The Laryngoscope

HOW I DO IT

New Treatment Strategy for Subglottic Stenosis Using the Trachealator, a Novel Non-occlusive Balloon

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INTRODUCTION

Subglottic stenosis is a severe and, when progressive, life-threatening condition. Throughout the past decennia, numerous surgical approaches for subglottic stenosis have been used but the optimal procedure is yet to be determined. The surgical approaches are generally categorized as either endoscopic or open surgical repair. The most common endoscopic strategies are dilatation (through rigid or flexible dilatators or balloon dilatation), incision (cold steel or CO_2 laser) followed by dilatation, or excision (cold steel or CO_2 laser). All these procedures may be combined with additional stenting or (local) medical therapy.[1]

Historically, for subglottic stenosis, we performed dilatation tracheoscopy using the Groningen Dilatation Tracheoscope (Karl Storz GmbH & Co, Tuttlingen, Germany).[2] During this dilatation tracheoscopy, ventilation of the airway distal to the stenosis is maintained through the tracheascope. This allows for continuous dilatation of up to 10 consecutive minutes. This longer duration of dilatation is thought to be an advantage compared to the shorter duration of dilatation which is achieved by balloon dilatation. With the conventional balloon dilatation, the airway is blocked, hence only allowing for intermitted dilatation for approximately 30–60 s each time avoiding patient hypoxemia.[3] A recent study in rabbits, showed significantly more effect after long compared to short dilatation.[4]

The main disadvantage of the Groningen Dilatation Tracheoscope is an increased risk of damage to the airway epithelium due to the exerted sheer stress. During balloon dilatation, airway epithelium only endures the acting radial forces in the balloon, which has a lower risk of causing epithelial damage.

Considering the trade-offs, it is concluded that continuous ventilation is advantageous during dilatation because this allows prolonged dilation. At the same time, a preference for balloon dilatation is argued due to the lower risk of impairing the airway epithelium.

In this case series, we describe a new endoscopic strategy combining a novel balloon with high-frequency jet ventilation to achieve both advantages.

METHODS

Between October 2020 and June 2021, seven patients with idiopathic subglottic stenosis were operated on in our institution using this new endoscopic strategy (Table S1). According to the Central Committee on Research involving Human Subjects, this new treatment strategy does not require approval from an ethics committee in the Netherlands. However, all patients gave their informed consent for the procedure.

Patients were brought under general anesthesia by total intravenous anesthesia and monitored muscle relaxation. After pre-oxygenation through mask ventilation, a modified Bouchayer laryngoscope (Carl Reiner GmbH, Vienna, Austria) was introduced. Once the clear vision of the glottis and subglottic stenosis was achieved, the supraglottic superimposed high-frequency jet ventilation (SSHFJV) was connected (TwinStream™ Multi-Mode Respirator; Carl Reiner GmbH, Vienna, Austria). The SSHFJV uses two jet streams with different frequencies simultaneously to provide adequate oxygenation and decarboxylation. With the fast stream the SSHFJV fires on a high frequency (usually 600/min but up to 1500/min) to provide oxygenation. On the slow stream,

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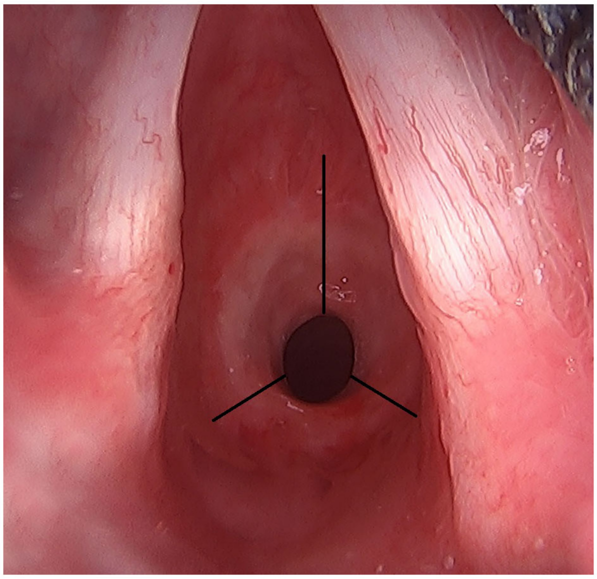


