Insertion of endobronchial valves for lung volume reduction in emphysema

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NICE interventional procedure guidance 465
guidance.nice.org.uk/ipg465
1 Recommendations

This document replaces previous guidance on bronchoscopic lung volume reduction with airway valves for advanced emphysema (interventional procedure guidance 318).

1.1 Current evidence on the efficacy of insertion of endobronchial valves for lung volume reduction in emphysema shows some clinical and quality-of-life benefits. However, this evidence includes data from patients who have and those who have not had assessment of collateral ventilation, which specialists now advise as fundamental to selection for treatment. Evidence of safety in the short term is adequate but the evidence of safety in the longer term is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake insertion of endobronchial valves for lung volume reduction in emphysema should take the following actions.

- Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

- Audit and review clinical outcomes of all patients having insertion of endobronchial valves for lung volume reduction in emphysema (see section 7.1).

1.3 Patient selection should be done by a multidisciplinary team experienced in the management of emphysema including a chest physician, a chest radiologist and a thoracic surgeon.

1.4 This procedure should only be carried out by clinicians with specific training and expertise in interventional bronchoscopy (including provision of sedation), who should perform their initial procedures with an experienced mentor.

1.5 NICE encourages further research into insertion of endobronchial valves for lung volume reduction in emphysema. Research should take the form of studies that allow comparison of the procedure with the natural history of the
disease and other treatment options including surgery. The studies should define the criteria and techniques used for patient selection. Outcome measures should include lung function, dyspnoea score, exercise tolerance, quality of life and long-term safety.

2 Indications and current treatments

2.1 Emphysema is a chronic lung disease, which is usually smoking related 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 Treatment may include pulmonary rehabilitation advice (guidance 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) or lung transplantation may be indicated.

3 The procedure

3.1 The aim of insertion of endobronchial valves for lung volume reduction in emphysema is to achieve atelectasis of selected lung segments. It uses an endoscopic approach, which is less invasive than open or thoracoscopic lung volume reduction surgery.

3.2 Before the procedure, it is usual practice to assess the presence of collateral ventilation (when air enters a lobe of the lung through a passage that bypasses the normal airway). A surrogate for this is CT scanning to assess the completeness of fissures. A functional approach, specially developed for use before insertion of airway valves, involves a specially designed balloon catheter with a flow sensor.

3.3 Insertion of endobronchial valves is done with the patient under sedation or general anaesthesia. Using a delivery catheter passed through a bronchoscope, a synthetic valve is placed in the target location and fixed to the
bronchial wall. The valve is designed to prevent air inflow during inspiration but to allow air and mucus to exit during expiration. Several valves may be needed (one or more for each segment of the lung to be treated). Patients may sometimes be given antibiotics and/or steroids.

3.4 Different devices are available for this procedure.

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 Two randomised controlled trials (RCTs) of 321 and 171 patients treated by insertion of endobronchial valves or standard medical care (control group), reported mean increases of 4% and 7% in forced expiratory volume in 1 second (FEV₁) in the endobronchial valve groups, compared with a decrease of 3% and an increase of less than 1% respectively, in the control groups at 6-month follow-up (p=0.005 and p=0.067 respectively). Patients with complete fissure (assessed by CT) treated by insertion of endobronchial valves (n=44) showed a mean improvement of 15% in the FEV₁ at 12 months compared with 0% in patients with incomplete fissure treated by insertion of endobronchial valves (n=67), in the RCT of 171 patients. An RCT of 73 patients treated by insertion of endobronchial valves or bronchoscopy only (control group) reported no improvement in FEV₁ in either group at 3-month follow-up (p=0.065 for change from baseline, treatment versus control).

4.2 A case series of 96 patients treated by insertion of endobronchial valves with assessment of collateral ventilation reported that patients with no collateral ventilation had a greater increase in FEV₁ from baseline than patients with collateral ventilation at 30-day follow-up (16% compared with 1%, p=0.0013).

