoflurane in air and oxygen (F<sub>i</sub>O<sub>2</sub> = 0.4), using volume control ventilation (V<sub>t</sub> ≈ 10 ml.kg<sup>-1</sup>, 14 to 20 breaths per minute). Analgesia was provided using intravenous fentanyl (titrated, 5–10 mcg.kg<sup>-1</sup>). Peripheral pulse oximetry, electrocardiography, airway pressures, ventilation volumes and end-tidal waveform capnography were continuously measured using a calibrated Datex-Ohmeda S5 ADU anaesthesia workstation with slaved electronic data capture unit. Circuit airway pressures were measured at the Y-connector, as per standard practice. All measurements were performed on a single day.

Using an existing commercially available multiport bronchial blocker adaptor (Cook Medical, Bloomington, Indiana), a 3.7 mm flexible fibreoptic bronchoscope and the study device were introduced through the ETT, advanced to a mid-tracheal position, and the balloon inflated. Without altering ventilator settings, tidal volume (V<sub>t</sub>), circuit peak and plateau airway pressures (P<sub>peak</sub>/P<sub>plat</sub>) were recorded with the ETT alone (pre-deployment), with the deflated balloon and bronchoscope in the trachea (pre-inflation), and with the balloon inflated (inflation). After all measurements, the balloons were deflated and removed to allow unrelated investigations for another study. On study completion, the subjects were euthanised, tracheas were excised, and macroscopically inspected for trauma.

*Statistical analysis:* Pre-deployment, pre-inflation and inflation airway pressures, ability to ventilate, presence of consistent waveform capnography, and incidence of complications of balloon deployment were assessed using simple descriptive statistics. Distribution normality was tested using the D'Agostino-Pearson test.

**Results**

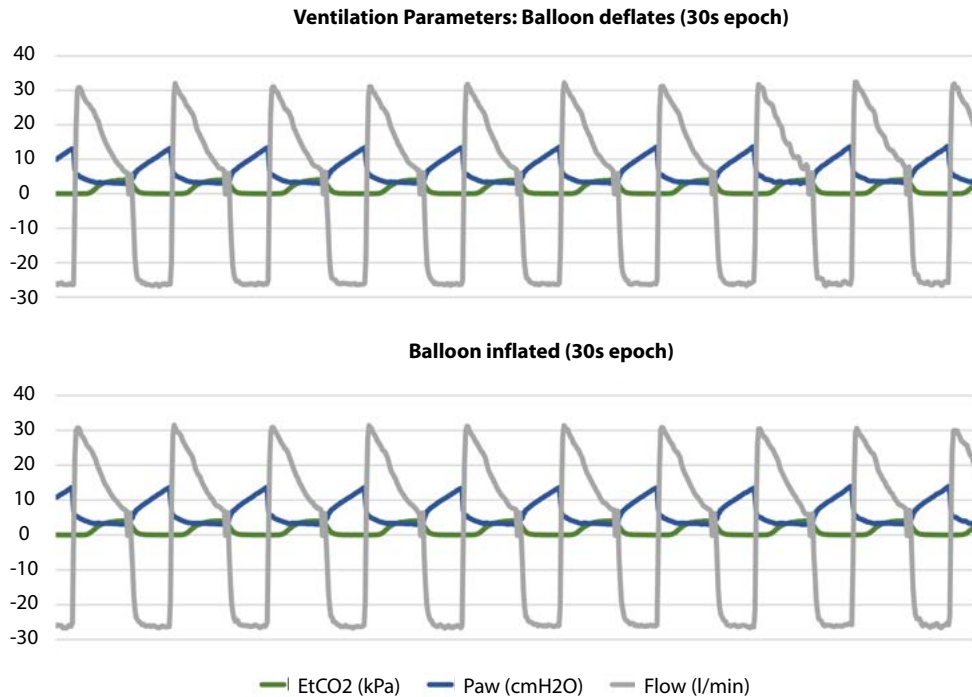
All subjects could be ventilated continuously, and at no time during balloon deployment and inflation was there a loss of capnograph waveform or peripheral arterial desaturation (Figure 2). There was a wide range of tidal volumes (320 to 870 ml), partially due to the range of body mass of the ovine subjects. While there was a slight trend to increased pressures and decreased tidal volumes after balloon insertion and inflation in keeping with extra resistance provided by the balloon, these changes were not clinically relevant (Figures 2 and 3, and Table II).

