NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endobronchial nerve ablation for chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease is the name for a group of lung conditions including emphysema and chronic bronchitis. The airways in the lungs become narrowed and secrete too much mucus, causing breathing difficulties.

In this procedure, a bronchoscope (a tube with a camera on the end) is passed through the mouth or nose and into the lungs. A balloon and an electrode are used to destroy (ablate) the nerves on the outside of the airway (endobronchial nerves) using radiofrequency energy, to widen the airway and reduce mucus production. The aim is to improve breathing.

NICE is looking at endobronchial nerve ablation for chronic obstructive pulmonary disease.

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 <u>draft guidance for consultation</u>. 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 The draft guidance may change after this consultation.

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 <u>resolution process</u> 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: 19 August 2021

Target date for publication of guidance: December 2021

1 Draft 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 <u>what only in research</u> <u>means on the NICE interventional procedures guidance page</u>.
- 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, 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

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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.

Committee comments

3.4 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. NICE interventional procedures consultation document, July 2021

- 3.5 The committee was informed 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.
- 3.6 The committee noted that pulmonary rehabilitation plays an important role in optimising outcomes for patients with chronic obstructive pulmonary disease.
- 3.7 The committee was informed that measures of pulmonary function do not necessarily correlate with quality of life.

Tom Clutton-Brock

Chair, interventional procedures advisory committee July 2021

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