

Bronchoscopic lung volume reduction with airway valves for advanced emphysema

1 Guidance

- 1.1 Current evidence on the efficacy of bronchoscopic lung volume reduction with airway valves for advanced emphysema shows some improvement in patient-reported quality of life outcomes but there is inadequate evidence of improvement based on objective outcomes of efficacy. There are no major safety concerns in the short term, but there is inadequate evidence on safety in the long term. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake bronchoscopic lung volume reduction with airway valves for advanced emphysema should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers 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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG318publicinfo).
 - Audit and review clinical outcomes of all patients having bronchoscopic lung volume reduction with airway valves for advanced emphysema (see section 3.1).
- 1.3 This procedure should be carried out only by clinicians with specific training and expertise in interventional bronchoscopy, who should perform their initial procedures with an experienced mentor.
- 1.4 NICE encourages further research into bronchoscopic lung volume reduction with airway valves for advanced emphysema. Research should take the form of studies that allow comparison

with the natural history of the disease. The studies should define patient selection criteria. Outcome measures should include exercise tolerance, ventilation-perfusion (VQ) mismatch, quality of life and long-term safety. NICE is aware of current clinical trials involving this procedure, and may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Emphysema is a chronic lung disease, which is usually smoking-related but may also be inherited. It forms part of chronic obstructive pulmonary disease (COPD).
- 2.1.2 Common symptoms of emphysema are shortness of breath, coughing, fatigue and weight loss.
- 2.1.3 Treatment may include pulmonary rehabilitation (smoking cessation, patient education, exercise and breathing training) and use of inhaled or oral bronchodilators and steroids. Some patients benefit from oxygen treatment.
- 2.1.4 In advanced disease, lung volume reduction surgery or lung transplantation may be indicated.

2.2 Outline of the procedure

- 2.2.1 The aim of bronchoscopic lung volume reduction with airway valves for advanced emphysema is to limit airflow to the least functional lung segments in order to improve gas exchange in healthier parts of the lung.
- 2.2.2 The procedure is undertaken via a bronchoscope with the patient under sedation or general anaesthesia. Computed tomography (CT) and VQ scans are used to identify parts of the lung(s) with poor function. Using a delivery catheter, a synthetic valve is delivered into the target

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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location and expanded against the bronchial wall. The valve prevents air inflow during inspiration but allows air and mucus to exit during expiration. Several valves may be needed for different lung segments.

2.2.3 Different devices are available for this procedure.

Sections 2.3 and 2.4 describe efficacy and 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, available at www.nice.org.uk/IP770overview

2.3 Efficacy

2.3.1 A case series of 98 patients with end-stage emphysema treated by the procedure reported that mean forced expiratory volume (FEV₁) values increased significantly by 10.7% from baseline to 3-month follow-up (absolute values not stated) ($p = 0.007$). A case series of 19 patients with COPD and dyspnoea despite optimal medical therapy reported a significant improvement after 4 weeks in predicted FEV₁ (from 28.4% to 31.5%, $p = 0.047$) and a non-significant increase in actual FEV₁ (from 0.9 to 0.99 litres, $p = 0.071$).

2.3.2 Case series of 57 and 98 patients reported significant improvement in St George's Respiratory Questionnaire (SGRQ) score (from 0 to 100 points; lower values better) from 58.2 to 50.0 points and from 57 to 48 points at follow-ups of 6 and 12 months respectively ($p < 0.0001$ at 6 months, significance not stated at 12 months). Another case series of 19 patients reported no significant improvement in SGRQ score at 12- and 24-month follow-up (significance not stated).

2.3.3 The Specialist Advisers listed key efficacy outcomes as quality of life (SGRQ score), lung volume and exercise capacity.

2.4 Safety

2.4.1 In the case series of 98 patients, death following pneumonia-related complications was reported in 1 patient at 25-day follow-up. In the case series of 30 patients (66 procedures), pneumonia was

reported in 6% (4/66) and bronchitis in 4% (3/66) of procedures at 30-day follow-up.

2.4.2 In 4 studies, bronchospasm shortly after the procedure occurred in 5% (5/98), 5% (1/20), 5% (1/19) and 4% (2/57) of patients.

2.4.3 Pneumothorax occurred across 4 studies in 20% (4/20), 10% (2/19), 7% (4/57) and 5% (1/19) of patients; most resolved spontaneously but 1 patient needed valve removal and 2 needed chest tube insertion.

2.4.4 The case series of 19 patients reported that a patient developed bronchial hypersecretion with worsening clinical status, managed with removal of 3 valves. Valve displacement (not otherwise described) requiring removal occurred in another patient at 1-month follow-up.

2.4.5 Post-procedural exacerbation of COPD occurred across 2 case series in 35% (20/57) and 17% (17/98) of patients (follow-up ranging from 30 to 90 days).

2.4.6 The Specialist Advisers considered theoretical adverse events to include bronchitis, haemoptysis, haemothorax, airway blockage, persistent cough and mucus plugging.

2.5 Other comments

2.5.1 The Committee noted that the VENT trial is currently in progress. This will be incorporated into the evidence base upon review of the guidance.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed audit support (which is for use at local discretion) available from www.nice.org.uk/IPG318

3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG318publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2026 for this guidance or N2027 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which 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 avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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