frequent. Quality of life was significantly better according to the modified Brunner-Score in N compared to the FEC group.

Conclusion: As to the preliminary results the mono-compared to the poly-chemotherapy regimen didn't appear to show a difference in efficacy but a significantly better tolerability.

The study is on going.

The study was supported by Wyeth-Lederle.

647 ORAL

Prospective randomized study of mitoxantrone (M) and vinorelbine (V) vs fluorouracil (F), epirubicin (E) or adriamycin (A) and cyclophosphamide (C) in patients with advanced breast cancer (ABC)

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Background: A woman with ABC has a life expectancy of 18–24 months under treatment and the key point thus remains quality of life. Side-effects most feared by women are alopecia, nausea/vomiting.

Methods: This study compared the new combination MV (M 12 mg/m^2 D1, V 25 mg/m^2 D1 and 8 if PN > 1000/mm^3) to FAC or FEC: F 500 mg^2, A or E 50 mg^2, C500 mg/m^2, D1. Stratification was based upon prior adjuvant chemotherapy (CT). Each cycle was repeated every 21 days.

Results: 281 patients (pts) were randomized between UV MV (142) and FAC/FEC (139). 89 pts had received prior adjuvant CT (76 with anthracyclins). 82% pts had visceral metastasis and the median number of metastatic sites was 2 (1–7). Overall, 698 MV and 841 FAC/FEC cycles were given (median/pt: 5 [MV]; 6 [FAC/FEC]). The mean dose intensity (%) was respectively 95, 96, 96 for FAC/FEC and 92, 77 for MV. Hematological toxicity delayed courses in 22% (MV) and 14% (FAC/FEC) and led to withholding of V on day 8 in 29%. Febrile neutropenia requiring antibiotics occurred in 6% (MV) and 0.6% (FAC/FEC) of cycles and led to hospitalization in respectively 16% and 3% of pts (p = 0.001). Cardiac events were mostly minor: 10 in FAC/FEC and 9 in MV. Grade 3–4 nausea/vomiting occurred in 8% [MV] and 16% [FAC/FEC] of pts (p = 0.03); alopecia was more frequent with FAC/FEC (p = 0.0001). Toxicity led to one death in each group. The objective response rates (OR) were similar: 35.5% [MV], 33.3% [FAC/FEC], p equivalency = 0.014) but the OR was higher in the pts on MV with prior adjuvant CT (33% vs 13%) and in those on FAC/FEC who had not (43% vs 35%). Time to progression and overall survival were not different in the two groups but showed a similar divergence when prior adjuvant CT was taken into account.

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648 ORAL

CAF vs CMF both with tamoxifen in postmenopausal patients with advanced breast cancer – A randomized study with more than 10 years follow-up from the Danish breast cancer cooperative group

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In the largest study ever reported comparing CMF-like regimens with CAF, postmenopausal advanced breast cancer (ABC) patients naive to chemotherapy <66 years accrued during 1980–84 and followed through 1995 received Tamoxifen daily 30 mg and cyclophosphamide 400 mg/m^2, doxorubicin 25 mg/m^2 and 5-fluorouracil 500 mg/m$_2$ (CAF) or methotrexate 40 mg/m^2 instead of A (CMF) i.v. days 1 and 8 q 4 weeks. A was substituted by M at a cumulative dose of 550 mg/m^2. Among 341 eligible patients (CAF 161, CMF 180) response rate and median time to progression was significantly in favour of CAF: 53% *vs* 36% (p = 0 002) and 11.8 months *vs* 6.5 months (p = 0.001). Duration of response was 19.5 *vs* 18.0 months, and survival 20.8 *vs* 17.4 months (ns). Treatment intensity and toxicity was equal. After 3 years 44 *vs* 38 patients were still alive. Long recurrence free interval, good status of performance, and no visceral involvement was significantly related to long survival, while treatment was not. At end of follow-up, 3 and 4 patients were still alive. Doxorubicin-containing regimens remain the first choice of chemotherapy for ABC until newer treatments have proved superior.

