NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endoscopic balloon dilation for subglottic or tracheal stenosis

Subglottic and tracheal stenosis is a narrowing of the airway between the throat and the lungs, which can cause difficulty breathing. This can occur after you have had a tube in your airway to help you breathe, after surgery to the airway or you can be born with it. This procedure is mostly done in young children, although it is also done in adults. Under general anaesthesia, a camera attached to a long rod (endoscope) is used to guide the balloon into the narrowed airway. A thin flexible tube (catheter) with a small balloon is inserted down the throat into the airway. The balloon is then inflated for a short time, deflated, then removed. The aim is to widen the airway and improve symptoms.

Contents

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Abbreviations

Word or phrase	Abbreviation
Airway Intervention Registry	AIR
Balloon dilation	BD
Body mass index	BMI
Confidence interval	CI
Controlled Radial Expansion	CRE
Endoscopic balloon dilation	EBD
Food and Drug Administration	FDA
Grade, roughness, breathiness, asthenia, strain	GRBAS
Hospital Episode Statistics	HES
Intensive care unit	ICU
Laryngotracheoplasty	LTP
Manufacturer and User Facility Device Experience	MAUDE
Multilevel stenosis	MLS
Odds ratio	OR
Preferred Reporting Items for Systematic reviews and Meta-Analyses	PRISMA
Subglottic stenosis	SGS
Tracheal stenosis	TS
Quality of life	QoL
Voice-Related Quality of Life	V-RQOL

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in May 2021.

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Procedure name

- Endoscopic balloon dilation for subglottic or tracheal stenosis

Professional societies

- Difficult Airway Society
- British Association of Paediatric Otolaryngology
- British Association of Otorhinolaryngology – Head and Neck
- British Paediatric Respiratory Society
- British Laryngology Association
- Association of Paediatric Anaesthetists of Great Britain and Ireland
- Royal College of Anaesthetists

Description of the procedure

Indications and current treatment

Subglottic or tracheal stenosis is a narrowing of the airway that can be congenital, traumatic or, most commonly, iatrogenic after prolonged endotracheal intubation. Symptoms include hoarseness, stridor, exercise intolerance and respiratory distress. In severe cases complete obstruction may occur, requiring continued intubation or tracheostomy.

Treatment options include inhaled or oral steroids to treat inflammation and reduce the severity of stenosis. A cricoid-split operation can decompress the subglottis and prevent development of stenosis in neonates. For people with severe and established stenosis, endoscopic techniques such as stent insertion or laser ablation are used. Alternatively, open surgical repair is performed to either increase the diameter of the stenosed segment with a graft or stent (expansion surgery) or to remove the stenotic area (resection surgery).

What the procedure involves

The aim of endoscopic balloon dilation is to dilate airway strictures with minimal mucosal trauma by applying pressure to an area of stenosis. The procedure is most commonly performed on iatrogenic stenosis as the stenosis is typically soft, and is less commonly performed on harder, established stenosis.

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The procedure is usually done under general anaesthesia and using direct laryngoscopic or bronchoscopic visualisation. A balloon device is introduced into the airway and the balloon is gently inflated, applying radial pressure circumferentially to the stricture. After dilation, the balloon is deflated, and the device withdrawn. The procedure may be used in combination with other treatments. The procedure can be repeated if required. The aim of the procedure is to widen the stenotic airway and thereby improve symptoms.

Outcome measures

Cotton-Myer grading system

The Cotton-Myer grading system is used for classifying the severity of subglottic stenosis, as follows:

- Grade 1 – up to 50% airway obstruction
- Grade 2 – from 51% to 70% airway obstruction
- Grade 3 – above 70% airway obstruction with any detectable lumen
- Grade 4 – an airway with no lumen.

V-RQOL

The V-RQOL is a validated, disease-specific, self-administered 10-item QoL instrument for adults. It allows patients to rate their own self-perceived voice quality. It measures social-emotional and physical-functional aspects of voice problems. It is scored on a 0 to 100 scale, with higher scores indicating better QoL.

Efficacy summary

Avoidance of invasive surgery

An analysis of the Airway Intervention Registry (AIR) of 52 paediatric patients with glottic, subglottic, or tracheal stenosis receiving balloon dilation as primary treatment reported that 65% (34/52) avoided further surgery over a median follow-up period of 869 days per patient. In the presence of a tracheostomy, 22% (4/18) avoided further surgery and with no tracheostomy, 88% (30/34) avoided further surgery. In 7 patients who had balloon dilation as an adjunctive treatment after open reconstructive surgery, avoidance of further surgery was 71% (5/7) (Powell, 2020).

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A meta-analysis of 6 case series of paediatric patients with subglottic stenosis reported that use of balloon dilation as primary treatment successfully avoided invasive surgery in 65% of patients (6 studies, 95% CI 60% to 71%, p<0.001, I^2=0%). The mean follow up of studies included in the meta-analysis was 7 months. A further meta-analysis of 3 case series reported that use of balloon dilation as secondary treatment following tracheotomy or laryngotracheal reconstruction successfully avoided further invasive surgery in 61% of patients (3 studies, 95% CI 45% to 78%, p<0.001, I^2=88%). The I^2 statistic indicated considerably more between-study heterogeneity in the meta-analysis of secondary treatment than the meta-analysis of primary treatment (Lang, 2014).

A retrospective case series of 27 patients 21 years old or younger with subglottic stenosis receiving balloon dilation reported that 100% (27/27) were successfully decannulated or avoided tracheotomy, and that 52% (14/27) successfully avoided laryngotracheoplasty. The duration of follow up was not reported (Maresh, 2014).

A case series of 60 paediatric patients with subglottic, tracheal, or laryngeal stenosis receiving balloon dilation reported that 77% (46/60) avoided laryngotracheoplasty or tracheostomy, or had decannulation of previous tracheotomy, over a mean follow up of 21.7 months (Wentzel, 2014).

A case series of 54 adult patients with subglottic stenosis receiving balloon dilation as part of a multimodality endoscopic treatment approach reported that 78% (42/54) of patients could be managed with minimally invasive surgery. Patients who had balloon dilation as part of a multimodality endoscopic treatment approach had a 5-year actuarial success rate in the avoidance of open surgery of 87.5% for subglottic-only stenosis, and 18.7% for concomitant glottic and subglottic stenosis (Nouraei, 2013).

QoL

A retrospective case series of 27 adult patients with laryngotracheal stenosis reported statistically significant improvements in V-RQOL after receiving balloon dilation. Overall, the mean V-RQOL improved from 70.4 preoperatively to 80.0 postoperatively (p=0.025). Postoperative data were obtained between 3 weeks and 5 months after balloon dilation. In patients with subglottic or tracheal stenosis, V-RQOL statistically significantly improved from 82.8 to 93.8 (p=0.047). In patients with multilevel stenosis, there was a numerical improvement in V-RQOL from 48.0 to 55.3 after balloon dilation, but this was not statistically significant (p=0.31) (Hillel, 2015).

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Repeat procedures and readmissions

An analysis of the AIR of 40 paediatric patients with glottic, subglottic, or tracheal stenosis receiving balloon dilation as primary treatment reported that patients had 119 hospital visits (including 69 balloon and 50 non-balloon visits) in the follow-up period. The 45 patients linked to HES made 500 hospital visits (median 8 per patient) in the follow-up period. The median follow-up period was 869 days per patient. Using HES data, 49% (29/59) of patients were readmitted to hospital a total of 83 times within 30 days of a balloon dilation procedure. Thirty-two of these 30-day readmissions were related to airway stenosis (Powell, 2020).

A meta-analysis of 6 case series of paediatric patients with subglottic stenosis reported that the mean number of dilation procedures for secondary therapy (that is, after open surgery) was 2.1 dilation procedures per patient. This was numerically higher than for patients who had balloon dilation as primary therapy (1.6), but this difference was not statistically significant (p=0.08) (Lang, 2014).

A retrospective case series of 27 patients 21 years old or younger with subglottic stenosis reported that, compared with 63 patients who had initial treatment with laryngotracheoplasty, patients who had initial treatment with balloon dilation were statistically significantly more likely to need unplanned surgical intervention during their course of treatment (22% compared with 5%, p=0.01), but had a statistically significantly lower number of airway interventions and evaluations under anaesthesia during their course of treatment (mean 7.3 compared with 9.2, p=0.003). The duration of follow up was not reported (Maresh, 2014).

