Age at baseline (yrs)	Predicted proportion of patients with FN (95% CI)			
	Disease stage I–III at baseline		Disease stage IV at baseline	
	PPP (N = 930)	CP (N = 646)	PPP (N = 361)	CP (N = 273)
40	3% (2%, 6%)	22% (12%, 36%)	5% (2%, 9%)	28% (16%, 45%)
50	4% (2%, 8%)	25% (15%, 40%)	6% (3%, 11%)	32% (19%, 49%)
60	5% (3%, 9%)	29% (17%, 45%)	7% (3%, 13%)	37% (22%, 54%)
70	6% (3%, 11%)	33% (20%, 50%)	8% (4%, 15%)	41% (25%, 60%)

490 Poster

Patients' views of distress & interference with daily activities due to side effects in the TACT (Taxotere as Adjuvant ChemoTherapy) trial

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Introduction: TACT trial randomised 4162 women with early breast cancer to FEC-T (FEC × 4 → taxotere × 4) or Control (FEC × 8 or Epirubicin × 4 → CMF × 4). Quality of Life (QL) was an important secondary endpoint. In addition to a formal QL assessment (EORTC C30 & BR23), patients' (pts) self assessment of distress (D) & interference with daily activities (IDA) caused by toxicities during & after chemotherapy (CT) in the two arms were recorded & reported here.

Methods: Pts completed a diary card, rating each of 15 possible toxicity items as either 'did not suffer from', 'not at all', 'a little', 'quite a bit', 'very much' as D & IDA for cycles (C) 1, 5, & 8 and at 9, 12, 18 & 24 months (M). The proportion of pts at each time point rating toxicities as D &a IDA (quite a bit/very much) were compared between FEC-T & Control, a significance level of p = 0.01 allowed for multiple testing.

Results: 829 (418 FEC-T; 411 Control) pts entered the QL study. Diary Cards were completed by 458 at C1, 410 at C8, 633 at 12M & 539 at 24M. Median age was 49yrs (range 27–71).

At C1 rates of D & IDA did not differ significantly between FEC-T & Control and only vomiting, nausea & tiredness were reported as causing D & IDA by >10% pts.

During CT (C5&8) Control pts reported nausea & vomiting as causing significantly more D & IDA than FEC-T pts (approximately 3-fold difference in frequencies).

During C5&8 FEC-T pts reported pain in muscles/joints, tingling hands/feet, sore mouth & nail changes as significantly causing more D & IDA than Controls. Tiredness was reported as causing D & IDA by ⩾40% of all pts during CT, with a significant difference at C8 (Control: D 40% & IDA 43%, FEC-T: D 53% & IDA 61%).

Overall, tiredness, constipation, mouth ulcers, sore mouth, breathlessness & painful gritty eyes, caused D to >10% pts on C5&8 but only tiredness, sore mouth, breathlessness, pain in muscles/joints caused IDA for >10% pts.

After CT, toxicity rates decreased substantially; but at 24M tiredness & pain in muscles/joints were still reported as causing D & IDA by 13–22% pts, with no difference between regimens.

Conclusion: CT side effects caused more D than IDA, during CT. The majority of side effects resolved following CT but >13% pts reported a longer term impact of D & IDA from tiredness & pain in muscles/joints. More pts reported toxicities in FEC-T than control, a finding worth noting given that no overall difference in efficacy between FEC-T & control in terms of DFS was observed.

491 Poster

Acupuncture for the treatment of hot flushes in breast cancer women treated with an estrogen antagonist

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Background: The object of this study was to investigate the efficacy of acupuncture in women operated for breast cancer suffering from hot flushes, a side effect of anti-estrogen medication.

Materials and Methods: In a prospective, controlled trial, 59 women suffering from hot flushes following breast cancer surgery undergoing adjuvant estrogen-antagonist treatment were randomised to either 10 weeks of traditional Chinese acupuncture or sham acupuncture. Number of hot flushes at night and daytime were recorded for 4 weeks prior to treatment, during treatment and during a 12 week follow up period. A validated health score (Kupperman index) was conducted at baseline, after 15 treatment sessions and 12 weeks post-treatment.

Results: During thetreatment period and the following 12 weeks, a 50% reduction of hot flushes both during the day and night was seen in the active treatment group, paralleled with a similar improvement in Kupperman index. Although a smaller treatment effect was observed in the sham acupuncture group during treatment, this effect could not be detected during the next 12 weeks.

Conclusion: Acupuncture seems to provide effective relief of hot flushes both day and night in women operated for breast cancer, treated post operativly with anti-estrogens. This treatment effect seems to coincide with a general health improvement measured with the validated Kupperman index.

492 Poster

Safety and efficacy of the novel antiemetic neurokinin-1 (NK-1) receptor antagonist, casopitant, in women with breast cancer (BC) receiving moderately emetogenic chemotherapy (MEC) – subgroup analysis from a randomized, double-blind, placebo-controlled phase II trial

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Background: Casopitant is a potent, selective, NK-1 receptor antagonist that increased the rate of control of chemotherapy-induced nausea and vomiting (CINV) when added to an ondansetron/dexamethasone (OND/DEX) prophylactic regimen administered to patients (pts) with solid tumors receiving MEC in a phase II trial (J Clin Oncol. 2006;24:471s. #8512). The current analysis examines the safety and efficacy in the subgroup of women with BC.

Methods: Pts received OND 8 mg PO BID D1–3 + DEX 8 mg IV D1 with either active control, casopitant 50 mg, 100 mg, or 150 mg PO D1–3. Additionally, 2 exploratory arms were included to evaluate alternate dosing of casopitant and OND (150 mg D1 only (with OND/DEX) and casopitant 150 mg D1–3 with OND 16 mg/d). Pts with BC received MEC consisting of ⩾1 of the following (mg/m^2): cyclophosphamide (C) 500–1500 with other MEC; C 750–1500 if given alone or with non- or minimally emetogenic agents; doxorubicin (A) ⩾60; or epirubicin (E) ⩾90. Adjuvant regimens were not permitted. The primary endpoints were complete response (CR; no vomiting, retching, rescue medications, or premature withdrawal) and rate of significant nausea (⩾25 mm on VAS) during the first 120 hrs after chemotherapy.

	120 h CR rate (%)					
	Active control	Casopitant				
		50 mg	100 mg	150 mg	150 mg D1*	150 mg + OND 16 mg/d*
Primary analysis (N = 723)	69	81	79	84	79	84
Pts with BC (N = 176)	26 (69)	38 (82)	32 (75)	23 (87)	30 (73)	27 (81)

*Exploratory arms, not included in primary analysis.
† P = 0.012.

Results: Of the 176 pts with BC receiving MEC, the majority received a combination of AC or EC (n = 102) or a taxane (n = 37). In the primary