249 Poster

Feasibility and Toxicities Associated with PEG Doxo Versus Capecitabine as First-line Chemotherapy in Elderly Metastatic Breast Cancer (MBC) Patients; Results From the Randomized OMEGA Study of the Dutch Breast Cancer Trialists' Group (BOOG)

C. Seynaeve[1], H. van Tinteren[2], A.N.M. Wymenga[3], J.W.R. Nortier[4], E. Maartense[5], F.E. de Jongh[6], H. de Graaf[7], S.M. de Groot[8], J.J. Braun[9], C. Smorenburg[10]. [1]*Erasmus MC Daniel den Hoed Cancer Center, Medical Oncology, Rotterdam, The Netherlands;* [2]*Antoni van Leeuwenhoek Hospital/NKI, Statistician, Amsterdam, The Netherlands;* [3]*Medisch Spectrum Twente, Medical Oncology, Enschede, The Netherlands;* [4]*Leids University Medical Center, Medical Oncology, Leiden, The Netherlands;* [5]*Reinier de Graaf Hospital, Medical Oncology, Delft, The Netherlands;* [6]*Ikazia Hospital, Medical Oncology, Rotterdam, The Netherlands;* [7]*Medical Center Leeuwarden, Medical Oncology, Leeuwarden, The Netherlands;* [8]*Comprehensive Cancer Center, Datamanager, Amsterdam, The Netherlands;* [9]*Vlietland Hospital, Medical Oncology, Schiedam, The Netherlands;* [10]*Medical Centre Alkmaar, Medical Oncology, Alkmaar, The Netherlands*

Background: The absolute number of elderly women developing MBC and at some stage requiring chemotherapy is increasing. However, randomized evidence on the effectiveness and tolerability in these patients (pts) is scarce. The Dutch multicenter randomized OMEGA study compared liposomal doxorubicin (PEG doxo/Caelyx®) vs Capecitabine (Cape) as first line chemotherapy in elderly MBC pts. The current analysis focused on toxicities and feasibility of both regimens in this population.

Patients and Methods: Elderly MBC pts ($\geqslant$ 65 yrs) eligible for first-line chemotherapy were randomized between PEGdoxo (45 mg/m^2, IV, q 4 wks) or Cape (daily 2$\times$ 1000 mg/m^2, days 1−14, q 3 wks). Other eligibility criteria were: PS $\leqslant$ 3, acceptable bone marrow and liver functions, creatinine clearance $\geqslant$ 40 ml/min, adequate cardiac function. Stratification factors were PS (0−1 vs 2−3), HER2 status, visceral/non-visceral disease, adjuvant hormonal therapy (HTx), and HTx for MBC. Chemotherapy was continued for 24 weeks in the absence of progressive disease (PD) or unacceptable toxicity.

Results: Demographics of the 78 randomized pts (PEGdoxo 38, Cape 40) were: median age 75 yrs (range 65−86, 74% $\geqslant$71 yrs, 9% $\geqslant$81 yrs), median PS 1 (0/1: 77%), HER2 positive: 6.4% (unknown 19%), visceral/non-visceral MBC: 74%/26%, adjuvant HTx: 44.9%, HTx for MBC: 56.4%. Chemotherapy was administered for 24 wks in 29.5%, and discontinued due to PD in 30.8% (PEGdoxo 34%, Cape 27.5%) or intercurrent death in 5.1% (PEGdoxo: 1, Cape: 3). Chemotherapy was stopped due to toxicity/lack of benefit in 15 pts (PEGdoxo 9, Cape 6), and misinterpretation in 2 pts. Grade 3/4 toxicities (see table) were reported in 26 pts (33.3%) during 43 cycles (35%). Grade 3/4 AEs reported during $\geqslant$ 2 cycles were fatigue in 2 PEGdoxo, and 1 Cape pt (each in 2 cycles), and HFS in 2 Cape pts (in 2, and 3 cycles, resp.).

Conclusion: PEG doxo and Capecitabine are both feasible options as first-line chemotherapy for elderly MBC patients. Toxicity was acceptable, mainly being fatigue, HFS, and mucositis.

Grade 3/4 toxicity (N/% of pts)	PEG doxo	Cape
Hand Foot Syndrome (HFS)	4 (10.5%)	6 (15%)
Skin	2 (5.3%)	−
Allergy/Hypersensitivity	1 (2.6%)	−
Mucositis/stomatitis	4 (10.5%)	−
Nausea/Vomiting	−	1 (2.5%)
Diarrhoea	1 (2.6%)	1 (2.5%)
Neutropenia/Infection	2 (5.3%)	−
Fatigue	4 (10.5%)	5 (12.5%)
Cardiac events	1 (2.6%)	−
Pulmonary Embolism	−	1 (2.5%)
Neurologic symptoms	−	1 (2.5%)

250 Poster

The Secondary Breast Cancer Multidisciplinary Forum (SBC- MDF): a Novel Strategy to Improve Patient Care and Allow Prospective Data Collection

A. Caley[1], E. Hodges[1], P. Barrett-Lee[1], A. Borley[1], J. Abraham[1]. [1]*Velindre Cancer Centre, Clinical Oncology, Cardiff, United Kingdom*

Background: Although multidisciplinary meetings take place throughout the UK, they have been designed with early breast cancer in mind. Secondary breast cancers are not routinely discussed. The management of this group of patients is often complex and the relevant support groups may not be accessed early.

