NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic balloon dilation for subglottic or tracheal stenosis

Narrowing of the airway between the throat and the lungs (a subglottic stenosis or a tracheal stenosis) can cause difficulty breathing. It can happen 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. Under a general anaesthetic, a tube with a camera on the end (endoscope) is inserted down the throat and used to guide a deflated balloon into the narrowed part of the airway. The balloon is inflated for a short time, then deflated and removed. The aim is to widen (dilate) the airway and improve symptoms.

NICE is looking at endoscopic balloon dilation for subglottic or tracheal stenosis. This is a review of NICE's interventional procedures guidance on endoscopic balloon dilatation for subglottic or tracheal stenosis.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

Issue date: July 2021

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 18 November 2021

Target date for publication of guidance: February 2022

1 Draft recommendations

1.1 Evidence on the safety of endoscopic balloon dilation for subglottic or tracheal stenosis is adequate and shows the potential for serious complications including tracheal laceration.

- 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 procedure 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 11 sources, which was discussed by the committee. The evidence included 1 registry study, 1 systematic review and meta-analysis, 1 systematic review, 4 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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
July 2021

ISBN: