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Giving to Women with Metastatic Breast Cancer a Choice Between Oral or Intravenous Chemotherapy: Which the Patient Preference? a Prospective Analysis Focused On Quality of Life and Compliance Through Two Consecutive Phase II Trials

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Background: Our Group had previously reported results of two parallel consecutive phase II trials in women with HER2-negative metastatic breast cancer (MBC) given full-oral chemotherapy (CT) with vinorelbine (VNR) and capecitabine (CAP) in combination (Trial A) or Trastuzumab plus i.v./oral VNR in patients with HER2-positive disease (Trial B). Here we present the final results of the prospective analysis focused on patient preference, treatment compliance and quality of life (QoL).

Patients and Methods: Overall, 188 patients have been treated and evaluated. QoL was assessed every two cycles using the EORTC QLQ-BR23 questionnaires. Patient's preference was evaluated using a 10-item questionnaire designed to measure the women opinion and perception regarding oral versus intravenous treatments. To investigate treatment tolerability both the patient and physician were asked to quantify their opinion as insufficient-satisfactory-good and very good (score 0 to 3).

Results: All but two patients returned the completed modules at the start of each CT cycle. Over 90% of patients and physicians rated the tolerability of full oral regimen (Trial A) or osVNR/Trastuzumab as 'very good' or 'good' throughout the treatment, with a slight higher physician-detected score. An improvement in tolerability was reported by 92% of patients from their last therapy to present CT: median scores changed from 1 to 2 in 41% and from 2 to 3 in 45% of cases, respectively. Tolerability at 4th and 6th cycle was also positively associated with better progression-free-survival ($p=0.02$). A statistically significant difference was observed regarding some aspects of QoL, as body image ($p=0.02$), sexual functioning ($p=0.01$) and future perspectives ($p=0.03$). Oral treatment was perceived as advantageous by 98.5% of women, because of reduced hospital admissions (73.8%) and feeling of 'freedom' deriving from the home-based therapy (16.6%).

Conclusions: Our data confirm the good compliance of oral CT, both as *all-oral* combination (VNR/CAP) or associated with Trastuzumab (osVNR/Trastuzumab) as first-line treatment in women with MBC. The most interesting findings were the observed beneficial effect of oral CT on sexual functioning and the significant impact of each degree of improvement in tolerability on the clinical outcome. We believe that by giving the patients a choice between oral or i.v. treatment, patients often sense a feeling of control over the treatment and thereby a control over their life.

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Implementation of Palliative Care in German Breast Centers - First Results of a National Questionnaire

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Background: In Germany, the majority of breast cancer cases are treated at breast centers (BC) which are certified according to the German Society of Senology and Cancer Society. At the Center of Integrated Oncology (CCO) Cologne-Bonn including its BC, early integration of palliative care (PC) is a clinical and scientific hallmark. Yet, the logistics of actual PC integration into metastatic breast cancer (MBC) care at other centers are not well documented. In view of the encouraging data from NSCLC demonstrating the benefits of early integration of PC, this topic has become increasingly important.

To gain some structural information about the degree and concept of PC integration, a questionnaire to assess the available PC infrastructure was distributed to all certified German BC.

Materials and Methods: We used the national AGBZB Email-distribution and mail system to contact all directors of officially certified BC in Germany (June 2011: 207). The questionnaire contains 10 questions defined by our interdisciplinary team and assesses the available infrastructure of the center (availability of yearly follow up data, implementation of an interdisciplinary tumorboard for MBC, application of systemic treatment in the department of gynecology or oncology) as well as the availability of specialised PC (in- and outpatient PC, home palliative and hospice care, interdisciplinary approach, pain management). The questionnaire

also gives the opportunity to provide comments (as free text) concerning the integration of PC.

Results: The number of patients with MBC treated per year in the BC in an interdisciplinary approach spreads from 0 to 500. In more than 20% there are no PC beds available at the BC or the hospital. In about 40% there is no PC available for outpatient needs. The actual integration of PC in the MBC occurs rather late (only in 23% integration of PC takes place at the time of diagnosing MBC, in more than 70% PC is involved for dying patients only).

Conclusion: Infrastructure and concepts for integration of PC into MBC therapy are still scarce and vary extremely in quality and quantity. This highlights the need for institutional guidelines and an interdisciplinary consensus on the national level.

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Primary Tumor in Breast Cancer and Its Phenotype in Positive Lymph Nodes and Later Disease Recurrence (metastatic Breast Cancer): Results of the PRIMET-trial (WSG/DETECT)

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Background: For various and unknown reasons, tumor phenotype changes in ER/PR expression and or HER 2 status overexpression between primary tumor (PT) and disease recurrence (DR) in the course of disease. The clinical relevance of this possible changes between PT, lymph nodes (LN) at the time of primary breast cancer (BC) and recurrence remains unclear. In PRIMET we evaluate discordance rates between PT, LN and DR to find predictors for patient outcome and to establish a database and tumorbank for further analysis.

Materials and Methods: PRIMET is a prospectively planned, retrospective multicenter quality assurance study comprising BC phenotype in PT, its corresponding LN and DR. Included were patients of 11 centers in Germany, from the WSG trial group and the DETECT group, with BC diagnosed first from the early 1980s to 2010. Patients with unilateral BC with subsequent/synchronous local-regional and/or distant DR were included. A systemic chart review and in Cologne a LN subprotocol with central pathology was performed.

Results: 436 patients were entered into PRIMET. 414 had no evidence of a primary metastatic disease (M0). Median follow-up in patients alive at time of analysis (Oct 2010) was 73.1 months. Median disease free survival (DFS) was 45.1 months. Triple receptor status for PT and DR was available in 377 patients. Discordance rates were seen in 22% for ER, in 30% for PR and 22% for HER 2 status. Significant differences regarding post recurrence survival (PRS) and DFS were observed with persistent triple negative breast cancer (TNBC) being associated with particularly low DFS and PRS. In a subset of patients (n=20) tumor phenotype was analysed in corresponding LN at primary diagnosis. In 60% of those cases discordance regarding triple receptor expression was observed with a majority in difference between PT and LN.

Conclusions: The results of PRIMET show that the triple receptor status of PT and DR are associated with DFS and PRS. We provide evidence regarding phenotype changes in PT, LN and DR and its prognostic relevance. This confirms the national and international guidelines for re-verification of immunohistochemical status of PT, LN and DR.

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Efficacy of Aromatase Inhibitors in Male Breast Cancer - a Single Centre Experience

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Background: Male breast cancer is a rare cancer representing approximately 1% of all breast cancer cases. No randomised data exists to guide treatment. This case series shows the experience of 16 men treated with aromatase inhibitors for locally advanced or metastatic breast cancer in a single centre.

Materials and Methods: This is a retrospective review of all male breast cancer patients referred to Velindre Cancer Centre between 1997 and 2011.

Results: 64 patients were referred to Velindre Cancer Centre over the 14 year period.