171 days; P=0.015). Among patients with nonlytic lesions, multiple event analysis demonstrated a 12% reduction in the risk of skeletal complications for patients treated with zoledronic acid (n=188) compared with 226 pamidronate-treated patients (HR=0.878; P=0.385). Bone marker data for these patient subsets will be presented. Zoledronic acid was well tolerated with a long-term safety profile similar to that of pamidronate.

Conclusions: These data indicate that zoledronic acid is more effective than pamidronate for reducing the long-term risk of skeletal complications in patients with breast cancer, particularly those with at least 1 osteolytic lesion. Zoledronic acid is the only bisphosphonate to show superiority in a direct comparison with the active agent, pamidronate.

247 POSTER

Pre-operative chemotherapy with Navelbine (N) and Anthracycline in Locally Advanced Breast Cancer (LABC): A multicentric Egyptian Phase II trial

I. Abdel-Halim[1], A. Sabri[2], H. Tawfik[3], J. Gasmi[4]. [1]*Mansoura University, Oncology, Mansoura, Egypt;* [2]*Mantaria Hospital, Oncology, Cairo, Egypt;* [3]*Tanta University, Oncology, Tanta, Egypt;* [4]*Institut de Recherche Pierre Fabre, Oncology, Boulogne, France*

Navelbine and anthracycline are among the most active agents in the management of advanced breast cancer. Several clinical trials have demonstrated the high efficacy of this combination in advanced breast cancer (Pawlicki, The Oncologist 2002; Vici, JCO 2002). We conducted a multicentric phase II study to evaluate the activity in terms of pathological response rate and downstaging of the combination in locally advanced breast cancer.

Patients and Methods: from June 2002, thirty-four consecutive patients (pts) among the 40 planned have been enrolled in the study. Median age: 46 years (29–63), WHO PS: 0–1, median tumor size: 8 cm, clinical TNM staging was T2: 2 pts (6%), T3: 19 pts (56%), T4: 13 pts (38%), N0: 3 pts (9%), N1: 18 pts (53%), N2: 13 pts (38%), all pts were M0. Histological confirmation was performed by biopsy showing SBR I: 4 pts (12%), SBR II: 20 pts (59%), SBR III: 10 pts (29%). The chemotherapy consisted of 3 cycles of the combination of N: 25 mg/m^2 on day 1 & day 8 plus A: 50 mg/m^2 on day 1 or E: 75 mg/m^2 on day 1 on 3 week schedule. All pts were restaged after 3 cycles; pts showing clinical CR or PR received 3 additional cycles of the combination.

Results: twenty-eight pts were evaluable for clinical response and 34 pts for toxicity; 15 pts achieved a partial response and 8 pts a complete response for an overall response of 82%. The primary chemotherapy has allowed an impressive downstaging in these bulky diseases by reducing to 2 cm the median tumour size. Twenty-one pts went under surgery, 9 pts had a pathological complete response. A total of 169 cycles were administered with a median of 5 cycle/pt. The regimen was well tolerated. WHO neutropenia grade 3/4 was seen in 3 pts, one pt experienced grade 3 mucositis and another one grade 3 phlebitis. Nausea vomiting was moderate and alopecia was universal.

Conclusion: our results confirm that navelbine + anthracycline as pre-operative chemotherapy is a very active and safe regimen in locally advanced breast cancer allowing a high rate of pathological complete response.

248 POSTER

Efficacy and tolerability of combination docetaxel and cisplatin regimen in anthracycline pre-treated patients with advanced breast cancer

E. Szombara, I. Glogowska, R. Sienkiewicz-Kozlowska, T. Pienkowski, S. Jaczewska. *The Maria Sklodowska-Curie Memorial Cancer Center, Breast Cancer & Reconstructive Surgery Department, Warsaw, Poland*

Introduction: The combination of docetaxel (DTX) and cisplatin (DDP) is interesting because both of agents are active in metastatic breast cancer and options of systemic therapy in anthracycline pre-treated patients (pts) are limited. The efficacy and safety of DTX and DDP combinations in anthracycline pre-treated patients with locally advanced or metastatic breast cancer.

Material and Methods: 12 pts with advanced breast cancer were treated with combination of DTX (75 mg/m^2 iv d1q3 weeks) and DDP (75 mg/m^2 iv d1q3 weeks). Median age was 55 (range 34–66). One patient was treated because of locally advanced breast cancer, 11 pts because of metastatic disease with median number of metastatic sites 1.5 (range 1–4). All pts were previous treated with anthracycline: 8 as an neoadjuvant treatment, 4 due to metastatic disease. Median number of previous chemotherapy regimen – 1. All of patients were evaluable for toxicity and tumour response. The response was assessed according to WHO criteria.

