28 patients (32%); intermediate (risk factor=1), 50 patients (56%); poor (risk factor=2), 11 patients (12%). Median T-OS of good, intermediate and poor prognosis group was not-reached (more than 59.7), 29.7 and 15.3 months, respectively ($p < 0.001$).

Conclusion: Prognosis grouping based upon the prognostic factors might be useful to predict outcomes of patients with HO-MBC treated with trastuzumab containing chemotherapy.

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Phase II study of S-1 in combination with irinotecan (CPT-11) for patients with advanced/recurrent breast cancer (KSCOG-BC01)

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Background: Irinotecan and S-1 have been shown to be effective in patients with advanced/recurrent breast cancer and they have a considerable single-agent activity, respectively. We evaluated the combination of irinotecan (CPT-11) and S-1 as first-line chemotherapy for advanced or recurrent breast cancer (BC).

Methods: All patients with histologically confirmed BC with unresectable or metastatic diseases, measurable lesions, PS 0−2, age between 18 and 80, and no contraindication to chemotherapy were eligible in this study. Prior adjuvant chemotherapy finished at least 6 months before enrollment was allowed. Treatment included S-1 80 mg/m^2 p.o. twice daily on days 3 to 7, 10 to 14, and 17 to 21 and CPT-11 60 mg/m^2 i.v. on day 1, 8, 15 with a 1-week interval until disease progression or unacceptable toxicities. Both recommended doses of S-1 and CPT-11 was based on our previous Phase I study.

Results: Between May 2007 and August 2009, total 16 pts were enrolled in this study. The median age was 56.5 years (range, 38−73). Nine pts had recurrent disease after previous curative mastectomy and 7 had previous adjuvant chemotherapy. After a median 3 (range, 1−9) cycles of chemotherapy, 16 pts were evaluable for toxicity and 9 pts for response. The overall response rate was 33.3%, including 0 CR, 3 PRs, 4 SDs, and 2 PDs. The clinical benefit rate was 77.8%. Commonly observed grade 3/4 adverse events were neutropenia (12.5% of patients), diarrhea (12.5%). There was no neutropenic fever or treatment-related death.

Conclusions: The combination of CPT-11 and S-1 appear to have well efficacy, manageable toxicity and is well tolerated in patients with advanced/recurrent BC. Further studies of this combination are still ongoing.

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Clinical and pathological prognostic characteristic of breast cancer patients with brain metastases

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Improvement in breast cancer patient's treatment leads to life prolongation. This is connected with rising incidence of brain metastases (BM) which occurs in up to one third of patients with metastatic breast cancer. The aim of this study is to analyze clinical and pathological factors in patients with BM. This is a retrospective review of 177 breast cancer patients treated with brain radiotherapy between 2005–2007 at two Cancer Centers in Gliwice and Krakow.

Patient's age at the time of diagnosis was 50 years (28−80). Patient's stages at the time of cancer diagnosis were: T_{1-2} 42% T_{3-4} 37%, N_{0-1} 56%, N_{2-3} 23%. Majority were treated with radical intent 81%, 19% were treated palliatively. 79% were treated with chemotherapy, 36% with hormonal therapy, 44% of patients underwent loco-regional radiotherapy treatment. Pathological reports showed that lymph nodes metastases were not present only in 28%. Tumours were ER, PR receptor positive only in 34% and 26%, and only in 10% for ER and 12% for PR were highly positive. In 36% HER2 was negative, high expression or amplification was in 36%. All brain metastases were treated with radiotherapy, 20% metastasectomy, 25% stereotactic irradiation, in combination with WBRT 19% or alone 6%.

