NICE National Institute for Health and Care Excellence

NICE guidance

Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg268

1 Guidance

1.1 Current evidence on brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision (referred to hereafter as 'brachytherapy') raises no major safety concerns. Current evidence on its efficacy is limited in quantity and there is little information on long-term outcomes (5 years or more). Therefore, this procedure should be used only in the context of research, which should address control of local disease with a minimum of 5 years of follow-up. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 The evidence on which this guidance was based is derived from treatment of breast cancer in women. Treatment depends on pathology, stage and grade. Surgery is usually the first option and may involve removing all (mastectomy) or local excision of the breast. To reduce the risk of recurrence, adjuvant chemotherapy, hormone therapy and/or radiotherapy can be used.

2.2 Outline of the procedure

2.2.1 Brachytherapy can be delivered by an interstitial or a balloon technique under local or general anaesthesia. The aim is to reduce local recurrence. In interstitial brachytherapy, a number of catheters are inserted into the breast tissue surrounding the excised tumour bed. Wires incorporating radioactive implants are inserted through the catheters and left in place for a few minutes (high dose rate) or a few days (low dose rate). In balloon brachytherapy, a balloon device attached to a catheter is inserted through a small incision, into the excised tumour bed, and the balloon is inflated with the aim of coming into close contact with the surrounding breast tissue. The catheter is connected to a computer-controlled high dose rate radiotherapy machine which inserts a radioactive source. Balloon brachytherapy requires a number of treatment sessions over several days. After each session the radioactive source is removed and the catheter disconnected.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

2.3 Efficacy

2.3.1 In a randomised controlled trial of 258 patients treated with interstitial brachytherapy or whole-breast external beam radiotherapy, 5-year

actuarial local recurrence rates were 5% (6/128) and 3% (4/130), respectively (p = 0.50). There were no statistically significant differences in 5-year overall (95% versus 92%) or cancer-specific survival (98% versus 96%) (absolute numbers not given).

2.3.2 A non-randomised controlled trial of 398 patients treated with interstitial brachytherapy or external beam radiotherapy reported no statistically significant difference in 5-year actuarial rates of ipsilateral breast tumour recurrence between the two groups (1% in both, p = 0.65). Five-year overall actuarial survival rates were 87% in the interstitial brachytherapy and 93% in the external beam radiotherapy groups, respectively (p = 0.23). A second non-randomised controlled trial of 144 patients reported local or regional recurrence in 8% (4/51) in the brachytherapy group compared with 5% (5/94) in the external beam radiotherapy group after median follow-up of 75 months (p = 0.23). Disease-free survival at median follow-up of 75 months was 88% in the brachytherapy group and 92% in the external beam radiotherapy group (p value not stated; absolute numbers not given).

2.3.3 A case series of 1440 patients treated with balloon brachytherapy reported a 3-year actuarial survival rate of 96% in 400 of these patients. The 3-year actuarial rate of ipsilateral breast tumour recurrence was 2%.

2.3.4 The Specialist Advisers considered key efficacy outcomes to include local and regional recurrence rates, cancer-specific mortality, cosmetic outcome and quality-of-life outcomes.

2.4 Safety

2.4.1 In a case series of 103 patients, 17% of 75 patients treated with interstitial brachytherapy developed grade 1 and 5% developed higher grades of skin erythema, compared with 43% and 0%, respectively, of 28 patients treated with balloon brachytherapy (p = 0.01 and 0.06, respectively). In this study, subcutaneous fibrosis occurred in 32% of patients treated with interstitial brachytherapy and 11% of patients treated with balloon brachytherapy (p = 0.04). There was no statistically significant difference in symptomatic fat necrosis (12% for interstitial brachytherapy and 7% for balloon brachytherapy, p = 0.73) (absolute

numbers not given).

2.4.2 Complications of interstitial and balloon brachytherapy included: fat necrosis in 2% (22/1449) to 16% (8/50); symptomatic seromas in 10% (8/80) and 11% (153/1449); fibrosis in 10% (5/50) and 19% (53/274); telangiectasia in 2% (1/50) and 13% (35/274); breast pain in 3% (3/89) and 7% (20/274); and infection in 3% (9/274), 8% (92/1140) and 9% (4/43) of patients. A case series of 70 patients reported two severe infections (one mastitis and one abscess).

2.4.3 The Specialist Advisers considered adverse events to include erythema, infections, seroma formation, breast fibrosis, fat necrosis, skin telangiectasias, breast pain, oedema and hyperpigmentation.

2.5 Other comments

2.5.1 The Committee's recommendations were influenced by their view that any procedure for the treatment of early breast cancer should be supported by good quality evidence from large numbers of patients.

3 Further information

3.1 The Institute is developing clinical guidelines on early and advanced breast cancer [Now published as 'Breast cancer (early & locally advanced): diagnosis and treatment' and 'Advanced breast cancer: diagnosis and treatment'] and has published an update to the manual 'Improving outcomes in breast cancer'. The Institute has published interventional procedures guidance on interstitial laser therapy for breast cancer, low dose rate brachytherapy for localised prostate cancer, pre-operative high dose rate brachytherapy for rectal cancer, high dose rate brachytherapy for carcinoma of the cervix and high dose rate brachytherapy for prostate cancer.

Sources of evidence

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

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It has been incorporated into the NICE pathway on early and locally advanced breast cancer, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

10 January 2012: minor maintenance.

Your responsibility

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

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.