

Insertion of endobronchial nitinol coils to improve lung function in emphysema

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg517

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of the insertion of endobronchial nitinol coils to improve lung function in emphysema is limited in quantity and quality. Therefore the procedure should only be used in the context of research.
- 1.2 Research studies would preferably include observational data collection and should describe patient selection in detail. Outcome measures should include lung function, dyspnoea score, exercise tolerance, quality of life and long-term safety. Studies should also report on the influence of the procedure on subsequent lung surgery. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Emphysema is a chronic lung disease, which is usually related to smoking but may also be inherited. It is one of a group of diseases referred to as chronic obstructive pulmonary disease (COPD). Common symptoms of emphysema are dyspnoea, coughing, fatigue and weight loss.
- 2.2 Current treatment options include pulmonary rehabilitation (advice on smoking cessation, patient and carer education, exercise training and breathing retraining) and use of inhaled or oral bronchodilators and glucocorticoids. Some patients benefit from oxygen treatment. In advanced disease, lung volume reduction surgery (thoracoscopic or open), insertion of one-way endobronchial valves, or lung transplantation may be needed.

3 The procedure

- 3.1 Insertion of endobronchial nitinol coils is intended to be a minimally invasive alternative to lung volume reduction surgery. The procedure reduces the volume of diseased areas of the lungs. This minimises airflow to the least functional diseased lung segments, allowing air to flow to healthier parts of the lungs, with the aim of improving gas exchange and, as a result, lung function. The procedure is intended to improve lung function in patients with upper or lower lobe heterogeneous emphysema, as well as in patients with multiple emphysematous lobes with focal tissue defects.
- 3.2 Endobronchial nitinol coils can be inserted with the patient under general anaesthesia or sedation. The bronchial tree of the diseased area of the lung is visualised by bronchoscopy and a low-stiffness guidewire is advanced through the bronchoscope under fluoroscopic guidance. A catheter is then passed over the guidewire. The guidewire is removed and a straightened coil is introduced through the catheter. The catheter is withdrawn while the coil is held in place using a grasper. When released, the straightened coil springs back to a predetermined shape, pulling on the surrounding diseased tissue and reducing lung volume. Typically, 5 to 15 coils are inserted in each treated lobe and each lung is

treated in separate procedures. The coils are intended to remain in place permanently.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A randomised controlled trial of 47 patients compared patients with emphysema treated by endobronchial nitinol coils (n=24) against patients who had usual care (n=23; treatment included inhalers, bronchodilators, inhaled steroids and pulmonary rehabilitation). Mean baseline St George's Respiratory Questionnaire scores (scores range from 0 to 100 with lower scores indicating better quality of life) decreased by 8.11 points (from 65.17) in the endobronchial nitinol coil group and increased by 0.25 points (from 53.12) in the usual care group at 3-month follow-up (p value between groups=0.04).
- 4.2 In a case series of 60 patients, mean St George's Respiratory Questionnaire scores decreased by 11.1 points (from 61.5) at 12-month follow-up (p<0.05).
- 4.3 In a case series of 38 patients, median St George's Respiratory Questionnaire scores decreased by 4.2 points (from 63.2) at 1-year follow-up (p<0.05). At 2-year follow-up, median St George's Respiratory Questionnaire scores decreased from baseline by 8.0 points (p<0.05). At 3-year follow-up, median St George's Respiratory Questionnaire scores decreased from baseline by 7.2 points (not significant).
- 4.4 In the randomised controlled trial of 47 patients with emphysema treated by endobronchial nitinol coils or usual care, mean modified Medical Research Council dyspnoea scores (ranging from 0 to 4, with lower scores indicating decreasing breathlessness) decreased by 0.24 points and 0.09 points respectively, at 3-month follow-up (p value between groups not significant). Baseline values were not reported.
- 4.5 In the case series of 38 patients, median Medical Research Council

dyspnoea scores decreased by 0.5 points (from 3.0) at 3-year follow-up ($p < 0.05$).

