Results: Cytostatic treatment was prematurely stopped in 119 pts (4.4%) receiving FEC-DG and in 103 pts (3.8%) with FEC-D (p = 0.21). Dose reduction >20% (3.97% vs 2.90%) and postponement of treatment cycles >7die (22.85% vs 14.19%) was rare, but more frequent in the FEC-DG arm (both p < 0.001). G-CSF support was applied in 850 (29.2%) vs. 602 pts (20.7%, p < 0.001). Toxicities NCI grade >2 which occurred with incidence >1% or significantly different in the two arms are depicted in Table 1. Afebrile and febrile neutropenia and anemia did not differ between the two arms, but thrombocytopenia was more frequent in FEC-DG (1.7%, p = 0.007). Hand-foot syndrome and neuropathy was more frequent in the FEC-D arm (p = 0.09 and p = 0.02, respectively).

Conclusion: Severe adverse effects were rare in both treatment arms. The addition of gemcitabine to FEC-D adjuvant chemotherapy increases toxicity moderately. These findings will have to be interpreted in the context of survival outcome results.

Table 1

Toxicity	Grade >2		Percentage		p-value
	FEC-DG	FEC-D	FEC-DG	FEC-D	
Neutropenia	504	508	0.3490	0.3458	0.9984
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0×10^9/L, fever ⩾38.5ºC)	42	59	0.0291	0.0402	0.4454
Anemia	31	20	0.0215	0.0136	0.4556
Thrombocytopenia	25	6	0.0173	0.0041	0.0070
SGPT (ALT) (serum glutamic pyruvic transaminase) elevation	68	28	0.0471	0.0191	0.0004
GGT (Gamma-Glutamyl transpeptidase)	45	34	0.0312	0.0231	0.6205
Vomiting	55	58	0.0381	0.0395	0.9981
Nausea	43	45	0.0298	0.0306	0.9994
Stomatitis/pharyngitis (oral/pharyngeal mucositis)	24	26	0.0166	0.0177	0.9971
Diarrhea patients without colostomy	41	39	0.0284	0.0265	0.9927
Fatigue (lethargy, malaise, asthenia)	40	46	0.0277	0.0313	0.9539
Bone pain	28	44	0.0194	0.0300	0.3381
Thrombosis/embolism	28	22	0.0194	0.0150	0.8396
Arthralgia (joint pain)	24	29	0.0166	0.0197	0.9409
Headache	21	10	0.0145	0.0068	0.2469
Myalgia	20	37	0.0139	0.0252	0.1809
Dyspnea	19	24	0.0132	0.0163	0.9175
Hand-foot skin reaction	15	33	0.0104	0.0225	0.0876
Neuropathy	9	28	0.0062	0.0191	0.0227

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Economic assessment of late extended adjuvant letrozole following a prolonged therapy break from Tamoxifen – MA-17 post-unblinding analysis

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Background: The MA17 study was a randomized double-blind placebo-controlled trial of 5 years of letrozole (LET) 2.5 mg/d in 5187 post-menopausal women (median age 62 yrs) with early breast cancer after 5 years of adjuvant tamoxifen (TAM). Due to significant improvement in disease-free survival with LET, the study was unblinded at the first interim analysis (mean follow-up 2.4 years). At this point (median time from TAM, 2.5 years), patients receiving placebo (PLAC) were offered LET. 1,655 patients accepted LET, 613 patients elected no treatment. After a median 2 year follow-up, DFS and DDFS were highly significantly improved in the PLAC-LET group after adjusting for differential demographics and disease characteristics. This analysis estimates the incremental cost per QALY gained (ICQ) of 5 years LET after the observed 2.5 year therapy break after TAM versus no extended adjuvant therapy from a national health service perspective.

