

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Bronchial thermoplasty for severe asthma

Asthma affects the small tubes (airways) that carry air in and out of the lungs. In severe asthma the lining of the airways becomes inflamed and swollen. This narrows them and makes it harder for air to pass through. Muscle tissue lining the airways may become thickened, narrowing the airways even more. This procedure involves applying thermal energy (heat) to the inside walls of the airways. The aim is to reduce the amount of muscle tissue, so there is less to contract and narrow the airway.

The National Institute for Health and Care Excellence (NICE) is looking at bronchial thermoplasty for severe asthma. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations 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: 21 June 2018

Target date for publication of guidance: September 2018

1 Draft recommendations

1.1 The short-term evidence on bronchial thermoplasty for severe asthma raises no major safety concerns and shows improvements in quality of life and reduced frequency of exacerbations. However, evidence on its long-term safety and efficacy is limited. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do bronchial thermoplasty for severe asthma should:

- Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the uncertainty about the procedure's long-term safety and efficacy and provide them with clear written information to support [shared decision-making](#). In addition, the use of NICE's [information for the public](#) [*URL to be added at publication*] is recommended.

- 1.3 The procedure should only be done in specialist centres with on-site access to intensive care, by clinicians with training in the procedure and experience in managing severe asthma.
- 1.4 Clinicians should enter details of all patients who have the procedure on to the UK Severe Asthma Registry.
- 1.5 Further research should report details of patient selection and long-term safety and efficacy outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Asthma is a long-term condition of the airways in the lungs that affects children, young people and adults. It consists of inflammation and constriction of the smooth muscle in the airway walls (bronchoconstriction). This is triggered by increased responsiveness of the airways to various allergic stimuli, leading to airflow obstruction. Symptoms include recurring episodes of wheezing, breathlessness, chest-tightness and coughing.
- 2.2 Asthma is diagnosed and its severity assessed on the basis of symptoms and objective tests of lung function.

Current treatments

- 2.3 Treatment, including advice about lifestyle changes, aims to reduce the frequency and severity of attacks, allowing the person to lead a normal and active life. In the UK, treatment for asthma follows [NICE guideline 80](#) and guidelines from the [Global Initiative for Asthma](#).
- 2.4 Asthma is managed using a step-up approach. Mild intermittent asthma is treated using inhaled short-acting beta-2 agonists (bronchodilators) as needed (step 1). Step 2 includes inhaled corticosteroids in the treatment. Step 3 adds an additional therapy such as inhaled long-acting beta-2 agonists. At step 4, high-dose inhaled corticosteroids are used and an additional drug may be taken, such as a leukotriene receptor antagonist or theophylline. At step 5, continuous or frequent courses of oral corticosteroids are needed.

The procedure

- 2.5 The aim of bronchial thermoplasty for severe asthma is to reduce the smooth muscle mass lining the airways, decreasing their ability to constrict.
- 2.6 The procedure is usually done with the patient under sedation or general anaesthesia. A catheter is introduced into the bronchial tree. Short pulses of radiofrequency energy are applied circumferentially to sequential portions of the airway wall, moving from the distal to the proximal bronchi. Treatment is usually delivered in 3 sessions with an interval of at least 3 weeks between each session. After the first session, treated airways are evaluated by bronchoscopy before proceeding with further treatment.

3 Committee considerations

The evidence

- 3.1 To inform the committee, 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 12 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analysis, 1 randomised controlled trial, 3 case series (2 of which were extensions of randomised trials; evidence from 1 was extracted from 2 published sources), 1 non-randomised comparative study, 1 registry and 3 case reports, and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, reduced exacerbations and hospital admissions, and improved respiratory function.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pneumothorax, bleeding, admissions to intensive care and, in the longer term, airway stenosis and lung fibrosis.
- 3.4 This guidance is a review of NICE's interventional procedures guidance on [bronchial thermoplasty for severe asthma](#).

Committee comments

- 3.5 There is uncertainty about which patients may benefit from the procedure.
- 3.6 The committee noted that the device used in this procedure does not have a CE mark for use in people younger than 18 years.
- 3.7 This procedure may not be suitable for people with bronchiectasis.
- 3.8 The procedure should only be used for severe asthma that is not controlled despite optimal drug treatment.
- 3.9 The committee was informed that bronchial thermoplasty could complement the use of biologic treatment in the future.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

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