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Safety data from a phase II trial of weekly nab-paclitaxel in combination with bevacizumab as first-line treatment in metastatic breast cancer

M. Danso[1], J. Blum[2], N. Robert[3], L. Krekow[4], R. Rotche[5], D. Smith[6], P. Richards[7], T. Anderson[8], D. Richards[9], J. O'Shaughnessy[10]. *[1]Cancer Centers of Florida, Hem/Onc, Winter Park, USA; [2]Texas Oncology PA, Onc, Dallas, USA; [3]Fairfax Northern VA, Hem/Onc, Fairfax, USA; [4]Texas Oncology PA, Onc, Bedford, USA; [5]Blue Ridge Cancer Care, Hem/Onc, Christiansburg, USA; [6]Northern Cancer Specialists, Onc, Vancouver, USA; [7]Onc and Hem Assoc of Southwest VA, Onc/Hem, Salem, USA; [8]Mid Cities Oncology, Onc, Belford, USA; [9]Tyler Cancer Center, Onc, Tyler, USA; [10]Baylor Sammons Cancer Center Texas Oncology PA, Onc, Dallas, USA*

Background: In a clinical trial of 722 patients (pts) with locally recurrent metastatic breast cancer (MBC) solvent-based paclitaxel 90 mg/m^2 was administered intravenously (IV) over 1 hr weekly for 3 weeks followed by a week of rest (q3/4w) alone or in combination with bevacizumab 10 mg/kg every 2 weeks (q2w) [Miller et al., ASCO 2005]. As compared with single agent, the combination had a greater median progression-free survival (PFS; 11.4 vs. 6.11, $p < 0.0001$) and overall response rate (ORR; 30% vs. 14%, $p < 0.0001$). The purpose of the current study is to evaluate the safety of 130-nanometer albumin bound (nab-) paclitaxel in combination with bevacizumab in MBC.

Methods: In this multicenter, open-label study in the US Oncology Research Network, HER-2 negative pts with MBC, receiving first line chemotherapy were given weekly nab-paclitaxel 125 mg/m^2 IV infused over 30 minutes on days 1, 8, and 15, and bevacizumab 10 mg/kg on days 1 and 15 of a 28-day cycle. HER-2 negative pts with measurable adenocarcinoma of the breast with ECOG PS 0−2 were included.

Results: 49 women were enrolled from 19 October 2005 to 26 October 2007 with 41 pts treated (mean age, 59 years; mean # cycles, 4.0). 93% of pts had visceral disease, 59% had prior chemotherapy, 41% had anthracycline, 12% had docetaxel and 12% had paclitaxel in the adjuvant setting. Grade 3, 4 hematologic adverse events were neutropenia (30%, 16%) and anemia (8%, 3%). The most common non-hematologic grade 3, 4 adverse event was sensory neuropathy (10%, 2%).

Conclusions: Results on this preliminary analysis shows that nab-paclitaxel in combination with bevacizumab has an acceptable safety profile with no unanticipated toxicities. Updated safety data will be presented.

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Steroid aromatase inhibitors in metastatic breast cancer after disease progression to nonsteroid inhibitors-efficacy?

J. Pesic[1], D. Donat[1], S. Tesanovic[1], J. Trifunovic[1], T. Pesic[2], D.D. Donat[3], L.J. Muzikravic[4]. *[1]Institute of Oncology, Clinic for Internal Oncology, Sremska Kamenica, Serbia; [2]Clinical Center Novi Sad, Clinic for internal medicine, Novi Sad, Serbia; [3]Medical Faculty Novi Sad, Postgraduet study, Novi Sad, Serbia; [4]Institute of oncology, Clinic for internal oncology, Sremska Kamenica, Serbia*

Background: Aromatase inhibitors are standard treatment for steroid dependent breast cancer.The aim of the paper was to present the efficacy of steroid aromatase inhibitor (exemestane) used in the tretment of breast cancer patients with disease progression to nonsteroid aromatase inhibitors, such as letrozole and anastrozole.

Material: We included 34 patients that received steroid aromatase inhibitors after disease progression to nonsteroid aromatase inhibitors. All patients were treated at our Institute during the period from June 2006 to june 2007. Average age of the patients was 59 years (range: 40−78 years), with ECOG status 0 to 2. Disease involment of one organ was registered in 24 (70.5%) patientsand two or more organs involment was found in 10 (29.4%) patients. Metastatic disease in all patients was treated with nonsteroid aromatase inhibitors: 14 (41.1%) patients received letrozole and 20 (58.8%) were given anastrozole.

Results: Out of 34 treated patients 4 (11.7%) had CR, 7 (20.5%) responded with PR, SD was found in 12 (35.2%) patients, while PD was found in 11 (32, 3%) patients.RR (PR+CR) was evidenced in 11 (32.3%) patients and tumor control rate (TCR) in 23 (67.6%) patients. Better TCR was achieved in patients with nonvisceral metastases: 13 (38.2%) patients compared with 10 (29.4%) patients with visceral metastases, but thedifference did not reached statistical significance. Side effects were mild (grade 1 and 2) expressed mostly as menopausal discomforts, muskulosceletal pain and gastroinetstinal distress.

