

# Endobronchial ultrasound-guided transbronchial needle aspiration for mediastinal masses

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 safety and efficacy of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS–TBNA) for mediastinal masses appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.
- 1.2 This procedure requires a combination of skills, and clinicians planning to undertake it should receive specific training.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS–TBNA) is performed to investigate mediastinal masses, predominantly in the context of staging of lung cancer. Other conditions associated with mediastinal lymphadenopathy include cancer of other organs, atypical infections and sarcoidosis. EBUS–TBNA may also be used in the investigation of hilar lymph nodes.
- 2.1.2 After imaging studies (such as computer tomography [CT] and positron emission tomography [PET] scanning), histological investigation of mediastinal masses

may be required. A variety of biopsy techniques may be used such as conventional non-ultrasound-guided TBNA, transthoracic needle aspiration and endoscopic transoesophageal ultrasound-guided fine-needle aspiration (EUS–FNA). EUS–FNA involves insertion of an endoscope into the oesophagus and transoesophageal needle biopsy under ultrasound control. Occasionally mediastinoscopy or mediastinotomy may be required.

## 2.2 Outline of the procedure

- 2.2.1 EBUS–TBNA may be performed under local anaesthesia with sedation, or under general anaesthesia. A flexible bronchoscope containing an ultrasound probe is inserted via the trachea and guided through the bronchial tree towards the appropriate area of the mediastinum. The targeted lymph nodes or masses are identified using bronchoscopic visualisation and ultrasound imaging. A needle extended from the bronchoscope through the bronchial wall is used to puncture the mass and to aspirate tissue. A mass can be punctured several times to gain an adequate sample, and several masses can be punctured during the same session.
- 2.2.2 EBUS–TBNA is usually performed under real-time ultrasound, but has also been performed under non-real-time ultrasound.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about the procedure. For more details, see the [overview](#).

## 2.3 Efficacy

- 2.3.1 A study of 502 patients compared the diagnostic performance of EBUS–TBNA with more invasive procedures (thoracotomy, thoracoscopy, mediastinoscopy) or clinical follow-up. The reported sensitivity and specificity of EBUS–TBNA for detecting lymph node malignancy was 94% and 100%, respectively. The procedure was said to be 'accurate' if the patient's final diagnosis matched the EBUS–TBNA result. In this study, the accuracy of the procedure was 94%.

- 2.3.2 A case series of 108 patients compared EBUS–TBNA with final diagnosis based on the EBUS–TBNA result plus clinical course or other pathological confirmation. The reported sensitivity, specificity and accuracy for detecting the correct lymph node stage was 95%, 100% and 96%, respectively.
- 2.3.3 Two studies of 102 and 33 patients compared EBUS–TBNA with final diagnosis based either on thoracotomy or clinical follow-up. In the first study, the reported sensitivity, specificity and accuracy for detection of malignancy was 92%, 100% and 98%, respectively. In the second study, the reported sensitivity, specificity and accuracy was 85%, 100% and 89%, respectively.
- 2.3.4 A case series of 100 patients compared EBUS–TBNA with final diagnosis ascertained by surgery. The reported sensitivity and specificity for detecting lymph node malignancy was 92% and 100%, respectively.
- 2.3.5 With regard to the accuracy of alternative techniques, the study of 102 patients compared CT scanning and PET scanning with final diagnosis based either on surgical staging or clinical follow-up. The reported sensitivity, specificity and accuracy was 77%, 55% and 61%, respectively, for CT and 80%, 70% and 73%, respectively, for PET. In the study of 33 patients, EUS–FNA was compared with final diagnosis based either on surgical staging or clinical follow-up, and the reported sensitivity, specificity and accuracy was 80%, 100% and 86%, respectively.
- 2.3.6 A study of 65 patients with suspected sarcoidosis compared EBUS–TBNA against final diagnosis based on clinical and radiological findings, plus pathology and microbiological culture results from EBUS–TBNA or surgical biopsy. The reported sensitivity, specificity and accuracy was 88%, 100% and 88%, respectively.
- 2.3.7 A randomised controlled trial of 100 patients who had EBUS–TBNA and 100 patients who had conventional TBNA found that EBUS–TBNA successfully obtained a mediastinal lymph node aspirate (either positive or negative for malignancy) in 80% (80 out of 100) of patients, compared with 71% (71 out of 100) for conventional TBNA ( $p < 0.05$ ).
- 2.3.8 The Specialist Advisers listed key efficacy outcomes as the ability to stage mediastinal malignancy, the quality and adequacy of pathological specimens and

the diagnostic accuracy of EBUS–TBNA in comparison with CT scans, PET, mediastinoscopy or lung resection.

## 2.4 Safety

- 2.4.1 One case series of 108 patients reported minor bleeding at the puncture site in some patients (no further information provided), but no other complications. The remaining seven studies reported no complications.
- 2.4.2 The Specialist Advisers listed theoretical adverse events as hoarse voice, sore throat, cough, coughing up a small amount of blood, fever, significant bleeding, pneumothorax, pneumomediastinum, mediastinitis and respiratory failure. One Adviser reported a case of asymptomatic pneumomediastinum.

## 2.5 Other comments

- 2.5.1 The Committee noted that some patients reported pain during EBUS–TBNA. Particular attention should therefore be paid to the use of analgesia during the procedure.

## 3 Further information

- 3.1 NICE has published a [guideline on lung cancer: diagnosis and management](#).

## 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 decision made, and has been written with patient consent in mind.

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## Endorsing organisation

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