A case series of 54 adult patients with subglottic stenosis receiving balloon dilation as part of a multimodality endoscopic treatment approach reported a mean endoscopic intervention rate of 1.07 to 0.79 per year (Nouraei, 2013).

Airway patency

An analysis of the AIR of 76 pre- and postoperative airway diameter measurements in paediatric patients with glottic, subglottic, or tracheal stenosis receiving balloon dilation as primary treatment reported a decrease in Cotton-Myer grade in 57% (43/76) procedures, and no change in 43% (33/76). By linkage of AIR data to the HES database, 30 patients (91 measurements) had a statistically significant 0.8 mm per year increase in the diameter of the subglottic airway over the follow-up period (p<0.001) (Powell, 2020).

Combination outcomes

A systematic review of 10 studies evaluating the efficacy of balloon dilation for paediatric subglottic stenosis reported that a grand total of 97 of the 109 patients (89%; range 66% to 100%) reached a successful outcome over a follow-up

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period ranging from 5 days to 7 years. Differing between studies, a successful outcome was defined as symptom improvement, improvement in airway patency, decannulation, or avoidance of further surgery (Schweiger, 2020).

Safety summary

Death

A systematic review of 7 studies noted that 1 case series of 37 patients reported 1 death from tracheal laceration (Lang, 2014).

A case series of 54 adult patients with subglottic stenosis receiving balloon dilation as part of a multimodality endoscopic treatment approach reported that 1 patient died 7 months after endoscopic treatment at a local hospital from an airway infection. It is not reported whether this was considered related to balloon dilation (Nouraei, 2013).

Tracheal laceration

A systematic review and meta-analysis of 7 studies noted that 1 case series of 37 patients reported 2 cases of tracheal laceration, 1 of which resulted in death, as described above (Lang, 2014).

A case series of 54 adult patients with subglottic stenosis receiving balloon dilation as part of a multimodality endoscopic treatment approach reported 2 mucosal tears associated with balloon dilation. Both were treated with antibiotics and did not cause acute mediastinitis or long-term complications (Nouraei, 2013).

Asymptomatic pneumomediastinum

A systematic review of 7 studies noted that 1 case series of 37 patients reported 1 case of asymptomatic pneumomediastinum (Lang, 2014).

Respiratory tract infection and tracheitis

An analysis of the AIR of 59 paediatric patients reported 1 in-hospital lower respiratory tract infection. This analysis also reported the following 2 out-of-hospital complications: 1 case of airway obstruction and lower respiratory tract infection 4 days post-balloon dilation, and 1 case of prolonged intubation because of lower respiratory tract infection (Powell, 2020).

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Airway oedema

An analysis of the AIR of 59 paediatric patients reported 1 case of progressive subglottic oedema. Upon clinical review, this was considered by the authors as related to the efficacy of the balloon dilation procedure (Powell, 2020).

A case report described 1 adult patient who experienced generalised mucosal oedema, haemorrhagic mucosal lesions, and haemorrhagic endobronchial effluent immediately after balloon dilation. The patient was successfully extubated in the procedure room to a face mask supplying oxygen, improved over several hours, and remained symptom free during a 24 hours' observation period (Morales-Estrella, 2018).

Tracheal collapse and atelectasis

A case report described 1 adult patient who had dyspnoea with laryngeal stridor because of tracheal collapse. A stent was inserted, and the patient was gradually relieved from respiratory distress (Li, 2018).

A systematic review of 7 studies noted that 1 case series of 37 patients reported 3 cases of atelectasis (Lang, 2014).

Dysphagia

A systematic review of 10 studies on paediatric subglottic stenosis noted that 1 study reported 4 patients presenting dysphagia in the postoperative period (Schweiger, 2020).

Balloon malfunction

An analysis of the FDA MAUDE database identified 5 balloon dilator failures that occurred in the airway between 2014 and 2017. There is no further information about the nature of these 5 failures. Note that there are no balloon dilator failures reported in this study that involve the CE marked device (Strong, 2018).

A case report described 1 case of balloon failure during dilation of an adult patient. During inflation, the balloon, while still partially inflated, migrated from the stenotic site. The balloon became trapped and took multiple attempts to remove. The removal was rapid and the patient maintained oxygen levels above 95% (Achkar, 2013).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur,

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even if they have never happened). For this procedure, the professional expert did not list any adverse events that had not been described in the literature.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoscopic balloon dilation for subglottic or tracheal stenosis. The following databases were searched, covering the period from their start to 13 April 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality, larger (30 patients or more) studies. Case reports were included if they reported novel adverse events that were not identified in larger studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with subglottic or tracheal stenosis.
Intervention/test	Endoscopic balloon dilation.
Outcome	Articles were retrieved if the abstract contained information relevant to safety and efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

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List of studies included in the IP overview

This IP overview is based on 494 patients (accounting for the overlap between Lang, 2014 and Schweiger, 2020) from 1 registry study, 1 systematic review and meta-analysis, 1 systematic review, 4 case series, 3 case reports, and 1 database analysis.

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

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Summary of key evidence on endoscopic balloon dilation for subglottic or tracheal stenosis

Study 1 Powell S (2020)

Study details

Study type	Registry analysis
Country	England
Recruitment period	2015 to 2019
Study population and number	n=59 Patients younger than 18 years old with airway stenosis
Age and sex	No average age reported. Age distribution reported as: Less than 1 year: 21 patients (36%) 1 to 2 years: 7 patients (12%) 3 to 11 years: 28 patients (47%) 12 to 18 years: 3 patients (5%). 61% (36/59) male
Patient selection criteria	Inclusion criteria: Patients younger than 18 years old with airway stenosis (including glottic, subglottic, and tracheal) treated by balloon dilation within an acute NHS hospital. Exclusion criteria: Procedures conducted for indications other than airway stenosis and records with no balloon dilation procedure data.
Technique	Balloon dilation. Of 133 total balloon dilation procedures, 69 (52%) were conducted with a tracheostomy in place, 50 (38%) alongside cold steel or laser incisions, 79 (59%) in combination with steroid treatment, 35 (26%) alongside other concomitant procedures (such as cyst, granulation or scar tissue removal, web division, stent insertion, endoscopic cricoid split, endoscopic posterior cartilage graft, laryngotracheal reconstruction with cartilage, recurrent respiratory papillomatosis debridement, suture lateralisation of vocal cord, triamcinolone injection) and 15 (11%) as adjunctive/secondary treatment after open reconstruction surgery.
Follow-up	Each patient was followed from the date of their earliest balloon dilation procedure until either 2019 (if matched to HES database), the latest date in the registry for the patient (if unmatched to HES), or date of death, if sooner.
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: Several authors are employed by The Newcastle upon Tyne Hospitals NHS Foundation Trust

Analysis

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Follow-up issues: After the first recorded balloon admission, follow-up information from the registry was available in 40 (68%) patients. Additionally, there were 45 (76%) patients who were linked to the HES database. Across both data sources, there was a median follow-up duration of 869 days per patient (range 0 to 1,511).

Study design issues: This prospective, multicentre analysis of the AIR assessed the efficacy and safety of balloon dilation for glottic, subglottic, and tracheal stenosis in patients younger than 18 years old.

Using in-hospital data, 2 efficacy outcomes were assessed: intra-operative change in airway diameter and Cotton-Myer grade directly before and after balloon dilation. Using follow-up data from the registry and from linking to HES, longer-term outcomes were also assessed. These outcomes included changes in airway diameter over time, hospital admissions, further respiratory surgical intervention, in-hospital deaths, and all reported post-procedural complications. Overall procedural success at the end of the study was defined as avoidance of surgical intervention (for example, laryngotracheal reconstruction or tracheostomy insertion) for those with no tracheostomy present at the time of the index balloon procedure and maintained decannulation for those with tracheostomy in place.

Study population issues: Most patients (105; 79%) had subglottic stenosis; 27 (20%) had a stenosis of the glottis and 1 had tracheal stenosis. A breakdown of outcomes by stenosis location was not reported. The mean pre-balloon subglottic diameter was 4.2 mm (95% CI: 3.8 to 4.5). Thirty-nine patients (40%) had a Cotton-Myer grade 1 stenosis (least severe), 32 (33%) had grade 2, 26 (27%) had grade 3, and 0 had grade 4. Sixty-one percent of patients were born prematurely; 51% had 3 or more intubations, 49% had chronic lung disease, and 12% had adjunctive treatment post-laryngotracheal reconstruction.

