narcotic scores (PNS). Init. Perf. status (PS)0–1 in 50 pts and 3–4 in 22 pts; the upper, mid & lower halves of the body were treated in 39, 31 & 2 pts.

Results: Pain relief seen in 96% pts [50%CR & 46% PR] within 3–7 days. Aver. surv. [OS, MST, pain-free (PFS)] was 203, 177 & 144 days respect. Quality of life (QOL) assessed by % remaining life pain-free (71%) plus sig. improv, in PS & PNS after HBI. Very acceptable tox. (39% norte, 49% mild/mod. & 13% severe but transitory). Upper HBI was more toxic.

Conclusion: All Rx arms similar in pain relief, time-to-response, OS, PFS, QOL and overall tox. Arm (A) has sig. longer MST (225 days) than arms (B)&(C) [174 days]. Arm (B) had less CR's (24%) and higher severe tox. (20%). Study indicates that schedules (B)&(C) are faster, more convenient, more economical and equally effective than more protracted HBI for palliating WSBM from breast cancer.

697 POSTER

First-line endocrine therapy in postmenopausal (PM) patients (pts) with advanced breast cancer (ABC) and visceral metastases (mets): Anastrozole (AN) versus tamoxifen (TAM)

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Purpose: Based on the combined analysis of two large, randomized, controlled clinical trials, AN 1 mg once daily (od) was superior to TAM 20 mg od in pts with ABC known to have hormone-sensitive tumours, in terms of time to progression (TTP) (p = 0.022). We have carried out a sub-group analysis to investigate the effectiveness of AN vs TAM overall in pts with and without visceral mets and in those pts with hormone-sensitive tumours.

Methods: Clinical benefit (CB; complete response + partial response + stable disease ≥ 24 weeks) was assessed for pts in each sub group. Visceral mets includes pts with pulmonary and intra-abdominal mets.

Results: CB following AN or TAM in the overall population and in pts with hormone-sensitive tumours (ER/PR) are shown in the table below.

	AN 1 mg od (n = 511)	TAM 20 mg od (n = 510)
Overall popn with visceral mets (N)	186	211
Gaining CB (no. of pts [%])	92 [49.5]	99 [46.9]
Median duration of CB (months)	15.3	16.6
Overall popn with no visceral mets (N)	321	297
Gaining CB (no. pts [%])	200 [62.3]	166 [55.9]
Median duration of CB (months)	16.4	14.5
ER/PR +ve popn with visceral mets (N)	131	154
Gaining CB (no. pts [%])	68 [51.9]	64 [41.6]
Median duration of CB (months)	15.7	16.6
ER/PR +ve popn with no visceral mets (N)	172	150
Gaining CB (no. pts [%])	113 [65.7]	88 [58.7]
Median duration of CB (months)	16.9	14.5

Conclusions: AN is highly effective in ABC PM pts with visceral mets and indicate that endocrine treatment, preferably with AN, should be considered as a first option in pts with hormone-sensitive non-life threatening visceral disease.

698 POSTER

Cardiac safety and antitumor activity of doxorubicin and taxol followed by weekly taxol (AT&T) when herceptin is initiated with AT or with T alone in women with HER2-positive advanced breast cancer

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Background: The combination of H with AT is attractive based on: 1) the activity of AT; 2) the survival improvement observed when H is added to A or T in HER2-positive metastatic breast cancer. The risk of cardiac toxicity when H is added to A restricts its use. Therefore, we performed a pilot study to compare the efficacy and cardiac tolerability of AT followed by T when H was started with AT or with T alone and to investigate pharmacokinetic interactions.

Methods: All patients received 3-weekly AT (60/150mg/m2) for 3 cycles followed by weekly T 80mg/m2 for 9 cycles. The initial 16 patients (cohort 1) received weekly H (4mg/m2 initial dose followed by 2mg/m2) until progression starting with AT; H was initiated with T in the other 16 (cohort 2). Cardiac function was assessed prospectively by echocardiography every 3 weeks. Pharmacokinetic interactions were evaluated by administering H 24 hours after AT in cycle 1 and before AT in cycle 2.

Results: All 32 HER2-positive patients have been recruited and are evaluable. Mean age was 49.7 and 55.4 years in cohorts 1 and 2, respectively. Response rate was 87.5% (1 CR, 13 PR) in cohort 1 and 75% (2 CR, 10 PR) in cohort 2. High ECD levels decreased at response in both cohorts whether or not Herceptin was present. Cardiac function was CTC G1 in 4 and G2 in 3 patients in cohort 1; 6/7 recovered normal function. At median follow-up of 12 months none had developed cardiac symptoms. In cohort 2, 1 patient developed CTC G1 and later recovered. No unexpected side effects were observed. Analysis in cohort 1 showed that pharmacokinetics of T, T metabolites and A were similar without and with Herceptin.

Conclusion: Comparison of the cohorts suggests that response rates are similar whether H is administered with AT or with T. No patient has developed clinical heart failure, but delaying Herceptin until A therapy is complete appears to cause fewer decreases in LVEF. AT&T plus H is highly active without irreversible or clinical cardiac effects.

699 POSTER

Capecitabine: The new standard in metastatic breast cancer failing anthracycline and taxane-containing chemotherapy? Mature results of a large multicenter phase II trial

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Capecitabine (C) is a rationally designed, oral, tumor-activated fluoropyrimidine carbamate. It is converted to 5-FU preferentially at the tumor site exploiting the higher levels of thymidine phosphorylase found in malignant cells compared to normal tissue. C has shown promising efficacy in metastatic breast cancer (MBC) compared to CMF in untreated or paclitaxel in pretreated patients (pts).

In this ongoing study we investigate the activity and toxicity of C in MBC after pretreatment with either paclitaxel or docetaxel. Treatment consists of C 1,250mg/m2 b.i.d. orally for 14 days followed by 7 days rest (=1 cycle).

Results: 136 pts have been entered so far. The median age is 56 years (range 32-77), and the median Karnofsky-index is 90% (range 60-100). Pretreatment included anthracycline-based chemotherapy in 93% and taxanes in 100%. 136 and 125 pts are evaluable for toxicity and response, respectively. Median number of cycles administered is 3 (range 1-21). Toxicity was generally low with grade 1 or 2 hand-foot syndrome (40%), nausea/vomiting (43%), diarrhea (22%), stomatitis (15%) and lethargy (16%). Grade 3/4 toxicity consisted of hand-foot syndrome in 12%, nausea/vomiting in 4%, and diarrhea in 5% of pts. Responses so far included 2 CR (2%), and 21 PR (17%). Disease stabilization occurred in another 48% of pts, accounting for an overall tumor control rate of 67%. Progressive disease as best response was seen in 41 pts (33%).

Conclusions: Capecitabine produces a high tumor control rate with low toxicity in an outpatient setting in heavily pretreated metastatic breast cancer. Our results, confirming previously reported data, suggest that capecitabine should be considered as a reference treatment in anthracycline and taxane refractory breast cancer.

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700 POSTER

A phase II study of oral vinorelbine (NVBo) in first line locally advanced/metastatic breast cancer (ABC) chemotherapy. Final results

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Purpose: Oral Vinorelbine (NVBo) is a soft-gelatin capsule formulation with absolute bioavailability of 43 ± 14% (AACR 1997, 4009). Its pharmacokinetic behavior in fed and fasting patients is similar. We conducted a phase II study