Methods: A Markov model described the natural history of breast cancer via contralateral tumour, locoregional, and distant recurrence, also accounting for the effects of osteoporosis. Annual contralateral, recurrence and osteoporosis rates were obtained from the PLAC arm of the post-unblinding analysis, to which the adjusted HRs for the PLAC-LET group were applied. Effects of osteoporosis and recurrent events, and health state utilities were informed by published studies. Costs (2006 £) of breast-cancer care were obtained from a primary costing study in 2006. A probabilistic sensitivity analysis was undertaken, and all outcomes were discounted at 3.5% annually.

Results: The results show that the PLAC-LET group gain 14.14 QALYs compared to 13.84 in the PLAC group, lifetime costs £8,477 and £4,524, respectively. The mean incremental cost per QALY is £13,154. The probabilistic sensitivity analysis estimates a 95% credible interval of £9,153–27,094, with an 87% probability of cost-effectiveness at a £20,000 value of a QALY.

Conclusions: Late extended adjuvant Letrozole therapy after a prolonged therapy break from Tamoxifen (1−5 years) is a cost-effective use of health care resources.

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99mTc-MIBI elimination by a tumor and response to chemotherapy in locally advanced breast cancer patients

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Aim: To estimate predictive significance of 99mTc-MIBI accumulation and elimination by tumor on the effectiveness of neoadjuvant chemotherapy in locally advanced breast cancer patients.

Materials and Methods: Investigation of accumulation and elimination of 99mTc-MIBI by tumor was performed in 45 breast cancer patients (stages: IIa − 1, IIb − 1, IIIa − 7, IIIb − 31, IIIc − 5 patients) before the beginning of chemotherapy (CAF, FAC, docetaxel, 3−6 cycles). 99mTc-MIBI was introduced intravenously (555 MBq), with the following two-phase (in 15 min and in average 3 hours) static scintigraphy of a breast. Coefficient of relative accumulation (CRA) of 99mTc-MIBI in tumors in 15 min after injection (CRA1), CRA after 3 hours (CRA2), and percent of elimination (PE) were calculated [PE = (CRA1 − CRA2)×100/CRA1]. All patients were operated. “No residual tumor” and “Microscopic residual tumor” were united as “pathological effect”.

Results: Clinical effect was observed in 82% (complete effect in 6, partial effect in 31, stabilization in 7, and progression in 1 patient). Pathological effect was observed in 29% (no residual tumor in 4, and microscopic residual tumor in 9 cases). The levels of CRA1 and CRA2 did not influence on the frequency of clinical or pathological effects. In patients with high level of the PE pathological effect was not attained (see table). High level of the PE was reviewed more rarely (2p < 0.05) in patients with ER− HER2neu− tumors (19%), than in patients with ER+ HER2neu− tumors (47%), and than in patients with HER2neu+ tumors (75%).

Table. PE level and frequency of clinical and pathological effects

PE level	Frequency of clinical effects	Frequency of pathological effects
Low (<21%)	87% (26/30)	43%* (13/30)
High (>22%)	73% (11/15)	0%* (0/15)

*- 2p < 0.05.

Conclusion: Our first results confirm the main hypothesis: rapid 99mTc-MIBI elimination by a tumor predicts the low pathological response to chemotherapy. Detection of the high level of 99mTc-MIBI PE by tumor can indicate that neoadjuvant target therapy may be more preferential, than chemotherapy.

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Safety and feasibility of biweekly neoadjuvant gemcitabine, epirubicin, and albumin bound nab-paclitaxel (GEA) in locally advanced breast cancer – results of a phase II study

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Background: The triplet combination of gemcitabine (G), anthracyclines and taxanes have demonstrated significant activity as neoadjuvant therapy. Nab-paclitaxel is a novel albumin-bound form of paclitaxel that allows for the preferential delivery of paclitaxel to the site of the tumor via gp60/caveolin-1 transcytosis and the albumin binding protein SPARC. In preclinical models as well as in a phase III metastatic breast cancer trial, single agent nab-pacltiaxel was shown to increase both response rate and TTP compared with standard solvent based paclitaxel. In this multicenter phase II study, the