NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Bronchoscopic thermal vapour ablation for upper-lobe emphysema

Emphysema is a chronic lung disease. It causes the walls of the smaller airways in the lungs to break down and create abnormally large spaces, which compress the healthy parts of the lung. In this procedure, a bronchoscope (a thin tube with a camera on the end) is passed through the mouth or nose and into the lungs. It is used to deliver thermal vapour (steam) to destroy the diseased parts of the lung and allow the healthy parts to expand and work better.

The National Institute for Health and Care Excellence (NICE) is looking at bronchoscopic thermal vapour ablation for upper-lobe emphysema. 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, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 February 2019

Target date for publication of guidance: May 2019

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of bronchoscopic thermal vapour ablation for upper-lobe emphysema is inadequate in quantity and quality. Therefore the procedure should only be used in the context of research.

1.2 Further research should evaluate safety and efficacy in the short and long term and include details of patient selection. NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Emphysema is a chronic lung disease that typically happens with chronic obstructive pulmonary disease. In emphysema, the walls of the air sacs (alveoli) in the lungs weaken and disintegrate. This leaves behind abnormally large air spaces that stay filled with air even when the patient breathes out. The most common symptoms of emphysema are shortness of breath, coughing, fatigue and weight loss. Recurrent illnesses (such as chest infections) often lead to exacerbations, for which patients may need hospitalisation. Emphysema is usually related to smoking but other risk factors include air pollution and an inherited alpha-1-antitrypsin deficiency.

Current treatments

2.2 Treatment options include pulmonary rehabilitation (exercise training, breathing retraining, and patient and carer education), stopping smoking, and using inhaled or oral bronchodilators and corticosteroids. Oxygen therapy may also be needed in more severe cases. Lung volume reduction surgery is an option for patients who experience breathlessness, and whose pulmonary function tests and CT scans show severe disease and enlarged air spaces. Surgery can be done thoracoscopically or using an open approach. Endoscopic lung volume reduction techniques include implanting valves or coils. The aim is to reduce the morbidity and mortality associated with conventional surgery.

The procedure

2.3 Bronchoscopic thermal vapour (steam) ablation for upper-lobe emphysema is usually done using general anaesthesia. A bronchoscope is passed down the airway to the diseased areas of the lung. The most severely affected and hyper-inflated lung segments are targeted for treatment. A special catheter is used to deliver a patient-specific predetermined dose of thermal vapour through the bronchoscope. A balloon at the tip of the catheter is inflated to seal off the targeted area. The dose of thermal vapour

depends on the mass, volume and diseased state of the affected area. The thermal vapour ablates the diseased tissue, which the body removes through the natural healing process. Multiple treatments can be done over time, targeting different segments as the patient's disease progresses. This procedure is not done when there is proven active infection in the lung. The removal of disease tissue results in a reduction of lung volume and subsequent remodelling of the lung. Lung volume reduction typically happens gradually over a 4 to 6 week period. Respiratory symptoms may worsen in the first 2 to 4 weeks after 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 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (reported in 2 studies) and 2 case series (1 of which was reported in 2 studies), 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 and improvement in FEV_1.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: worsening lung function, infection, bleeding and pneumothorax.

Committee comments

3.4 The committee noted that the dose of thermal vapour for each patient is calculated by the company that supplies the vapour generator, using imaging done before the procedure.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
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