There were no incidences of technique or device failure, tracheal trauma, noteworthy changes in cardiovascular parameters, or any other complication. After euthanasia, the explanted tracheas were examined for any signs of injury. Other than some mild erythema at the sites of the tracheal tube cuff and balloon inflation, there were no changes found.

**Discussion**

Tracheal dilatation remains an important treatment modality for tracheal stenosis, and is particularly useful in resource-constrained clinical settings where resection and reconstruction is not readily available, or in patients with unfavourable anatomy or comorbidities.<sup>7,10-12</sup> Occlusive balloons and bougies limit the duration of dilatation to the period determined by effective preoxygenation, and can also obstruct the clinician’s view, making accurate placement difficult. This may then necessitate positioning with fluoroscopy, increasing the cost, complexity and duration of the procedure. Sequential dilatation with increasing sizes of rigid bronchoscopes does allow continued ventilation, but is very invasive, and adds the risk of longitudinal shear forces and additional tracheal trauma.<sup>16,17</sup>

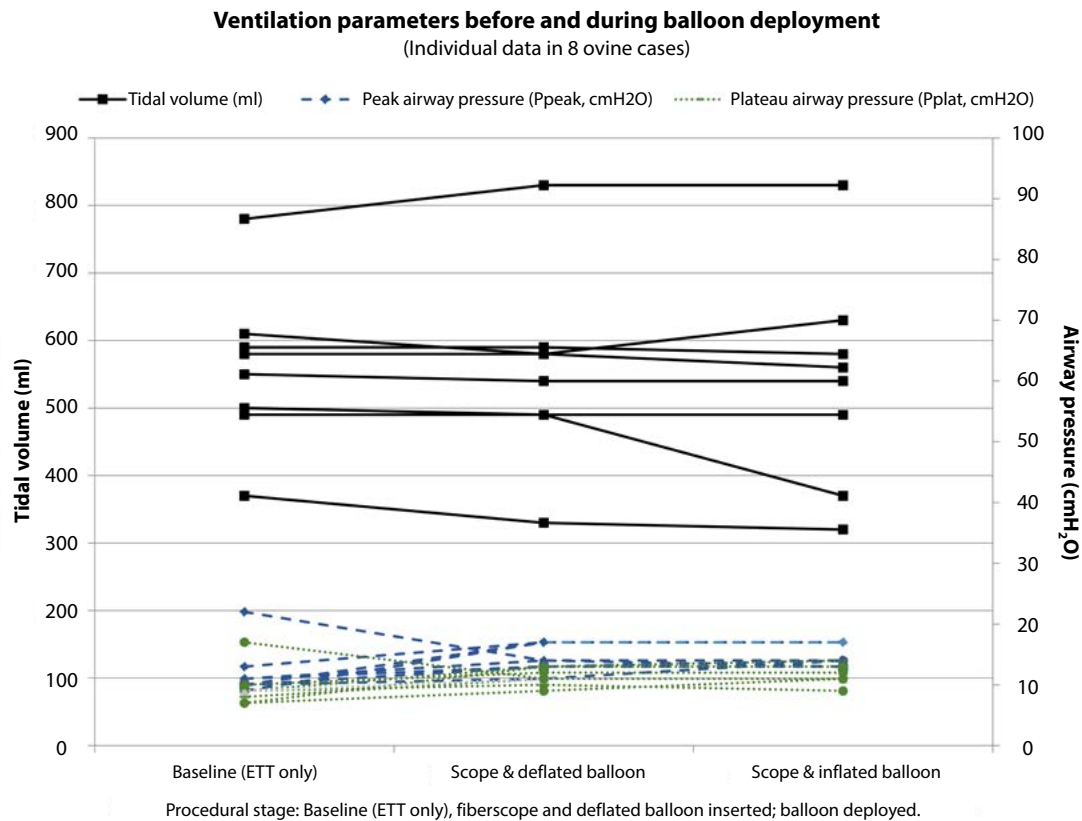
No previous reports of the use of a flow-through airway dilatation balloon in an animal model could be found in the literature.<sup>18</sup> This study demonstrates that continued oxygenation and ven-



