NICE National Institute for Health and Care Excellence

NICE guidance

Interstitial laser therapy for fibroadenomas of the breast

HealthTech guidance
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www.nice.org.uk/guidance/htg80

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.

Contents

This guidance replaces IPG131.

1 Recommendations

1.1 Current evidence on the safety and efficacy of interstitial laser therapy for fibroadenomas of the breast does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake interstitial laser therapy for fibroadenomas of the breast should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Audit and review all patients having interstitial laser therapy for fibroadenomas of the breast.
- Ensure that patients understand the benign nature of fibroadenomas, and that watchful waiting is an option. Patients should be provided with clear written information and use of NICE's information for the public is recommended.

1.3 This procedure should be carried out only within specialist breast services.

1.4 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 A fibroadenoma is a benign solid lump of breast tissue, which is thought to result from an increased sensitivity to oestrogen. Fibroadenomas are very common and it is not unusual to have more than one. They are mostly found in young women but can occur in women of any age.

2.1.2 Most fibroadenomas do not enlarge after diagnosis. Some get smaller and some eventually disappear over time. These recommendations relate to options for breast fibroadenomas that do not resolve.

2.1.3 Once the diagnosis has been confirmed, conservative management is often agreed, with clinical review only. If the fibroadenoma persists or grows, or if the patient is anxious for it to be removed, it can be excised by a small open operation using general anaesthesia. Interstitial laser therapy is an alternative to open surgery.

2.2 Outline of the procedure

2.2.1 High-energy light delivered via a laser fibre is used to destroy the fibroadenoma. The fibre is positioned through a needle inserted percutaneously under local anaesthesia. The tip of the needle is positioned at the centre of the lump under ultrasound guidance. Laser energy is delivered through a pre-sterilised bare fibre passed through the needle a short distance beyond the tip. The energy is delivered in continuous wave mode for a few minutes. For larger lumps, multiple needles are inserted 1 cm apart, with a laser fibre through each.

2.2.2 There may be lower rates of infection with interstitial laser therapy compared with open surgery, and a more acceptable aesthetic result.

2.3 Efficacy

2.3.1 In a case series of 24 patients, interstitial laser therapy reduced fibroadenoma size (as assessed by ultrasound measurement) from a mean length of 25 mm at baseline to 14 mm at 3 months, 10 mm at 6 months, and 0 mm at 12 months. There were no palpable fibroadenomas in the 14 women followed-up for 12 months.

2.3.2 In another case series, the mean volume of the fibroadenomas in 27 women was significantly smaller 8 weeks after the procedure (0.68 cm^3 compared with 2.17 cm^3 at baseline; $p < 0.001$). Clinical assessment also demonstrated a significant decrease in area following interstitial laser therapy (a mean of 1.25 cm^2 compared with 2.60 cm^2 at baseline; $p < 0.001$). However, at 8 weeks 37% (10/27) of women had a residual lump with a diameter of more than 1 cm. For more details, see the overview.

2.3.3 The Specialist Advisors noted that the lack of material for biopsy with this procedure (in contrast to surgical excision) means that the benign diagnosis cannot be confirmed.

2.4 Safety

2.4.1 In a case series of 24 women who had undergone interstitial laser therapy, 83% (20/24) reported some discomfort during the procedure. Severe pain in 17% (4/24) of women led to the treatment being stopped prematurely. In this case series and another that involved 27 women, local tenderness that lasted from 1 to 8 weeks was reported in all of the women.

2.4.2 In one of the case series, 30% (8/27) of women had skin blanching at the needle site after 80–100 seconds of the treatment, and these women later developed epithelial breakdown and hyperpigmentation in the same area (follow-up 8 weeks). In the second case series, 17% (4/24) of women had bruising that resolved within 1 week. For more details, see the overview.

2.4.3 The Specialist Advisors noted that the reported adverse events include local burns at the needle site, and that the theoretical complications include local

infection, and bleeding if the needle strikes a blood vessel.

2.5 Other comments

2.5.1 It was noted that there are variations in the technique that have potentially different efficacy profiles.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 131 has been migrated to HealthTech guidance 80. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.