NICE guidance

Insertion of endobronchial valves for persistent air leaks

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg448

1 Guidance

1.1 Current evidence on the efficacy and safety of insertion of endobronchial valves for persistent air leaks is limited in both quantity and quality. 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 persistent air leaks should take the following actions:

- Inform the clinical governance leads in their 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 persistent air leaks (see section 3.1).

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1.3 Selection of patients for insertion of endobronchial valves for persistent air leaks should be done by a multidisciplinary team including a chest physician and a thoracic surgeon.

1.4 NICE encourages further reporting about patient selection and outcomes (including long-term outcomes). NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Leakage of air from the lungs into the pleural space can lead to collapse of the lung and difficulty in breathing. Persistent air leaks from the lungs can occur after thoracic operations or trauma, or because of underlying pulmonary disease.

2.1.2 Persistent air leaks may initially be treated with a temporary chest drain to remove the air from the pleural space. If air continues to leak from the lung, a surgical repair may be needed. Pleurodesis may be an alternative option.

2.2 Outline of the procedure

2.2.1 Insertion of endobronchial valves for persistent air leaks aims to reduce or eliminate airflow through the leaks so that the rest of the lung can function normally. It may also allow the tissues around an air leak to heal so that the leak stops.

2.2.2 The procedure is done using flexible bronchoscopy with the patient under sedation or general anaesthesia. The area of air leak is identified by occluding suspected segments with a saline-filled balloon and monitoring the air flow. A one-way valve mounted on a flexible catheter is passed through the bronchoscope and inserted into the target airway.

2.2.3 More than 1 valve may be inserted during a procedure. Valves may be

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removed when the defect on the lung surface has sealed.

2.2.4 Several 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.

2.3 Efficacy

2.3.1 A case series of 40 patients treated by insertion of endobronchial valves reported a complete cessation of air leak in 48% (19/40) of patients, partial cessation in 45% (18/40), and no change in 5% (2/40) (range of follow-up 5–1109 days).

2.3.2 A case series of 7 patients (8 procedures) reported successful removal of chest drains in 5 patients at a median of 16 days after valve insertion.

2.3.3 A case report of 4 patients treated by insertion of endobronchial valves reported a reduction in pneumothorax in 3 patients. Re-expansion of both lungs was reported in 1 patient within 2 days and at 6 months in another patient. Improvement of the pneumothorax in 1 lung was reported in a third patient (timing unclear).

2.3.4 In the case series of 7 patients, a 'reduced' air leak returned after valve removal in 1 patient (15 days after the procedure).

2.3.5 The Specialist Advisers listed efficacy outcomes as duration of air leak, reduction or resolution of air leak, reduction in hospital stay, reduction in intensive care or high-dependency unit stay, reduction in the use of non-invasive or intermittent positive pressure ventilation, and improvement in health-related quality of life.

2.4 Safety

2.4.1 Valve migration was reported in a case report (discovered on chest X-ray

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2 months after the procedure). The valve was removed 5 months after the procedure.

2.4.2 Initial valve malpositioning (needing redeployment) was reported in the case series of 40 patients (numbers of patients not stated and timing of event not described).

2.4.3 Expectoration of a valve was reported in the case series of 40 patients (number of patients not stated and timing of event not described).

2.4.4 Recurrent chest infection was reported in a case report at 5 months after the initial procedure; the 2 valves were removed.

2.4.5 Partial atelectasis of the lower lobe was reported in a case report (timing unclear; no further details).

2.4.6 The Specialist Advisers listed anecdotal adverse events as haemoptysis, respiratory failure, distal infection or pneumonia, and granulation tissue formation around valves. They listed death as a theoretical adverse event. The Specialist Advisers also listed recurrence of air leak or pneumothorax.

2.5 Other comments

2.5.1 The Committee noted that insertion of endobronchial valves for persistent air leaks is typically considered for patients when other treatment options have been exhausted.

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 has developed an audit tool (which is for use at local discretion), which will be available when the guidance is published.

3.2 For related NICE guidance see the NICE website.

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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 procedure 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.

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.

Yourresponsibility
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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

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