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A study of margin width and local recurrence in breast conserving therapy for invasive breast cancer

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Abstract

Purpose: Debate continues on what is an adequate margin width to define a clear margin and whether there is a need to excise pectoral fascia or remove skin in breast conserving surgery. This study set out to provide answers to these questions.
Patients and methods: 1411 patients with invasive breast cancer were treated by breast conserving surgery and post-operative whole breast radiotherapy from January 2000 to December 2005. Distance from each margin to any *in situ* or invasive cancer was measured and recorded. If full thickness of breast tissue was removed no re excision of anterior and posterior margins was performed even if disease was <1 mm from a margin. Patients ≤50 years of age and those with anterior or posterior margins <1 mm to invasive cancer had a radiation boost. Median follow-up time was 6.4 years.
Results: Local in breast tumour relapse (IBTR) occurred in 50 patients. The overall actuarial IBTR rate at 5 years was 2.2%. There was no difference in IBTR when comparing patients with radial margins of 1–5 mm or 5–10 mm. Anterior and posterior margins <1 mm or with ink on tumour cells were not associated with an increase in IBTR.
Conclusion: There is no justification for radial margins of greater than 1 mm. If the anterior or posterior margin is <1 mm and full thickness of breast tissue has been removed, then re excision of these margins is unnecessary if boost radiotherapy is delivered.
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Keywords: Margin width; Local recurrence; Breast conserving surgery; Invasive breast cancer

Introduction

Numerous randomised controlled clinical trials have established the safety and effectiveness of breast conserving therapy in the treatment of early invasive breast cancer.[1–5] Breast conserving therapy consists of complete excision of all invasive and *in situ* breast cancer followed by radiation therapy. The need for whole breast radiotherapy has been established by a series of trials showing not only that radiation produces a significant reduction in local recurrence following breast conserving surgery but provides a long term survival benefit with an estimated 5.4% absolute reduction in breast cancer deaths at 15 years.[6] The breast after breast conserving surgery must look satisfactory in terms of cosmetic appearance[7,8] if one is to maximise the psychological benefits of breast preservation.[9,10] Numerous studies have investigated patient, tumour and therapeutic factors that influence the risk of in-breast local recurrence (IBTR) following breast conserving surgery for invasive breast cancer.[6–8,11–24] Much of the literature has focused on the type and extent of surgery and the status of the surgical margins.

The risk of local recurrence is increased significantly if the surgical margins are positive (tumour cells are present at the resection margin).[8,11,13,16,18,20,23,25–29] There is huge variation in practice between individual clinicians, centres and countries as to what constitutes an adequate margin width following breast conserving surgery. This lack of agreement is evident in surveys and consensus

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reports.[13,30–32] There is emerging evidence that shows that increasing the negative margin width will not reduce local recurrence rates.[11,14,33,34]

Little attention in the literature has been paid to which margins matter most. Many advocate removal of a cylinder of breast tissue from the subcutaneous fat down to the pectoral fascia.[10,35] Advocates argue that this controls the front and back margins even if these margins are involved. There is however no consensus on this issue because if disease is reported within 1 mm of the anterior margin, 35% of surgeons would re-excise and if disease is reported <1 mm from the posterior margin 10% would re-excise.[30] Some surgeons take pectoral fascia routinely, while others do not.

The Edinburgh Breast Unit is the largest single Breast Unit in the United Kingdom. A prospective database is kept of all patients treated by the team of surgeons and oncologists in Edinburgh. The primary aim of the current study was to investigate from a prospectively collected dataset whether local recurrence rates vary in relation to margin width. The second aim was to determine whether local recurrence rates are increased in patients who have anterior and posterior margins <1 mm but who have had full thickness of breast tissue excised and were not subjected to re-excision of these margins.

Patients and methods

Patients diagnosed and treated with invasive breast cancer between 1st January 2000 to 31st December 2005 who were treated by breast conserving surgery and had whole breast radiotherapy in the Edinburgh Cancer Centre were identified from the South East of Scotland Cancer Area Network (SCAN) prospective database. Patients had a core biopsy to establish a diagnosis of invasive cancer. Following full imaging assessment of the primary cancer, axillary nodes and appropriate scans to detect metastatic disease, all patients were discussed at a multidisciplinary team meeting. Patients who underwent breast conserving surgery by a team of specialist surgeons based in the Edinburgh Breast Unit were identified from the data base. Patients having breast conserving surgery after neoadjuvant chemo or hormonal therapy were excluded. The aim was to excise the cancer with a 1 cm macroscopic margin. In almost all patients (>95%) full thickness of breast tissue from subcutaneous fat down to pectoral fascia was removed. All specimens were orientated in a standard fashion with metal clips and underwent intra-operative specimen radiography and where appropriate further tissue was removed.[36] It was not routine to take cavity shavings: the only margins that were re-excised were those considered involved based on the routine specimen radiograph or on palpation by the surgeon. It was not routine practice to remove skin overlying the cancer or pectoral fascia. Only patients with cancers that were considered very close to the overlying skin or were involving pectoral fascia before or during surgery had these excised.

All excision samples were fixed immediately in formalin. They were processed by specialist breast pathologists in a standard manner with specimens being sliced parallel to the chest wall. Standard pathology reports were issued and included the microscopically measured distance in mm to all six margins (anterior, posterior and the radial margins: medial, lateral, superior and inferior). The distance in mm from the surgical margin to the edge of both invasive and *in situ* cancer was reported. All patients were then discussed at a second multidisciplinary meeting after surgery when the full pathology report was available. If a radial margin (medial, lateral, superior or inferior) was less than 1 mm clear of either invasive cancer or DCIS, then re-excision was advised unless the surgeon reported in the operation note that he or she had excised tissue to the limit of the breast at that margin. If the pathologist reported disease <1 mm from the anterior or posterior margin of the specimen and full thickness of breast tissue had been taken and this had been recorded by the operating surgeon, then no re-excision of these margins was performed even if there was tumour on ink. Patients having a re-excision were considered to have clear margins if the new radial margin was 1 mm or greater from both invasive and *in situ* disease. A small number of patients underwent more than one re-excision to obtain clear margins.

All patients had adjuvant systemic therapy (see Table 1) and whole breast radiotherapy and received a whole breast dose of 45 Gy in 20 fractions. Patients aged 50 years of age or younger and patients who had an anterior or posterior margin distance to invasive cancer of <1 mm received a tumour bed boost of 15 Gy delivered by external beam radiotherapy. Patients with DCIS within 1 mm of anterior or posterior margins did not receive a boost. All patients had an annual review consisting of clinical examination and two view mammography. Patients with suspicious abnormalities on clinical or mammographic assessment were investigated further by ultrasound and/or core biopsy to establish the presence or absence of any in-breast tumour recurrence. The median follow-up time was 6.4 years. All patients with a diagnosis of invasive or *in situ* disease which occurred anywhere in the treated breast were considered to have in breast tumour relapse (IBTR). Cross tabulation with other databases and clinical records confirmed the validity and completeness of the data and allowed confirmation of all in breast tumour recurrence events.

Statistical methods

Actuarial survival and relapse rates were calculated using the Kaplan–Meier method.[37] The log rank test was used for statistical comparison between curves.[38] A Cox proportional hazards regression model[39] was used to assess the independent prognostic significance of variables. All

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