NICE guidance

Insertion of endobronchial valves for persistent air leaks

Interventional procedures guidance
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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 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).

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 removed when the defect on the lung surface has sealed.

2.2.4 Several different devices are available for this procedure.

2.3 Efficacy

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.

2.3.1 A case series of 40 patients treated by insertion of endobronchial valves reported a complete cessation of air leak in 48% (19 out of 40) of patients, partial cessation in 45% (18 out of 40), and no change in 5% (2 out of 40; range of follow-up 5 to 1,109 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 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.

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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.