NICE guidance

Image-guided percutaneous laser ablation for primary and secondary liver tumours

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg788

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 Recommendations

1.1 Image-guided percutaneous laser ablation for primary and secondary liver tumours can be used in the NHS while more evidence is generated. It can only be used with special arrangements in place for clinical governance, informed consent and audit.

1.2 Clinicians wanting to do image-guided percutaneous laser ablation for primary and secondary liver tumours should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.

- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team experienced in managing primary and secondary liver tumours.

More research

1.5 More research is needed on:

- patient selection
- ablation success
- longer-term outcomes.

Why the committee made these recommendations

The evidence raises no major safety concerns. There is some evidence that the procedure can destroy tumours (tumour ablation), but more evidence is needed on longer-term outcomes. The procedure may benefit particular groups of patients, but more evidence is needed to confirm this.

2 The condition, current treatments and procedure

The condition

2.1 The most common type of primary liver cancer is hepatocellular carcinoma (HCC). Secondary cancer in the liver can arise from any primary site, but it most commonly spreads from cancers of the bowel, breast, lung, pancreas, stomach, ovary, and neuroendocrine tumours.

Current treatments

2.2 Treatment for primary liver cancer depends on several factors, including the exact location and stage of the cancer, the person's liver function and any patient-related comorbidities. The treatment options include:

- surgical excision
- chemotherapy (conventional or hepatic artery infusion)
- transarterial chemoembolisation (TACE)
- selective internal radiation therapy
- percutaneous ethanol injection
- local ablation techniques such as cryotherapy, radiofrequency, and microwave ablation.

A liver transplant (with curative intent) may be appropriate for some people.

2.3 Treatment for secondary liver cancer depends on the site of the primary cancer, which parts of the liver are affected and whether the cancer has metastasised further. The most common treatment is chemotherapy, but other treatments include surgery, hormonal therapies, targeted therapies, ablation and embolisation treatments.

The procedure

2.4 Image-guided percutaneous laser ablation is done under general anaesthesia or local anaesthesia with sedation. Depending on the size of the tumour, 1 or more (usually up to 4) optical fibres are percutaneously inserted into the liver using a small introducer needle. The fibre distance and energy delivery per fibre are adjusted to shape the area to be ablated. The fibres deliver laser energy for several minutes to heat the tissue until it is destroyed with a sufficient safety margin. The fibres work simultaneously to amplify the ablation volume. Image guidance is used to check the positioning of the fibres, monitor the treatment, and verify the effective ablation area. The aim is to destroy the tumour.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 13 sources, which was discussed by the committee. The evidence included 4 randomised controlled trials, 1 quasi-randomised controlled trial, 1 retrospective non-randomised comparative study, 1 case-control study, 5 cohort studies and 1 case report. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: complete tumour ablation, local tumour progression, local or distant recurrence, overall survival and disease-free survival.

3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, bleeding, infection and damage to surrounding tissues.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 A clinical expert advised that this procedure could allow better control of the ablation area, but further evidence is needed to support this.

3.6 The procedure has evolved over time, including techniques to visualise the ablation area.

3.7 Multiple laser fibres can be used for each treatment session and the fibres can be moved.

3.8 Tumour ablation procedures are commonly done under general anaesthesia to prevent the person moving during treatment.

3.9 The committee was informed that a software planning system can be used to help with planning the size and location of ablation.

3.10 The committee noted that the quality of evidence was higher for hepatocellular carcinoma.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation