

Endobronchial ultrasound-guided transbronchial biopsy for peripheral lung lesions

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 of endobronchial ultrasound-guided transbronchial biopsy (EBUS–TBB) for peripheral lung lesions supports the efficacy of the procedure in producing a high diagnostic yield. With regard to safety, there is an incidence of false negative results in malignant disease, so negative or inconclusive specimens should be further investigated using other biopsy techniques. The procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 This procedure should only be carried out by a bronchoscopist who has had specific training and mentoring in the technique.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 In this guidance, 'peripheral lung lesions' describes lung lesions that cannot be visualised using conventional bronchoscopy because they do not protrude into the bronchial tree. This guidance is concerned only with the diagnosis of such lesions, and not with their treatment.
- 2.1.2 Patients with peripheral lung lesions are often asymptomatic and the abnormality is detected incidentally on chest X-ray or computed tomography (CT) scanning. Symptoms of cough, haemoptysis and breathlessness may be present, but are

more often associated with endobronchial tumours that are accessible to standard bronchoscopic biopsy.

- 2.1.3 Current biopsy techniques include blind transbronchial lung biopsy, image-guided percutaneous lung biopsy, or (thoracoscopic or open) surgical biopsy.

2.2 Outline of the procedure

- 2.2.1 The procedure can be undertaken with the patient under general anaesthesia or under local anaesthesia with or without sedation. The lesion is identified by prior CT, positron emission tomography (PET) or conventional chest X-ray imaging. A flexible fiberoptic bronchoscope with a radial mini-probe or catheter is inserted through the nose or mouth, and advanced towards the peripheral lung lesion using endobronchial ultrasound (EBUS) guidance. Once the bronchoscope is in the appropriate location, the ultrasound mini-probe or catheter is withdrawn and biopsy forceps or needles are introduced into the working channel to obtain a histological sample of the target lesion, with or without fluoroscopic guidance. Use of a guide sheath can help to keep the bronchoscope in place during the removal of the probe and insertion of biopsy instruments.

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 randomised controlled trial (RCT) of 293 patients investigated by transbronchial biopsy (TBB) with or without EBUS guidance reported a diagnostic yield of 79% (48 out of 61) for malignant lesions and 69% (18 out of 26) for benign lesions in the EBUS–TBB group compared with 55% (46 out of 83) and 44% (16 out of 36) in the TBB-alone group (without EBUS guidance).
- 2.3.2 An RCT of 202 patients investigated by either EBUS–TBB plus bronchial washing (BW) or EBUS transbronchial needle aspiration (TBNA) plus TBB plus BW,

reported diagnostic yields of 61% (57 out of 94) and 78% (69 out of 88) respectively ($p=0.015$). Without EBUS guidance, the diagnostic yield was 63% (55 out of 88) for TBNA, 49% (89 out of 182) for TBB ($p=0.049$ compared with TBNA) and 20% (36 out of 182) for BW ($p<0.001$ compared with TBNA).

- 2.3.3 An RCT of 120 patients investigated by EBUS–TBB, or electromagnetic navigation bronchoscopy (ENB)–TBB, or a combination of EBUS or ENB–TBB reported diagnostic yields of 69% (27 out of 39), 59% (23 out of 39) and 88% (35 out of 40) respectively ($p=0.02$ for comparisons between the groups).
- 2.3.4 A non-randomised comparative study of 261 diagnostic procedures using EBUS–TBB (using a guide sheath [GS]) or percutaneous CT-guided fine needle aspiration (CT–FNA) reported sensitivity values of 66% (93 out of 140) and 64% (77 out of 121) respectively (significance not stated).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as diagnostic yield, sensitivity, specificity, positive and negative predictive values, avoidance of CT-guided procedures (that is, reducing radiation exposure for the patient) and patient acceptability.

2.4 Safety

- 2.4.1 The RCT of 120 patients reported pneumothorax in 5% (2 out of 39) of the EBUS–TBB group, 5% (2 out of 39) of the ENB–TBB group and 8% (3 out of 40) of the combined EBUS/ENB–TBB group; 4 patients were treated with chest drain insertion and 1 was managed with aspiration and observation. The other 2 patients were managed by observation and supplemental oxygen.
- 2.4.2 Pneumothorax was reported in 1% (2 out of 140) of patients in the EBUS–GS transbronchial lung biopsy group compared with 22% (27 out of 121) of patients in the percutaneous CT–FNA group ($p<0.01$) in the non-randomised comparative study of 261 procedures.
- 2.4.3 Pneumothorax was reported in 3% (3 out of 119) of patients in the TBB-alone group compared with none of the patients in the EBUS–TBB group in the RCT of 293 patients. Pneumothorax determined by chest radiograph taken 1 to 2 hours

after the procedure was reported in 2% (2 out of 88) of patients in the EBUS–TBNA plus TBB plus BW group and 2% (2 out of 94) of patients in the EBUS–TBB plus BW group in the RCT of 202 patients.

- 2.4.4 The RCT of 293 patients reported bleeding in none of the patients in the EBUS–TBB group compared with 6% (7 out of 119) of patients in the TBB-alone group. The RCT of 202 patients reported bleeding in 5% (4 out of 88) of patients in the EBUS–TBNA plus TBB plus BW group compared with 2% (2 out of 94) of patients in the EBUS–TBB plus BW group.
- 2.4.5 The Specialist Advisers listed adverse events reported in the literature as pneumothorax and haemorrhage. They listed a theoretical adverse event as false negative rate.

2.5 Other comments

- 2.5.1 The Committee noted the risk of false negative results using this procedure. Any negative or inconclusive findings should be investigated using other biopsy procedures.

3 Further information

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](#).