reliably assess the optimal duration of TAM must be large with long follow-up if any worthwhile benefit is to be detected. So, results of small trials of 5 versus 10 years of TAM are conflicting with some studies, perhaps wrongly, suggesting that 5 years is sufficient.

ATLAS is an international randomised trial of longer versus shorter hormonal therapy. It aims to assess reliably the effects of prolonging TAM by an extra 5 years in women who have already had some years of treatment and for whom there is uncertainty as to whether they should stop now. 10–20,000 women will be randomised, usually after 5 years of TAM, to either stop, or continue TAM for 5 more years. This large, simple trial is designed to integrate into routine clinical practice with almost no documentation; since the main analysis will be of all-cause mortality. ATLAS will also provide information on both cause-specific mortality and non-fatal, but important events. If, by 2020, ATLAS shows improved long-term survival with 10 years of TAM (e.g. 27.5% vs. 30% dead), this result will save thousands of lives annually, and will be relevant to the appropriate use of hormonal therapies in general.

178 POSTER

Dose-dense weekly docetaxel and CBDCA in adriamycin-resistant metastatic breast cancer (MBC)

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We have studied 60 Pts. with MBC with the following characteristics: median age 55 (range 30–73) ECOG-PS 0:10 1:38 II:12

Protocol Design: Docetaxel (D) 60 mg/m^2 as one hour infusion followed in one hour by Carboplatin (C) 200 mg/m^2 as 30 min infusion weekly for 6 wks. Median dose intensity (mg/m^2/week, based on 6 wks of treatment and 2 wks rest period): Docetaxel: 42 mg/m^2, Carboplatin 142 mg/m^2. Hematoligical toxicity (WHO-Grading): Hbl:12 (20%); II:8 (13%) III:6 (10%); Leukocytes 21 (35%); II:8 (13%); III:6 (10%); Platelets I:14%; II:6%.

Peripheral Side Effects: Alopecia I:20 (33%), II:30 (50%); Sensory neuropathy I:10 (16%), II:5 (8%), no other side effects other than the above-mentioned observed.

Response Analysis: CR: 15 (25%), PR:33 (55%), NC:7 (11%), PD:5 (8%).

Conclusions: Dose-dens weekly Docetaxel/Carboplatin is active in Adriamycin-resistant MBC. Hematological and peripheral toxicities are not significant. A platelet sparing effect seems to exist with this regimen. Overall treatment time is shortened in comparison with Q.3 WK schedules, whereas dose intensity for Docetaxel is increased. The excellent tolerability recommends weekly D/C for ambulatory treatment.

179 POSTER

Hormonotherapy with goserelin depot after adjuvant chemotherapy in premenopausal women with early breast cancer: Is there any benefit?

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There is the definite evidence that adjuvant chemotherapy can affect both recurrence and survival with 21% reduction for recurrence and 11% reduction for mortality. Ovarian ablation in women aged under 50 was associated with 6% fewer recurrence and deaths after 15 years. Adding hormonotherapy to chemotherapy theorically could improve results depriving ER+ cells of oestrogen stimulus. In order to evaluate the effectiveness of hormonotherapy with Goserelin depot given soon after adjuvant chemotherapy with Epirubicin (110 mg/sqm) d 1 q 3 weeks × 4 followed by CMF d 1,8 q 4 weeks × 4 cycles, 92 premenopausal patients with ER+ breast cancer were randomly allocated after chemotherapy to stop therapy or to receive Goserelin depot 3.6 mg s.c. q 28 d × 2 years. In our experience the addition of Goserelin depot to sequential chemotherapy Epirubicin and CMF showed no benefit in terms of overall survival and DFS after a median follow-up of 46 months. This is not surprising if we keep in mind that chemotherapy caused amenorrhoea in up to two thirds of our patients during adjuvant treatment. Therefore, adding LHRH analogues may not result in significant additional benefit in the majority of women treated, but we can also hypotize that very large numbers of patients may be required before such a benefit can be seen.

180 POSTER

Second- and third-line treament of metastatic breast cancer with gemcitabine

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In the present study, 24 female breast cancer patients with visceral metastases were treated with intravenous gemcitabine 1250 mg/m2 on days 1, 8, and 15, q28d. In 6 patients gemcitabine was administered as second-line chemotherapy, whereas 18 patients received gemcitabine as third-line chemotherapy with previous chemotherapeutic regimens containing an anthracycline in all patients and taxanes in 8 patients.

2 (33%) of the 6 patients receiving gemcitabine as second-line chemotherapy showed a PR, and 4 patients (67%) developed SD. The median overall survival was 15.1 ± 6.7 months (range: 11.4–27.3), the median time to progression was 12 ± 3.4 months (range: 5.6–15.1). In the third-line setting, 1 (6%) out of 18 patients gained CR, 6 (33%) SD and 11 (61%) PD with a median overall survival of 6.3 ± 5.9 months (range: 2.4–23.8) and a median time to progression of 3.9 ± 1.7 months (range: 1.5–8) ($p < 0.01$).

Treatment-related toxicity in the two subgroups was similar. Second-line: anemia WHO grade I or II occurred in 3 (50%) patients; leukopenia grade I or II in 2 (34%), grade III in 4 (67%) patients; thrombopenia grade I or II in 4 (66%) patients, grade IV in 1 (17%) patient. In patients receiving gemcitabine as third-line therapy, 11 (61%) patients developed anemia WHO grade I or II, 2 (11%) patients anemia grade III. Leukopenia grade I or II was observed in 10 (55%) patients, grade III or IV in 4 (23%) patients. Thrombopenia grade I or II occurred in 9 (50%), grade III in 3 (17%) patients.

We thus conclude that gemcitabine was an effective therapy in patients with advanced breast cancer after previous chemotherapeutic agents including anthracyclines and taxanes. When administered early, gemcitabine led to a prolonged interval until progression occurred.

181 POSTER

Mitomycin (M), epirubicin (E) and vinorelbine (V) first-line chemotherapy for metastatic breast cancer (MBC). A feasibility study

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In our experience the combination of M and E showed high activity and good tolerability in MBC (Pacini P., EJC, 1994), with a response rate of 70%. The addition of V to E and M could improve these results without compromising tolerability. In order to evaluate the feasibility and compliance of MEV combination, a pilot study started on June 1996. Treatment schedule was: E 75 mg/sqm and M 10 mg/sqm on d. 1; E 75 mg/sqm and V 25 mg/sqm on d. 21; V 25 mg/sqm on d. 28 (1 cycle). Cycles were repeated every 3 weeks. G-CSF administration was planned according to the hematologic toxicity observed during the treatment. So far 16 patients (pts) were enrolled. Median age was 56 ys (37–70), median PS was 1 (0–3); all pts had visceral metastases. No pt was excluded from evaluation for response and toxicity. Patients received a median of 3 cycles (2–4). We observed 2 CR, 9 PR, 5 NC, no pts showed disease progression. As for toxicity, alopecia was universal, granulocytopenia grade 3–4 occurred in 8 pts, no other grade 4 toxicity was recorded; G-CSF was administered to 7 pts. On conclusion, MEV is a safe and probably very active chemotherapy for MBC as outpatients. Accrual of pts is ongoing in oredr to fully assess activity in a large series.

182 POSTER

Sequential or simultaneous chemo-radiotherapy in operable breast cancer. A French multicentric phase III study – State of inclusions

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Purpose: We compare two adjuvant modalities in operable breast cancer patients. After initial surgery (tumorectomy or mastectomy) with axillary