Results: A total of 72 cycles were given to 12 patients (median 6, range 3–8). The objective response (OR) was observed in 8 patients (67%): CR in 2 patients, PR in 6 patients, SD in 3 patients (25%) and progression of disease (PD) in 2 patients. In the median follow up 13.7 months, median time to progression (mTTP) was 9.5 months. One patient died because of progression. In our group no severe toxicity was observed. The most common (grade 1 or 2) were: nausea and vomiting, asthenia, arthralgia and myalgia, diarrhea, polineuropathy, oedemas.

Conclusions: Combination of docetaxel and cisplatin is effective and safety regimen in anthracycline pre-treated patients with advanced breast cancer.

249 POSTER

Metastases of adenocarcinoma in axillary lymph nodes of unknown origin

J. Piekarski, P. Pluta, D. Nejc, A. Jeziorski. *Medical University of Lodz, Poland, Department of Surgical Oncology, Lodz, Poland*

Background: In patients presenting with metastases of adenocarcinoma in axillary lymph nodes, and no evidence of primary cancer on physical and radiological examination, the most probable source of metastases is undetected microfocus of breast cancer. Therefore in such patients, diagnosis of "occult" breast cancer is made. The incidence of the entity ranges form 0.3% to 1.0% of all breast cancers. However, the diagnosis of occult breast cancer does not necessarily mean that the primary focus must be in the ipsilateral breast. The best method of evaluation of such patients is magnetic resonance imaging of the breast. However the method is not universally available.

Objective: To summarize our experience with occult breast cancer patients in whom magnetic resonance was not performed.

Material and Methods: Study group was composed of twenty two patients with diagnosis of occult breast cancer operated on from January 1982 to December 2002 in our Clinic. The patients files were examined for details of treatment and results of pathological examinations.

Results: In 8 cases (36.4%) mastectomy was performed without the diagnosis of primary focus in the breast. In one case surgical biopsy of upper-outer quadrant of the breast revealed the presence of cancer. It was the only case when mastectomy was performed after the breast cancer diagnosis. Altogether, mastectomy was done in 9 women. In remaining 13 cases, mastectomy was not performed. In 63.5% of women (5/8) who underwent mastectomy despite lack of evidence of breast cancer, pathologic examination did not reveal the presence of cancer. In 53.8% (7/13) of women in whom mastectomy was not performed, primary focus was identified in the breast during follow-up. Altogether, the ipsilateral breast was identified as a source of axillary metastases in 50.0% of women from the studied group. In 45.5% of women the primary focus remained undetected. In one patient (4.5%), the primary focus of cancer was found 9 months after mastectomy in the ipsilateral kidney.

Conclusions: In patients with occult breast cancer efforts should be undertaken to identify the primary focus using modern imaging techniques. As mastectomy seems to be a gross over-treatment, more conservative methods of treatment are advised.

250 POSTER

Modalities in the routine use of trastuzumab (Herceptin®) in advanced breast cancer

C. Jackisch[1], W. Schoenegg[2], G. Krieger[3], U. Söling[4], P. Klare[5], B. Mohr[6], A. Hinke[7]. [1]*Klinik für Gynäkologie, Philipps-Univ. Marburg, Germany;* [2]*DRK-Kliniken Westend Abt. Gynäkologie, Berlin, Germany;* [3]*Hegau-Klinikum Singen, Germany;* [4]*Hämatolo.-okolog. Praxis, Kassel, Germany;* [5]*Gynäkolog.-Onkolog. Praxis, Berlin, Germany;* [6]*Onkolog. Praxis, Berlin, Germany;* [7]*WiSP Research Institute Langenfeld, Germany*

Background: Routine treatment of advanced breast cancer (BC) has been monitored in a postmarketing surveillance study in Germany.

Results: Data from 265 patients (pts) from 80 centers have been collected. About 75% of pts (n=196) received trastuzumab (T) plus concomitant chemotherapy (CT) (mainly paclitaxel, docetaxel, vinorelbine or capecitabine), and 69 pts received T alone. Endocrine therapy was administered for 55% of pts in the T alone group and 37% in the T+CT group. Mean age was 55.5 years (range 28–82). Mean time since initial diagnosis of BC was 4.1 yr in the T alone compared to 2.9 yr in the T+CT group. 84% of pts tested HER2 3+ by IHC, others were confirmed for HER2 positivity by FISH. ER/PR was positive in 59% of pts. Some pts had been pre-treated with cytostatic (53%) or endocrine (37%) treatment for advanced BC and with CT (70%) for early disease. Out of 94% of pts with distant metastasis at onset of T therapy, the liver was the most frequently involved organ in the T+CT group (52%). In contrast, T alone pts predominantly suffered from bone lesions (51%). Performance status at study entry was rather impaired with 53% categorized as ECOG 1 and another 21% as ECOG 2/3. Median duration of documented T treatment