Endoscopic balloon dilatation for subglottic or tracheal stenosis

Interventional procedures guidance
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nice.org.uk/guidance/ipg425

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. However, 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.

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.

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.

1 Guidance

1.1 Current evidence on the safety and efficacy of endoscopic balloon dilatation for subglottic or tracheal stenosis is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
1.2 Clinicians wishing to undertake endoscopic balloon dilatation for subglottic or tracheal stenosis should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers or parents understand the uncertainty about the procedure’s safety and efficacy, and provide them with clear written information. In addition, the use of NICE’s information for patients is recommended.
- Clinicians should enter details for paediatric patients having endoscopic balloon dilatation for subglottic or tracheal stenosis onto the Airway Intervention Registry (accessible from any computer connected to the N3 [NHS] network) and for adult patients having the procedure into the ENT UK national audit database.

1.3 Further information from research and collaborative data collection would be useful. This should include clearly defined patient selection criteria and long-term outcomes. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Subglottic or tracheal stenosis is most often caused by prolonged endotracheal intubation, but it may also result from other types of trauma. In some patients it is congenital. Symptoms include hoarseness, stridor, exercise intolerance and respiratory distress. In severe cases the airway may be completely obstructed, requiring continued intubation or tracheostomy. This guidance only refers to benign strictures excluding those caused by malignancy.

2.1.2 Treatments for subglottic or tracheal stenosis include inhaled or oral steroids to reduce inflammation and swelling. Severe stenosis may be treated endoscopically, by stent insertion or laser ablation, or by open surgery (stenting, grafting or resection of the stenosed segment).

2.2 Outline of the procedure

2.2.1 Endoscopic balloon dilatation aims to dilate the narrowed airway with minimal mucosal trauma.
2.2.2  The procedure is usually done with the patient under general anaesthesia and using direct laryngoscopic or bronchoscopic visualisation. A balloon catheter is introduced into the airway and the balloon is gently inflated, applying radial pressure circumferentially to the stricture. After dilatation, the balloon is deflated and the device withdrawn. The procedure may be used in combination with other measures and techniques (described in section 2.1.2). The procedure can be repeated if required.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3  Efficacy

2.3.1  A case series of 10 infants with acquired subglottic stenosis reported that 70% (7/10) had resolution of symptoms after the first or second balloon dilatation. A second case series of 10 children with subglottic or tracheal stenosis reported that symptoms were resolved or improved in 70% (7/10) at mean follow-up of 10 months.

2.3.2  A case series of 35 patients, which included 11 patients with tracheal stenosis after prolonged mechanical ventilation, reported that all patients had initial symptom relief. Insertion of a stent within 30 days of balloon dilatation was needed in 36% (4/11) of patients (details not provided).

2.3.3  The Specialist Advisers listed key efficacy outcomes as avoidance of need for tracheostomy or surgery to the airway, improvements in lung function tests and exercise tolerance, reduction in stridor and shortness of breath and voice, and anatomical improvements on endoscopy or radiological imaging.

2.4  Safety

2.4.1  A case series of 37 patients reported 1 death thought to be related to balloon dilatation. This was a patient with severe stenosis at the carina who developed a bronchial leak following their fourth weekly dilatation. The leak was repaired, but the patient died as a result of respiratory insufficiency (no further details).
2.4.2 A case report described a patient who had a transmural tracheobronchial disruption after a second balloon dilatation procedure for tracheal stenosis. The injury was repaired by open surgery and the patient recovered.

2.4.3 A case series of 97 patients reported tracheobronchial lacerations in 52% (64/124) of procedures but all resolved spontaneously.

2.4.4 Two case series, each including 10 infants or children with subglottic or tracheal stenosis, reported that there were no complications.

2.4.5 The Specialist Advisers listed reported adverse events as airway obstruction, vocal cord avulsion, bleeding and tracheobronchial tears. They listed theoretical safety concerns as ruptured trachea or bronchi, arytenoid dislocation, pneumothorax, aspirated balloon fragments (which could cause airway obstruction) and tracheobronchomalacia.

2.5 Other comments

2.5.1 The Committee noted that the published evidence was related to a variety of different techniques, some of which are no longer used. There was very little evidence on balloon devices in use at the time this guidance was produced.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.
We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication

**November 2015:** Minor maintenance.

**September 2014:** Minor maintenance.

**March 2015:** Minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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**Endorsing organisation**

This guidance has been endorsed by [Healthcare Improvement Scotland](http://www.hics.scot.nhs.uk/).
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