parameters for 30 patients (p) with metastatic breast cancer (MBC) for which they got docetaxel-based chemotherapy in our clinic (september 2004-may 2005).
Docetaxel 25 mg/m, day 1, 8, 15 was associated to Epirubicin 60 mg/m^2 day 1 (23 p), to 5 Fluorouracil 450 mg/m, day 1, 8 (2 p) or to Carboplatin AUC6 day 1 (5 p) and the cycles were repeated every 21 days.
All patients were evaluated after 4 cycles of therapy. Response rate was 86.6% (26 p) (4p had disease progresion). Common secondary effects were: neutropenia (grade 3; only 1p, after cycle 4, grade 2; 8p, after cycle 3, grade 1; 12p, during chemotherapy), mucositis (grade 2; 3p after cycle 2, 4p after cycle 3, 3p after cycle 4, grade 1; 20p during chemotherapy), nausea (grade 2; 8p after cycle 1, 9p after cycle 2, 7p after cycle 3 and 7p after cycle 4) and fatigue (grade 3; 1p after cycle 1, 1p after cycle 2, 2p after cycle 3, 2p after cycle 4, grade 2; 15p after cycle 1, 14p after cycle 2, 20p after cycle 3, 21p after cycle 4). All toxicities were corrected by supportive means, none was life threatening.
Comparing our results to the published data on Docetaxel 3 weekly chemotherapy we consider the weekly Docetaxel schedule highly effective and better tolerated with one exception: fatigue, that is obviously worse for Docetaxel weekly schedules than for 3 weekly schedules, but manageable with regular supportive means.

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Preliminary results of a Phase II study of neoadjuvant treatment with docetaxel (T), doxorubicin (A) and capecitabine (X) in locally advanced or inflammatory breast cancer

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Background: Previous studies suggest that combined treatment of chemotherapy+surgery+radiotherapy has a high survival rate in patients with locally advanced or inflammatory breast cancer. Primary objective was evaluate response rate. Secondary objectives were time to progression and toxicity profile of neoadjuvant chemotherapy T, A and X in patients with locally advanced or inflammatory breast cancer.
Patients and methods: Eligibility criteria: Patients with histological confirmation of locally advanced or inflammatory breast cancer, ECOG PS $\leqslant$ 2, age $\leqslant$ 75 years and LVEF >50%, adequate bone marrow, renal and hepatic function. Prior systemic therapy, surgery or radiotherapy for breast cancer was not allowed. Patients with invasive bilateral breast cancer were not included. Treatment: T (30 mg/m^2) iv day 1, 8 and 15, A (50 mg/m^2) iv day 1 and X (1500 mg/m^2 o.d.) days 1–14, in a 4 weeks course. This scheme was repeated up to 4 cycles followed by surgery. According to investigator criteria patients receive a maximum of six cycles. Radiotherapy and hormonal treatment are allowed depending on molecular markers. Expression of markers was performed by inmunohistochemistry before chemotherapy.
Results: thirty-four patients were included in this interim analysis, with a median age of 48 years (25–68). The ECOG PS was 0 in 31.3% and 1 in 68.8% of patients. Hormonal receptor status was ER+ 30%, PR+ 42% and C-erb2+ 50%. Primary tumour sites were breast: left (n = 18) and right (n = 16). A total of 118 cycles (median 3.5, range 1–4) were administered. Median relative dose intensity was 87% for T, 91% for A and 92% for X. Thirteen patients are still undergoing treatment; of 29 evaluable patients for efficacy, 9 achieved CR, 19 PR and 1 PD resulting in an ORR of 96.6% (95%CI: 90–100). Surgery was performed in 25 patients: three (12.0%) of them achieved pathological CR. All patients were evaluable for toxicity. Grade III/IV toxicity per patient was neutropenia (70.6%), leucopenia (50.0%), febrile neutropenia (8.8%); diarrhea (11.8%), mucositis (11.8%), nausea/vomiting (5.9%), dysgeusia (5.9%) and asthenia (2.9%). Median follow up time was 5.7 months.
Conclusions: T, A and X every 28 days administered during 4 cycles as neoadjuvant chemotherapy in locally advanced or inflammatory breast cancer is an active and well tolerated regimen.