Key efficacy findings

Overall procedural success

Number of patients analysed: 52

- Overall procedural success rate in patients who had balloon dilation as the primary treatment of stenosis was 65% (34/52). In the presence of tracheostomy, 22% (4/18) were successfully decannulated; in patients with no tracheostomy, 88% (30/34) avoided further surgery.

Number of patients analysed: 7

- In 7 patients who had balloon dilation as an adjunctive treatment after open reconstructive surgery, overall procedural success was 71% (5/7). In the presence of tracheostomy, 67% (4/6) were successfully decannulated; in patients with no tracheostomy, 100% (1/1) avoided further surgery.

In-hospital findings

Number of patients analysed: patient number not reported (76 paired measurements)

- There was a decrease in Cotton-Myer grade in 43 procedures (57%), and the Cotton-Myer grade was unchanged in 33 procedures (43%).

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- The starting airway diameter, stenosis type (oedema, soft and hard), Cotton-Myer grade (pre-balloon), and procedure number did not affect the change in subglottic airway diameter after balloon dilation.

Long-term findings

Airway diameter

Number of patients analysed: 30 (91 measurements over follow-up period)

- There was a 0.8 mm per year rate of increase of the diameter of the subglottic airway over the follow-up period ($p<0.001$).

Hospital readmission

Number of patients analysed: 40 patients from the AIR and 45 from the AIR linked to HES

- The 40 patients followed-up in the AIR made 119 hospital visits (including 69 balloon and 50 non-balloon visits) in the follow-up period.
- The 45 patients linked to HES made 500 hospital visits (median 8 per patient) in the follow-up period.
    - Using HES data, 49% (29/59) of patients were readmitted to hospital a total of 83 times within 30 days of a balloon dilation procedure. Thirty-two of these 30-day readmissions were related to airway stenosis.

Key safety findings

In-hospital findings

Discharge location

Number of patients analysed: patient number not reported (127 balloon dilation visits)

- Of 127 balloon dilation visits, 94% were discharged to the expected location, 4 procedures with no tracheostomy resulted in an unplanned ICU visit with intubation, 3 procedures with no tracheostomy resulted in an unplanned high-dependency unit visit without intubation, and 1 patient with a tracheostomy was admitted to a ward (rather than anticipated high-dependency unit).

Complications

- In-hospital complications were reported in 11 hospital visits where a balloon dilation procedure was conducted, 3 of which were excluded following clinical review as they were not considered to be a complication of the procedure. The 8 complications that were considered to be related to the procedure included:
    - Airway obstruction, n=6
    - Lower respiratory tract infection, n=1

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    - Prolonged intubation, n=1
- Of the 64 balloon dilation visits with a tracheostomy in place, 1 reported an in-hospital complication (lower respiratory tract infection). Of the 64 balloon dilation visits without a tracheostomy, 7 reported complications (5 airway obstruction, 1 emergency tracheostomy and 1 staged tracheostomy with prolonged intubation).
    - There were higher odds of a complication without a tracheostomy (versus with), but these were not statistically significant (OR 7.7 [95% CI 0.9 to 64.8], p=0.06).

Long-term findings

Complications

- Of the 59 patients having balloon dilation procedures, 19 out-of-hospital complications occurring in 12 patients were recorded in AIR.
- This included 1 death which was considered unrelated to the balloon dilation procedure by the treating clinician.
- Following clinical review of the 19 complications:
    - 6 were considered related to the efficacy of the balloon dilation procedure, including:
        - Airway obstruction, n=3
        - Croup, n=1
        - Progressive subglottic oedema, n=1
        - Worsening of stridor, n=1.
    - 1 related to safety: airway obstruction and lower respiratory tract infection 4 days post-balloon, n=1
    - 1 related to safety and efficacy: prolonged intubation due to lower respiratory tract infection, n=1
    - The remaining 11 outcomes were considered unrelated to the balloon procedure and likely due to natural history of stenosis.

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Study 2 Lang M (2014)

Study details

Study type	Systematic review and meta-analysis
Country	Not reported
Recruitment period	Publication date: 1991 to 2012
Study population and number	n=150 (7 studies, mean 20 patients, range 5 to 44) Paediatric patients with subglottic stenosis
Age and sex	Mean age 2.2 to 60.0 months; sex not reported
Patient selection criteria	Inclusion criteria: Sample size of 5 or more; use of endoscopic balloon dilation for paediatric patients (0 to 18 years); and use of endoscopic balloon dilation as the primary treatment of paediatric subglottic stenosis to avoid more definitive airway management to include tracheostomy and laryngotracheal reconstruction. Exclusion criteria: Not reported.
Technique	Endoscopic balloon dilation under general anaesthesia. Pressure ranged from 2 to 16 atmospheres, for 30 seconds to 2 minutes, or until desaturation, either with or without concomitant topical steroids or mitomycin C. Mean number of dilations was 1.9 per patient.
Follow-up	Mean 7 months (6 of 7 studies reported follow-up)
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: No funding source

Analysis

Study design issues: This systematic review and meta-analysis evaluated the efficacy and safety of endoscopic balloon dilation for the treatment of paediatric patients with subglottic stenosis. This study was performed according to the PRISMA guidelines. The primary outcome was balloon dilation treatment success in avoidance of more invasive procedures (such as tracheostomy and laryngotracheal reconstruction). Secondary outcomes were complications and need for further balloon dilation.

Two independent reviewers extracted data from relevant studies, with a third reviewer used to settle any discrepancies. Meta-analysis was performed only if the studies were judged to be sufficiently similar to produce meaningful results. Quality assessment was also performed. All 7 studies used a case series design. Overall, the studies were judged to be of acceptable to high quality (interpreted from scoring of + [3 studies], ++ [2 studies], and +++ [2 studies]). There were several differences among the studies, including: use of topical steroids or mitomycin C, the use of postoperative intubation after balloon dilation, and the balloon pressure used for dilation. However, the studies were considered sufficiently similar for meta-analysis.

Random effects modelling was used to calculate summary effect measures with corresponding 95% CIs, and Forest plots were generated. Heterogeneity was assessed using the I^2 statistic. Publication bias was assessed using graphical funnel plot analysis.

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Study population issues: The mean sample size of studies was 20 patients. Only 1 study reported complications associated with balloon dilation.

Key efficacy findings

Avoidance of more invasive surgery

Number of patients analysed: not reported.

- Meta-analysis of 6 studies produced a summary estimate of 65% for primary treatment success of using balloon dilation for treatment of paediatric subglottic stenosis (6 studies, 95% CI 60% to 71%, p<0.001, I^2=0%, Figure below).

Forest plot of treatment success of balloon dilation as primary treatment for paediatric subglottic stenosis

[Figure removed for publication]

- Considering the 3 studies that included data on the use of balloon dilation for secondary treatment (that is, after tracheotomy or laryngotracheal reconstruction), the summary estimate of treatment success was 61% (3 studies, 95% CI 45% to 78%, p<0.001, I^2=88%).
    - As shown by the I^2 statistic, there was substantially more between-study heterogeneity in the meta-analysis of secondary treatment success than primary treatment success.
- The mean number of dilation procedures for secondary therapy (2.1 dilation procedures per patient) was numerically higher than for primary patients (1.6), but this difference was not statistically significant (p=0.08).

Further efficacy findings:

- In multivariate analysis, Cotton-Myers grade was statistically significantly associated with decreased odds of treatment success (OR=0.198, 95% CI 0.045 to 0.870, p=0.032).
- In multivariate analysis, neither increasing age quartile nor increasing number of dilations were statistically significantly associated with increased odds of treatment success.

The Funnel plot of treatment success versus standard error of treatment success shows an asymmetrical plot (Figure below). This indicated that there may have been some publication bias, with an absence of studies reporting lower success rates.

Funnel plot of balloon dilation treatment success

[Figure removed for publication]

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Key safety findings

Complications

Only 1 study (37 patients) reported complications. These complications included:

- Tracheal laceration, n=2
    - Death from tracheal laceration, n=1
- Atelectasis, n=3
- Tracheitis, n=2
- Pneumomediastinum (asymptomatic), n=1

No other study reported significant complications.

