

Results: 29 consecutive pts were included as eligible. As of July 2007, all are evaluable for toxicity, and 26 for response. Earlier therapies consisted of T (100%), anthracyclines (100%), vinorelbine+T (93%), docetaxel+T (62%), and capecitabine+T (69%). 19% experienced PR, and SD $\geq$ 6 months was observed in further 27%, resulting in a CBR of 46%. Time to progression (TTP) was median 3 m, range (r) 1–10, 95% CI 1.89–4.11, and overall survival 17 m, r 4–31+, 95% CI 14.68–19.36. CBR and TTP were superior in the 2nd-line setting.

Neutropenia (21%), thrombocytopenia (14%), and nausea (3%) were the only treatment-related adverse events that occurred with grade 3 or 4 intensity. Four pts (14%) developed brain metastases while on therapy.

Conclusions: While CBR was low when compared to T-based first-line therapy, it is higher than what might be expected from G alone in a similar setting. In a trial of G after anthracycline and taxane failure, 26% of pts had SD for $\leq$ 4 m, and no case of PR was observed. Together with the favourable toxicity profile, the regimen appears to be a safe and potentially effective therapy option in a heavily pre-treated population.

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Poster

Clinical usefulness of high-dose toremifene for patients failed by treatment with aromatase inhibitor

H. Iwase¹, Y. Yamamoto¹, T. Ohtake², N. Masuda³, H. Yamashita⁴, S. Saji⁵, I. Kimijima⁶, Y. Kasahara⁷, T. Ishikawa⁸, M. Sawaki⁹. ¹Kumamoto University, Breast and Endocrine Surgery, Kumamoto, Japan; ²Fukuashima Medical University, Surgery, Fukushima, Japan; ³Osaka National Hospital, Surgery, Osaka, Japan; ⁴Nagoya City University, Breast Surgery, Nagoya, Japan; ⁵Tokyo Metropolitan Cancer and Infection diseases center Komagome Hospital, Clinical Oncology, Tokyo, Japan; ⁶Northern Fukushima Medical Center, Surgery, Tokyo, Japan; ⁷Fukui Saiseikai Hospital, Surgery, Tokyo, Japan; ⁸Yokohama City University, Surgery, Yokohama, Japan; ⁹Nagoya University, Clinical Oncology, Nagoya, Japan

Aromatase inhibitors (AIs) have been employed as adjuvant therapy or as first or second treatment for recurrent case. However, when AI treatment fails, it is unclear what endocrine therapy is appropriate and how effective it is. Here we administered toremifene (TOR, Fareston®), a selective estrogen receptor modulator (SERM), at 120 mg/day and investigated its efficacy and safety. Of patients with recurrent or advanced breast cancer who had measurable or evaluable lesions, those who were diagnosed as having progressive disease during AI treatment and given TOR at 120 mg/day (high-dose TOR, TOR120) for endocrine therapy were selected and analyzed retrospectively in relation to the patients' medical history. Of a total of 63 cases examined, the response rate was 14.3%, clinical benefit (CB) rate was 34.9%, and median of time to failure (TTF) was 7.4 months. The last AI used was anastrozole in 20 cases and exemestane in 40 cases. The response rates to TOR120 were 15% in both groups regardless of the kind of preceding treatment drug. When TOR120 was used for secondary or tertiary treatment, the response rate was 20% (8/40), and it was 5.3% (1/20) when used as quaternary or later treatment. There was no response in five ER-negative cases, and was effective at 15.5% (9/58) in ER-positive or unknown cases. There was no difference in the rate between PgR-positive and negative cases. In cases with a HER2 score of 0, the response rate was 17.9% (5/28), while few cases showed efficacy in cases with scores of 1+ to 3+. In cases having received tamoxifen (TAM) previously, TOR120 was effective, with a response rate of 13.2% and CB of 31.6%. With regard to adverse effects, hot-flush and/or night sweating were observed in 10 cases, but all of them were categorized as Grade 1, and the treatment was rated excellent in acceptability. TOR120 was rated excellent in acceptability and high efficacy was observed when it was used up to tertiary treatment for AI failure cases. In addition, it was also considered effective for TAM failure cases.

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Treatment of advanced breast cancer with gemcitabine and vinorelbine

C. Gennatas¹, V. Michalaki¹, J. Psychogios¹, S. Gennatas¹. ¹University of Athens, Oncology Clinic Department of Surgery Areteion Hospital, Athens, Greece

Background: Gemcitabine and vinorelbine are both active as single-agent therapy for metastatic breast cancer with favorable toxicity profiles. The purpose of this study was to evaluate the efficacy and safety of the combination of these agents in patients with advanced breast cancer, previously treated with anthracyclines alone or with taxanes.