There is also currently no prospective database for this population in the UK.

In South Wales, a network-wide, SBC- MDF has been running since March 2010 and is attended by clinical and medical oncologists, breast care and clinical trials nurses, radiologists and palliative care specialists. The aim of this forum is to agree a treatment plan for all new cases, and record this information prospectively, (including data on performance status, clinical trial eligibility and palliative care).

Methods: All new patients with secondary breast cancer discussed at the South Wales SBC- MDF between March 2010 and March 2011 were analysed for their presenting characteristics and the treatments they received.

Results: 139 patients with secondary breast cancer were identified, 29% stage IV at presentation. The commonest sites for metastatic disease were multiple (47%) and bone only (29%). Performance status at presentation was as follows: stage 0 − (43%), 1 − (29%), 2 − (19%), 3 − (9%). Of those with relapsed disease, 49% had undergone a mastectomy as part of their early breast cancer management, 60% had received adjuvant chemotherapy, 66% adjuvant hormones and 13% adjuvant trastuzumab. 70% of patients were ER positive, 23% ER negative, 5% unknown. 62% were HER−2 negative, 28% HER 2 positive, 9% unknown. Chemotherapy was used first line in 73 patients (52%), single agent capecitabine (16%) or docetaxel (9%) the most common regimens used. 87% of HER−2 positives received trastuzumab and 86% with bony metastases received bisphosphonates as part of their initial therapy.

Conclusions: The secondary breast cancer forum is a novel project which is coordinating the care of patients with secondary breast cancer whilst collecting invaluable statistics on this complex group. It has achieved a process of standardising treatments across a region through a panel of experts using guidelines, evidence based practice and experience.

Patients have benefitted from improved access to clinical trials and palliative medicine. Ongoing prospective studies on these patients will lead to treatment outcomes and survival data which will undoubtedly inform clinical practice.

251 Poster

Retrospective Analysis of the Relative Efficacy and Toxicity of Nab-paclitaxel and Docetaxel in Metastatic Breast Cancer

S.J. Howell[1], A.C. Armstrong[2], L. Ashcroft[3]. [1]*University of Manchester, School of Cancer and Enabling Sciences, Manchester, United Kingdom;* [2]*The Christie NHS Foundation Trust, Department of Medical Oncology, Manchester, United Kingdom;* [3]*The Christie NHS Foundation Trust, Department of Medical Statistics, Manchester, United Kingdom*

Background: Taxanes (T) are effective drugs in metastatic breast cancer. Docetaxel (D) q3 wks is associated with significant risks of febrile neutropenia (FN) and non-haematological toxicity. In 2009 nab-paclitaxel (N-P) was approved for use in place of D at our institution due to trial data demonstrating comparable efficacy but reduced toxicity. We report the efficacy and toxicity data on all patients treated with N-P in 2010 and all those treated with D in 2008 as a comparator.

Methods: Retrospective case note review of patients receiving non-trial single agent D q3 wks at any of the three recommended dose levels (60,75 or 100 mg/m^2) or N-P (all 260 mg/m^2) in 2008 and 2010 respectively. Co-administration of trastuzumab was permitted. Response rates (RR) were assessed from radiology reports in patients with measurable disease. These and toxicities were compared between D and N-P groups using Pearson chi squared tests. Progression free survival (PFS) was compared by log-rank analysis.

Results: 81 patients were identified -41 received D and 40 N-P. The groups were well balanced for ER, HER2, grade, age, prior adjuvant treatment and metastatic disease and sites of metastasis. 14 patients in each group had HER2+ tumours and received T plus trastuzumab. Ts were first line chemotherapy for MBC in 30/41 (73%) with D and 25/40 (62%) with N-P (p = 0.59). D dose was: 60 mg/m^2 in 14(34%), 75 mg/m^2 in 6(15%) and 100 mg/m^2 in 21(51%). Response was assessable in 48 patients treated with single agent T: RR was 6/25 (24%) for N-P and 14/23 (52%) for D (p = 0.004). Median number of cycles was 6 for D and N-P. Median PFS was comparable: D 203 days vs N-P 171 days (p = 0.65) although duration of follow up was significantly shorter for N-P. D induced more FN (8 vs 1 patient). Two treatment related deaths were seen with D (both FN) but none with N-P. No FN was seen when primary or secondary prophylactic GCSF was used. N-P resulted in significantly more reports of moderate-severe pain (43% N-P vs 10% D; p = 0.01) which was mostly myalgia/arthralgia and resulted in the admission of 3 patients for analgesia. Peripheral neuropathy and fatigue were comparable between groups.