counterparts. Higher levels of androgenic hormones in Indian breast cancer patients may have etiological and therapeutic implications.

5075 POSTER

Non-pegylated Liposomal Doxorubicin (Myocet ®) Plus Docetaxel (Taxotere ®) (MYTAX), as First-line Chemotherapy (CHT), in Metastatic Breast Cancer (MBC): Results of a Phase II Study

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Background: The combination of anthracyclines and taxanes is considered among the most effective treatments in MBC. The main limitation of these regimens is the cumulative cardiotoxicity of anthracyclines.
The liposomal doxorubicins have been demonstrated to be less toxic for myocardial tissue, resulting in a better cardiac safety profile.
Purpose: We report our experience regarding efficacy and safety of the combination of Myocet ® with Taxotere ® in first-line treatment of MBC patients (PTS).
Patients and Methods: All 16 PTS with median age of 61 years (range 54−75), had histologically confirmed MBC. Anti-allergic premedication with steroids and H1/H2 receptor antagonists was administered to all PTS 12 hours before Taxotere ®.
Treatment plan was: Myocet ® (60 mg/m^2, i.v. on day 1) followed by Taxotere ® (35 mg/m^2 i.v. on days 2 and 9), every 3 weeks.
A total of 92 cycles of CHT were delivered. Mean number was 5.75 (range 2−8). Seventy-six percent of PTS received at least 6 cycles of CHT.
The primary endpoint was overall response rate (ORR), whilst time to progression (TTP) and safety were considered as secondary end points.
Results: According to the WHO criteria, 3 PTS (18.5%) achieved a complete remission and 4 (25%) a partial remission for an ORR of 44%. We report a median TTP of 9.5 months. Two patients who achieved RC had lymph nodal disease, one patient had liver disease. None of the PTS experienced severe cardiac toxicity. The most common hematological toxicity was grade 3−4 neutropenia, according to WHO criteria, detected in 68% of PTS. Use of G-CSF, in 55% PTS, for treatment and prophylaxis of severe neutropenia allowed to maintain adequate dose-intensity. Stomatitis occurred in 25% of PTS, while grade 3 neurological toxicity in 12.5%.
Conclusions: Our report confirms the effectiveness of the Myocet ®-Taxotere ® combination administered in MBC according to the schedule described above. Moreover the substitution of conventional doxorubicin with Myocet ® probably reduced cardiotoxicity. Myelotoxicity rate is in line with other similar reports.

5076 POSTER

Phase II Study of Vinorelbine Plus Trastuzumab in HER-2 Overexpressing Metastatic Breast Cancer Pretreated With Anthracyclines and Taxanes

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Background: The role of first-line trastuzumab-based therapy has been firmly established in HER-2 positive metastatic breast cancer patients. In this trial, we evaluated the efficacy and safety of a vinorelbine and trastuzumab combination chemotherapy failed to anthracyclines and taxanes.
Methods: Thirty-three patients with HER-2 overexpressing metastatic breast cancer, all of whom had previously been treated with anthracyclines and taxanes, were included in this study. The patients were treated with 25 mg/m^2 of vinorelbine (over a 15-minute infusion) on days 1 and 8 every 3 weeks. Additionally, trastuzumab was administered at an initial dose of 4 mg/kg over 90 minutes, and was subsequently administered at weekly doses of 2 mg/kg (over 30 minutes).
Results: The median age of the patients was 53 years (range: 39−72 years). The overall response rate was 30.3% (10 patients, 95% confidence interval [CI]: 23−57%). The median time to progression was 6.8 months (95% CI: 5.3−8.2 months). The median overall survival was 12.4 months (95% CI: 10.3–14.6 months). In the 194 cycles of treatment, the incidence rates of grade $\geqslant$ 3 neutropenia and anemia were 7.2% and 1.0%, respectively. Neutropenic fever was detected in 3 cycles (1.5%). The non-hematological toxicities were not severe: grade 1 or 2 nausea or vomiting was detected in 15.2%, and grade 2 neuropathy was noted in 6.1% of the patients. None of the patients experienced any serious cardiac toxicity, and no treatment-related deaths occurred.
Conclusions: These results show that a combination chemotherapy consisting of vinorelbine and trastuzumab is useful in HER-2-overexpressing metastatic breast cancer patients failed to anthracyclines and taxanes, with a favorable toxicity profile.