4.3 The 2 RCTs of 321 and 171 patients reported mean decreases in the St George's Respiratory Questionnaire score (range 0 to 100, where 100 represents the worst and 0 indicates the best possible health status) of 2.8 and 5 points from baseline in the endobronchial valve groups compared
with increases of 0.6 and 0.3 points respectively in the control groups at 6-month follow-up (p=0.04 and p=0.047 respectively).

4.4 The RCT of 321 patients reported a median distance increase of 3% in a 6 minute walk test in the endobronchial valve group compared with a decrease of 3% in the control group at 6-month follow-up (p=0.04). The RCT of 171 patients reported a mean increase of 15 metres from baseline in the 6 minute walk test in the endobronchial valve group compared with 10 metres in the control group at 6 month follow-up (p=0.696).

4.5 The specialist advisers listed key efficacy outcomes as improved lung function, quality of life, 6 minute walk test, improvement in dyspnoea, and survival.

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 One patient died from tension pneumothorax 4 days after valve insertion in a case series of 91 patients. The death of 1 patient 241 days after valve placement, in the randomised controlled trial (RCT) of 73 patients, was assessed as possibly related to the endobronchial valve treatment (no further information given).

5.2 Massive haemoptysis was the cause of death of 1 patient within 90 days of endobronchial valve insertion in the RCT of 321 patients (no further information given). Haemoptysis within 90 days was reported in 6% (12/214) and 5% (6/111) of patients treated by insertion of endobronchial valves compared with 0% (0/87) and 2% (1/60) of patients treated by standard medical care in the RCTs of 321 and 171 patients (p=0.02 and p=0.42).

5.3 Bronchospasm associated with the procedure was reported in 5% (2/37) of patients treated by endobronchial valve insertion and 6% (2/36) of patients in the control group treated by bronchoscopy alone in an RCT of 73 patients. Bronchospasm within 3 days of the procedure was reported in 9% (8/91) of
patients in the case series of 91 patients. One of these was described as serious and was associated with respiratory failure and myocardial infarction that began the evening after the procedure.

5.4 Valve expectoration, aspiration or migration within 90 days was reported in 5% (10/214) of patients treated by endobronchial valve insertion in the RCT of 321 patients. Valve expectoration occurred in 7% (8/111) of patients within 90 days of the procedure in the RCT of 171 patients.

5.5 COPD exacerbation needing hospitalisation was reported in 8% (17/214), 12% (13/111), and 30% (11/37) of patients treated by endobronchial valve insertion compared with 1% (1/87), 10% (6/60), and 22% (8/36) of patients in the control groups in 3 RCTs of 321, 171 and 73 patients respectively (p=0.03, p=0.80 and p=0.60).

5.6 Pneumothorax or prolonged air leak (duration longer than 7 days) within 90 days was reported in 1% (3/214) and 4% (4/111) of patients treated by endobronchial valve insertion and none (0/87, 0/60) of the patients treated by standard medical care in the RCTs of 321 and 171 patients respectively (p=0.56 and p=0.30). Pneumothorax was reported in 12% (11/91) of patients in the case series of 91 patients at a follow-up of 12 months.

5.7 Pneumonia distal to the valve was reported in 1% (2/214) and 4% (4/111) of patients within 90 days of endobronchial valve insertion in the RCTs of 321 patients and 171 patients respectively, and in 7% (6/91) of patients in the case series of 91 patients at 12-month follow-up.

5.8 Respiratory failure within 3 months was reported in 1% (3/214) and 4% (4/111) of patients treated by endobronchial valve insertion and 0% (0/87) and 2% (1/60) of patients treated by standard medical care in the RCTs of 321 and 171 patients respectively (p=0.56 and 0.66). Respiratory failure was reported in 1 patient in a case series of 96 patients.

5.9 The specialist advisers described infection as an additional adverse event reported in the literature.
6 Committee comments

6.1 The Committee noted that there may be a subgroup of patients that will benefit more from the procedure than others and that research is in progress into methods to improve the selection of patients most likely to benefit from this procedure.

7 Further information

7.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

7.2 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. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

It updates and replaces NICE interventional procedure guidance 318.
We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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