Results: Considering a cohort of 1000 patients modelled for 25 yrs, anastrozole was estimated to lead to 184 discounted LYG at an additional cost of £2.1 million. Consequently, the discounted ICER of anastrozole compared to tamoxifen was estimated to be £11,747/LYG (95% CI £1946–£21,984). Furthermore, acceptability curves showed that the estimated cost/LYG at 25 yrs was below £20,000 with a probability greater than 90%. T he result compared favourably with commonly accepted thresholds for cost-effectiveness of other cancer drugs and was robust to all the parameters (including adverse events) tested in the sensitivity analysis.

Conclusions: Anastrozole is a cost-effective alternative to tamoxifen for the adjuvant treatment of postmenopausal women with HR+ early breast cancer.

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Neoadjuvant tamoxifen for hormone-sensitive non metastasis breast carcinomas in early post-menopausal women: a 118–month median follow-up

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Purpose: An initial analysis was published and showed the feasibility of this strategy, obtaining a conserving treatment rate of 50%. We now report the long-term analysis of this series with a 118-month median follow-up. The aim of this study is to verify that a conserving treatment after neoadjuvant endocrine therapy does not hamper overall survival.

Patients and methods: Between 1985 and 1996, 199 women from 50 to 70 years old, having a too big tumor to be treated with conserving surgery or a T4 tumor, were treated at Institut Bergonié with neoadjuvant endocrine therapy. All of these tumors had steroid receptor positivity with at least one positive receptor. Tamoxifen was given for 4 to 6 months at a 30 mg dosage per day. Median duration of treatment was 5.34 months. Ninety seven women (48.7%) benefited from a conserving treatment, 38 with an exclusive irradiation, 57 with a conserving surgery plus an irradiation and 2 with a preoperative irradiation. Remaining patients (n=102) were treated by modified radical mastectomy (n=57) or received another medical treatment.

Results are presented with a 118 month median follow-up. In the group treated with modified radical mastectomy, 46 patients (54%) had a recurrence, 16 with local relapse (18%) and among them 9 were isolated local relapse and 7 were associated with metastatic disease. In the group treated with conserving therapy, 44 (45.3%) had a recurrence. Eighteen had local relapse (18.5%) and, among them, 10 had **isolated local relapse**. The others had metastatic disease (n=26) as first recurrence. In this series of patients having benifited from conserving treatment after neo-adjuvant tamoxifen, 10 women could have their outcome hampered by their local relapse. The probability to have an isolated local relapse is 6.3% at 3 years, 8.4% at 5 years and 21.4% at 10-year follow-up. Treatment of local relapses was performed in 2 cases with second line conserving surgery, thanks to small recurrence size and in 4 cases with total mastectomy. Complete remission was obtained after this salvage surgery and no adjuvant medical treatment was delivered afterwards. Three patients refused salvage surgery and were treated by an other hormonotherapy. The onset of **metastatic disease** is equivalent in the 2 groups of patients having had a conserving surgery (20% and 41.5%) or a modified radical mastectomy (21.2% and 57.9%) at 5- and 10-year follow-up respectively.

Concerning overall survival, the 2 curves are identical, whatever the loco-regional treatment carried out, 88.6% and 79.9% at 5-year follow-up and 62.9% and 57% at 10-year follow-up respectively.

In conclusion, there was no difference in clinical outcome in terms of locoregional recurrences, metastatic free survival and overall survival between patients undergoing conserving treatment and patients who were submitted to radical mastectomy after neoadjuvant tamoxifen.

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Disease free survival (DFS) in breast cancer patients older than 70 years compered to younger patients groups

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Introduction: Breast cancer in the elderly is a common disease that is usually undertreated compared to younger patients (pts). The aim of our analysis was to find out the differences in tumor characteristics, treatment modalites and DFS in pts over 70 years (y) in comparison with pts 50–70y and younger than 50y.