Fig. 1. Schematic representation of a so-called CO_2 laser Mercedes incision, where three radial incisions are made from superior to inferior of the stenosis, to create smooth end transitions from subglottis to trachea.

a superimposed low frequency shifts the pressure level at the tip of the laryngoscope (some 10–20 cm H_2O) up and down, typically at a frequency of 12–20/min, allowing for CO_2 elimination. Oxygenation and CO_2 are continuously measured transcutaneously.

Subsequently, the surgical microscope and CO_2 laser were adjusted and a "Mercedes" incision of the subglottic stenosis was made by CO_2 laser (Figure 1). This involves radial incisions to create smooth end transitions from subglottis to trachea. The stenosis was incised over its entire length at approximately 12.00, 4.00, and 8.00 o'clock (adjusted to the shape of the stenosis).

After the Mercedes incision, the Trachealator was introduced. The Trachealator is a novel, non-occlusive balloon dilator, designed for single-use (DISA Medinotec, Cape Town, South Africa). Depending on its diameter, it is made up of between six and eight separate compartments. When inflated, each compartment exerts a force on the two adjacent compartments, forming a self-contained construction with an open lumen allowing for ventilation and oxygenation by the SSHFJV. (Fig. 2).

The diameter of the Trachealator balloon was selected according to the expected subglottic diameter for the patient based on age and sex (Table I). Each Trachealator balloon has a rated burst pressure of 14 atmospheres regardless of the size. After inflating the Trachealator, it was held in place for 10 min in each patient, and once deflated the Trachealator was removed and the procedure was ended. Subsequently, muscle relaxation was antagonized, anesthesia stopped and the patients returned to spontaneous breathing.

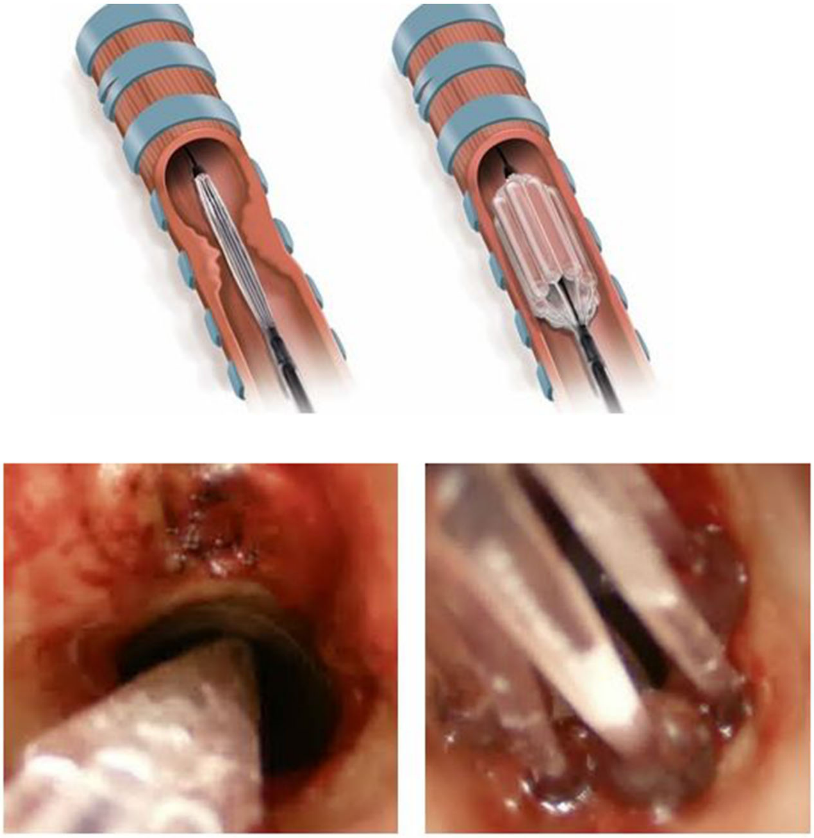


Fig. 2. (A) Schematic drawing of Trachealator Balloon. Left: deflated, during insertion. Right: inflated. (B) Left: Trachealator Balloon in the subglottic region and trachea before inflation. Right: inflated. The central lumen that can be used for ventilation and oxygenation now becomes apparent.

