

Endoscopic balloon dilation for subglottic or tracheal stenosis

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg719

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG425.

1 Recommendations

- 1.1 Evidence on the safety of endoscopic balloon dilation for subglottic or tracheal stenosis is adequate. The most serious complication related to the procedure, independent of age, is tracheal laceration but this is well recognised.
- For babies, children, and young people, evidence on the efficacy of the procedure is adequate to support using it, provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
 - For adults, 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do endoscopic balloon dilation for subglottic or tracheal stenosis in adults should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.

- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedures outcomes audit tool](#) (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 This procedure should only be done in specialist centres by clinicians trained in the technique, and with anaesthesia and intensive care support.

1.5 Report any problems with a medical device using the [Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme](#).

2 The condition, current treatments and procedure

The condition

- 2.1 Subglottic or tracheal stenosis is a narrowing of the airway. It 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 happen, needing continued intubation or tracheostomy.

Current treatments

- 2.2 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 babies. For people with severe and established stenosis, endoscopic techniques such as stent insertion or laser ablation are used. Alternatively, open surgical repair is done to increase the diameter of the stenosed segment with a graft or stent (expansion surgery) or to remove the stenotic area (resection surgery).

The procedure

- 2.3 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 done on iatrogenic stenoses, which are typically soft. It is less commonly done on harder, established stenoses.
- 2.4 The procedure is usually done under general anaesthesia, 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 is withdrawn. The procedure may be used in combination with other treatments. It can be repeated if needed. The aim is to widen the stenotic airway and improve symptoms.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 13 sources, which was discussed by the committee. The evidence included 1 registry study, 1 systematic review and meta-analysis,

1 systematic review, 1 cohort study, 5 case series, 3 case reports, and 1 database analysis. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, increase in tracheal diameter, reduction in need for further surgery, and permanent tracheostomy decannulation.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: tracheal laceration, oedema, and bleeding.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that most of the data it reviewed came from babies, children, and young people.
- 3.6 The committee encourages data entry to a registry for this procedure to collect long term outcomes.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).