Patients and Methods: We analysed the data of 1541 pts with operable breast cancer that were treated at the Institute of Oncology during the period September 1993–October 2002. All patients had radical local therapy and systemic therapy performed according to the institutional guidelines at that time. The differences in tumor characteristics (nodal status, grade, tumor size, tumor type, hormonal receptors [HR] and PAI 1) and treatment modalites (type of surgery, radiotherapy (RT) and systemic therapy offered) in pts over 70y (n=305), 50–70y (n=769) and less than 50y (n=473) were examined by χ^2 test. The 3-year DFS in all three groups was calculated according to Kaplan-Meier method and log-rank test.

Results: Patients >70y had compared to pts <50y statistically significant more HR+ tumors (p=>0.0001) and tumors ⩾2 cm (p=0.004), less N+ tumors (p=0.023) and less histological type of invasive ductal carcinoma (p=0.001). Borderline significance was found for grade III tumors (p=0.059). When tumors characteristics of pts >70y were compared with pts 50–70y, statistical significance was found only for tumor size (p=0.041). Regarding local treatment, pts >70y had statistically less conservative surgery done, compared to both younger pts groups (p=>0.0001). The same was found for RT (p=>0.0001). Regarding systemic therapy more hormonal therapy was offered to pts >70y than to pts <50y (p=>0.0001) and pts 50–70y (p=0.013). The opposite was shown for chemotherapy (p=>0.0001).

The 3-year DFS for patients >70y was 82% (HR+ 86% and HR− 61%), for groups of patients 50–70 years and pts <50y DFS was 83% (HR+ 85%, HR− 74%) and 79% (HR+ 82% and HR− 69%), respectively. The difference in DFS in hormonal responsive disease between pts >70y and <50y was statistically significant (p=0.0134).

Conclusion: Women over 70y do not have more indolent breast cancer than pts 50–70y, but have more favorable tumors characteristics in terms of HR+, lymph node+ and histological type than pts less than 50y.

Patients over 70y with hormonal responsive disease treated with radical local therapy and systemic therapy (mostly HT) have significantly better DFS than pts less than 50y and comparable DFS to pts 50–70y. However in hormonal unresponsive disease in pts over 70 is a trend to worse DFS compared to both younger groups and we suppose that this is a group of the elderly patients where clinical trials of adjuvant chemotherapy is urgently needed.

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Effects of fulvestrant in premenopausal women with oestrogen receptor-positive primary breast cancer

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Background: Fulvestrant is an estrogen receptor (ER) antagonist that has no agonist effects. While fulvestrant reduces cellular levels of markers of hormone sensitivity and proliferation in postmenopausal women, its effects on these markers in premenopausal women with ER-positive primary breast cancer have not yet been studied.

Methods: This randomised, double-blind trial evaluated the anti-oestrogenic effect (expression of ER and progesterone receptor [PgR] indices) and the anti-proliferative effect (Ki67 labelling index) of a single 250 mg intramuscular (im) dose of fulvestrant. Premenopausal patients were randomised to receive fulvestrant (n=39) or placebo (n=40) on Day 1, with surgery for primary breast cancer occurring between days 15–22. Tumour biopsy samples were evaluated before trial treatment and at the time of surgery.

Results: Patients in the fulvestrant and placebo groups were well matched, with similar proportions of patients in each group in the luteal and follicular phases of their menstrual cycle. There were no statistically significant differences between treatments for any of the primary endpoint indices (Table 1) and there was no association between plasma fulvestrant concentration and changes in the endpoint indices.

Table 1

	Lsmean	Treatment effect* (95% CI)	p-value
ER Index (H-score)			
Fulvestrant (n=29)	49	5 (−9, 20)	p=0.48
Placebo (n=31)	44		
PgR Index (H-score)			
Fulvestrant (n=26)	65	−23 (−49, 3)	p=0.08
Placebo (n=26)	88		
Ki67 Index			
Fulvestrant (n=30)	24	0 (−7, 7)	p=0.97
Placebo (n=32)	24		

Lsmean, least squares mean; CI, confidence interval; *difference in Lsmeans.