TABLE I.
Results of Treatment of Seven Consecutive Non-Pediatric Patients with Subglottic Stenosis, using CO_2 Laser, and Trachealator Balloon Dilator

Sex (M: male. F: female) and Age (years)	M 13	F 21	F 26	F 38	F 40	F 60	F 62
Trachealator diameter used (mm)	12	16	16	16	16	14	16
Peakflow (%*) preoperatively	27%	-	45%	53%	60%	38%	48%
Peakflow (%*) 3 months postoperatively	82%	82%	90%	85%	96%	94%	102%
Complaints 3 months postoperatively							
Dyspnea on exertion	No	Yes, however much less than preoperatively	No	No	No	No	No
Inspiration stridor	No	No	No	No	No	No	No
Globus sensation	No	No	No	No	Yes	Yes	Yes
Dysphagia	No	No	No	No	No	No	No
Dysphonia	No	No	No	No	No	No	No

Peakflow was always calculated as the mean of three subsequent measurements.
*Peakflow was expressed as a percentage of the normal range peak flow (normalized for gender, length, and age).

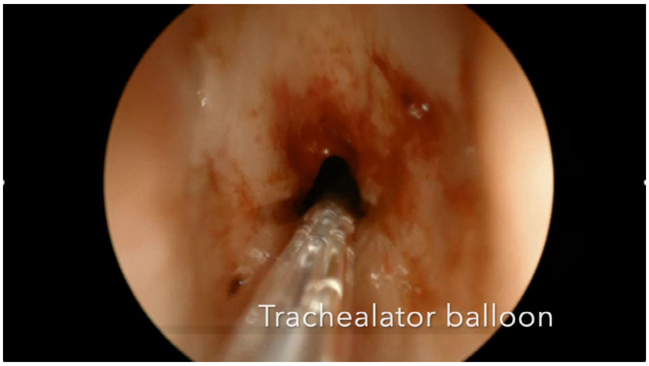
To quantify the functional level of subglottic stenosis, peak-flow levels were measured pre- and post-operation (Video S1).

RESULTS

During CO_2 laser incision and dilation with the Trachealator, all patients (13–62 years of age) were adequately ventilated and oxygenated by SSHFJV. There were no perioperative or postoperative complications. All patients were examined 2–4 weeks and 3 months after surgery.

Figure S1 shows the pre-, peri-, and post-operative images of the patients.

All patients reported less dyspnea/better breathing after surgery. Although subjective, all patients reported increased exercise tolerance. Two to four weeks after surgery 4 out of 7 patients reported glottic mucus and the need to scrape their voice. Preoperatively our patients had a peak flow that measured 45% of their normal rates (normalized for age, gender and height; Table I). Three months post-operation peak-flow levels had increased to 90% of their normal rates ($p < 0.05$).



Video 1. Tncision and dilation of subglottic stenosis: improved treatment through a combination of supraglottic jet ventilation, CO_2 laser incision, and prolonged dilatation with a the Trachealator, a novel, non-occlusive balloon.
Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lary.30234

DISCUSSION

With this case series, we report a new endoscopic strategy, in which CO_2 laser incision is combined with prolonged balloon dilatation for the treatment of subglottic stenosis. Our new endoscopic strategy was proven to be safe because it did not lead to perioperative or postoperative complications. All patients, including two pregnant women, were adequately ventilated and oxygenated by SSHFJV.