**Figure 2:** Airway pressure, flow and end-tidal capnography waveforms for two 30-second epochs in one subject, showing identical pattern before and during balloon inflation. (EtCO<sub>2</sub> – end-tidal carbon dioxide, P<sub>aw</sub> – airway pressure)

**Table II:** Summarised ventilatory parameters before insertion of balloon, pre- and during inflation. All distributions except baseline peak and plateau airway pressures were normal\*

Parameter	Time point	Min	Max	Median (95% CI)	Mean (95% CI)	SD
Tidal volume (ml)	Baseline	370	780	565 (467 to 642)	558 (460 to 657)	118
	Pre-inflation	330	830	560 (459 to 635)	554 (436 to 670)	140
	Balloon inflated	320	830	550 (360 to 667)	540 (408 to 671)	158
Peak airway pressure (cmH <sub>2</sub> O)	Baseline*	9	22	11 (9.8 to 14.7)	12 (8.5 to 15.5)	4.2
	Pre-inflation	13	17	14 (13.0 to 17.0)	14 (13.4 to 16.4)	1.8
	Balloon inflated	11	17	14 (12.6 to 17.0)	14 (12.6 to 16.4)	2.3
Plateau airway pressure (cmH <sub>2</sub> O)	Baseline*	7	17	9 (7.0 to 11.3)	9 (6.8 to 12.2)	3.2
	Pre-inflation	9	13	11 (9.8 to 13.0)	11 (10.1 to 12.4)	1.4
	Balloon inflated	9	14	11 (10.6 to 13.2)	11 (10.2 to 12.8)	1.5



**Figure 3:** Ventilation parameters before and during balloon deployment

tilation with a non-occlusive balloon is feasible and practical. The reduced risks of hypoxia and/or hypercarbia, barotrauma and mechanical trauma are noteworthy. Furthermore, the advantages offered by endoscopic placement and guidance of the dilatation balloon through an airway device (rather than the open system of suspension laryngoscopy, or rigid bronchoscopy, or requirement for fluoroscopy) may greatly alter the risk profile and acceptability of the procedure.

The study demonstrated the ease with which both balloon and flexible endoscope could be manipulated in the airway using the combination of an endotracheal tube and multi-port adaptor. The endoscopic view was routinely excellent, and an unexpected benefit was the ability to pass the endoscope through the inflated balloon to confirm positioning.

This study had several limitations. Only a small number of procedures were performed, in ovine subjects with healthy lungs and no tracheal disease or stenosis. The use of large (8.0–9.0 mm) ETTs suitable for the sheep no doubt facilitated easy placement and may have reduced airway resistance inside the ETT due to the bronchoscope and balloon shafts. The use of a larger (23 mm external diameter) balloon to match the greater-than-human tracheal diameter of the sheep may have influenced airway resistance. Absence of a stenotic segment in which the deflated balloon may cause obstruction prior to dilatation may have led to an underrepresentation of this effect, although observation of the cases suggests that flow may immediately improve once the balloon is inflated and the stenosis has been dilated. As noted above, the wide range of body masses of the subjects

led to significant variation in the tidal volumes. Furthermore, although the *set* tidal volumes were unchanged during each case, momentary changes in resistance, compliance and/or biological variability may have influenced the *measured* volumes. Thus, interpretation of these parameters should be limited to assessment of trends. Since the study primarily aimed to determine whether ventilation and oxygenation were possible during inflation, histopathological assessment of the explanted tracheas was not performed, nor did the study design allow for assessment of tracheal changes over time.

In summary, although undertaken in healthy tracheas in an animal model, this study demonstrates that continued oxygenation and ventilation through the study device is possible, effective and practical. Further study is required to apply this non-occlusive balloon dilatation technique in tracheal stenosis and human patients.

#### Acknowledgements

The author-investigators wish to thank the staff of the University of Stellenbosch Animal Research Laboratory for their skilled and conscientious assistance with this research. An early version of this work was presented in abstract form at the 2017 European Association for Cardiothoracic Anaesthesia (EACTA) meeting in Berlin, Germany.<sup>1</sup>

#### Conflicts of interest

RH, JMcG, PM and HW have no conflicts of interest. KP, MP and ML have at some time been employed by DISA Medinotec, the manufacturer of the experimental device.

### Funding source

This study was supported by funding and materials provided by DISA Medinotec, Cape Town, South Africa.

### Ethics approval

This study was completed under institutional and Animal Research Ethics Committee approval from the University of Stellenbosch, reference SU-AUCD16-00058.

