Conclusion: There is a rationale for use of Capecitabine in the earlier course of metastatic disease, especially after progression of first-line chemotherapy for MBC.

481 PUBLICATION

Multicenter study of weekly trastuzumab, paclitaxel and carboplatin followed by a week of rest every 28 days in patients with her-2+ metastatic breast cancer (MBC)

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Background: Combination of Trastuzumab with Carboplatin and Paclitaxel have shown a significant activity in HER2 positive metastatic breast cancer (MBC). We have conducted a Phase II study to investigate the efficacy and safety of the combination given weekly × 3 followed by a week of rest. We present here preliminary results. Primary endpoint was objective response rate and secondary endpoints were time to progression, overall survival and toxicity of the combination.
Methods: Between October 2003 and April 2005, 16 patients (pats) with Her-2+ MBC (IHC 3+ or FISH+) have been included in the study. Pats received Trastuzumab (loading dose of 4 mg/kg/wk and 2 mg/kg/d following weeks), Paclitaxel (80 mg/m^2) and Carboplatin (AUC 2) all given weekly × 3 followed by 1 week of rest. Treatment was given until disease progression or unacceptable toxicity.
Results: Sixteen patients have been enrolled. Median age was 50 years (range 30–60). All pats received prior adjuvant/neoadjuvant treatment and 4 pats received one prior line for metastatic disease. All pats had PS = 0–1. Disease sites were liver 9 (56%), bone 7 (44%), lymph nodes 5(31%) and lung 3 (19%). Ten pats (63%) had ⩾ 2 lesions. 16 patients are evaluable for toxicity and have received 89 cycles with a median of 5 cycles (range 2–13). Grade 3/4 toxicities were: 4 (5%) leukopenia, 12 (13%) neutropenia, 2 (2%) thrombopenia, 3 (4%) alopecia and 1 (1%) nausea and vomiting. 14 patients have been evaluable for response; 6 CR (43%), 3 PR (21%), 3 SD lasting more than 3 mo (21%) and 2 PD (14%) resulting in an ORR of 64% (95%CI: 39.2–89.4%) and tumor growth control rate (RR+SD) in 86% of patients (95%CI: 67.4–100%). Two pats were not evaluable in this analysis for efficacy (1 too early and 1 lost to follow-up). Median duration of response is 8.4 mo. Median TTP 7.7 mo (95%CI: 2.9–12.5 mo).
Conclusions: This interim analisis shows a good safety profile and a promising activity. Further results would be available for presentation.

482 PUBLICATION

Results of Intercancer Cohort: epidemiologic Brazilian data of women with HER-2 positive metastatic breast cancer treated with trastuzumab as first-line therapy

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The efficacy and safety of trastuzumab in HER-2 positive metastatic breast cancer have been documented in clinical trials. In particular, these trials have demonstrated that treatment with trastuzumab improves overall survival and disease-free survival in first-line therapy as monotherapy and in combination with chemotherapy. Three years after the Brazilian approval of trastuzumab it was of great interest to determine the profile of patients that are being treated with trastuzumab in first-line in clinical practice and the treatment regimens that are being used. Intercancer is a large epidemiological Brazilian data base. Eligible patients (> 18 years) were all HER-2 positive metastatic breast cancer women who started trastuzumab between October 2003 and April 2005. Patients were followed-up for at least 8 months. A total of 106 oncologists agreed to participate and to enroll all their patients data treated with trastuzumab as first-line therapy in the period.

Table 1: Patients characteristics

Pre-menopausal	40.6%	Post-menopausal	40.6%
ER+	34.9%	ER−	49.1%
PR+	41.5%	PR−	33%
HER-2 IHQ 3+	77.4%	HER-2 FISH+	13.2%
Family History	38%	No family history	62%
Smoker	15%	Non smoker	85%
Oral contraceptives	45%	No oral contraceptives	55%

Results are presented on 123 patients. Trastuzumab was used as monotherapy in 52% of the patients. The prefered dose scheduling was the 3 weekly regimen. Table 1 resumes the main patients characteristics.

Central Nervous System

Oral presentations (Mon, 31 Oct, 9.15–11.15)
Central nervous system

483 ORAL

Impact of extent of resection on overall survival in newly-diagnosed glioblastoma after chemo-irradiation with temozolomide: further analysis of EORTC study 26981

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Background: The impact of the extent of surgery on survival in patients with newly-diagnosed glioblastoma multiforme (GBM) remains controversial. A recent, large, multicenter, randomized controlled trial of radiotherapy (RT) versus RT with concomitant and adjuvant temozolomide chemotherapy (RT/TMZ) showed an improved median survival after combined RT/TMZ (14.6 months, 95% confidence interval (CI): 13.2–16.8); as compared to 12.1 months (95%CI: 11.2–13.0) after standard RT alone). This trial also provided an opportunity to retrospectively examine the impact of extent of resection on the outcome, and relate this to the type of adjuvant treatment.
Methods: 573 newly-diagnosed GBM patients were randomized to either RT or RT/TMZ. Extent of surgery was estimated by the surgeon at the time of surgery (either biopsy, partial resection, complete resection). Overall median survival (MS) and 2-year survival (2-yr S; both intent-to-treat analysis) was examined for patients receiving biopsy only (16%), partial resections (44%), or complete resections (39%) per treatment arm.
Results: The two treatment groups were well balanced with regard to extent of resection. Treatment with RT/TMZ was superior (in terms of overall survival) to RT alone across all groups with varying degrees of resection. This benefit was most striking in patients with complete resections, where 2-yr S was 37.1% months (95%CI: 28.0–46.3) for patients receiving RT/TMZ, compared with 14.5% (95%CI: 7.8–21.2) in those receiving RT alone. For patients with a biopsy only, 2-yr S after RT/TMZ was 10.0% (95%CI: 1.3–18.7), in contrast to 4.6% (95%CI: 0.00–10.8) for RT patients. 2-yr S in partially resected patients was 23.2% (95%CI: 15.5–30.9) after RT/TMZ, and 8.94% (95%CI: 3.9–14.0) after RT. MS in biopsied patients treated with RT/TMZ was 9.4 months (mo, 95%CI: 7.5–13.2), and 7.9 mo (95%CI: 5.4–10.6) in RT patients. For partially resected patients MS was 13.5 mo (95%CI: 11.9–16.3) after RT/TMZ and 11.7 mo (95%CI: 9.7–13.1) after RT. However, after complete resection MS was 18.3 mo (95%CI: 15.7–22.5) in RT/TMZ patients, but 14.2 mo (95%CI: 12.7–16.2) in RT patients.
Conclusion: The benefit of combined RT/TMZ in GBM is more pronounced in patients that have undergone more extensive resections as compared to biopsied patients. This provides a further rationale to aim for extensive resections in GBM patients.

484 ORAL

Functional outcome and local control after radiotherapy for metastatic spinal cord compression in breast cancer and prostate cancer patients

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Background: Breast cancer and prostate cancer patients presenting with metastatic spinal cord compression (MSCC) have a better survival