the successful treatment of patients following completion of adjuvant trastuzumab suggests a role for trastuzumab rechallenge. Evidence for the benefit of continued anti HER-2 therapy "beyond progression" in MBC supports this approach. The scientific challenge, if recurrence is truly so rare, is to collect sufficient patient numbers to derive evidence based treatment recommendations in these patients.

56 Poster

Influence of neoadjuvant chemotherapy upon survival of patients with locally advanced stage II and III breast cancer

G. Christodoulidis[1], D. Xafis[2], K. Papakonstantinou[3], M. Spyridakis[1], E. Athanasiou[1]. *[1]University Hospital of Larisa, General Surgury Department, Larisa, Greece; [2]University Hospital of Dusseldorf, Gynecology Department, Dusseldorf, Germany; [3]Naval Hospital of Athens, Gynecology Department, Athens, Greece*

Background: Preoperative chemotherapy is able to improve surgical treatment by increasing the rate of breast conservation surgery. Response to preoperative chemotherapy is a predictor of long-term outcome and gives prognostic information after a short-term interval. The purpose of this study was to evaluate the extent of tumor downstaging, to determine the local regional recurrence rates, and to estimate the impact upon surgical planning and treatment strategies.

Patients and Methods: Between 2005 and 2009, 60 women with stage II or IIIA (T3N1) breast carcinoma including 19 with axillary node metastases shown on fine-needle aspiration (FNA) biopsy, were treated on three prospective neoadjuvant chemotherapy trials utilizing four cycles of 5-fluorouracil, doxorubicin, and cyclophosphamide (FAC, N = 32) or four cycles of paclitaxel (n = 28) followed by breast-conservation surgery.

Patients with significant tumor shrinkage after two cycles of chemotherapy underwent sonographically guided placement of metallic markers (n = 27) around the tumor site to facilitate later localization of the initial tumor site. After the neoadjuvant chemotherapy, patients underwent a segmental mastectomy with pathologically negative margins (n = 58) and axillary lymph node dissection. Postoperatively, all patients received four additional cycles of FAC. Postoperative radiotherapy was delivered to the breast after the completion of chemotherapy. The median follow-up was 32 months.

Results: The median tumor size was 3.5 cm at presentation and only 1.2 cm after neoadjuvant treatment. The primary tumor could not be palpated after chemotherapy in 25 patients (41.6%) of 60 patients presenting with a palpable mass and therefore required needle localization or ultrasound guidance for surgical resection. The response of primary tumor to neo-adjuvant chemotherapy was 58.3%, complete response 18% and partial response 50%. Patients with primary tumors $\leqslant$2 cm were significantly more likely than patients with larger tumors to have complete eradication of the primary tumor prior to surgery ($P < 0.001$). The 5-year local-regional recurrence rate was 3.6%. The median time to local-regional recurrence was 21 months.

Conclusion: These results suggest that primary (neoadjuvant) systemic therapy for locally advanced, stage II and stage III breast cancer may have a potential survival benefit. Neo-adjuvant chemotherapy resulted in significant down staging of breast cancer.

57 Poster

Neoadjuvant doxorubicin/cyclophosphamide followed by weekly paclitaxel for operable or locally advanced breast cancer: outcome analysis of 72 patients treated at a single institution

M. Tokar[1], M. Koretz[2], T. Hertz[1], O. Bloshitski[1], B. Delgado[3], N. Sion-Vardy[3], S. Ariad[1], M. Bayme[4], D.B. Geffen[1]. *[1]Soroka University Medical Center, Department of Oncology, Beer-Sheva, Israel; [2]Soroka University Medical Center, Department of surgery A, Beer-Sheva, Israel; [3]Soroka University Medical Center, Institute of Pathology, Beer-Sheva, Israel; [4]Soroka University Medical Center, Department of Surgery A, Beer-Sheva, Israel*

Background: To determine the response rate, treatment toxicity and survival of patients (pts) with operable or locally advanced breast cancer (OLABC) treated with neoadjuvant doxorubicin-cyclophosphamide (AC) followed by weekly paclitaxel (T).

Material and Methods: Between April 2003 and March 2006, 72 newly diagnosed pts with OLABC entered the treatment program, consisting of doxorubicin 60 mg/m^{2}and cyclophosphamide 600 mg/m^2 every three weeks for 4 cycles followed by paclitaxel 80 mg/m^2/week administered for 12 weeks. Eligibility criteria included early stage breast cancer (BC) with extent of local disease precluding cosmetically acceptable breast conservation (BCT), or locally advanced BC; and adequate hematologic, renal and cardiac function. Median age 49 (range 23−72) years. Clinical stage: T2 − 22.2%, T3 − 57% and T4 − 12.5%; N0 − 25%, N1,2 − 75%. Estrogen receptor (ER) positive (pos) − 52 (72.2%). Triple negative (neg) − 11 (15.3%). Post-operatively pts received radiotherapy and endocrine therapy as per standard indications. Of the 15 (20.7%) pts with Her-2 positive tumors 7 (8.7%) received trastuzumab for one year.