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Study 3 Schweiger C (2020)

Study details

Study type	Systematic review
Country	Not reported
Recruitment period	Publication date: 2007 to 2017
Study population and number	n=109 (10 studies, mean 11 patients) Paediatric patients with subglottic stenosis
Age and sex	Age ranged from 23 days old to 15 years old; sex not reported.
Patient selection criteria	Inclusion criteria: randomised controlled trials, phase 1 and 2 prospective studies, case series and case reports; including neonatal (0 to 28 days old) and paediatric (29 days to 18 years old) patients; and reporting results on pharmacological and endoscopic treatments as primary approaches for ongoing (acute; fewer than 30 days since extubation) laryngeal stenosis. Reports in English, Portuguese, Spanish, Italian, and German were eligible. Exclusion criteria: reviews, editorials, letters to the editor, guidelines, study protocols, or position papers. All open surgical approaches (even if endoscopic procedures were performed as adjunctive treatment) were excluded. Studies including adult patients (exclusively or alongside paediatric patients) were excluded. Congenital stenosis or those acquired by other causes not associated with endotracheal intubation were excluded because they do not share the same pathologic mechanisms.
Technique	Balloon dilation was performed under general anaesthesia in all studies, using a high pressure, non-compliant balloon catheter. Two studies used only the INSPIRA AIR balloon. The other 8 studies did not mention the brands of their balloons or used different brands. In 8 studies, the balloon size was selected according to the ideal subglottic diameter for the patient's age. An inflation/deflation handle mounted with a syringe and gauge assembly designed to monitor and maintain the pressure was used in all studies. The balloon was inflated to rated burst pressure by 3 studies. Of the other studies, each mentioned pressure between 2 and 15 atmospheres. The balloon was inflated for 30–60 seconds or until the patient's oxygen saturation level dropped below 90–92%. Patients had 1 to 6 dilations, with an average of 1.8 dilations per patient.
Follow-up	Ranged from 5 days to 7 years
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: Not reported

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Analysis

Study design issues: This systematic review evaluated the efficacy of endoscopic approaches for management of ongoing (acute; fewer than 30 days since extubation) paediatric subglottic stenosis. Studies were identified for elective endotracheal intubation (3 studies), balloon dilation (10 studies) and balloon dilation with adjunctive techniques (4 studies), rigid dilation (1 study), use of carbon dioxide laser (6 studies), and use of a microdebrider (1 study). The authors note that this systematic review was performed according to the PRISMA guidelines. However, key elements of the PRISMA checklist, such as a bias/study quality assessment, were not reported. Outcomes for the systematic review were not defined, however, treatment success was defined as an improvement of symptoms, decrease in Myer-Cotton level of stenosis, decannulation of previous tracheostomy, or avoidance of reconstructive surgeries and tracheostomy.

Two independent reviewers screened the abstracts and full-texts for relevance, with a third reviewer used to settle any discrepancies. No quantitative meta-analysis of data was performed due to the heterogeneity of interventions and scarcity of comparative trials. All 10 studies reporting on balloon dilation were either a case report or case series design. Four studies were also captured in Lang, 2014.

Study population issues: The mean sample size of studies was 11 patients. Only 1 study described complications of the procedure.

Key efficacy findings

In the 10 studies, the success rate ranged from 66% to 100%, with a grand total of 97 of the 109 patients (89%) reaching a successful outcome.

Key safety findings

Complications

One study described that 4 patients presented dysphagia in the postoperative period. No other studies reported complications of the procedure.

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Study 4 Hillel AT (2015)

Study details

Study type	Case series
Country	US
Recruitment period	2010 to 2013
Study population and number	n=38 Adult patients with laryngotracheal stenosis
Age and sex	Mean 48.7 years; 82% female
Patient selection criteria	Inclusion criteria: patients who had suspension microlaryngoscopy or bronchoscopy and balloon dilation for laryngotracheal stenosis. Exclusion criteria: patients who did not receive balloon dilation for laryngotracheal stenosis or if they had supraglottic stenosis.
Technique	Dilation was performed using CRE pulmonary balloon dilators (Boston Scientific, Natick, Massachusetts, US) of various sizes for durations less than 5 minutes. Some patients (number not specified) had lysis of dilation with cold instruments, some had lysis by laser, some had topical mitomycin C, and most had intralesional steroid injection at the time of surgery.
Follow-up	Up to 5 months
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: 1 author reported funding from the Scientific and Technological Research Council of Turkey

Analysis

Follow-up issues: Matched preoperative and postoperative outcome data were available for 27 patients.

Study design issues: This single-centre, retrospective case series assessed the impact of balloon dilation on voice-related QoL of adult patients with laryngotracheal stenosis. The primary outcome was perioperative change in V-RQOL scores. As described in the outcome measures section, the V-RQOL is a validated disease-specific QoL instrument that allows patients to rate their own self-perceived voice quality. The V-RQOL is scored on a 0 to 100 scale, with higher scores indicating better QoL. The most recent V-RQOL data collected before any surgical procedure was considered preoperative, and data obtained between 3 weeks and 5 months following dilation was considered postoperative. Other outcomes included analysis of the GRBAS and fundamental frequency of voice samples before and after dilation.

Statistical analysis of voice outcomes over time, as when assessing V-RQOL before and after dilation, were done with paired t-tests.

Study population issues: Of the 38 total patients, 26 (68%) had subglottic or proximal tracheal stenosis, and 12 (32%) had multilevel stenosis – patients who had both glottic and subglottic/tracheal stenosis. Outcome

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data are presented for the overall population and stratified by subglottic or proximal tracheal stenosis and multilevel stenosis. The subglottic or proximal tracheal stenosis cohort had statistically significantly more females, fewer males, and a higher body mass index (BMI) than the multilevel stenosis cohort.

There were 18 patients with a history of tracheotomy, 12 of whom were decannulated prior to this study. There were 10 patients who had a previous history of open laryngotracheal surgery.

Key efficacy findings

V-RQOL analysis

Number of patients analysed: 27

- Overall, there was a statistically significant improvement in V-RQOL score after balloon dilation (p=0.025).
- Patients with multilevel stenosis reported statistically significantly worse preoperative and postoperative voice quality than patients with subglottic/tracheal stenosis (p<0.0001).
- Patients with subglottic/tracheal stenosis had statistically significantly improved V-RQOL scores after balloon dilation (p=0.047).
- Patients with multilevel stenosis did not have statistically significantly improved V-RQOL after balloon dilation (p=0.31).

V-RQOL scores for patients with laryngotracheal stenosis before and after balloon dilation

Analysis population	n	Preoperative V-RQOL	Postoperative V-RQOL	p-value, preoperative compared with postoperative
Overall	27	70.4	80.0	0.025
SGS or TS	17	82.8	93.8	0.047
MLS	10	48.0	55.3	0.31
Male	5	48.5	57.0	0.54
Female	22	75.9	85.1	0.028
History of prior surgery	17	70.0	75.9	0.138
No history of prior surgery	7	61.7	88.9	0.056

GRBAS analysis

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Number of patients analysed: 10

- Each parameter of GRBAS numerically improved following balloon dilation, though none were statistically significant.

Key safety findings

No safety findings were reported.

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Study 5 Maresh A (2014)

Study details

Study type	Comparative case series
Country	US
Recruitment period	2006 to 2012
Study population and number	n=90 (balloon dilation n=44) Patients 21 years old or younger with subglottic stenosis
Age and sex	Median 1.4 years (range 4 weeks to 19 years); 54% male
Patient selection criteria	Patients were excluded if they were older than 21 years, if they did not have subglottic stenosis, or if they did not have follow-up records.
Technique	The specifics of the dilation technique were not reported. 44 patients had a total of 94 balloon dilation procedures, of whom 27 received primary treatment with 47 balloon dilation procedures. The remaining 17 had balloon dilation as part of their follow-up following initial treatment with laryngotracheoplasty (n=63).
Follow-up	Not reported
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: Not reported

Analysis

Study design issues: This retrospective, single-centre, comparative case series compared outcomes of endoscopic balloon dilation with laryngotracheoplasty for paediatric subglottic stenosis. The primary outcome measure was avoidance of tracheotomy or decannulation for patients with existing tracheotomy. Secondary outcomes included total number of procedures and number of unplanned procedures.

Univariate chi-square analysis was used to identify differences in outcomes between treatment groups, including overall success as well as number of interventions and number of unplanned interventions. Multivariate regression was performed to identify patient and disease factors that were statistically associated with outcomes in successful and unsuccessful balloon dilations.

