56% (41 of 70) were defined as basal-like breast cancers. Tumour staging was as following: T1 (4 patients), T2 (33 patients), T3 (28 patients) and T4 (5 patients), ganglionnair staging was as following: N0 (30 patients), N1 (34 patients), N2 (6 patients). Pathological complete response (pCR) was achieved in 25 TNBC patients (35%) according to Chevallier's classification restricted to breast. According to Sataloff classification the pCR (TANA or TANB) was achived in 23 patients (32%), The pCR rate in the basal-like phenotype was signicantly lower than in the non-basal-like phenotype (14 vs 38%, respectively: $P = 0.03$). The level of expression of KI67 was not considered as predictive factors for a better response from NAC.
Conclusions: A non-basal-like phenotype was favorable factor for NAC in our study. Currently, in the absence of reliable surrogate markers or clinically available gene expression profiling, it is difficult to further define subtypes within TNBC. A minority of patients have highly chemosensitive disease with excellent outcome, however tools to prospectively identify these patients and guide chemotherapy agent selection are lacking.

5053 POSTER

Randomized Phase III Study of First-line Bevacizumab in Combination With Capecitabine or Paclitaxel for HER2-negative LR/MBC: Interim Safety Data

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Background: The ongoing CECOG-sponsored TURANDOT study (CECOG/BC.1.3.005) is investigating the efficacy of bevacizumab (Bev) + paclitaxel (P) vs Bev + capecitabine (X) in LR/MBC. Preliminary safety data from the first 167 pts [Lang, ASCO 2010] were in accordance with previously published data for these regimens. We report interim safety results after reaching the recruitment target of 560 pts.
Materials and Methods: Pts aged $\geqslant$18 years with HER2-negative, chemonaïve LR/MBC and ECOG PS 0−2 were enrolled. Prior (neo)adjuvant chemotherapy was permitted if completed $\geqslant$6 months before randomization or $\geqslant$12 months if taxane based. Pts were randomized to receive Bev+P (Bev 10 mg/kg d1, 15 + P 90 mg/m^2 d1, 8, 15, q28d) or Bev+X (Bev 15 mg/kg d1 + X 1,000 mg/m^2 bid d1−14, q21d) until PD, unacceptable toxicity or consent withdrawal. Primary objective is non-inferiority in OS with Bev+P vs Bev+X.
Results: 564 pts were randomized (Bev+P: 285, Bev+X: 279) but 3 withdrew prior to treatment (consent withdrawn/randomization failure). As of 12 January 2011, 561 pts are eligible for safety analyses (Bev+P: 284, Bev+X: 277). Median number of Bev cycles: 6.5 with P, 9.0 with X. Median age 59 years (range: 27−86). Most pts are postmenopausal (82%), ECOG PS 0 (68%), ER+ (74%). Most frequent sites of metastasis are lymph nodes and bone (54% of pts each). Overall, 39% of pts received adjuvant anthracyclines with/without taxane. Treatment-emergent AEs (TE-AEs; onset during study or within 28 days post-treatment) occurred in 91% and 89% of pts in the Bev+P and Bev+X arms, respectively, with 82% considered treatment related (Bev+P: 85%, Bev+X: 78%). Grade $\geqslant$3 TE-AEs were seen in 51% and 41% of pts, respectively, and 19% and 17%, respectively, had any serious AEs. Most frequent TE-AEs (all grades) were fatigue (Bev+P: 31%, grade 1−5, Bev+X: 23%, grade 1−3) and hand-foot syndrome (Bev+P: 2%, grade 1−2; Bev+X: 49%, grade 1−3), while diarrhea was the most frequent serious TE-AE (Bev+P: 0.4%, Bev+X: 1.4%). Overall, 22% of patients withdrew Bev/P/ X due to an AE (Bev+P: 28%, Bev+X: 15%).
Conclusions: The safety profile of Bev in combination with commonly used chemotherapy regimens for MBC in the TURANDOT study is consistent with reports from three large, phase III trials, with no new safety issues observed.

