days 1 and 8, 5-FU 500 mg/m$^2$ (iv): days 1 and 8, plus TAM 20 mg/day (po) for 2 years] and 177 patients in the UFT + TAM group [UFT 270 mg/m$^2$/day (po) plus TAM 20 mg/day (po), both given for 2 years], were included in a subset analysis of relapse-free survival (RFS) based on ER status, a stratifying factor for randomization.

**Results:** Five-year overall RFS was 76.3% and 72.3% in the CMF and UFT groups, respectively, showing no significant difference between the two groups (Hazard ratio (HR): 1.18 (0.76−1.79), p = 0.456). In ER(−) patients, RFS was 74.7% and 61.4% in the CMF (n = 73) and UFT (n = 72) groups, respectively (HR: 1.63 (0.90−3.02)). In ER(+) patients, RFS was 75.7% and 80.8% in the CMF (n = 89) and UFT (n = 91) groups, respectively (HR: 0.72 (0.37−1.38)). An interaction was observed between ER status and the efficacy in each group (test for interaction: p = 0.07). RFS was not significantly different between ER(−) and ER(+) in the CMF group (p = 0.79), but was markedly different between ER(−) and ER(+) in the UFT group (p = 0.002).

**Conclusions:** UFT may be very promising in preventing relapse of ER(+) breast cancer. While there have been many reports that postoperative chemotherapy is not very effective for ER(+) breast cancer, tegafur-based oral chemotherapy such as UFT and S-1 (tegafur, CDHP, Oxo) are expected to be effective preoperative chemotherapy for ER(+) breast cancer, if used in combination with endocrine therapy. This possibility needs to be investigated in a future study.

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**Letrozole or anastrozole for the prevention of early recurrences in post menopausal women with early stage breast cancer: using number needed to treat (NNT) to compare benefit**

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**Background:** The ATAC (Lancet, 2005) and BIG 1-98 (NEJM, 2005) randomized trials demonstrated that anastrozole and letrozole were more effective than tamoxifen in preventing disease relapse in postmenopausal women with early stage breast cancer. However, recent secondary analyses of these trials revealed important differences between letrozole and anastrozole in the prevention of early distant recurrences; early being defined as less than three years following the initiation of treatment. NNT represents the number of patients that need to be treated with a new intervention in order to avoid one additional event, and is a powerful approach that can be used to make sense of numerical results from clinical trials. In this exploratory analysis, the NNT approach was used to compare letrozole and anastrozole in preventing early recurrences in this patient population.

**Methods:** The early recurrence data from the pivotal trials for letrozole and anastrozole were reviewed (Mauriac, 2007, Houghton, 2006). A key requirement for a NNT analysis is that all outcomes must be considered over similar time periods. The time points for evaluating early recurrences for anastrozole and letrozole were at 2.5 and 2 years respectively. Patients remaining disease free beyond these time points were censored. NNT, which is the reciprocal of the percent difference in efficacy relative to tamoxifen was calculated for each agent with respect to all recurrences; local-regional, distant recurrences and contralateral breast cancer.

**Results:** For all recurrences, letrozole and anastrozole had a comparable NNT of 75 (95% CI: 46–200) and 77 (95% CI: 39–2349) patients to avoid one recurrence. However, a 3-fold difference in NNT was noted for distant recurrences in favor of letrozole; 100 (95% CI: 58–371) patients would have to be treated with letrozole to avoid one such event compared to 300 (95% CI: 74−$\infty$) with anastrozole.

**Discussion:** In situations of multiple numerical outcomes from randomized trials, the NNT approach is a simple and effective method to express the findings in a clinically meaningful way. In this analysis, it appears most of the clinical benefit associated with anastrozole in the first 2−3 years is in reducing the risk of local and regional relapses, while letrozole shows a pronounced impact in reducing distant metastases in these first 2−3 years. These findings are particularly relevant because distant metastases are associated with the lowest survival rates and represent a major economic burden to health care systems.

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**Taxane-containing primary chemotherapy for inflammatory breast cancer: INT experience**

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**Background:** The effect of taxanes on the survival of patients with IBC (inflammatory breast cancer) has not been established since these patients generally represent a subset of global primary chemotherapy or phase II trials.

**Material and Methods:** We analyzed the medical records of 93 women consecutively treated at the Istituto Nazionale Tumori in Milan from October 1992 to August 2007 with an integrated program of primary ± adjuvant chemotherapy, surgery, radiotherapy and endocrine therapy and/or trastuzumab if indicated.

**Results:** From October 1992 to November 1994, 13 patients were treated with primary single agent anthracycline (A) followed by postoperative CMF. Subsequently, till August 2007, 80 patients were given primary chemotherapy containing both anthracyclines and taxanes (AT). Main pretreatment characteristics were fairly well distributed between the two case series. Treatment outcome in terms of clinical complete remission (cCR), disease progression while on primary chemotherapy (PD), absence of invasive breast cancer (pCR) and absence of involved axillary nodes (pN0), freedom from progression (FFP) and overall survival (OS) at 5 years is reported in the table.

| | % cCR | % PD | % pCR | % pN0 | % FFP | % OS |
|---|---|---|---|---|---|---|
| A | 8 | 0 | 8 | 0 | 12±10 | 44±10 |
| AT | 34 | 2.5 | 20 | 36 | 45±6 | 62±6 |
| | | | | P = 0.005 | P = 0.20 | |

Multivariate analysis on FFP revealed pN0 as the strongest indicator of prognosis (HR 3.5, P = 0.006). However pCR (HR 2.8, P = 0.09) and AT regimen (HR 1.8, P = 0.10) also played an important role. In the AT series the only variable able to significantly predict the achievement of pathological complete remission in both breast and axilla was the status of PgR (negative v. positive, odds ratio 1.5, P = 0.03), which however failed to reach conventional statistical significance in the multivariate analysis (P = 0.17).

**Conclusions:** The retrospective analysis shows that the use of AT-containing regimes is associated with higher likelihood of pCR and pN0, which represent the factors more strongly associated with a favorable long term outcome.

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**The SUCCESS-Trial – toxicity analysis of a phase III study evaluating the role of Docetaxel and Gemcitabine in the adjuvant therapy of breast cancer patients**

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**Background:** In several randomized trials, taxane containing regimens have demonstrated superiority compared to mere anthracycline containing schedules for the adjuvant treatment of patients with early breast cancer. Given an array of novel drugs, continued improvements in the adjuvant setting may further reduce breast cancer mortality in future.

**Methods:** The SUCCESS-Study is an open-label randomized controlled, Phase III study comparing the disease free survival after randomisation in patients treated with 3 cycles of Epirubicin(100 mg/m$^2$)–Fluorouracil(500)–Cyclophosphamide(500) (FEC)-chemotherapy, followed by 3 cycles of Docetaxel(100 mg/mg$^2$) (D) versus 3 cycles of FEC, followed by 3 cycles of Gemcitabine(1,000 mg/m$^2$ d1, 8)–Docetaxel(75 mg/m$^2$) (DG). Complete, monitored toxicity data of 2.691 pts were available for this analysis.