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## Entry to breast cancer clinical trials: The importance of specialist treatment teams

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**Purpose:** To identify the factors influencing recruitment of women with breast cancer to clinical trials.

**Methods:** All women diagnosed with breast cancer in Scotland during 1987 and 1993 were identified from cancer registry data. Their case records were reviewed and entry to a clinical trial at any time following diagnosis recorded along with clinical and demographic data.

**Results:** Over the 2 years, 501 patients made 522 entries to 34 clinical trials. In 1987 the percentage of women entering clinical trials was 12% and allowing for shorter follow-up this was unchanged in 1993. Patients seen by a surgeon with a high case load of breast cancer patients were approximately seven times, and those referred to an oncologist three times, more likely to enter a clinical trial ($P < 0.0001$). The area of Scotland (Health Board) where the patients was treated also influenced study entry ($P < 0.0001$). Social deprivation had no effect ($P = 0.9$) but older women, especially those over 80, were less likely to enter studies ($P = 0.05$).

**Conclusions:** Extending the management of patients by specialist multidisciplinary teams should increase recruitment to clinical trials and help to identify better treatments for women with breast cancer.

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## Long-term survival in axillary node-positive breast cancer treated with locoregional therapy alone

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**Purpose:** We investigated the clinical and histopathological data of breast cancer patients with histologically confirmed axillary nodal metastases (pN+) diagnosed in a defined geographical area and followed up for 15 to 41 yrs after the diagnosis in order to estimate the possible cure rate with locoregional therapy alone.

**Methods:** The clinical and autopsy records, and histological slides of 1,172 patients with breast cancer diagnosed in the city of Turku, Finland, in 1945–79 were reviewed. The series includes 339 patients with invasive, unilateral breast cancer with histologically confirmed axillary nodal metastases, who were treated with mastectomy and axillary nodal evacuation, locoregional irradiation (84%) and without any adjuvant systemic treatment.

**Results:** None of the 35 (10%) patients with pN2 diasease survived for 15 yrs. The 15- and 30-yr overall survival rates of the 304 patients with pN1 disease were 19% and 9%, respectively, and the 15- and 30-yr survival rates corrected for intercurrent deaths 29% and 24%, respectively. In a multivariate analysis the primary tumour size, histological grade and axillary nodal status (pN2 vs. pN1) had independent prognostic value.

**Conclusion:** A considerable proportion of women with pN1 breast carcinoma treated with locoregional therapy alone are long-term survivors, which suggests that locoregional treatment has been curative in such cases.

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## Adjuvant CMF improves outcome of node negative breast cancer (BC) in premenopausal women: 10 years results of a randomized study

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**Methods:** 345 premenopausal pts with N-, M0 BC were randomized to control (163 pts) or adjuvant CMF (Cyclo-phosphamide: 400 mg/m$^2$; methotrexate: 40 mg/m$^2$; fluorouracil: 400 mg/m$^2$ d1&8 q 28 days for 6 cycles) (172 pts).

Arms were well balanced for age (median = 43.4 years), pathology, grade (grade 2: 57.5%), T (1&2: 87.1%), ER status (positive: 55.5%), p53 expression (positive 23.5%) type of surgery (conservative: 220 pts).

**Results:** In the CMF arm, no pt experienced grade III–IV neutropenia, 20% had grade III–IV emesis, 30% had permanent amenorrhoea. No early or late Severe Adverse Events have been observed.

With a median follow-up of 10 years, following events have been observed; local relapses: 49 (14.6%); regional relapses: 8; metastatic progressions: 46 (13.7%), contralateral breast cancers: 16 (4.8%). 43 pts have died.

Adjuvant CMF significantly improved event-free survival ($p = 0.03$) while overall survival is similar in both arms.

Adverse prognosticators (multivariate analysis) were: T stage and grade; p53 did not impact on prognosis or outcome of chemotherapy.

**Conclusion:** CMF improved outcome of N- breast cancer in premenopausal women and should thus be considered in those women. More effective regimen are currently studied in such patients with adverse prognosticators.

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## Paget's disease of the breast treated with radiotherapy only

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Paget's disease, confined to the nipple-areola complex, without signs of underlying tumor (invasive or in situ) may be treated safely by radiotherapy only. We present our experience since 1971.

Between 1986 and 1996, 14 patients with histopathological confirmed Paget's disease, were treated with radiotherapy only. Mammogram and ultrasound were negative. Delay in diagnosis varied between 2 and 48 months. All patients were treated with radiotherapy 50 Gy to the whole breast and a boost of 14 to 16 Gy to the nipple. Follow-up ranged from 8 to 112 months. One patient died of non tumor-related causes. Four recurrences were detected, one of them being invasive but without distant metastasis. All 4 patients underwent a mastectomy. Follow-up thereafter, ranges between 1 and 67 months. No further events have occurred until now. Between 1971 and 1985, another 14 patients have been treated in the same way. At 52 months, median follow-up, no recurrences were present. We expect to have long time follow-up data on a total of 28 patients at the time of the conference.

In literature, similar series report comparable local recurrence rates. In these rare cases optimal results can be obtained with radiotherapy only but close follow-up is warranted to detect recurrences at an early stage.

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## Adjuvant chemotherapy with ac versus high dose mitoxantrone, cyclophosphamide (MC), filgrastrim in operable breast cancer involving 10 or more axillary lymph nodes: 3 years follow-up results

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Between 01/92 and 12/94, 150 patients (pts) with operable breast cancer involving 10 or more axillary lymph nodes ($N+ \geq 10$) were randomised after surgery. Group A (74 pts) received 4 cycles with AC (Adriamycin 60 mg/m$^2$, Cyclophosphamide 600 mg/m$^2$) q 3 weeks. Group B (76 pts) received 4 cycles with MC (high dose Mitoxantrone 23 mg/m$^2$, Cyclophosphamide 600 mg/m$^2$) q 3 weeks and filgrastrim (G-CSF) from days 2 to 15. Clinical prognostic factors were equally distributed in both arms, post menopausal pts: 54%, median age: 54 y. (30–70), median number of involved lymph nodes: 13.

**Results:** The mean dose intensity was respectively 94%–93% for A–C and 95%–95% for M–C. Three years disease-free survival (DFS) is 46% (arm A) and 59% (arm B), $p = 0.31$, 3 year distant disease-free survival (DDFS) is 49% (arm A) and 59% (arm B), $p = 0.57$. There is no difference in overall survival (OS), 3 years OS is 75% and 73% respectively. A multivariate analysis shows that MC improves DDFS only for the subgroup $N+ > 14$ (59 pts, RR = 3, $p = 0.03$) with 3 year DDFS: 12% in AC arm *Vs* 52% in MC arm.

**Tolerability:** febrile neutropenia occurred in 1/287 (0.3%) and 10/294 (3%) of cycles in arm A and B, respectively. Alopecia was less frequent with MC ($p < 0.001$).

**Conclusion:** At 3 years, there is no significant difference between the 2 arms, nevertheless for the subgroup $N+ > 14$, our results suggest that MC decreases the risk of distant relapse compared to AC.