649 ORAL

Navelbine (NVB), and fractionated dose doxorubicin (DX) improves first line advanced breast cancer (ABC) chemotherapy. An overview of 3 phase II trials

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Aim: Anthracycline combinations represent the most powerful chemotherapeutic approach in the treatment of ABC, but their limiting toxicities are neutropenia and cardiac impairment. NVB as a single agent has demonstrated a high activity and good tolerance in ABC: 40%–60% response rate (RR). Promising results have previously been obtained with NVB 25 mg/m^2 D1 & 8 + DX 50 mg/m^2 D1 (q 3 w): 74% RR (21% CRs), mainly in visceral sites (JCO 94). This was confirmed by a significant survival advantage observed in pts with liver metastases treated with NVB + DX compared to CAF (ESMO 96). Dividing the DX dose and administering it at weekly intervals may reduce the cardiotoxicity without substantially impairing the efficacy. 3 studies were conducted with NVB + DX, both at 25 mg/m^2 D1 & 8 (q 3 w, 8 cycles) to check the efficacy, improve the tolerance and to ease outpatient administration.

Results: 120 pts were included: age 30–73y; PS 0–1: 85%; visceral involvement: 52%; adjuvant C: 18%. 668 18%.668 cycles were administered; WHO grade (G) 3–4 neutropenia: 24%; infection G 3: 6/120 pts; G 3–4 nausea/vomiting: 17 pts; G 3–4 constipation 1.5%; G 1 peripheral neuropathy: 13%; G 3 alopecia: 53.5%. No G 3–4 cardiotoxicity. The RR ranges from 70% to 77% (18–35% CRs) RR on visceral sites: 56%–86%.

Conclusion: These results confirmed that NVB + DX (25 mg/m^2 D 1 & 8) has major and reliable activity as 1st line therapy. Given its very favourable tolerance, low morbidity and absence of life threatening cardiotoxicity, out patient administration of this regimen could be recommended as 1st line treatment for ABC.

650 ORAL

Taxotere™ (docetaxel, D), doxorubicin (Dx) and cyclophosphamide (CTX) (TAC) in the treatment of metastatic breast cancer (MBC)

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Considering the promising results of combination of taxanes and anthracyclines, we conducted a phase II study of D (75 mg/m^2, 1 hour iv infusion) with Dx (60 mg/m^2, iv bolus) and CTX (500 mg/m^2, slow iv bolus) q.3 weeks (maximum 8 courses) in patients (pts) with MBC without prior anthracyclines or taxanes. Forty-five pts (238 courses delivered) were treated as follows. Characteristics: moan age: 52 years (34–70); prior adjuvant chemotherapy (CMF) 10 pts (22%); visceral metastases 29 pts (64%); bone 24 pts (53%); 3 and more sites: 18 pts (40%). Median follow-up: 7 months (3–11). Thirty-three pts are evaluable for response. The major response rate is 85% with CR: 4 pts (12%), PR 24 pts (73%), SD 5 pts (15%), PD 0 (0%), with no progression yet reported. Forty-five pts are evaluable for toxicity. Neutropenia is the main toxicity (grade 4: 78%, lasting less than 7 days), febrile neutropenia: 12.1% of courses (courses given with ciproflexacine (C): 10.8% and without C: 24%). There was no extrahematologic grade 4 toxicity, while Grade 3 occurred in 25 cycles (10.5%) (nausea/vomiting, pain, fatigue, diarrhea). Grade 3 fluid retention was seen in 1 pt (2.2%). No clinical cardiotoxicity occurred while 5 pts presented with a moderate asymptomatic and usually reversible decrease of LVEF on MUGA scan (11.1%). TAC is a well-tolerated and active regimen with no evidence of cardiac toxicity and is the base of 2 large international randomized multicentric randomized trials comparing TAC to FAC in metastatic and adjuvant setting.

651 POSTER*

Treatment of recurrent cutaneous metastatic breast cancer with tin ethyl etiopurpurin (SnET2) photodynamic therapy

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Introduction: Breast cancer recurrence of the chest wall following mastectomy, radiation and chemotherapy poses a therapeutic dilemma. Further intervention with any or all of these modalities is often futile and morbid. Left untreated severe pain, infection and suffering will occur. Photodynamic therapy presents as a palliative option for these individuals.