Study population issues: There were no differences in distribution of sex or ethnicity, or the mean age, among patients who had balloon dilation or laryngotracheoplasty as initial treatment.

Key efficacy findings

Outcomes by initial treatment

Number of patients analysed: 27

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- The overall success rate of balloon dilation in decannulation or tracheotomy avoidance was 100% (27/27).
- The overall success rate of balloon dilation in laryngotracheoplasty avoidance was 52% (14/27).
- Patients who had initial treatment with balloon dilation were statistically significantly more likely to require unplanned surgical intervention at some point during their treatment (6/27;22%) compared with patients who had initial treatment with laryngotracheoplasty (3/63;5%) (p=0.01).

Outcomes by initial treatment

Initial treatment	Total patients	Successful treatment (decannulation or tracheotomy avoidance), No. (%)	Successful treatment (avoidance of LTP), No. (%)	Procedures, mean	p-value, EBD compared with LTP	Unplanned procedures, mean (%)	p-value, EBD compared with LTP
EBD	27	27 (100)	14 (52)	7.3	0.003	6 (22)	0.01
LTP	63	59 (94)	-	9.2		3 (5)	

Correlations

- There were statistically significantly more patients with severe (Cotton-Myers grade 3 or 4) stenosis who failed initial treatment with balloon dilation than who had successful initial treatment with balloon dilation (13/13 patients who failed initial treatment [100%] versus 4/14 patients who had successful initial treatment [29%]).
    - Using multivariate analysis, presence of severe stenosis was the only statistically significant variable for predicting balloon dilation failure (p=0.002).

Key safety findings

- No posttreatment complications occurred after balloon dilation.
- After laryngotracheoplasty, 3 patients had wound infections, 4 patients had treatment for pneumonia, 1 patient had pneumomediastinum that was managed conservatively, and 1 patient had chronic aspiration. One patient died of a non-airway cause 3 days after laryngotracheoplasty with no preceding airway or respiratory events.

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Study 6 Wentzel JL (2014)

Study details. Each study identified in the systematic review is also captured in the Lang, 2014 systematic review and meta-analysis. This study summary therefore only presents results from the case series.

Study type	Systematic review and case series
Country	US
Recruitment period	2007 to 2013
Study population and number	n=60 Patients under the age of 18 years with laryngotracheal stenosis
Age and sex	Mean 36.4 months; 59% male
Patient selection criteria	Inclusion criteria: the use of balloon dilation for laryngotracheal stenosis in a patient under the age of 18 at time of surgery Exclusion criteria: not reported
Technique	Balloon dilation was performed under general anaesthesia. A bronchoscope was introduced to examine the subglottis, trachea, carina, and mainstem bronchi. The airway was then sized at the point of stenosis using endotracheal tubes. At this point the patient was extubated, and an appropriately sized sinoplasty, esophageal, or cardiac balloon was placed, inflated, and held for a maximum of 2 minutes, assuming maintenance of oxygen saturation. The balloon was deflated and removed and the airway re-examined for patency. Follow-up endoscopy was generally performed 1 week after the procedure. Pre- and postoperative medications and additional procedures varied by case and surgeon preference. The use of topical medications, such as mitomycin, was generally not a part of the treatment algorithm. In 29 patients, balloon dilation was the primary course of treatment. In the remaining 31 patients, balloon dilation was used as an adjunct to open or endoscopic surgical or laser procedures or tracheotomy. There were 144 total balloon dilations.
Follow-up	Mean 21.7 months
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: No funding source

Analysis

Follow-up issues: One patient had surgery within 30 days of balloon dilation, so it was not possible to adequately determine success or failure of balloon dilation. One further patient was lost to follow-up.

Study design issues: This retrospective, single-centre case series assessed the efficacy of balloon dilation in paediatric patients with laryngotracheal stenosis. Success was defined as decannulation of previous tracheostomy or avoidance of open laryngotracheoplasty or tracheostomy. Data on complications were also extracted from the database.

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Descriptive statistics were generated for the case series data, and successful versus failed cases were compared. Bivariate logistic regression analyses were conducted to assess Cotton-Myer grade, number of dilations, age at first procedure, gender, and acquired versus congenital stenosis as potential predictors of balloon dilation failure in subglottic stenosis.

Study population issues: In total, 44 patients had subglottic stenosis and 16 had upper tracheal or laryngeal stenosis through cysts, mucoceles, webs, scar bands, or complete tracheal rings. Subglottic stenoses were of mixed aetiologies – 27% were congenital, and 73% were acquired through prolonged intubation – and of mixed severity: 14 had grade 1 stenosis, 8 had grade 2 stenosis, 13 had grade 3 stenosis, and in 9 the level of stenosis was unable to be determined.

Key efficacy findings

Overall success

Number of patients analysed: 60

Success was achieved in 46 of the 60 total patients (77%), 12 required open surgical laryngotracheal reconstruction, tracheotomy, or maintained a pre-existing tracheostomy at the final follow-up, and as discussed above, 1 patient could not be evaluated due to further surgery, and 1 patient was lost to follow-up.

In bivariate regression analyses, there were no correlations between the effect of age, gender, average number of dilations, Cotton-Myer stenosis grade, and whether the dilation was a primary or adjunctive treatment on the odds of treatment failure in subglottic stenosis.

Key safety findings

Complications

There were no complications.

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Study 7 Nouraei SA (2013)

Study details

Study type	Case series
Country	UK
Recruitment period	2004 to 2012
Study population and number	n=54 Adult patients with idiopathic subglottic stenosis
Age and sex	Mean 47.8 years; 100% female
Patient selection criteria	Inclusion criteria: female patients with idiopathic subglottic stenosis and no history of significant laryngotracheal injury
Technique	Dilation was performed using a CRE pulmonary balloon dilator (Boston Scientific, Natick, MA, US). No further details of balloon dilation are reported. All patients received multimodality treatment. In total, 54 (100%) patients received carbon dioxide laser surgery, 54 (100%) had intralesional corticosteroid injection, 21 (39%) had topical mitomycin C application, 10 (19%) had intraluminal stents inserted, 4 (4%) had endoscopic laser arytenoidectomy, and 1 (2%) had intracordal collagen injection.
Follow-up	Mean 44.7 months
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: No funding source

Analysis

Study design issues: This prospective, single-centre case series reports on treating idiopathic subglottic stenosis with a multimodality treatment approach, which involved both endoscopic and open surgical techniques. For the purposes of this study summary, only outcomes relating to endoscopic techniques are reported. Outcomes included therapeutic intervention rates and the need for open surgery.

Key efficacy findings

Number of patients analysed: 54 (234 endoscopic treatments)

- Overall, 78% of patients could be managed with minimally invasive surgery. Five-year actuarial success rate in the avoidance of open surgery for endoscopic treatment was 87.5% for subglottic-only disease, and 18.7% for concomitant glottic and subglottic disease.
- Mean endoscopic intervention rate was 1.07 to 0.79 per year.
    - Independent predictors of treatment frequency were Myer-Cotton grade of the stenosis and concomitant glottic involvement.

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Key safety findings

- There were no intraoperative and 30-day mortality. One patient died 7 months after endoscopic treatment at a local hospital from an airway infection.

- There were 2 mucosal tears associated with balloon dilation, which were treated with antibiotics and did not cause acute mediastinitis or long-term complications.

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Study 8 Strong EB (2018)

Study details

Study type	Database analysis
Country	US
Recruitment period	2014 to 2017
Study population and number	420 reported balloon malfunctions (including balloons used for oesophageal and tracheal dilation)
Age and sex	Not applicable
Patient selection criteria	The FDA MAUDE database was queried for adverse events associated with tracheal and oesophageal dilators.
Technique	Not applicable
Follow-up	Not applicable
Conflict of interest/source of funding	Conflict of interest: 1 author reported consultancy for Cook Medical Source of funding: No funding source

Analysis

Study design issues: This study was a retrospective analysis of the FDA MAUDE database to determine the rate of balloon dilator failure when used in oesophageal and tracheal dilation. The data are primarily concerning oesophageal dilation. There were no balloon dilator failures that involved the CE marked device.

Key safety findings

Number of patients analysed: 420 balloon dilator malfunctions reported between 2014 and 2017.

A total of 5 (1.2%) balloon dilator failures occurred in the airway. A further 101 cases (24.0%) occurred in unreported anatomical locations, some of which may have been the airway.

