



Percutaneous radiofrequency ablation for primary or secondary lung cancers

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Current evidence on the efficacy of percutaneous radiofrequency ablation (RFA) for primary or secondary lung cancers is adequate in terms of tumour control. There is a small incidence of complications, specifically pneumothorax, which may have serious implications for these patients with already compromised respiratory reserve. This procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- Patient selection for percutaneous RFA for primary or secondary lung cancers should be carried out by a multidisciplinary team, which will usually include a thoracic surgeon, an oncologist and a radiologist.
- 1.3 This procedure should only be carried out by radiologists who regularly undertake image-guided interventional procedures.
- 1.4 NICE encourages further research into this procedure. Research studies should include a clear description of case mix and lesion size, and report long-term survival.

2 The procedure

2.1 Indications and current treatments

2.1.1 Both primary and metastatic lung cancer are common, and the prognosis for

most patients is poor.

2.1.2 Treatment depends mainly on tumour histology and stage, and may include surgical resection (open or thoracoscopic), external beam radiotherapy, chemotherapy or a combination of these treatments. If the tumour protrudes into major airways, bronchoscopic treatments including diathermy, laser therapy, cryotherapy, brachytherapy and photodynamic therapy may be used.

2.2 Outline of the procedure

- 2.2.1 Percutaneous radiofrequency ablation (RFA) may be used in patients with small, early-stage lung cancers or small numbers of lung metastases who are unsuitable for, or prefer not to undergo, surgery. It may also have a place in multi-modality treatment of more advanced primary lung cancers.
- 2.2.2 The procedure is usually carried out with the patient under local anaesthesia with conscious sedation, but general anaesthesia may be required. The procedure involves inserting a small needle electrode percutaneously directly into the tumour, normally under CT guidance. Radiofrequency energy is passed through the electrode causing heating of the tissues around the tip of the needle. The tumour tissue in the target area is coagulated. A small margin of normal tissue around the tumour is also destroyed to reduce local recurrence risk.
- 2.2.3 The procedure can be applied to more than one tumour during one or more treatment sessions, and can be used alone or in combination with surgery, radiotherapy or chemotherapy.

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 <u>overview</u>.

2.3.1 A case series of 100 patients with inoperable colorectal lung metastases reported

median overall survival and overall 5-year survival after RFA treatment of 36 months and 30% respectively. A systematic review of 46 studies including a total of 1,584 patients reported a mean overall survival rate of 59% over a mean follow-up period of 18 months.

- 2.3.2 Another case series of 100 patients reported median overall survival of 27 months for patients with primary lung cancer, 33 months for patients with recurrent lung cancer and 18 months for patients with metastatic disease.
- 2.3.3 A case series of 153 patients reported that the median time to progression (assessed by follow-up CT scans and also positron-emission tomography scans in selected patients) for tumours of 3 cm or smaller was 45 months, with 1-, 3- and 5-year local tumour progression-free rates of 83%, 57% and 47% respectively. Median time to progression for larger tumours was 12 months, with 1-, 3- and 5-year progression-free rates of 45%, 25% and 25% respectively. A case series of 78 patients with colorectal lung metastases reported 1-, 3- and 5-year overall progression rates (assessed by CT) of 10%, 21% and 21% respectively.
- In a case series of 106 patients, there was no significant difference between quality of life at baseline and at 12 months after RFA, using the Functional Assessment of Cancer Therapy Lung and Short-Form 12 questionnaires.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as symptomatic improvement, quality of life, local tumour control, progression-free survival, overall survival, respiratory morbidity and the need for repeat interventions.

2.4 Safety

Four procedure-related deaths within 30 days were reported in the case series of 153 patients, 2 of which were in single-lung patients. The causes of death were haemorrhage into the pleural space; exacerbation of underlying pulmonary fibrosis; congestive heart failure; and respiratory arrest while undergoing conscious sedation. Two deaths were reported in a case series of 137 patients: 1 from intractable pneumothorax and pneumonia at 53 days, the other from massive haemoptysis 28 days after RFA. Two deaths resulting from interstitial

pneumonia were reported in a case series of 130 patients (timing of events not stated). One case series of 100 patients reported no treatment-related mortality.

- 2.4.2 Pneumothorax requiring chest tube insertion was reported in less than 10% of patients in 4 centres and in 10% to 30% of patients in 3 centres in a case series of 493 RFA procedures performed. In 5 further case series, rates of pneumothorax requiring chest tube drainage ranged from 10% (18 out of 183) to 20% (27 out of 137).
- 2.4.3 Pleural effusion requiring drainage was reported in less than 10% of patients in 6 centres and more than 30% in 1 centre in the case series of 493 RFA procedures. In 3 further case series, rates of pleural effusion requiring drainage were 2% (4 out of 211), 3% (4 out of 137) and 3% (3 out of 100).
- 2.4.4 The Specialist Advisers considered theoretical adverse events to include abscess, infection, pulmonary embolism, pain, damage to other intrathoracic structures, post-procedure mortality and death from interstitial pneumonitis.

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 <u>information for the public on this procedure</u>. 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 <u>Healthcare Improvement Scotland</u>.