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Analysis of Metastatic Breast Cancer Management Across Europe – the EOS Study (European Observatory & Survey)

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Background: Metastatic breast cancer (MBC) is a heterogeneous disease with many treatment options, including single-agent or combination chemotherapy. We analyzed in a real-life setting the therapeutic decision for treating MBC with non-pegylated liposomal doxorubicin (Myocet®, LED) or another chemotherapeutic agent (non-LED).
Material and Methods: A European, multicentre, prospective, 6-month cohort study, with a treatment group comparison at the time of inclusion (LED vs. non-LED), is currently recruiting across 7 countries adult women with confirmed MBC and scheduled first cycle of chemotherapy. LED and non-LED patients (pts) were matched on MBC chemotherapy line.
Results: We analyzed 606 pts (410 LED, 196 non-LED) included from Jan-09 to Mar-11. 84% had a WHO performance status of 0–1 and the median age was 60 yrs. 26% were HER2-positive at initial diagnosis. The median number of metastatic sites per pt was 2, and main sites of metastases were bone (62%), liver (44%) and lung (39%). The comparison of 195 pt pairs showed that LED pts were older (median 61 vs. 58 yrs, $p = 0.022$) and had more frequently comorbidities than non-LED pts (40% vs. 29%, $p = 0.020$). In particular the proportion of hypertensive pts was more important in the LED group (25% vs. 14%, $p = 0.004$). LED pts had more frequent pleural (17% vs. 12%, $p = 0.024$) and peritoneal (7% vs. 4%, $p = 0.022$) metastases, but these locations were less frequently assessed than in non-LED pts. The previous use of anthracyclines was similar in both groups (61% vs. 62%, $p = 0.814$). Overall, major reasons given by investigators for choosing LED were: among patient-related factors: stage of disease (70%); among factors related to previous anti-cancer treatment: treatment failure (50%); and among factors related to the chosen treatment: patient eligibility (64%). Single agent chemotherapy was given to 38% of LED and 60% of non-LED pts. LED was mainly combined with cyclophosphamide (48%) and taxanes (15%). 44% pts had LED with cyclophosphamide only. Non-LED agents were mainly taxanes (46%), vinorelbine (20%) cyclophosphamide and capecitabine (15% each).
Conclusions: EOS provides information on MBC epidemiology and management in Europe. These results suggest that the therapeutic decision is influenced by demographic and clinical characteristics. Further data are needed to refine the analysis and to compare MBC management per country.

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Capecitabine Alone or in Combination in Metastatic Breast Cancer – a Single-Institution Experience