Of 104 dilator failures that were associated with deflation/removal issues, 3 (3%) occurred in the airway. A further 12 (12%) occurred in unreported anatomical locations, some of which may have been the airway (Table below).

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Balloon malfunction data reported to the FDA MAUDE database

Variable	**% (420 dilator malfunctions)**
Balloon brand	
Hercules 3 Stage (Cook)	53.6
CRE (Boston Scientific)	32.4
Quantum TTC (Cook)	9.0
Rigiflex II Achalasia (Boston Scientific)	0.7
Eclipse TTC (Cook)	0.5
Other	3.8
Dilation area	
Upper gastrointestinal tract	72.6
Lower gastrointestinal tract	1.9
Airway	1.2
Not reported	24.3
Malfunction type	
Inflation/leak issue	31.4
Rupture	30.7
Deflation/removal issue	24.8
Detachment of device component	14.5
Broken prior to use	6.7
Insertion issue	2.9
Not reported	0.5
Variable	**% (104 devices with deflation or removal issues)**
Balloon brand	
Hercules 3 Stage (Cook)	20.2
CRE (Boston Scientific)	77.9
Rigiflex II Achalasia (Boston Scientific)	1.9
Dilation area	
Upper gastrointestinal tract	80.8
Lower gastrointestinal tract	4.8
Airway	2.9
Not reported	11.5
User-ascribed cause	
Unknown deflation issue	57.7
Kinked/broken catheter	18.3
Other	24.0

IP overview: Endoscopic balloon dilation for subglottic or tracheal stenosis

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Study 9 Achkar J (2013)

Study details

Study type	Case report
Country	US
Recruitment period	Not reported
Study population and number	n=1 Adult patient with idiopathic subglottic stenosis
Age and sex	39 years; Female
Patient selection criteria	Not applicable
Technique	Prior to the procedure described in this case report, the 14×40-mm Inspira AIR balloon had been used multiple times to dilate this patient without complications. Under general anaesthesia, suspension microscopic direct laryngoscopy was performed. A carbon dioxide laser was used to perform radial cuts down to cartilage on the circumferential fibrotic scar. The 14×40-mm Inspira AIR balloon was then inserted under direct vision and inflated up to a pressure of 8 atmospheres. The inflation was performed twice without difficulty, before a third inflation dislodged the balloon.
Follow-up	Not reported
Conflict of interest/source of funding	Conflict of interest: Not reported Source of funding: Not reported

Analysis

Study design issues: This retrospective case report describes the failure of a 14×40-mm Inspira AIR balloon during dilation of a patient with idiopathic subglottic stenosis.

Key safety findings

During inflation, the balloon migrated away from the constricted area. On the third inflation, saline solution was observed at the distal end of the laryngoscope. The balloon was thought to have ruptured, and the pressure from the catheter was felt to have loosened by the surgeon securing the balloon. There was difficulty encountered in trying to deflate the balloon. As the catheter was withdrawn from the laryngoscope, the catheter became detached. The detached, partially inflated balloon was trapped within the subglottic area. Multiple attempts to remove the firmly fixed balloon from the subglottis were successful after 2 large forceps were used to grasp the sidewalls of the balloon.

Extraction of the balloon took only a ‘matter of minutes’ and the patient maintained oxygen levels above 95%. The mucosa was still intact, there was adequate haemostasis, and there were no retained foreign bodies within the airway.

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Study 10 Li N (2018)

Study details

Study type	Case report
Country	China
Recruitment period	2017
Study population and number	n=1 Adult patient with tracheal stenosis
Age and sex	52 years; Male
Patient selection criteria	Not applicable
Technique	Balloon dilation was performed under general anaesthesia. No further details of the technique are reported.
Follow-up	Not reported
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: Not reported

Analysis

Study design issues: This retrospective case report describes a patient with tracheal stenosis who experienced tracheal collapse after balloon dilation.

Key safety findings

Immediately following balloon dilation and extubation, the patient had dyspnoea with laryngeal stridor. There were no breathing sounds on auscultation and the oxygen saturation of the patient dropped below 80% with a progressively rapid heartbeat. Despite use of a pressurised facemask ventilation, oxygen saturation continued to decrease. Following further bronchoscopy, a stent was inserted, and the patient was gradually relieved from respiratory distress.

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Study 11 Morales-Estrella JL (2018)

Study details

Study type	Case report
Country	US
Recruitment period	2017
Study population and number	n=1 Adult patient with tracheal stenosis
Age and sex	83 years; Female
Patient selection criteria	Not applicable
Technique	Prior to the procedure described in this case report, the patient had received balloon dilation twice in the previous 4 years. Under general anaesthesia, the tracheal stenosis was dilated using a CRE balloon dilator (CRE Balloon Dilator, Boston Scientific, Marlborough, MA, US) at 12 mm diameter using 3.0 atmospheres pressure for 60 seconds. This was followed by repeat dilation at 13.5 mm diameter using 4.5 atmospheres for 60 to 70 seconds.
Follow-up	24 hours
Conflict of interest/source of funding	Conflict of interest: No conflicts of interest Source of funding: Not reported

Analysis

Study design issues: This retrospective case report describes a patient with tracheal stenosis who experienced pulmonary oedema and haemorrhagic lesions after balloon dilation.

Key safety findings

Following balloon dilation, examination of the distal tracheobronchial tree found new punctate haemorrhagic mucosal lesions, generalised mucosal oedema and a frothy haemorrhagic endobronchial effluent, persisting despite repetitive suctioning. There was no evidence of bleeding from the treatment site. Further airway inspection revealed diffuse mucosal oozing and failed to identify a single source of bleeding. The endobronchial findings were similar to acute pulmonary oedema. Thirty-five minutes after the induction, the balloon dilation procedure was concluded, and the patient was successfully extubated in the procedure room to a face mask supplying oxygen at 4 litres per minute. The patient improved over the subsequent hours. The patient remained free of symptoms during a 24 hours' observation period before discharge.

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Validity and generalisability of the studies

- The studies were heterogeneous with regard to patient populations and included adults, children, and infants with acquired and congenital subglottic or tracheal stenosis.
- Studies that only included patients with bronchial stenosis were excluded. Studies that included both patients with bronchial stenosis and subglottic/tracheal stenosis, and did not present separate outcomes for both stenosis locations, were not included in the key evidence.
- The balloon dilation technique was consistent across studies, but there were considerable differences in the number of procedures, number of dilations per procedure, balloon pressure, and in the frequency of use of adjunctive therapy.
- None of the studies used the CE marked device available for use in the NHS.
- There are data from the UK, US, and a case report from China.
- Most of the studies had small sample sizes.
- No randomised experimental studies were identified by this search, or by the Lang, 2014 and Schweiger, 2020 systematic reviews.
  - All the primary studies included in the evidence base were therefore observational studies.
- The longest follow-up was 7 years – this was the upper bound of a range reported by a study captured in the Schweiger, 2020 systematic review.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

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- Endoscopic balloon dilatation for subglottic or tracheal stenosis. NICE interventional procedures guidance 425 (2012). Available from https://www.nice.org.uk/guidance/ipg425

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaire for endoscopic balloon dilation for subglottic or tracheal stenosis was submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 0 completed submissions.

Issues for consideration by IPAC

- The original guidance cited that the evidence was insufficient in quality and quantity, so this overview used an inclusion criterion of studies with at least 30 patients who had treatment with balloon dilation. Studies with fewer than 30 patients were considered if they had long follow-up, or if infrequently reported outcomes (such as QoL) were assessed.

- Studies that only included patients with bronchial stenosis were excluded.

- Although there is a balloon catheter device that has been CE marked for use in the airways, none of the identified studies used it.