Conclusion: Although a small number of patients was studied, the achieved RR and TCR responses are indicative for the application of steroid aromatase inhibitors in the treatment of metastatic breast cancer after failure of nonsteroidal aromatase inhibitors. Toxic effects were mild. We did not observed any difference in RR in the patients group previously treated with letrozole and anastrozole.

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A phase II study of, Docetaxel (T), Doxorubicin (A) and Cyclophosphamide (C)-TAC, in metastatic breast cancer – experience on 139 cases from Bangladesh

A.B.M.F. Karim[1], A.M.M. Shariful Alam[2], P.S. Akhtar[2], P.A. Banu[3], M.A. Hai[4], M.S. Reza[5], Q. Chowdhury[2], E. Hoque[2], T.U. Ahmed[6]. *[1]Salahuddin Hospital, Oncology, Dhaka, Bangladesh; [2]National Institute of Cancer Research & Hospital, Oncology, Dhaka, Bangladesh; [3]Delta Medical Centre, Oncology Unit, Dhaka, Bangladesh; [4]Bangladesh Cancer Society and welfare Home, Radiation Oncology, Dhaka, Bangladesh; [5]Ahsania Mission cancer Hospital, Oncology, Dhaka, Bangladesh; [6]Bangladesh Medical College & Hospital, Medical Oncology, Dhaka, Bangladesh*

Background: TAC has shown significant anti-tumour activity in operable node positive breast cancer. We conducted a prospective study to evaluate the effect of this regimen in metastatic breast cancer.

Materials and Methods: One hundred and thirty-nine patients with metastatic breast cancer were included in this study between January 2001 and December 2003. Median age was 55.5 year (range 45−66). The sites of metastasis were liver, lung, bone, lymph nodes and skin. 15.1% (21 pts) had more than 2 metastatic sites. Chemotherapy with TAC – Docetaxel 60−75 mg/m^2, Doxorubicin 50 mg/m^2, Cyclophosphamide 500 mg/m^2, all on day-1 were administered at 3 weeks interval. Growth factor support with lenograstim was prophylactically given to all patients for 3−5 days following chemotherapy.

Results: Total number of evaluable patients was 136. Two patients died due to other complications and one withdrew consent. Performance status ranged from ECOG 1−3. The overall response rate was 67%, of which 13.6% (10) had complete responses. Overall survival was mean 23.8 (9.2−32.6) months. Neutropenia was the commonest toxicity occurring in 13 pts (17.6%) with febrile neutropenia in 6 (8.16%) of cases. There were no grade 4 toxicities. Grade 3 toxicities were limited to neutropenia in 6 pts (8.16%), nausea in 8 (10.88%), diarrhea in 5 (6.8%), vomiting in 12 (16.3%), stomatitis in 5 (6.8%) and allergic reaction in 2 (2.72%) of pts. No cardiac or neuro-toxicity was observed.

Conclusions: Our experience shows that TAC is a well tolerated and highly effective regimen in metastatic breast cancer. The ORR and OS are impressive for the breast cancer patients with metastatic disease. Neutropenic complication was manageable. This result should be substantiated by larger studies before adoption as a standard practice.

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Combination of trastuzumab and gemcitabine as salvage therapy in heavily pretreated patients with metastatic breast cancer

R. Bartsch[1], C. Wenzel[1], U. Pluschnig[1], G. Altorjai[1], P. Dubsky[2], R. Scheurer[1], A. Rottenfusser[3], M. Gnant[2], C.C. Zielinski[1], G.G. Steger[1]. *[1]Medical University of Vienna, First Department of Medicine and Cancer Centre, Vienna, Austria; [2]Medical University of Vienna, Department of Surgery, Vienna, Austria; [3]Medical University of Vienna, Department of Radiotherapy, Vienna, Austria*

Background: Her2+ breast cancer is associated with high recurrence rates and poor outcome. The advent of trastuzumab (T) (RhMab45D), a monoclonal humanized antibody directed against the extracellular domain of Her2 (human EGFR related 2), was a major breakthrough.

The combination of T and taxanes is the best established first-line treatment option, with vinorelbine being a possible alternative. When T however is administered in multiple lines, no standard of care exists. We initiated this study to evaluate the potential activity of the combination of T and gemcitabine (G) in patients (pts) pre-treated with T, anthracyclines, taxanes and/or vinorelbine, and capecitabine.

Patients and Methods: Pts received G at a dose of 1250 mg/m^2 on days 1+8, every 21 days. T was administered in three-week cycles. Re-evaluation of tumour status was performed with CT-scans every three cycles. Clinical benefit rate (CBR; CR+PR+SD $\geqslant$6 months[m]) was defined as primary endpoint.

Based on previous data, a 50% CBR was considered to indicate clinical activity, and a CBR < 25% was considered unacceptable. The targeted accrual for this study was set at 26 evaluable pts. If $\geqslant$11 patients experienced clinical benefit, a sample size of 26 pts provides statistical power of 80% to reject the null hypothesis that the CBR is <25% with an α of 0.05.