Median time from diagnosis to BM was 2.74 years (range 0−19). Single BM were in 29%, multiple metastases in 30%, remaining had 2−7 lesions. First metastatic site was brain in 41%. Median time from treatment dissemination to brain relapse was 0.1 years (range 0−9.2). In patients treated with radical intent, median time to BM was longer in ER+ 4.5 years vs ER− 2.9. ($p = 0.1$) and in PR+ 4.7 years vs PR− 2.7 ($p = 0.04$). Median time to BM was longer in HER2− 3.2 years vs HER2+ 2.5 years (NS). There was trend towards shorter time to BM in triple negative receptor status in comparison to others ($p = 0.09$). Higher node ratio was a significant risk factor for faster BM ($p = 0.04$). A median time to BM significantly shortened with T stage and was 4.5, 3.4, 2.7 and 1.5 years for T_1-T_4 respectively and also shortened with N stage and was 4.0, 3.0, 1.5 and 1.0 for N_0-N_3, differences were statistically significant ($p < 0.001$). There was no difference in overall survival between patients, whose primary metastatic site was brain or other localization. Increased number of brain metastases had inverse effect on survival, patient's with single BM had a significantly higher 5-year overall survival (75%) in comparison with multiple BM (35%), ($p = 0.03$). Also time from brain metastases to death was longer in single BM ($p < 0.0001$).

Advanced stages of the disease, ER-, PR-, HER2+ are related to higher risk of faster BM. Higher number of BM is related to shorter survival. Major cause of death was brain metastases, therefore further studies are needed for early BM patient's selection.

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RIBBON-1: efficacy of capecitabine-bevacizumab in patients with triple-negative metastatic breast cancer (MBC)

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Background: The RIBBON-1 phase-III study of bevacizumab (A) or placebo was performed in two independently powered cohorts, with patients also receiving capecitabine (X) or taxane/anthracycline. Progression-free survival (PFS; the primary endpoint) was significantly greater with A combined with chemotherapy in both cohorts. The prognosis for patients with ER/PgR/HER2 triple-negative breast cancer is particularly poor. Here we present analysis outcomes from the X cohort of the RIBBON-1 study for patients with triple-negative MBC.

Methods: Recruitment to RIBBON-1 was open to patients with previously untreated, HER2-negative locally recurrent or MBC, with ECOG PS 0 or 1 and no known CNS metastases. In the X cohort, women were randomised (2:1) to X 1,000 mg/m^2 b.i.d. with placebo, or X with A 15 mg/kg q3w, with stratification by disease-free interval ($\leqslant$12 or >12 months), prior adjuvant chemotherapy (yes or no), and number of metastatic sites (<3 or $\geqslant$3). PFS outcomes were analysed in patients with or without triple-negative disease.

Results: The X cohort of RIBBON-1 enrolled 615 patients (XA 409; X-placebo control: 206). Approximately 24% of patients had ER/PgR/HER2 triple-negative disease (XA 21.7%; control 25.3%). In the X cohort overall, a significantly greater improvement in investigator-assessed PFS was achieved with the XA combination (stratified analysis hazard ratio [HR] 0.69 [0.56–0.84], $p = 0.0002$; median PFS 8.6 [XA] vs 5.7 [control] months). In the subgroup of patients with triple-negative disease, PFS appears to be similarly extended with XA (HR 0.72 [0.49–1.06]; 6.1 vs 4.2 months).

Conclusions: MBC patients with triple-negative disease have a poor prognosis and represent a difficult-to-treat population with relatively few therapeutic options. This analysis suggests that the XA combination increases PFS, and so may represent an effective option in this patient group.

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Possible predictive role of prior endocrine therapy on fulvestrant treatment outcome

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Background: Fulvestrant (F) is an estrogen receptor antagonist with no agonist effects that is licensed for the treatment of postmenopausal women with hormone-sensitive metastatic breast cancer (MBC). F use in pretreated MBC patients (pts) is associated with variable response rates. We investigated possible predictive role of treatment delivered prior to fulvestrant.

Material and Methods: From March 2005 to March 2009 124 MBC pts were treated with F at Institute of Oncology Ljubljana, 120 pts were evaluable. The median age of pts was 63 years (range 42−92), median ECOG performance status was 1 (range 0−3). All pts were pre-treated with other endocrine therapy (ET) (including adjuvant), median number of prior ET was 3 (range 1−4): 6/120 (5%) received 1, 52/120 (43.3%) 2 lines, 52/120 (43.3) 3 lines and 10/120 (8.3%) 4 lines of prior ET. The median number of chemotherapy (CT) regimens (including adjuvant)