

Interstitial laser therapy for fibroadenomas of the breast

1 Guidance

- 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 the Institute'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,

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland

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 cm³ compared with 2.17 cm³ at baseline; $p < 0.001$). Clinical assessment also demonstrated a significant decrease in area following interstitial laser therapy (a mean of 1.25 cm² compared with 2.60 cm² 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, refer to the Sources of evidence (see below).

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, refer to the Sources of evidence.

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.

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Chief Executive
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Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG131publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of interstitial laser therapy for fibroadenomas of the breast, December 2004

Available from www.nice.org.uk/ip275overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0865. *Information for the public* can be obtained by quoting reference number N0868.

The distribution list for this guidance is available at www.nice.org.uk/IPG131distributionlist

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