5077 POSTER

Inflammatory Breast Cancer (IBC): Does the Confirmation of Dermal Lymphatic Invasion (DLI) Predict the Worst Outcome?

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Background: IBC presents the most aggressive form of BC, with poor prognosis and low rate of complete remission to induction chemotherapy (iCT). Dermal lymphatic invasion (DLI), although not necessary for IBC diagnosis, is identified in fewer than 75% patients, mainly because of sampling heterogeneity. The aim of this retrospective analysis is to evaluate if DLI is related to poorer prognosis, by comparing two groups of IBC patients: with and without confirmed DLI.
Materials and Methods: At Institute for oncology and radiology of Serbia (IORS), in period 2008–2010, we have registered 98 female pts with IBC stage III. 85 medical records were available for evaluation. IBC is defined as BC with typical clinical signs of cancer-mastitis, with or without pathologically confirmed skin lymphangiosis and with or without underlying tumour.
Results: The incidence of IBC at IORS is 2.8%. There were 40pts (47%) with confirmed DLI and 45pts (53%) without DLI at skin biopsy.

	Pts, % (n)	CR/PR to iCT	PD to iCT	PD (pts)	TTP	Died	OS
With DLI	47% (40)	55%	35%	40%	12.8 mo	10%	12.5 mo
Without DLI	53% (45)	75%	13%	22%	14.8 mo	4%	20 mo

In these two groups the median age at diagnosis was 54.7 years (range 34−76) and 56.8 years (range 28−77), respectively. Pathohistological analysis confirmed ductal carcinoma in 35% (14pts) and 64.5% (29pts); underlying tumour in 72.5% (29pts) and 93.5% (42pts); ER+ 57.5% (23pts) and 31% (14pts); HER2+ 50% (20pts) and 46.5% (21pts). Good clinical response to induction chemotherapy, estimated as complete (CR) or partial response (PR) was registered in 55% (22 pts) and 75% (34pts); stable disease (SD) in 10% (4pts) and 11% (5pts), while 35% (14pts) and 13% (6pts) failed to respond to iCT (PD), all respectively. Median time to progression (TTP) was 12.8 and 14.8 months, registered in 40% (16pts) and 22% (10pts). In a group of pts with confirmed DLI 4pts (10%) died, compared to 2pts (4%) in group without confirmed DLI, with overall survival (OS) respectively12.5 and 20 months.
Conclusions: In this study we showed that IBC pts with confirmed DLI have worse outcome, including lower response rate to iCT (55% vs. 75%) and more common disease progression (40% vs. 22%) with shorter TTP (12.8 vs. 14.8 months) and OS (12.5 vs. 20 months). We also found that DLI in IBC is associated with more frequent ER positivity (57.5% vs. 31%) and absence of underlying tumour (27.5% vs. 6.5%).

5078 POSTER

Polymorphisms in Genes Involved in Drug Detoxification and Response to Anthracyclines Chemotherapy in Chinese Han Breast Cancer Patients

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Background: Chemotherapy drug efficacy is complex and can be influenced by cellular detoxification mechanisms involving drug metabolism and transport pathways. This study aimed to assess whether the known polymorphisms in genes related to metabolizing enzymes (MnSOD, CAT and GSTs) and transporter MDR1 are associated with response to anthracycline-based chemotherapy in Chinese Han breast cancer patients.
Materials and Methods: Genotyping was performed by allele-specific oligonucleotide ligation reaction (*MnSOD*, *CAT*, *GSTP1*), multiplex PCR (*GSTM1*, *GSTT1*), and PCR-RFLP (*MDR1*). Based on 153 evaluable patients received anthracycline-based neoadjuvant chemotherapy, the associations of these genotypes, their combinations or their haplotypes with clinical responses were analyzed.
Results: Patients with *GSTP1* 313 AA genotype had inferior response rates relative to those with AG or GG (58.4% *vs* 77.8% or 100.0%; χ^2=4.922, P = 0.027); Moreover, the response rate of the combination of *GSTP1* AA with both *GSTT1* and *GSTM1* present was 44%, which was also lower comparing with the other groups (70.3%; χ^2=6.454, P = 0.011). A similar result was noticed for *MDR1* 3435 TT genotype, which had a significantly worse chemotherapy response compared with wild-type C allele carrier (33.3% *vs* 71.2%; χ^2=11.586, P = 0.001); Further, the