particularly where external beam radiotherapy (EBRT) cannot be offered due to various reasons.

Methods: Patients with invasive breast cancer underwent wide local excision followed by IORT (n = 75) using the Intrabeam system containing a miniature electron gun and accelerator. Low energy x-rays (50 kV) are emitted from the point source, delivering 20 Gy to the breast tissue at the surface of the tumour bed using a spherical applicator. Patients who were deemed unfit for surgery (n = 3) received interstitial radiotherapy alone using Intrabeam, with only the point source placed at the tumour centre under stereo-guidance under local anaesthetic, and were followed up with serial MRI scans.

Results: Over the past 7 years 78 patients have been treated in this way in centres in 3 countries (UK, Germany and Australia). To date there have been no local recurrences. One patient developed a second primary and subsequently died of brain metastases.

Conclusions: This cohort adds to the evidence that targeted radiotherapy using Intrabeam (either IORT or interstitial) could offer a safe and effective method of delivering radiotherapy to breast cancer patients in whom EBRT is not an option.

Table

Reason for IORT	No. of patients	Age (years)*	Follow-up (months)*	Outcome
Previous EBRT	22	64 (54−74)	35 (15−50)	All free of LR; 2 died
Collagen vascular disease	5	63 (57−64)	24 (22−35)	All free of LR
Co-morbidities	24	79 (66−83)	22 (16−35)	All free of LR; 7 died
Other	27	62 (52−73)	29 (22−48)	All free of LR; 1 died

* median (IQR). LR = local recurrence.

Thursday, 17 April 2008 12:30–14:30

POSTER SESSION

Sentinel node – technique, diagnosis and management

334 Poster

Axillary and extra-axillary lymph node recurrences after a tumor-negative sentinel node biopsy for breast cancer using intra-lesional tracer administration

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Background: A recent literature review of sentinel node-negative breast cancer studies with a median follow-up of 46 months revealed an axillary recurrence rate of 0.4%. At our institution, the tracer fluids are administered in the primary breast cancer. Sentinel nodes both in and outside the axilla are pursued. The objective of the present study of sentinel node-negative breast cancer patients was to determine the lymph node recurrence rates in the axilla and elsewhere, the false-negative rates, and survival.

Methods: Between January 1999 and November 2005, 1,019 patients underwent a sentinel node biopsy for breast cancer with intra-lesional tracer administration of technetium-99m-nanocolloid (GE-Healthcare). Lymph node recurrence rates were calculated as a percentage of the tumor-negative sentinel node biopsies. The false-negative rate reflects the percentage of missed involved sentinel nodes and was calculated by dividing the number of lymph node recurrences by this same number plus all tumor-positive sentinel node biopsies. Survival was calculated by Kaplan–Meier analyses.

Results: In 748 patients, 755 sentinel node biopsies revealed a tumor-negative sentinel node and axillary dissection was omitted. The median follow-up time was 46 months. Two of the 748 patients developed an axillary lymph node recurrence after 10 and 44 months, and are both alive without tumor-activity 46 and 15 months later, respectively. Two other patients developed a supraclavicular lymph node recurrence after 8 and 52 months and both died of distant metastases after 2 years and 9 months, respectively. The lymph node recurrence rate was 0.5%; 0.25% for the axillary and 0.25% for the extra-axillary nodes.

In 271 patients, 284 sentinel node biopsies revealed metastases: in 247 of them in the axilla, in 20 outside the axilla, and in 17 patients both in the axilla and elsewhere. The false-negative rates were 1.4% overall, 0.8% for the axilla and 5.1% for the extra-axillary nodes.

After five years, 95.9% of all patients were alive and 89.7% were alive without disease.

Conclusion: The low recurrence and false-negative rates and promising survival figures show that our lymphatic mapping method with intra-lesional tracer administration is accurate for the axilla. Outside the axilla, 5.1% of involved sentinel nodes were missed.

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Current status of the EORTC 10981–22023 AMAROS trial – After mapping of the axilla radiotherapy or surgery

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Background: The AMAROS trial is a phase III study comparing axillary lymph node dissection (ALND) with axillary radiation therapy (ART) in patients with proven axillary metastasis by sentinel node biopsy (SNB). The main objective of the trial is to prove equivalent locoregional control and reduced morbidity for ART. The aim of this report is to discuss the progress of the trial.

Material and Methods: Patients with operable unifocal invasive breast cancer (5−30 mm) and clinically negative lymph nodes are randomized between ALND and ART. SNB is performed using preoperative lymphoscintigraphy, blue dye and a gamma-ray detection probe. Quality of Life, arm- and shoulder function is evaluated after 1, 3, 5 and 10 years. The primary endpoint is axillary recurrence rate. The calculated sample size was 3485 patients to be registered, assuming a SNB positive rate of 40%.

Results: In Europe 30 institutes are participating. Between 2000 and 2007, 3494 patients have been enrolled. Accrual rate is 60 patients per month. Of the first 3100 patients, 1000/3100 (32%) patients were SNB positive and 2006/3100 (65%) were SNB negative. The identification rate was 97%: in 3% (89/3100) the sentinel node was not identified. Three percent (32/759) of patients with a positive SNB were ineligible, mainly due to absence of invasive breast cancer or clinically positive axillary lymph nodes. Fifteen percent (112/759) of patients had tumors >30 mm or multifocal tumors on final pathological assessment, while at baseline, they complied with the inclusion criteria. Protocol treatment compliance was 90%. Main reasons for non-compliance were cross over, no further treatment because of isolated tumor cells (<0.2 mm) and patient refusal. Thus far, in 7/3100 enrolled patients, axillary lymph node metastases became apparent.

Conclusion: The SNB identification rate is above the mandatory 90% and is similar to the results of other multicenter trials. The SNB positive rate is lower than expected, 32% instead of 40%. To randomize the required 1394 SNB positive patients and to compensate for 10% treatment non-compliance, the trial will remain open for another 2 years, until 4766 patients are registered. The allowed maximum tumor size will be increased from 30 mm to 50 mm since it is nowadays considered to be safe to perform a SNB in these patients and it will be allowed to omit further axillary treatment if only isolated tumor cells are found.