

Endobronchial nerve ablation for chronic obstructive pulmonary disease

Interventional procedures guidance

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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of endobronchial nerve ablation for chronic obstructive pulmonary disease (COPD) is inadequate in quantity. Therefore, this 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 be randomised controlled trials comparing the procedure with sham treatment. It should report details of patient selection, and short and long-term functional outcomes including lung functional outcomes, quality of life and patient-reported outcomes, incidence of exacerbations and hospital admissions, and all adverse events.

2 The condition, current treatments and procedure

The condition

- 2.1 Chronic obstructive pulmonary disease (COPD) includes emphysema and chronic bronchitis. It's a common condition that mostly affects middle-aged and older adults. Approximately 4.5% of over 40s in the UK have diagnosed COPD. The main cause of COPD is smoking. The main symptoms are breathlessness, a persistent cough and wheezing, and frequent chest infections. COPD gradually gets worse over time and people can have sudden flare-ups (exacerbations).

Current treatments

- 2.2 Although the damage to the lungs caused by COPD is permanent, treatment can help slow disease progression. Treatments include stopping smoking, pulmonary rehabilitation, inhaled beta-2 agonists, antimuscarinic and steroid inhalers, oral medication such as bronchodilators, mucolytics and steroids, and oxygen. In a very small number of people, surgery or lung transplant may be indicated.

The procedure

- 2.3 In COPD, acetylcholine released from parasympathetic airway nerve fibres mediates smooth muscle tone, reflex bronchoconstriction, mucus hyper-secretion and airway inflammation. This procedure disrupts parasympathetic signalling to the lungs and decreases neuronal release of acetylcholine. The aim is to produce permanent bronchodilation, decrease mucus production and improve breathing.
- 2.4 Endobronchial nerve ablation is a minimally invasive outpatient procedure carried out under general anaesthesia. A bronchoscope is used to visualise the airways and a dual-cooled radiofrequency (RF) catheter, which has a balloon and an electrode on the end, is positioned in the distal mainstem bronchus. Once in position, coolant is passed through the catheter and the balloon inflates, pressing the electrode against the airway wall. RF energy is then delivered from the electrode to ablate the parasympathetic nerves that run along the outside of the mainstem bronchus. The balloon is then deflated and rotated, and the ablation repeated until the whole circumference of the bronchus has been treated. Both main bronchi are treated during a single procedure. Most patients return home on the day of the procedure.

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 6 sources, which was discussed by the committee. The evidence included 2 non-randomised clinical trials, 1 randomised clinical trial (including a dose evaluation study and an open-label confirmation study), 1 randomised controlled clinical trial and 2 additional papers that reported longer-term outcomes from the 2 randomised clinical trials. 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: improvement in quality of life and functional measures of activity, and a reduction in exacerbations and hospital admissions.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: periprocedural adverse events, bronchial damage and gastrointestinal effects.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that there were a few well conducted but small trials, which primarily focused on safety. The committee noted that larger, suitably powered trials are needed to provide more evidence on efficacy.
- 3.6 The committee was told that the procedure is evolving, including different power levels and a change from rigid to flexible bronchoscopic delivery. These changes may affect the safety of the procedure.
- 3.7 The committee noted that pulmonary rehabilitation plays an important role in optimising outcomes for patients with chronic obstructive pulmonary disease.
- 3.8 The committee was told that measures of pulmonary function do not necessarily correlate with quality of life.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.