

Insertion of endobronchial nitinol coils to improve lung function in emphysema

Interventional procedures guidance

Published: 27 March 2015

www.nice.org.uk/guidance/ipg517

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 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 [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 (FEV₁) were 0.72 litres and 0.78 litres respectively. At 3-month follow-up, FEV₁ 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 [overview](#).

- 5.1 Pneumothorax was reported after 5% (2 out of 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 out of 44) of endobronchial nitinol coil procedures and in 4% (1 out of 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 out of 44) of endobronchial nitinol coil procedures and in 9% (2 out of 23) of patients who had usual care. Serious exacerbations of COPD were reported in 17.2% (10 out of 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 out of 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 out of 28) of endobronchial nitinol coil procedures between 1 and 6 months after treatment.

- 5.4 Pneumonia was reported after 7% (2 out of 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 out of 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 out of 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 out of 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

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

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

ISBN 978-1-4731-1119-6

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).