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10. Li N, Zhu L, Sun J et al. (2018) Difficulty in tracheal extubation followed by tracheal collapse after balloon dilatation for tracheal stenosis therapy: A case report. Medicine 97(22):e10907
11. Morales-Estrella JL, MacHuzak M, Pichurko B et al. (2018) Suffocation from Balloon Bronchoplasty. Journal of Bronchology and Interventional Pulmonology 25(2):156-60

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Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	13/04/2021	Issue 4 of 12, April 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	13/04/2021	Issue 4 of 12, April 2021
International HTA database (INAHTA)	13/04/2021	n/a
MEDLINE (Ovid)	13/04/2021	1946 to April 12, 2021
MEDLINE In-Process (Ovid)	13/04/2021	1946 to April 12, 2021
MEDLINE Epubs ahead of print (Ovid)	13/04/2021	April 12, 2021
EMBASE (Ovid)	13/04/2021	1974 to 2021 April 09

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

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The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	trachea/
2	glottis/
3	(trache* or glotti* or laryngotrach* or subglot* or windpip* or airway*).tw.
4	or/1-3
5	constriction, pathologic/
6	(steno* or narrow* or constric* or contract* or reduc* or tighten* or malform* or stricture*).tw.
7	5 or 6
8	4 and 7
9	laryngostenosis/
10	laryngosteno*.tw.
11	tracheal stenosis/
12	(trache* adj4 steno*).tw.
13	(respiratory adj4 (distress* or difficult*)).tw.
14	edema/
15	or/9-14
16	8 or 15
17	balloon dilation/
18	(balloon* adj4 (dilat* or expand* or inflat* or catheter*)).tw.
19	17 or 18
20	endoscopy/
21	laryngoscopy/
22	endoscope/
23	laryngoscope/
24	(endoscop* or laryngoscop*).tw.
25	or/20-24

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Number	Search term
26	19 and 25
27	16 and 19
28	16 and 26
29	27 or 28
30	(tracoe or aeris or inspira or metic).tw.
31	29 or 30
32	animals/ not humans/
33	31 not 32
34	limit 33 to ed=20111125-20190531

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Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Allen CT, Lee CJ, Meyer TK et al. (2014) Risk stratification in endoscopic airway surgery: Is inpatient observation necessary? American Journal of Otolaryngology - Head and Neck Medicine and Surgery 35(6):747-52	Retrospective case series n=91 BD procedures=126	Patients undergoing endoscopic surgery for airway stenosis rarely have post-operative complications, and outpatient surgery appears to be a safe alternative to post-operative admission and observation.	Outcomes for balloon and rigid dilation techniques are not presented separately.
Alshammari J, Alkhunaizi AA, and Arafat AS. (2017) Tertiary center experience with primary endoscopic laryngoplasty in pediatric acquired subglottic stenosis and literature review. International Journal of Pediatrics & Adolescent Medicine 4(1):33-7	Case series n=45 BD n=45 FU=1 year	**Paediatric** Primary endoscopic management was successful in 82% of cases of acquired subglottic stenosis including those with high grade stenosis. There were no clinically significant observed complications with endoscopic management.	Study is included in the Schweiger, 2020 systematic review.

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Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Avelino M, Maunsell R, and Jubé Wastowski I. (2015) Predicting outcomes of balloon laryngoplasty in children with subglottic stenosis. International journal of pediatric otorhinolaryngology 79(4):532-6	Prospective case series n=48 BD n=48	**Paediatric** Success rate was 100% for acute and 39% for chronic subglottic stenosis. Success was associated with several factors, including recently acquired stenosis, initial grade of stenosis, younger patient age, and the absence of tracheotomy. Complications were transitory dysphagia observed in 3 children and a submucosal cyst in 1 of the patients.	Study is included in the Schweiger, 2020 systematic review.
Bo L, Li C, Chen M et al. (2018) Application of Electrocautery Needle Knife Combined with Balloon Dilatation versus Balloon Dilatation in the Treatment of Tracheal Fibrotic Scar Stenosis. Respiration 95(3):182-187	Retrospective case series n=43 BD n=43	**Adult** After treatment the symptoms, such as shortness of breath, were markedly improved immediately in all cases. The stenosis degree of patients who were treated with the electrocautery needle knife combined with balloon dilation had better improvement compared with that of those treated with balloon dilation treatment alone after 3 months. Mild mucosal laceration occurred in 5 after dilation, and the lacerations self-healed without special treatment.	Larger studies included.

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Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Chen C, Ni WH, Tian TL et al. (2017) The outcomes of endoscopic management in young children with subglottic stenosis. International Journal of Pediatric Otorhinolaryngology 99:141-145	Retrospective case series n=56 BD n=56 FU=0.5 to 7 years	**Paediatric** Of patients who received balloon dilation alone, 19/19 (100%) had a successful efficacy outcome. Of patients who received balloon dilation and endoscopic anterior cricoid split, 30/37 (81%) had a successful efficacy outcome. No procedure-related complications were observed.	Study is included in the Schweiger, 2020 systematic review.
Cho YC, Kim JH, Park JH et al. (2015) Tuberculous Tracheobronchial Strictures Treated with Balloon Dilation: A Single-Center Experience in 113 Patients during a 17-year Period. Radiology 277(1):286-93	Retrospective case series n=113 BD n=113 FU=mean 30.3 months	Balloon dilation of tuberculous tracheobronchial strictures is a safe, minimally invasive primary treatment that relieved symptoms in a large percentage of patients (73%).	Most patients (88) had bronchial stenoses. Larger studies including patients with tracheal or subglottic stenosis are included.
Chueng K and Chadha NK. (2013) Primary dilatation as a treatment for pediatric laryngotracheal stenosis: a systematic review. International Journal of Pediatric Otorhinolaryngology 77(5):623-8	Systematic review n=12 studies, 34 patients	**Paediatric** In studies using balloon dilation alone (6 studies, n=10) the average success rate was 50%. In studies using balloon dilation with adjuvant therapy (6 studies, n=24) success rates ranged from 50% to 78%.	More recent systematic reviews included.

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Feinstein AJ, Goel A, Raghavan G et al. (2017) Endoscopic Management of Subglottic Stenosis. JAMA Otolaryngology–Head & Neck Surgery 143(5):500-5	Retrospective case series n=101 BD n=96 FU=mean 2.8 years	Endoscopic surgery for subglottic stenosis is a critical aspect of patient management. Neither surgical technique nor grade of stenosis was seen to alter the surgical intervals. Mitomycin application was associated with an extended time interval between endoscopic treatments.	Efficacy outcomes not reported.
Fernando HC, Dekeratry D, Downie G et al. (2011) Feasibility of spray cryotherapy and balloon dilation for non-malignant strictures of the airway. European Journal of Cardio-Thoracic Surgery 40(5):1177-80	Retrospective case series n=35 BD n=35 FU=median 8.2 months	Initial experience with spray cryotherapy and balloon dilation for benign airway stenosis suggests that this can be used safely. This is effective in improving symptoms and reducing the severity of airway narrowing. Re-intervention is still required.	Larger studies included. Outcomes for tracheal/subglottic and bronchial stenoses are not presented separately.
Gunaydin RO, Suslu N, Bajin MD et al. (2014) Endolaryngeal dilatation versus laryngotracheal reconstruction in the primary management of subglottic stenosis. International Journal of Pediatric Otorhinolaryngology 78:1332-36	Retrospective case series n=35 BD n=13 FU=median 4 years	**Paediatric** This study compared endolaryngeal dilations with laryngotracheal reconstruction with cartilage grafting in terms of restenosis. Restenosis was higher in the dilation group (63.2%) than the laryngotracheal reconstruction group (31.3%).	Larger studies included.

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Hautefort C, Teissier N, Viala P et al. (2012) Balloon dilation laryngoplasty for subglottic stenosis in children: eight years' experience. Archives of Otolaryngology – Head & Neck Surgery 138(3):235-40	Retrospective case series n=44 BD n=44	**Paediatric** A total of 52 balloon dilation laryngoplasties were performed, and 37 (71%) were successful. Of patients who had primary dilation, 20/31 (65%) had successful outcomes. Of patients who had balloon dilation as a secondary procedure after recent open surgery, 17/21 (81%) were successful. There were no clinically significant observed complications with balloon dilation (notably, no haemorrhage, cervical emphysema, or pneumothorax).	Study is included in the Lang, 2014 systematic review.
Hebra A, Powell DD, Smith CD et al. (1991) Balloon tracheoplasty in children: results of a 15-year experience. Journal of Pediatric Surgery 26:957–61	Retrospective case series n=37 BD n=37	**Paediatric** Almost all patients received some immediate benefit from balloon dilation, with 54% of the patients achieving long-term improvement (with a minimum follow-up of 2 months). There were 4 deaths, 1 of which was reported to be related to the procedure.	Study is included in the Lang, 2014 systematic review.
Hseu AF, Benninger MS, Haffey TM et al. (2014) Subglottic stenosis: A ten-year review of treatment outcomes. Laryngoscope 124(3):736-741	Retrospective case series n=92 BD n=42 FU=median 2.4 years	**Adult** Mean time to next surgery with balloon dilation was 1.02 years. This was not statistically significantly different from bougie dilation. No significant complications were encountered after dilation.	No efficacy data for balloon dilation. Larger studies included.