In addition to being safe, our strategy proved to be effective because all patients reported less dyspnea and better exercise tolerance up to 3 months after surgery. This was objectified by peak flow levels that increased to 90% of their normal rates 3 months postoperatively.

The management of subglottic stenosis is complex and the optimal procedure is yet to be established.

Endoscopic procedures are less invasive and therefore have less complications compared to open surgery.[1] However, endoscopic procedures have a higher recurrence rate and therefore, a higher need for re-surgeries.

Traditionally, in endoscopic dilatation of subglottic stenosis, rigid bougie laryngeal dilators were used. The next development was repeated rigid bronchoscopy using increasingly wide bronchoscopes until these were subsequently replaced by balloons.

In a recent prospective multicenter study, three surgical strategies were compared: endoscopic dilation, endoscopic resection with adjuvant medical therapy, and open surgical repair (cricotracheal resection).[1] Most patients (74%) underwent endoscopic dilatation. Of these 28% needed a re-surgical procedure within three years. A smaller group (14.9%) underwent endoscopic resection (by CO_2 laser) with adjuvant medical therapy. Of these, 12% were in need of re-surgery within the 3 years of the study period. A few patients (10.6%) who on average had been operated on their subglottic stenosis 5 times before underwent cricotracheal resection. The need for re-surgery was very small (1.2%) in that group, but cricotracheal resection had the highest perioperative risk and worst long-term voice outcomes. This study concluded that endoscopic resection (combined with adjuvant medical therapy) has a lower recurrence rate than endoscopic dilatation.

We propose that a combination of endoscopic techniques (endoscopic CO_2 laser incision with prolonged balloon dilation) will be more effective than balloon dilatation or endoscopic resection alone. An earlier retrospective study did not show the benefit of combining laser radical incisions with dilatation above balloon dilatation apart.[3] However, in this study the duration of balloon dilatation was relatively short (60–90 s). We expect that a better effect will be achieved with long dilatation based on many years of experience with 10-minute dilatation tracheoscopy using the Groningen Dilatation Tracheoscope (Karl Storz).[2] Additionally, a recent study in rabbits, showed significantly more effect after long dilatation when compared to short dilatation.[4] In current studies, however, the duration of balloon dilation in humans varies widely and further research is required to confirm the optimal time of dilatation.

Thus, the presumed benefit of balloon dilatation above rigid dilatation needs to be taken into account. Radial inflation of the balloon avoids tangential shear forces on the mucosa, theoretically reducing the risk of inflammatory and fibrosing processes. Hence, a side note to the study of Gelbard et al.[1] is required, because the endoscopic dilatation group consisted of both balloon and rigid bougie dilated patients and no distinction was made between the two.

Our described new treatment strategy requires adequate ventilation through SSHFJV. A recent study concludes that SSHFJV is physically tolerated by almost every patient and is found to be safe, even in patients with severe cardiovascular and pulmonary comorbidities.[5] We are not aware of a ventilation technique, other than SSHFJV, that would allow the use of the Trachealator balloon. However, theoretically, a very thin cannula could be placed through the balloon to provide sufficient ventilation and oxygenation. Besides using the Trachealator in adults, we have experience in using the Trachealator in infants with an acute, membranous subglottic stenosis. These infants were breathing spontaneously and cold steel was used for the radial incisions of the stenosis.

Our study is limited by the relatively small group size used for our case series. This is partly due to the low incidence of subglottic stenosis (1/400.000 persons per year) and the limited timeframe in which the patients were included. Additionally, because all included patients have been treated over the last year, longer-term results of the treatment must still be taken into consideration to make a comparison between the new strategy and conventional treatments.

To conclude, with this case series we show that CO_2 laser incision combined with Trachealator balloon dilation and SSHFJV seems to be an effective and safe treatment combination for patients with subglottic stenosis when looking at short term effects. It offers theoretical and practical advantages over conventional methods. Future studies must be conducted to compare the long-term outcomes of this new strategy with traditional strategies.

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