

**Conclusions:** These preliminary data confirm the efficacy and safety of the proposed weekly XT combination as neoadjuvant therapy for LABC. Weekly XT is particularly attractive for treating HER2-positive tumours, because it can be combined with trastuzumab, the latter being cleared during the perioperative phase, avoiding the risk of overlapping cardiac toxicity with anthracyclines. The trial has been extended to other Belgian centres in order to specifically accrue pts eligible for receiving XT+trastuzumab.

376

PUBLICATION

#### Sentinel node biopsy after neoadjuvant chemotherapy in breast cancer

A. Conti<sup>1</sup>, C. Ferraris<sup>1</sup>, M. Gennaro<sup>1</sup>, M. Zambetti<sup>2</sup>, M. Greco<sup>1</sup>. <sup>1</sup>Istituto Nazionale Tumori, Breast Unit-General Surgery, Milan, Italy; <sup>2</sup>Istituto Nazionale Tumori, Medical Oncology A, Milan, Italy

**Background:** to evaluate the accuracy and feasibility of Sentinel Node Biopsy technique in patients with operable breast cancer clinically node negative after neoadjuvant chemotherapy irrespective of the initial stage.

**Material and methods:** the subject of this study was 20 consecutive patients, affected by T2 N1 M0 core biopsed breast cancer, treated at Istituto Nazionale Tumori, Milano. Age ranged from 24 to 58 years. They underwent neoadjuvant taxanes-anthracycline containing chemotherapy. Axillary mapping was performed in all patients using both lymphoscintigraphy with radioactive colloid and blue dye injection. After this a three-levels axillary dissection was performed after sentinel node biopsy at the time of definitive surgery. Breast conserving treatment was allowed in 11 patients; the remaining received total mastectomy.

**Results:** the detection rate of sentinel node was 20/20 with a full concordance between the two methods (blue dye and hot). Nodal involvement was found in 7 patients in agreement with sentinel node status. The sentinel node was the only positive in three of these patients. In this series 12 patients was node negative and false negative rate was 1/20.

**Conclusions:** neoadjuvant chemotherapy downstages axillary lymph nodes and sentinel node biopsy seems to be as accurate and feasible to stage axilla as in case of sentinel node biopsy performed during primary surgery.

377

PUBLICATION

#### Efficiency of Toremifene in the treatment of diffuse mastopathy

J. Aliyev, R. Jafarov, I. Kazimov, T. Najafov, M. Mamedov, R. Zeynalov, I. Musayev, J. Gasanzadeh, N. Dadasheva. *Oncologic research center, Baku, Azerbaijan*

**Background:** Diffuse mastopathy is the most common disease of breast of women. By the data of various authors the frequency of mastopathy occurs at the reproductive females is 24–40%. The rate of annual morbidity increase is 8–10%. The pathogenetical treatment of diffuse mastopathy is therapy with hormonal drugs. The aim of the research was comparative study of efficiency of Toremifene (second generation antiestrogen) in the complex therapy of patients with diffuse mastopathy.

**Materials and methods:** 254 patients with diffuse mastopathy were involved in this trial. Patients were divided on 2 groups. Patients of first group (n = 136) were treated with Toremifene at a dose of 20 mg once from 5-th to 25-th day of regular menstrual cycle or daily with impaired menstrual function and in menopause. The patients of second group (n = 118) were treated with Mastodyn. Duration of treatment in both group patients was 6 months. Efficiency of the treatment was determined with following criteria: dynamics of pain syndrome and changes of mammographic density of breast.

**Results:** In the group of patients treated with Toremifene 122 (89.7%) patients had complete response, which was defined as the disappearance of any pain, 14(10.3%) had reduction of pain. In the group of patients treated with Mastodyn, results were following: 22 (18.7%) patients had complete response, which was defined as the disappearance of any pain, 64 (54.2%) had reduction of pain, 32 (27.1%) had no response. The dynamics of changes of mammographic density in breast was following: in the first group 92 (67.6%) patients had the normal mammography, 29 (21.3%) patients had reduction of indurations, 15 (11.1%) patients had no changes in mammography. The results of second group patients were following: 11 (9.3%), 25 (21.2%) and 82 (69.5%) patients respectively.

**Conclusions:** The results of our study had demonstrated high efficiency of Toremifene compared to fitotherapy with Mastodyn in the treatment of diffuse mastopathy.