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Kim JH, Shin JH, Shim TS et al. (2007) Tracheobronchial laceration after balloon dilation for benign strictures: incidence and clinical significance. Chest 131: 1114–7	Retrospective case series n=97 FU=mean 6 months	Stenosis recurred during follow-up in 42/117 (35.9%) patients. Tracheobronchial lacerations occurred after 64/124 (51.6%) of procedures. 60/64 (94%) of the lacerations were superficial and 4/64 (6%) were deep. All 60 superficial lacerations healed spontaneously within 1 month. The deep lacerations healed after 2−9 months with conservative treatment.	Most patients had bronchial stenoses.
Kocdor P, Siegel ER, Suen JY et al. (2016) Comorbidities and factors associated with endoscopic surgical outcomes in adult laryngotracheal stenosis. European Archives of Oto-Rhino-Laryngology 273(2):419-24	Retrospective case series n=101 FU=median 1.7 years	**Adult** Number of balloon dilations ranged from 0 to 24 (mean=3.3). The average time between dilations was 38.4 weeks. No statistically significant correlation was found when the patients' age, BMI and comorbidites were compared with the grade of stenosis, number of balloon dilations needed and other surgical interventions.	Efficacy outcomes not reported.

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Lee KCH, Goh JK, Hsu AAL et al. (2020) Long-term outcomes of tracheobronchial stenosis due to tuberculosis (TSTB) in symptomatic patients: Airway intervention vs. conservative management. Journal of Thoracic Disease 12(7):3640-50	Retrospective database review n=131 BD n=60 FU=median 5 years	Bronchomalacia and prior bronchoscopic airway resection are associated with the recurrence of symptoms despite airway intervention. Patients who are diagnosed with tracheal stenosis due to tuberculosis early in the course of active tuberculosis may be conservatively managed.	Outcomes for tracheal/subglottic and bronchial stenoses are not presented separately.
Li LH, Liang YL, Li Y et al. (2018) Comparison between traditional and small-diameter tube-assisted bronchoscopic balloon dilatation in the treatment of benign tracheal stenosis. The clinical respiratory journal 12(3):1053-60	Retrospective case series n=58 BD n=58 FU=6 months	In patients who received traditional balloon dilation, there were statistically significant differences in oxygen saturation before and after dilation (p=0.005), while there was no statistically significant difference in patients who received small-diameter tube-assisted dilation (p=0.079). The immediately cure rate in both groups was 100%. Complications related to the procedures included mild chest pain, bleeding, tracheal laceration, respiratory tract infection and convulsion.	Studies with longer follow-up included.

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Liang W, Hu P, Guo W et al. (2019) Appropriate treatment sessions of flexible bronchoscopic balloon dilation for patients with nonmalignant central airway stenosis. Therapeutic Advances in Respiratory Disease 13	Retrospective case series n=150 patients with airway stenosis treated with BD. Of these, 111 patients had long-term effectiveness and were included in this study. FU=at least 1 year	Of 38 patients with stenosis of the lower glottis and upper airway, middle airway, or lower airway and carina, all had 6 treatment sessions or fewer. Results from all patients (including the 63 patients with bronchial stenosis) suggest that the maximum number of treatment sessions of balloon dilation may be 6, and patients requiring more treatment sessions were more likely to have delayed long-term effectiveness. Complications included different levels of mucosal injury (n=111, 100%), severe bronchial laceration (n=6, 5.4%) and slight mediastinal emphysema (n=2, 1.8%).	Outcomes for tracheal/subglottic and bronchial stenoses are not presented separately.
Martinez Del Pero M, Jayne D, Chaudhry A et al. (2014) Long-term outcome of airway stenosis in granulomatosis with polyangiitis (Wegener granulomatosis): an observational study. JAMA Otolaryngology–Head & Neck Surgery 140(11):1038-44	Retrospective case series n=44 BD procedures=130 FU=median 62.5 months	Using a range of interventions, including balloon and bougie dilation and laser treatment, a 12-month period of airway stability was achieved in 34 of 36 cases (97%) (5 had no procedures and 3 had follow-up shorter than 12 months). 14 adverse events were recorded (6.6%), though the number related to balloon dilation was not reported.	Outcomes for different stenosis types and for different treatments were not presented separately.

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Noppen M, Meysman M, D'Haese J et al. (1997) Interventional bronchoscopy: 5-year experience at the academic hospital of the Vrije Universiteit Brussel (AZ-VUB). Acta Clinica Belgica 52: 371-380.	Case series n=93	Bronchoscopic balloon dilation was helpful in the mechanical dilation of stenoses, and in the unfolding of unopened stents.	Combination of techniques used (laser surgery, stenting and balloon dilation).
Nouraei SAR, Ghufoor K, Patel A et al. (2007) Outcome of endoscopic treatment of adult postintubation tracheal stenosis. Laryngoscope 117: 1073–9.	Case series n=62	**Adult** 98% of reinterventions occurred within 6 months. Patients with old and long lesions are less likely to be cured endoscopically.	Combination of techniques used (steroids, laser surgery and balloon dilation).
Rahman NA, Fruchter O, Shitrit D et al. (2010) Flexible bronchoscopic management of benign tracheal stenosis: long term follow-up of 115 patients. Journal of cardiothoracic surgery 5: 2.	Retrospective case series n=115 Median FU=51 months	All patients underwent balloon dilation as an initial temporary relieving procedure. The overall success rate was 87%. Procedure complications were relatively minor and manageable.	Patients also treated by laser, stent insertion or brachytherapy.

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Shabani S, Hoffman MR, Brand WT et al. (2016) Endoscopic Management of Idiopathic Subglottic Stenosis: Factors Affecting Inter-Dilation Interval. Annals of Otology, Rhinology and Laryngology 126(2):96-102	Retrospective case series n=37 BD n=37	Patients had an average of 3.8 dilations and the average inter-dilation interval was 635 days. Inter-dilation interval was not associated with concomitant steroids, BMI, or number of comorbidities.	Larger studies included.
Sharma SD, Gupta SL, Wyatt M et al. (2017) Safe balloon sizing for endoscopic dilatation of subglottic stenosis in children. Journal of Laryngology & Otology 131(3):268-272	Retrospective case series n=166 BD n=166	**Paediatric** Study was primarily assessing the safe balloon size for dilation of subglottic stenosis. The publication reports that 'no significant unexpected events occurred' – though a definition of expected adverse events was not reported.	Primary outcomes are not high importance for efficacy assessment of balloon dilation. Safety outcomes are not reported in sufficient detail.
Shitrit D, Kuchuk M, Zismanov V et al. (2010) Bronchoscopic balloon dilatation of tracheobronchial stenosis: long-term follow-up. European Journal of Cardiothoracic Surgery 38:198–202	Case series n=35 BD n=35 FU=mean 33 months	**Adult** All patients had initial success characterised by increased luminal dimensions and symptom relief. There were no technical failures. 71% (25/35) of all patients required stent placement (at 210 ± 91 days after balloon dilation) for long-term improvement. No minor or major complications attributable to balloon dilation.	Large proportion of bronchial stenoses, larger studies included.

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Sinacori JT, Taliercio SJ, Duong E et al. (2013) Modalities of treatment for laryngotracheal stenosis: the EVMS experience. Laryngoscope 123(12):3131-6	Retrospective case series n=188 BD n=69	**Adult** Trends in surgical management of airway stenosis were assessed. Balloon dilation was most used in patients with multilevel tracheal stenosis (66%). Safety outcomes were not reported.	Study did not focus on efficacy assessment of balloon dilation.
Talwar R, Virk JS, and Bajaj Y. (2015) Paediatric subglottic stenosis - Have things changed? Our experience from a developing tertiary referral centre. International Journal of Pediatric Otorhinolaryngology 79(12):2020-2	Prospective longitudinal study n=33 FU=mean 12 months	**Paediatric** Patients with subglottic stenosis underwent 73 micro-laryngobronchoscopy interventions (2.21 per patient) such as incision and balloon dilation, tracheostomy (2 of 33) or ultimately, laryngotracheal reconstruction (2 of 33). There were no deaths and no significant unexpected events in these patients.	Unclear how many dilations were performed. No linkage of dilation to efficacy outcomes.

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