



Bronchoscopic thermal vapour ablation for upper-lobe emphysema

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www.nice.org.uk/guidance/ipg652

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 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. Find out what only in research means on the NICE interventional procedures guidance page.
- 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

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 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 FEV₁ (forced expiratory volume).
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: worsening lung function, infection, bleeding and pneumothorax.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 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.
- The committee was informed that the risk of pneumothorax is lower with this procedure compared with endobronchial valves.
- The committee noted that this procedure may have a role in patients with incomplete fissures.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.