



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER428
Topic:	Endoscopic balloon dilation for subglottic or tracheal stenosis
Summary of findings:	<p>An interventional procedures guidance (IPG) document was produced by the National Institute for Health and Care Excellence (NICE) in March 2022.</p> <p>The IPG concluded that the procedure is considered safe with low adverse events for both adults and children, although the evidence to support its efficacy is limited in adults. The conclusions generated from the evidence in the IPG are based on observational studies including two retrospective comparative studies.</p> <p>Health Technology Wales researchers did not identify any clinical or cost effectiveness data since the IPG in March 2022. We did not identify any on-going studies that are due for completion within the next year.</p>

Introduction and aims

Subglottic or tracheal stenosis is a narrowing of the airway. 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 usually done under general anaesthesia, using direct laryngoscopic or bronchoscopic visualisation. The aim of the procedure is to widen the airway and improve symptoms which include but not limited to respiratory distress and exercise intolerance.

Current treatment options for subglottic or tracheal stenosis can include inhaled or oral steroids, endoscopic techniques such as stent insertion, laser ablation, and resection surgery. In babies, a cricoid-split operation can decompress the subglottis and can prevent the development of stenosis.

Health Technology Wales researchers searched for evidence on the clinical effectiveness and cost effectiveness of endoscopic balloon dilation for adults and/or children with subglottic or tracheal stenosis. NICE interventional procedures guidance (IPG) was produced in March 2022 and included evidence on efficacy and safety published up to 4 October 2021. Health Technology Wales researchers searched for any additional clinical evidence published after October 2021 and searched for any cost-effectiveness data with no search limits.

Evidence overview

Guidance

One IPG, 'Endoscopic balloon dilation for subglottic or tracheal stenosis' published in March 2022 (NICE 2022) concluded that the evidence on the safety of endoscopic balloon dilation for subglottic or tracheal stenosis is adequate. However, evidence on the efficacy of the procedure is limited. So, it should only be used with special arrangements for clinical governance, consent, and audit or research. For children and babies, the evidence on efficacy and safety was reported as adequate providing those standard arrangements are in place for clinical governance, consent, and audit.

Evidence overview

The rapid review produced as part of the IPG included one registry study, one systematic review and meta-analysis, one systematic review, one cohort study, five case series, three case reports, and one database analysis. The systematic reviews included in the IPG studied the efficacy of endoscopic balloon dilation in babies and children. Three individual case reports, two case series reports and three retrospective papers studied adults. No randomised experimental studies were identified by this search, or by the systematic reviews. Most of the studies were based in the US, with one non-comparative case series study based in the UK. Other countries included Israel, China, and Saudi Arabia.

The IPG identified two studies where endoscopic balloon dilation was compared to either laryngotracheoplasty (Maresh et al. 2014) or rigid dilation (Glikson et al. 2021). We have only reported comparative evidence to demonstrate how effective the intervention compares with other treatment options for subglottic or tracheal stenosis

Comparative evidence

The IPG review included one comparative retrospective case series study based in the US and one comparative retrospective study based in Israel (Glikson et al. 2021). The comparative case series studied 27 people aged 21 years or under with subglottic stenosis undergoing endoscopic balloon dilation, retrospectively in comparison with laryngotracheoplasty. The paper reported that 100% of people were successfully decannulated or avoided tracheotomy, and that 52% avoided

laryngotracheoplasty. The paper also reported that when compared with 63 people who had initial treatment with laryngotracheoplasty, people who had initial treatment with balloon dilation instead 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, $p = 0.003$), although the duration of follow up was not reported.

The retrospective cohort study (Maresh et al. 2014) included 40 adults with laryngotracheal stenosis when endoscopic balloon dilation was retrospectively compared to rigid dilation. The paper reported that out of a total of 69 procedures, 71 percent were in remission at eight weeks follow up. This was statistically significantly more than a comparison cohort of people who had rigid dilation ($p < 0.05$) although the exact result figures for the control group were not reported in the IPG.

Economic evidence

HTW researchers did not identify any cost effectiveness data about endoscopic balloon dilation for subglottic or tracheal stenosis.

Areas of uncertainty

The evidence in the IPG includes retrospective comparative data about the clinical effectiveness of endoscopic balloon dilation when compared to other treatments for subglottic or tracheal stenosis, although prospective data is limited. The studies identified compared endoscopic balloon dilation to laryngotracheoplasty or rigid dilation although other treatment options may be available.

Since the IPG in March 2022, we did not identify any additional data to support the clinical and cost effectiveness of endoscopic balloon dilation.

Literature search results

Health technology assessments and guidance
NICE. (2022). Endoscopic balloon dilation for subglottic or tracheal stenosis. Interventional procedures guidance. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/ipg719 [Accessed 10 November 2022].
Evidence identified by NICE
Glikson E, Abbass A, Carmel E, et al. (2021). Endoscopic Management of Benign Laryngo-Tracheal Stenosis: Balloon vs. Rigid Dilatation. <i>Isr Med Assoc J.</i> 23(5): 297-301. Available at: https://pubmed.ncbi.nlm.nih.gov/34024046/
Maresh A, Preciado DA, O'Connell AP, et al. (2014). A comparative analysis of open surgery vs endoscopic balloon dilation for pediatric subglottic stenosis. <i>JAMA otolaryngology-- head & neck surgery.</i> 140(10): 901-5. doi: 10.1001/jamaoto.2014.1742. Available at: https://pubmed.ncbi.nlm.nih.gov/25170960/
Evidence reviews and economic evaluations
No evidence identified
Individual studies
No evidence identified
Ongoing research
No evidence identified

Date of search:	November 2022
Concepts used:	Endoscopic balloon dilation; subglottic and tracheal stenosis;