Results: Prophylactic treatment with pegfilgrastim alone or pegfilgrastim with C was associated with a lower incidence of febrile neutropenia, first cycle febrile neutropenia, hospitalization, and anti-infective use compared with daily G-CSF (see table). Pegfilgrastim alone or with C also showed a lower incidence of grade 3/4 stomatitis and diarrhea ($p < 0.05$) compared with daily G-CSF.

Conclusion: Pegfilgrastim alone or in combination with ciprofloxacin was a more effective treatment for prevention of neutropenia and its related complications than daily G-CSF in early stage breast cancer patients treated with TAC chemotherapy.

	Cohort A G-CSF (n = 385) 2086 cycles	*Cohort B* pegfilgrastim (n = 311) 1631 cycles	*Cohort C* pegfilgrastim + ciprofloxin (n = 219) 1074 cycles	Statistical comparison
Patient incidence of FN	17%	6%	5%	*** A vs B *** A vs C ns B vs C
Incidence of FN in the first cycle	9%	2%	0%	*** A vs B *** A vs C * B vs C
Number of hospitalizations	391	210	161	*** A vs B ** A vs C ns B vs C
Number of anti-infective[a] administrations	88	44	25	** A vs B ** A vs C ns B vs C

***$p < 0.001$; **$p < 0.01$; *$p < 0.05$; ns: not significant; FN: febrile neutropenia.
[a]defined as antibiotic, virostatic, or antifungal medications

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Amenorrhea as a prognostic factor in premenopausal endocrine responsive early breast cancer patients

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Objectives: Amenorrhea (Am) seems to be a prognostic factor in early breast cancer (EBC), especially in endocrine responsive disease. Aim of our analysis was to evaluate prognostic value of Am in premenopausal patients (pts) treated for EBC at Institute of Oncology in Ljubljana from 1986 to 1998.

Patients and Methods: To assure complete menstrual data, only 204 premenopausal HR positive pts included into international prospective trials evaluating the role of adjuvant systemic therapy (ChT alone n = 120, ChT plus Tam n = 19, ChT plus goserelin n = 37, goserelin alone = 28) were reviewed. Median age was 45 (27–54) years, majority of tumors (53%) were classified as T2, of median grade (43%), half of pts had positive lymph nodes. Amenorrhea was defined as a cessation of menstruation for at least 2 years. Endocrine responsive disease was defined as ER and/or PR $\geqslant$ 10 fmol/mg protein in primary tumor. Kaplan-Maier method and log-rank test were used for statistical analyses.

Results: Amenorrhea occurred in 85% (174/204) of all pts (in 76% of pts on ChT +/− Tam and in all patients on goserelin, respectively). Pts with Am had significantly higher 5-year DFS compared to pts without Am (75% vs. 53%; $p = 0.0081$). Also in the group of pts with Am induced by ChT alone, higher 5-year DFS rates were observed (76% vs. 57%; $p = 0.06$). Recovery of menstruation after 2 years of goserelin treatment did not affect 5-year DFS rates significantly ($p = 0.44$). After adjusting for ChT and Tam Am still showed borderline significance for DFS ($p = 0.06$). In Cox multivariate analyses with tumor size, tumor grade, nodal status and Am included, only nodal status retained independent prognostic value.

Conclusions: In our cohort of endocrine responsive premenopausal EBC patients, treatment related amenorrhea showed a prognostic impact on DFS. Also when Am was achieved only by ChT, it had a favorable effect with a trend to better DFS. No significant difference in DFS according to recovery of menstruation after goserelin cessation was observed.

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Cost-effectiveness of exemestane versus tamoxifen as adjuvant therapy for early-stage breast cancer after 2–3 years treatment with tamoxifen in Sweden

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Breast cancer is the most common cancer in Swedish women, with about 7000 new cases annually. Aromatase inhibitors are rapidly becoming the cornerstone of hormonal treatment for advanced disease and are now also used as adjuvant treatment in early-stage disease. The Intergroup Exemestane Study (IES) trial was a double-blind, randomized controlled trial in which postmenopausal women who had received two to three years of tamoxifen therapy following primary treatment of early-stage breast cancer were randomized to either continue on tamoxifen therapy or be switched to exemestane therapy. The results showed a disease-free survival hazard ratio of exemestane relative to tamoxifen in IES of 0.69.

The objective of this study was to assess the cost-effectiveness of adjuvant treatment with exemestane versus tamoxifen for early-stage breast cancer after 2–3 years treatment with tamoxifen in Sweden, based on findings in the IES. A Markov-type state-transition model was developed to simulate consequences after the end of the clinical trial, and to integrate the trial data with external data on mortality, costs and quality of life specific for Swedish women. The model used a life-long time horizon and the primary clinical outcome measure was quality adjusted life-years (QALYs).

Locoregional and distant recurrences occurred in about 18% of the patients, while new contralateral cancer occurred in 1–2%. Treatment of cancer recurrences contributed most to the total cost, while the largest difference in cost between the exemestane and tamoxifen groups was incurred by the adjuvant hormone treatments. The cost per QALY gained was about €20,000 in the base case analysis without inclusion of consequences of coronary heart disease. Inclusion of these events increased the cost-effectiveness ratio to about €31,000 for the base case assumption. Exemestane treatment in early breast cancer may therefore be a cost-effective option compared with tamoxifen, depending on the long-term effect of tamoxifen on coronary heart disease.

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Preoperative concomitant hormone-radiotherapy for locally advanced breast cancer: Long-term clinical results of the Montpellier feasibility study

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Purpose: To evaluate, with a 6-year median follow-up our data concerning survival and locoregional control in a pilot study of locally advanced breast cancer after primary hormonoradiotherapy (HT-RT).

Patients and Methods: Between 1987 and 2002, 80 patients (33 stage IIA, 27 stage IIB, 16 stage IIIA, and 4 stage IIIB according to AJCC staging system 2002) were treated by tamoxifen 20 mg daily and preoperative radiotherapy (50 Gy to the breast and nodal areas). Tamoxifen was started the first day of radiotherapy and was delivered for 3 months (median 90 days, range 60–130) before surgery.

Before any treatment, all patients were clinically evaluated by a surgeon and an oncologist and were considered not suitable for a conservative surgery. In all cases, primary tumors were histologically proven and were positive for estrogen (RE) and/or progesterone receptors (RP).

After surgery, tamoxifen was continued for 5 years, or until disease progression. Fifteen patients (19%) received adjuvant anthracyclin-based chemotherapy. Only four patients stopped tamoxifen before 5 years for toxicities.

Results: The median age of the patients was 60 years (range, 32–80 years). Sixteen (20%) patients were premenopausal and received LHRH analogues with tamoxifen. Compliance to neoadjuvant treatment was excellent and all patients received the complete sequence of preoperative radiotherapy and tamoxifen. Overall clinical response rate was 75% (64 patients), including a complete response rate of 8% (6 patients). Mastectomy and axillary dissection were performed in 44 patients (with clinical residual mass larger than 3 cm or central tumors), and conservative treatment in 36 patients (22 of them achieved clinical complete response or