NICE guidance

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

Interventional procedures guidance
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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 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. NICE may review the procedure on 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.

## 2.3 Efficacy

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, see the overview.

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 out of 128) and 3% (4 out of 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 2 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 out of 51) in the

brachytherapy group compared with 5% (5 out of 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 1,440 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 out of 1,449) to 16% (8 out of 50); symptomatic seromas in 10% (8 out of 80) and 11% (153 out of 1,449); fibrosis in 10% (5 out of 50) and 19% (53 out of 274); telangiectasia in 2% (1 out of 50) and 13% (35 out of 274); breast pain in 3% (3 out of 89) and 7% (20 out of 274); and infection in 3% (9 out of 274), 8% (92 out of 1,140) and 9% (4 out of 43) of patients. A case series of 70 patients reported 2 severe infections (1 mastitis and 1 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 NICE has issued guidelines on early and locally advanced breast cancer and advanced breast cancer and has published an update to the cancer service guideline on improving outcomes in breast cancer. NICE 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 for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.