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Background: The purpose of this study was to evaluate tolerability and efficacy of capecitabine (Cape) alone or in combination in metastatic breast cancer (MBC) patients (pts) treated in our institution.
Material and Methods: All pts included suffered from MBC disease. Cape alone was given at a dose of 1250 mg/ m2 twice daily (bid) for 14 days every 21 days (q21). Cape in combination with oral Vinorelbine (CapeVNR) was given at 500 mg/m^2/bid for 14 days and 60 mg/m^2 VNR on d1 and 8 q21. Dosage of Cape with docetaxel (CapeTXT) was 825 mg/m^2/bid and 30 mg/m^2 TXT d1 and 8 q21; with Gemcitabine (CapeGEM) was respectively 625 mg/m^2/bid and 1000 mg/m^2 d1 and 8 q21; with Carboplatin (CapeCARBO) was 825 mg/m^2/bid and AUC5 q21; with lapatinib was cape 1000 mg/m^2/bid and 1250 mg/day q21. We retrospectively assessed tolerability profile and efficacy.
Results: We analyzed 45 MBC pts treated in our institution. Median age was 51 years (range 28–87). 30 pts (66.6%) had a performance status (PS) ECOG of 0; 11 pts (24.4%) a PS of 1 and 4 pts (8.8%) had a PS of 2. 35 (77.7%) expressed estrogenic receptor; 7 pts (15.5%) had a HER-2 positive disease; 29 (64.4%) HER-2 negative and 7 pts (15.5%) had a triple negative MBC. 18 pts (40%) received cape as single agent. 21 pts (80.7%) CapeVNR; 1 pt (3.8%) CapeGEM; 1 pt (3.8%) CapeCARBO; 1 pt (3.8%) cape/lapatinib and 2 pts (7.6%) CapeTXT. Median number (nº) of metastatic (mts) sites was 2 (range 1–5). 36 pts (80%) previously received an adjuvant/neoadjuvant treatment. Median nº of prior mts lines was 3 (range 2–9). 12 pts (26.6%) received cape alone (66.6%) or in combination (33.3%) as first mts treatment. Median nº of single agent cape cycles administered was 8 (range 2–12) with a 25% dose-reduction in 16 pts (84.2%). Median time to progression (TTP) was 6 months (range 3–13). We observed a 84.2% objective response rate (ORR) according to RECIST criteria: 12 (63.1%) stable diseases (SD); 3 (15.7%) partial responses (PR) and 1 (5.2%) complete response (CR). 3 pts (15.7%) had a progression disease (PD). Median nº of CapeVNR cycles received was 8 (range 3–16) with a 25% dose-reduction in 14 pts (66.6%). Median TTP was 8 months (range 2–20). ORR was 66.6%: 9 (42.8%) SD and 5 (23.8%) PR; we observed 7 (33.3%) PD. 1 PD in the CapeGem pt; 1 SD in the Cape-lapatinib. 1 PD in the CapeCARBO pt. In the 2 CapeTXT pts we had 1 CR and 1 SD. Tolerability: in the cape monotherapy group, 7 (36.8%) fatigue G1-G2; 4 (21%) "hand and foot syndromes" (PPE) G1-G3; 3 (15.7%) diarrea G1-G2; 1 (5.2%) hyperpirexia and 1 (5.26%) nausea G1. Haematological toxicity: 4 (21%) anemia G1 and 1(5.2%) neutropenia G2. 7 pts (33.3%) in the combination CapeVNR referred fatigue G1-G2; 3 (14.2%) nausea G1-G2; 12 (57.1%) diarrea G1 and 3 (14.2%) PPE G1-G3. Thrombocytopenia G1-G2 in 4 pts (19%); 7 (33.3%) neutropenia G1-G3; 6 (28.4%) anemia G1. Both 2 CapeTXT pts had neutropenia G2; PPE G1-G2; vomiting G1-G2 and fatigue G2.
Conclusions: Cape is well-tolerated even in combination schedules and it shows an activity in heavily pre-treated MBC.

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Randomized Phase II Multicenter Trial of Oral Antiangiogenic Agent TSU-68 in Combination With Docetaxel Versus Docetaxel Alone in Patients With Metastatic Breast Cancer Previously Treated With an Anthracycline

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Background: Angiogenesis is a fundamental event of breast cancer growth and metastasis. The combined activity and safety of TSU-68, an oral small molecule inhibitor of VEGF, PDGF and FGF, with docetaxel were evaluated compared to those of docetaxel alone.
Materials and Methods: Between Oct 2006 and Feb 2010, 81 patients with anthracycline pretreated metastatic breast cancer received (1:1 randomization) either (1) docetaxel 60 mg/m^2, day 1 and 400 mg TSU-68 400 mg po bid, day 1–21 (Group A, $n = 41$) or (2) docetaxel 60 mg/m^2, day 1 of each cycle (Group B, $n = 40$).
Results: Median progression free survival (PFS) was 6.84 months (CI: 5.36, 12.50) and 8.13 months (CI: 3.98, 13.68), in group A and B, respectively ($p = 0.904$). Although one patient (2.6%) in the group A achieved complete response (CR), compared to no CR in the group B, there was no difference in terms of overall response rate between two groups (50% vs 41%, $p = 0.287$). There was no difference of one year survival rate between two groups(73.7% vs 66.7%, $p = 0.419$). Anthracycline resistance/sensitivity was a significant covariate ($p = 0.002$) in subgroup analysis for PFS. The most frequent grade 3 treatment-related emergent adverse events were leucopenia and neutropenia. It is notable that edema was more frequently observed in the group A than group B.
Conclusion: Even if docetaxel + TSU-68 did not have superiority in efficacy over docetaxel alone, given that better PFS in anthracycline resistant subgroup, one complete response, and greater number of alive patients at the end of the last follow-up, TSU-68 in combination with docetaxel provides an advantage for future phase III trial.