5054 POSTER

Efficacy of Biological Agents (BA) in Metastatic Triple Negative Breast Cancer (TNBC): a Systematic Review

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Background: TNBC accounts for about 15% of all invasive breast cancers, usually with an aggressive behavior and poor prognosis also because of lack of standard-of-care therapy. In this setting, BA in combination with chemotherapy (CT) may have a role, also based on TNBC cellular specific targets.
Methods: To assess the role of BA in metastatic TNBC, a systematic review of randomized controlled trials published from January 2006 to January 2011 and of communications presented at ESMO, ASCO and SABCS congresses in 2009 and 2010 was performed. Only studies comparing BA+CT versus CT alone in TNBC, or in unspecified advanced breast cancer but presenting data on TNBC subgroup, were considered. The relevant statistical variables for the pooled analysis were the log of hazard ratio (HR) and relative variance for progression-free survival (PFS) and overall survival (OS).
Results: Out of 346 Pubmed publications and 126 studies registered on http://clinicaltrial.gov/, 8 trials were selected for analysis. A total of 3463 patients were analyzed: 1286 of them were TNBC patients. BA studied were: bevacizumab (Miles 2010, Brufsky 2010 and Gray 2009), lapatinib (Finn 2009), iniparib (O'Shaughnessy 2011), sunitinib (Curigliano 2010), sorafenib (Gomez 2010) and cetuximab (Baselga 2010). A PFS improvement was detected in the group of pts receiving BA, with a relative risk reduction of 27% (95% CI: 18%-35%). I^2 statistic for quantifying heterogeneity among class of BA [1) anti-angiogenic, 2) EGFR inhibitors 3) Parp Inhibitors] was 43.8%; only class 1 and 3 showed a statistically significant improvement in PFS. No effect on OS was observed.
Conclusions: In our systematic review we detected:
1. Improvement of PFS in TNBC pts treated with BA+CT vs CT alone.
2. No single BA class showed a statistically significant superiority over others, however for EGFR inhibitors no statistically significant difference was reached.
3. The effect of BA on OS hasn't been demonstrated, similarly in the general population with non-TNBC advanced breast cancer.

5055 POSTER

The Palliative CMF is a Reasonable Salvage Treatment Option in Heavily Pretreated Patients With Metastatic Breast Cancer

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Purpose: Although cyclophosphamide, methotrexate, and fluorouracil (CMF) chemotherapy showed high efficacy and tolerability as adjuvant chemotherapy in breast cancer, anthracycline- and/or taxane-containing regimens have been a mainstay of adjuvant chemotherapy. Recently, many active agents, such as capcitabine, gemcitabine, and vinorelbine have improved treatment outcome in metastatic breast cancer (MBC). This study was motivated by an increasing need for effective alternative therapeutics for heavily treated MBC patients who have failed standard treatment. The aim of this study was to define the role of CMF in anthracycline and taxane pretreated MBC patients.
Material and Methods: We consecutively enrolled 44 MBC patients who underwent CMF chemotherapy with palliative intent after failure of anthracycline and taxane at Seoul National University Hospital between 2002 and 2010. The regimen of oral and intravenous CMF were administered in 25 patients (56.8%) and 19 (43.2%), respectively.
Results: Of 44 enrolled patients, median age was 50. All of patients had received prior taxane based chemotherapy, and all but one patient (97.7%) had received previous anthracycline-based chemotherapy. Forty three (97.6%), 34 (77.3%), and 36 (81.8%) were treated with fluorouracil, gemcitabine, and, vinorelbine based chemotherapy, respectively. Median 4 lines of systemic treatment were administered previously and median time to initiation of CMF chemotherapy from the diagnosis of metastasis or relapse was 20.2 months (range, 9.4–92.3 months). Median 3 cycles (range, 1−15) of CMF were administered and the relative dose intensity was 90.7%. The toxicity was mild with 11.4% of grade 2 and 18.2% of grade 3/4 neutropenia. The response rate was 15% (6/40), comprising one complete and six partial responses and disease control rate was 47.5% (19/40). The median progression free survival and overall survival were 3.3 months (95% CI, 1.3−5.2) and 9.0 months (95% CI, 6.5–11.4), respectively. The PFS of 3.5 months was better in patients with 1 to 3 metastatic sites than 1.3 months in patients with more than 3 metastatic sites. PFS and OS in triple negative breast cancer patients were not inferior to hormone positive and Her2 positive patients.
Conclusions: Palliative CMF chemotherapy is reasonable and safe as salvage treatment in heavily pretreated breast cancer patients.