Results: All 72 pts were evaluable for response and toxicity. Median follow-up was 48.5 (range 7−72) months. BCT was achieved in 38 (52.8%) of pts. Clinical complete response was recorded in 7 (9.7%) pts after AC and 26 (36.1%) pts after T. The overall pathologic complete response (pCR) rate was 13.9% (95% Confidence Interval (CI) 6.9%-24.1%). In the ER pos group the pCR rate was 5.8% (95% CI 1.2–15.9%) and in the ER neg group 35% (95% CI 15.4–59.2%). Five-year overall survival and disease free survival for the entire cohort was 76% and 62%, respectively. All side effects were well manageable. There were no treatment related deaths. Neutropenic fever occurred in 10 pts (13.9%). Grade III−IV myalgia and grade III−IV neutropenia were noted in 7 (9.7%) pts each.

Conclusion: The overall pCR rate and its CI include values previously reported for doxorubicin and taxane containing regimens. AC-weekly T is a well tolerated preoperative regimen suitable for routine practice which enables BCT in a majority of pts. A large proportion of pts, particularly with ER pos tumors do not achieve pCR. New approaches such as tailoring of therapy to the molecular signature of the tumor may improve results.

58 Poster

Exemestane in primary breast cancer patients who are eligible to receive neoadjuvant hormonal therapy

B. Sancho[1], I. Gonzalez[2], R. Noguero[3], A. Garcia[4], L.T. Gomez[5], M. Martin[6], S. Lujan[7], L.P. Albaina[8], J.L. de Pablo[9], G. Hernandez[10]. *[1]Hospital 12 de Octubre, Gynaecology, Madrid, Spain; [2]Hospital Universitario Río Ortega, Gynaecology, Valladolid, Spain; [3]Hospital de Parla, Gynaecology, Madrid, Spain; [4]Hospital Central de Asturias, Gynaecology, Oviedo, Spain; [5]Hospital de Valdecilla, Gynaecology, Santander, Spain; [6]Hospital de Galdakano, Gynaecology, Vizcaya, Spain; [7]Hospital de Cruces, Gynaecology, Bilbao, Spain; [8]Hospital Juan Canalejo, Gynaecology, La Coruña, Spain; [9]Hospital de Txagorritxu, Gynaecology, Vitoria, Spain; [10]Clinica Quirón, Gynaecology, Madrid, Spain*

Background: Primary hormonal therapies have demonstrated great activity in elderly women with locally advanced and hormone-dependent breast tumors. However, there is not so much information in operable disease specially outside elderly population. Exemestane, an esteroidal aromatase inhibitor, has demonstrated activity in the adjuvant and in the metastatic setting; smaller trials have also shown its efficacy in the neoadjuvant setting. The primary aim of this multicentre study was to analyze the efficacy of exemestane as a neoadjuvant treatment.

Material and Methods: Postmenopausal breast cancer patients (pts) with histologic diagnosis of infiltrating breast carcinoma and tumors expressing >50% ER+ were eligible. Tumor had to be measurable at least in one dimension by clinical exam, ECO, Mammography or MRI; no previous hormonal treatment/chemotherapy was permitted. At baseline, all p were considered non-eligible for breast-conserving surgery. Response was estimated by mammography and/or MRI every 3 months (RECIST criteria). Secondary endpoints were rate of breast-conserving surgery and rate of Patological Complete Response. Consecutive eligible pts received oral exemestane 25 mg/d for 6 months before surgery, unless disease progression or unacceptable toxicity were seen.

Results: 68 pts were included in the study. Patient characteristics were median age 83 (56.5–93.9); tumor stage: T1: 11, T2: 22, T3: 9 and T4: 11; nodal involvement was N0: 20, N1: 7, N2: 5 and N3: 2; tumor grade I:11, II: 24, III: 6 and 7 unknown. 38 pts have been evaluated for response, 7 were lost of follow up and 3 were screening failure and 1 remain in treatment (end 20 Nov). Up to date, 4 CRs (10.5%) and 27 PRs (71%), 4 SD (10.5%) and 3 PD (8%) out of 38 evaluable pts by any of the imaging methods or clinical exam.

At the time of this analysis, only 9 pts have been recovered for breast surgery and 6 continue with hormonotherapy for different reasons. Surgery offered to these pts were conservative in 4 pts and mastectomy in 5 pts. Partial pathologic remission was seen in 8 pts and in 1 there was a progression. During exemestane treatment one patient was changed to Letrozol due to toxicity.

Conclusions: Exemestane was found to be a well-tolerated and effective neoadjuvant treatment in elderly patients with a breast cancer tumor. Follow-up regarding the proportion of conservative surgery will be available shortly.