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### References

- 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. *Journal of Cardiothoracic and Vascular Anesthesia*. 2017;31:584. <https://doi.org/10.1053/j.jvca.2017.02.173>.
- Jović RM, Dragičević D, Komazec Z, et al. Laryngotracheal stenosis and restenosis. What has the influence on the final outcome? *Eur Arch Oto-Rhino-Laryngol*. 2012;269:1805-11. <https://doi.org/10.1007/s00405-012-1940-8>.
- Gelbard A, Francis DO, Sandulache VC, et al. Causes and consequences of adult laryngotracheal stenosis. *Laryngoscope*. 2015;125(5):1137-43. <https://doi.org/10.1002/lary.24956>.
- Gadkaree SK, Pandian V, Best S, et al. Laryngotracheal stenosis: risk factors for tracheostomy dependence and dilation interval. *Otolaryngol Head Neck Surg*. 2017;156(2):321-8. <https://doi.org/10.1177/0145599816675323>.
- Nair S, Mohan S, Mandal G, Nilakantan A. 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. <https://doi.org/10.1007/s12070-013-0663-5>.
- Bhatti NI, Mohyuddin A, Reaven N, et al. Cost analysis of intubation-related tracheal injury using a national database. *Otolaryngol Head Neck Surg*. 2010;143(1):31-6. <https://doi.org/10.1016%2Fj.otohns.2009.11.004>.
- 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(8):1417-21. <https://doi.org/10.1097/01.mlg.0000225377.33945.14>.
- Axon PR, Hartley C, Rothera MP. Endoscopic balloon dilatation of subglottic stenosis. *J Laryngol Otol*. 1995;109(9):876-9. <https://doi.org/10.1017/S0022215100131561>.
- Philippart AI, Long JA, Greenholz SK. Balloon dilatation of postoperative tracheal stenosis. *J Pediatr Surg*. 1988;23(12):1178-9. [https://doi.org/10.1016/S0022-3468\(88\)80337-3](https://doi.org/10.1016/S0022-3468(88)80337-3).
- Wright CD. Nonoperative Endoscopic management of benign tracheobronchial disorders. *Thorac Surg Clin*. 2018;28(2):243-7. <https://doi.org/10.1016/j.thorsurg.2018.01.009>.
- Sinacori JT, Taliercio SJ, Duong E, Benson C. Modalities of treatment for laryngotracheal stenosis: the EVMS experience. *Laryngoscope*. 2013;123(12):3131-6. <https://doi.org/10.1002/lary.24237>.
- Chhajed PN, Malouf MA, Glanville AR. Bronchoscopic dilatation in the management of benign (non-transplant) tracheobronchial stenosis. *Intern Med J*. 2001;31(9):512-6. <https://doi.org/10.1046/j.1445-5994.2001.00135.x>.
- Hebra A, Powell DD, Smith CD, Othersen HB Jr. Balloon tracheoplasty in children: results of a 15-year experience. *J Pediatr Surg*. 1991;26:957-61. [https://doi.org/10.1016/0022-3468\(91\)90843-1](https://doi.org/10.1016/0022-3468(91)90843-1).
- Achkar J, Dowdal J, Fink D, Franco R, Song P. 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. *The Annals of Otolaryngology, Rhinology, and Laryngology*. 2013;122(6):364-8. <https://doi.org/10.1177/014559981312200603>.
- Strong EB, Randall DR, Cates DJ, Belafsky PC. Analysis of reported balloon malfunctions and proposed rescue strategy for malfunction during airway dilation. *Otolaryngol Head Neck Surg*. 2018;158(2):331-6. <https://doi.org/10.1177/0145599817742356>.
- McLean GK, LeVeen RF. Shear stress in the performance of esophageal dilation: comparison of balloon dilation and bougienage. *Radiology*. 1989;172(3):983-6. <https://doi.org/10.1148/172.3.983>.
- Othersen HB Jr. Subglottic tracheal stenosis. *Semin Thorac Cardiovasc Surg*. 1994;6(4):200-5.
- Goh CS, Joethy JV, Tan BK, Wong M. Large animal models for long-segment tracheal reconstruction: a systematic review. *J Surg Res*. 2018;231:140-53. <https://doi.org/10.1016/j.jss.2018.05.025>.