378

PUBLICATION

#### Risk of breast cancer associated with the use of hormone therapy. Retrospective analysis using a logistic regression model

F. Lumachi<sup>1</sup>, A.C. Frigo<sup>2</sup>, U. Basso<sup>3</sup>, A.A. Brandes<sup>3</sup>, M. Ermani<sup>4</sup>.

<sup>1</sup>University of Padua, School of Medicine, Breast Unit, Endocrinesurgery, Dept Surg & Gastroent Sciences, Padova, Italy; <sup>2</sup>University of Padua, School of Medicine, Department of Environmental Medicine & Public Health, Padova, Italy; <sup>3</sup>Azienda Ospedaliera di Padova, Medical Oncology, Padova, Italy; <sup>4</sup>University of Padua, School of Medicine, Section of Biostatistic, Department of Neurosciences, Padova, Italy

**Background:** Breast cancer (BC) is the most common cancer among women and a significant global health problem. Several external and environmental risk factors (RF) have been reported, including the use of oral contraceptives and hormone replacement therapy. The aim of this study was to obtain data on the BC risk of women residing in the Northeast of Italy who take oral contraceptives and estrogen replacement therapy, comparing women who take hormone therapy with those who do not.

**Patients and Methods:** We retrospectively reviewed data regarding a series of 404 consecutive women (median age 57 years, range 26–89 years) who underwent curative surgery for primary breast cancer (pT1a = 3.7%, pT1b = 17.3%, pT1c = 35.4%, pT2 = 36.6%, pT3 = 7.0%). Cases were age-matched with a group of 407 patients (controls) without history of BC. Family history of BC, menstrual and reproductive factors, smoking, alcohol abuse, use of oral contraceptives and hormonal replacement therapy, and body mass index (BMI) were considered as risk factors. Odds ratios (OR) at 95% confidence interval (CI) were calculated for the variables considered as risk factors.

**Results:** Age at menarche (12.3±1.6 vs. 12.9±1.6 years), age at first pregnancy (25.34.4 vs. 24.2±3.8 years), and duration of breastfeeding (10.0±8.6 vs. 13.7±10.0 months) were significantly (p<0.01) different between cases and controls. Weight at birth, history of BC in mother, smoking, alcohol abuse, pregnancy after 30 years, and age at menopause were not RF in our patients. Multivariate analysis using a logistic regression model showed that history of BC in sisters (OR = 10.6, 95%CI: 2.7–41.1), menarche before 12 years (OR = 2.2, 95%CI: 1.5–3.1), use of oral contraceptives (OR = 2.2, 95%CI: 1.5–3.3), use of estrogen replacement therapy (OR = 2.1, 95%CI: 1.4–3.0), and BMI > 24 (OR = 1.9, 95%CI: 1.3–2.6) represented independent RF. Moreover, the duration of estrogen replacement therapy was significantly (p<0.01) different between of cases and controls (43.7±30.2 vs. 30.6±23.3 months).

**Conclusions:** Several parameters traditionally considered in epidemiological studies did not result useful as RF suggesting that environmental and external factors should be considered to correctly select high risk population. In conclusion, in our population, the use of both oral contraceptives and hormone replacement therapy do not represent strong RFs in patients with BC.

379

PUBLICATION

#### Neo-adjuvant sequential chemotherapy with FEC followed by docetaxel for primary breast cancer. A phase II study. Interest of NMR imaging for predicting pathological response

C. Focan, M. Graas, F. Kreutz, M. Lastra, B. Bourdoux, P. Cusumano, J.M. Dewandre, J. Weerts, D. Focan-Henrard. *CHC-Clinique St-Joseph, Medical Oncology, Liege, Belgium*

Women presenting with a primary breast carcinoma ≥3 cm were proposed to receive 4 courses of FEC-100 followed by 4 courses of docetaxel (TXT) as pre-operative neo-adjuvant chemotherapy. 58 patients (median age: 52; range: 27–73; stages: IIA: 17; IIB: 21; IIIA: 6; IIIB: 13) were included in the study between 04.2001 and 05.2005.

A median number of 8 courses could be delivered. The major toxicities were alopecia (universal) and granulocytes toxicity (gr 3–4: 81% of patients during FEC vs 62% under TXT). However, dose-adaptations or delays were rare (respectively 11.5 and 3.8%). Also, nausea-vomiting or diarrhea (3.8%) or cutaneous toxicity (5.8% under TXT) were uncommon; no significant cardiac event could be observed.

46 patients are actually fully evaluable for response. After 4 FEC, 93% patients were clinically responding (7% complete); after 4 further TXT, 24% were recorded as complete responders according to clinical examination and standard echo- and mammography. 34 patients could be evaluated by NMR after C8: 97% were considered responding, 29% completely. This assessment predicted for pathological response in 80% cases. In fact 13/44 pathological complete responses (pCR: 30%) were recorded with also 2 patients in almost pCR (1 microscopic node metastase; 1 intracanalicular residual carcinoma). The value of PET-CT for predicting pCR is actually under investigation.

Thus, 71% of patients could benefit from a limited conservative surgery. Further treatment was classical (radiotherapy ± curietherapy;