- 4.6 In a case series of 10 patients, median clinical chronic obstructive pulmonary disease (COPD) questionnaire scores (ranging from 0 to 6, with lower scores indicating decreasing COPD severity) decreased from 3.0 to 2.3 at 6-month follow-up (p value not significant).
- 4.7 In the randomised controlled trial of 47 patients with emphysema treated by endobronchial nitinol coils or usual care, mean baseline forced expiratory volumes in 1 second (FEV_1) were 0.72 litres and 0.78 litres respectively. At 3-month follow-up, FEV_1 increased by 14.19% and 3.57% respectively (p value between groups = 0.03).
- 4.8 In a case series of 16 patients, the mean distance walked in 6 minutes increased by 35.4 metres (from 338 metres), 1 month after an initial endobronchial nitinol coil treatment, and by 69.8 metres 1 month after a second endobronchial nitinol coil treatment (p values < 0.05). The mean distance walked in 6 minutes increased from baseline by 84.4 metres 6 months after a final endobronchial nitinol coil treatment ($p < 0.05$).
- 4.9 Specialist advisers listed key efficacy outcomes as reduction in the frequency of COPD exacerbations, as well as improvements in exercise capacity (for example, 6-minute walk test), lung function (for example, forced expiratory volume in 1 second, forced vital capacity and residual volume) and quality of life (for example, St George's Respiratory Questionnaire).

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Pneumothorax was reported after 5% (2/44) of endobronchial nitinol coil procedures and in no patients who had usual care (including inhalers, bronchodilators, inhaled steroids and pulmonary rehabilitation) at 1-month follow-up in a randomised controlled trial of 47 patients with

emphysema treated by endobronchial nitinol coils (n=24) or usual care (n=23).

- 5.2 Exacerbations of chronic obstructive pulmonary disease (COPD) were reported in the randomised controlled trial of 47 patients after 5% (2/44) of endobronchial nitinol coil procedures and in 4% (1/23) of patients who had usual care, at 1-month follow-up. At 3-month follow-up, exacerbations of COPD were reported after 7% (3/44) of endobronchial nitinol coil procedures and in 9% (2/23) of patients who had usual care. Serious exacerbations of COPD were reported in 17.2% (10/58) of patients, between 1 and 6 months after treatment, in a case series of 60 patients.
- 5.3 Chest pain was reported after 14% (4/28) of endobronchial nitinol coil procedures, within 1 month of first or second treatment, in a case series of 16 patients. In the same study, chest pain was reported after 7% (2/28) of endobronchial nitinol coil procedures between 1 and 6 months after treatment.
- 5.4 Pneumonia was reported after 7% (2/28) of endobronchial nitinol coil procedures, within 1 month of first or second treatment, in the case series of 16 patients. In the same study, pneumonia was reported after 11% (3/28) of endobronchial nitinol coil procedures between 1 and 6 months after treatment.
- 5.5 Lower respiratory tract infections were reported in the randomised controlled trial of 47 patients after 5% (2/44) of endobronchial nitinol coil procedures and in no patients who had usual care at 1-month follow-up. At 3-month follow-up, lower respiratory tract infections were reported after 0% of endobronchial nitinol coil procedures and in 4% (1/23) of patients who had usual care.
- 5.6 Specialist advisers listed bleeding, infection and pneumothorax as anecdotal adverse events. Haemorrhage, coil migration, pneumomediastinum, respiratory failure and the erosion of coils into major vessels were identified as theoretical adverse events.

6 Committee comments

- 6.1 The Committee noted that emphysema is a common and progressive condition. For most patients with distressing symptoms there is the possibility of established surgical treatments, but if further evidence supports the efficacy of insertion of endobronchial nitinol coils this procedure could provide a less invasive treatment option.
- 6.2 The Committee noted that this procedure may be used in some patients for whom lung volume reduction surgery and insertion of endobronchial valves are not suitable.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced [information for the public](#) explaining this guidance. Information about the [evidence](#) the guidance is based on is also available.

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