Patients and Methods: A total of 96 heavily pretreated patients with metastatic breast cancer (median age 63 years, range 35–75 years) with ECOG Performance status of 0–2, entered the study. All patients had received prior adjuvant chemotherapy. Thirty-six patients had been

pretreated with anthracyclines, and 8 were resistant. The combination of Gemcitabine (1000 mg/m²) and vinorelbine (25 mg/m²) was administered on days 1 and 8 every 3 weeks, for a total of 6 cycles.

Results: A total of 344 cycles of chemotherapy were administered (median 4 cycles per patient, range 1–9). Partial responses were observed in 34 patients (36.0%). The median duration of response was 7.5 months (range 3–11 months) and the median overall survival was 14 months. In the anthracycline pretreated population (n=36) there were 2 partial responses (5.5%).

The scheme was well tolerated. Grade 3/4 toxicity was limited to leucopenia in 4 patients (4.1%), thrombocytopenia in 2 patients (2%) and anemia in 13 patients (13.5%). No patient was hospitalized due to febrile neutropenia, and there were no treatment related deaths.

Conclusions: The combination of vinorelbine and gemcitabine is an active and manageable scheme in patients with metastatic breast cancer pre-treated with anthracycline-based schedules, or with combinations of anthracyclines and taxanes, demonstrating an acceptable toxicity profile.

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Hepatic metastases from breast carcinoma – suitability for resection?

P. Chan¹, A.S. Kaushal¹, L.K.C. Teo¹. ¹Tan Tock Seng Hospital, Breast Unit, Singapore

Background: Liver metastases is found in 6–25% of patients with metastatic breast cancer. The median survival in most of these patients is 1–14 months. As mortality & morbidity of liver resections decrease over the past decade, the indications of surgery has widened for metastatic disease. Hepatic resection for liver secondaries from breast cancer has showed significant improvement in survival. The aim of this study is to determine what proportion of breast cancer patients with hepatic metastases is suitable for surgical treatment.

Methods: This is a retrospective review of 58 patients with breast cancer from January 2002 to December 2007 who have hepatic metastases. Patients were divided into whether they have extra hepatic metastases (EHM). For patients without EHM, we consider standard indications for liver resections for any liver tumour to determine suitability. The indications include number of liver lesions, albumin levels, liver reserve, fitness for operation and good respond to chemotherapy.

Results: The mean age of the patients is 57. Incidence of hepatic metastases in our centre is 5.8%. 27 (47%) patients were found to have metastases at the time of diagnosis while the rest have systemic recurrence after initial treatment. The majority of our patients (84%) have EHM which we considered as an unfavourable indication for hepatic resection. Of the 11 patients without EHM, only 1 (2%) patient was considered to have been suitable for surgery. 6 patients had low liver reserve and low serum albumin while 4 patients with normal serum albumin had diffuse hepatic involvement. The last patient with normal albumin level had 2 lesions but the disease is bilobar and she did not respond to chemotherapy and died 3 months after diagnosis.

Conclusion: Majority of breast cancer patients with hepatic metastases present either with concurrent EHM or with diffuse disease and other unfavourable factors which preclude surgical resection. Nevertheless physicians must identify the small subset of patients who are suitable for liver resection as this is likely to significantly prolong survival.

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A phase II trial of weekly docetaxel and trastuzumab in metastatic breast cancer

A. Taran¹, K. Wollschlaeger¹, B. Blümel¹, E. Kettner², S.D. Costa¹, J. Bischoff¹. ¹Universitätsfrauenklinik, Gynecology, Magdeburg, Germany; ²Städtisches Klinikum, Gynecology, Magdeburg, Germany

Background: Docetaxel (D) in combination with trastuzumab (T) has demonstrated significant activity in patients with HER2neu positive metastatic breast cancer (MBC). Main toxicities of this regimen include leukopenia, febrile neutropenia and infections. Weekly administration of D has been reported to have reduced haematological side effects and comparable efficacy to 3 weekly protocols. In a multicentre trial we assessed tolerability and activity of a weekly schedule of D and T.

Material and Methods: 46 women with HER2neu positive metastatic breast cancer were treated with weekly doses of D (35 mg/m² for 10 weeks) and T (4 mg/kg loading dose, then 2 mg/kg). Median age was 55 (34–78) years, 80% of the patients had visceral metastases. Most patients had received adjuvant chemotherapy (66 %) (anthracyclines (A) 33%, CMF 33%, A-CMF 10%, taxanes 4%), and 33% have had chemotherapy for MBC.

Results: Objective response rate was 42% (6 CRs and 12 PRs) and 38% of the patients had stable disease. Median time to progression was 6 months (95 % CI 5–9), and a 1y – survival rate of 64% was noted. Median