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Preliminary analysis of cisplatin (C) and gemcitabine (G) as second-third line treatment in metastasic breast cancer (MBC)

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Background: Combination C and G has demonstrated to be an active treatment in patients (p) with MBC. The less number of previous treatments for MBC more effectiveness this combination has shown. We conducted a study of C and G to evaluate the activity and toxicity profile of this combination.
Patients and methods: P with histological confirmation of MBC, ECOG performance status < 2, age > 18 years and adequate bone marrow, hepatic and renal functions, were included. Prior therapy with anthracyclines, taxanes and herceptin (erb-2 positive p) is mandatory. Treatment: C 25 mg/m^2 iv day 1, 8 and G 1000 mg/m^2 iv day 1, 8, every 3 weeks. At least 6 cycles was administered and the schedule was continued until progressive disease, unacceptable toxicity, consent withdrawal or investigator criteria. Response was evaluated every 3 cycles according to RECIST criteria.
Results: 31 p were enrolled, with a median age of 57 years (31–76), ECOG PS was 0–1 in 92.9% of p, hormonal receptor status was positive in 51.6% and ductal carcinoma in 93.1% of p. Median number of metastatic sites was 2 (83.9% with $\geqslant$ 2 sites), bone (58.1%), lung (41.9%), liver (38.7%) and nodes (38.7%), mainly. Neoadjuvant and adjuvant chemotherapy was administered to 23% and 77% of p respectively, 26% of p had received a second line treatment of chemotherapy for advanced disease and none received a third line. P received anthracyclines in a 97%, taxanes in a 90% and herceptin in a 29% (of erb-2 positive p). Up to date, a total of 130 cycles (median 3, range 1–10) were administered. Median relative dose intensity was 95% for C and 97% for G. Intent-to-treat efficacy analysis: over 21 evaluable p, 1 achieved CR, 6 PR, 5 SD and 9 PD, resulting in an ORR of 33.3% (95%CI: 13.1–53.5). Ten p were not evaluated: 1 protocol deviation, 1 lost of follow-up, 2 withdrawal consent and 6 ongoing with no evaluation yet. All p were evaluable for toxicity. During C-G treatment, grade III/IV hematologic toxicity shown per p was neutropenia (22.6%) and anaemia (9.7%). Grade III/IV non-hematologic toxicity shown per p was nausea (6.5%), vomiting (6.5%), asthenia (6.5%), anorexia (3.2%) and fever (3.2%). Median follow up time was 3.8 months, median time to progression was 7.5 months (95%CI: 0.8–14.2) and median overall survival 9.4 months (95%CI: 4.6–14.3).
Conclusion: In the interim analysis, G and C combination appears to be an active and well-tolerated regimen as second-third line in p with MBC.

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Capecitabine second-line monotherapy for metastatic breast cancer

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Objective: objective measures of response and survival have been the targeted endpoints in clinical trial design and in physician selection of therapy for metastatic breast cancer (MBC). The evidence suggests that therapy for MBC should be continued until disease progression or development of unacceptable toxicities. Capecitabine is a useful and active oral chemotherapy in MBC, both in combination with paclitaxel in anthracycline-pretreated patients, and as moinotherapy in heavily pretreated patients. The proven activity of Capecitabine has provided the rationale to explore its use earlier in the course of the metastatic disease. Also there is a rationale for Capecitabine as maintenance therapy after response until progression.
Material and methods: The characteristics of the 62 evaluable patients(median age = 53 years) were well balanced. Around one half (46%) patients has more than one metastatic site involved. More than two-thirds (68%) of the patients has visceral metastases. All patients received first-line chemotherapy regimen. Approximately half of the patients had progressed while on prior anthracycline therapy; the others had progressed within 12 months of anthracycline therapy. Almost two-thirds(62%) of the patients had been exposed to 5-fluorouracyl (5-FU) and anthracyclines(67%).
Combination therapy consisted of Capecitabine 1250 mg/m^2 twice daily for 2 weeks of every 3-week cycle until grade 3/4 toxicities or progression.
Results: 62 patients are enrolled from our institution. Baseline characteristics were: median age 53 (34–75) years, KPS 80% (60–100%), 46% had 2 or more involved sites.
Median number of cycles was 9 (3–18). There were 17 complete and 32 partial responses so far (overall response rate in evaluable patients 69.5% [95%CI: 49.5–74.3%]) A further 19 patients had disease stabilisation.
The median time to disease progression was impressive. The primary objective of the study, to achieve a response rate in the range of 25–30% with Capecitabine, was met.
Furthermore, the time to disease progression and survival data (median survival in the subpopulation of patients who responded had not been reached at the time of the data analysis) were also encouraging. There were only five (5) relapses in this study so far. Hand–foot syndrome and gastrointestinal adverse events were the predominant toxicities. Most adverse events were mild: the incidence of grade 4 toxicities was very low, and the incidence of grade 3 hand–foot syndroma was <10%.