

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.

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PUBLICATION

Sentinel node biopsy after neoadjuvant chemotherapy in breast cancer

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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.

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PUBLICATION

Efficiency of Toremifene in the treatment of diffuse mastopathy

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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 Mastodynol. 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 Mastodynol, 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 Mastodynol in the treatment of diffuse mastopathy.

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

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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.

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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

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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;

hormonotherapy; immunotherapy as appropriate). At 3 years follow-up, 66% of patients are still disease free and 97% alive.

In conclusion: our results are in the line of most recent reports dealing with the possibility to enhance pCR for (moderately) advanced early breast cancer with an association of anthracyclines and taxanes. This sequential protocol was, in our hands, better tolerated than our previously reported epirubicine-taxol schedule (Anticancer Res 2005, 1211–18) with no cardiac toxicity. **Keywords:** anthracyclines, taxanes, early breast cancer

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PUBLICATION

The clinical outcome of 1034 Chinese patients after adjuvant therapies for female breast cancer, Hong Kong AR, China

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Background: The benefits of adjuvant therapies in breast cancer are well established in western populations but there are few large reports on the clinical outcome in Chinese patients (pts). This retrospective review analyzed clinical endpoints of local control (LC), axillary control (RC), metastasis-free survival (MFS), overall survival (OS), and relapse-free survival (RFS) in such pts after either adjuvant systemic or loco-regional (LR) therapies or both. In our institute, local chest wall radiotherapy (RT) after mastectomy is indicated when T size is ≥ 4 cm, resection margin is ≥ 0.5 cm and lymphovascular permeation (LVI) is present. Regional lymph node (LN) RT is indicated when there are ≤ 4 involved axillary LN (LN+), extensive extracapsular invasion (EC) and inadequate number of LN dissected. Adjuvant chemotherapy is indicated when pts have LN+, T size > 2 cm or grade 3 histology. Classical CMF and Tamoxifen constituted the majority of adjuvant chemotherapy and hormonal therapy regimens.

Material and methods: 1034 pts with invasive breast cancer who had received adjuvant therapy from 1996 to 1999 were stratified according to age, T stage, resection margin status, LVI status, menopausal status, estrogen-receptor (ER) status, progesterone-receptor (PR) status, LN status and presence or absence of LN EC before analysis. Overall, 346, 551, 80, and 45 pts had stage T1, 2, 3, and 4 cancers respectively. Among those 90.5% pts with invasive ductal carcinoma, 42.6%, and 38.3% had histological grades 3 and 2 respectively. ER and PR positive tumors were found in 58.4% and 48.8% pts respectively. There were 52.7% LN+ pts. While 35.6% pts received LR, RT and 29.6% local RT only, 55% pts had chemotherapy and 58.4% pts hormonal therapy.

Results: The median age was 54.7 (range: 24–102) and 52.9% pts were menstruating at presentation. Menopausal pts had higher rate of LN+ and higher T stage ($p < 0.01$). At a median follow-up of 56 months, the 5 year LC, RC, MFS, RFS and OS rates were 95.4%, 98.2%, 80.1%, 78.6% and 83.2% respectively. Altogether, 48 (4.5%), 20 (1.9%) and 217 (21%) pts had local, axillary and systemic relapses respectively. Statistically significant prognostic factors for various clinical endpoints are tabulated as follows.

Clinical endpoints	Significant prognostic factors in multivariate analysis
LC	T stage, PR status, LVI status
RC	nil
MFS	Age, menopausal status, T stage, LN status, ER status, LVI status
RFS	Age, LN status, PR status, LVI status
OS	Age, menopausal status, T stage, LN status, tumor grade, LVI status

Conclusion: This report demonstrated in Chinese pts the clinical significance of LVI and other common prognostic factors. The local and axillary control rates were excellent but there was room for improvement in preventing distant metastasis and especially in older pts. The increased use of anthracycline-based chemotherapy after 1999 may improve the outcome of subsequent pt cohorts.

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The relationship between serum cholesterol level and axillary lymph node status in breast cancer patients

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Background: Estrogen is known to decrease total cholesterol and low density lipoprotein levels whereas it increases high density lipoprotein level. The aim of the study is evaluation of the association between serum total cholesterol level, tumor size and axillary status.

Material and method: In this retrospective study, 150 patients who underwent breast cancer surgery and adjuvant chemotherapy were

evaluated for axillary lymph node status, tumor size and serum total cholesterol level. Measurement of serum total cholesterol level within 3 months before or after cancer surgery was accepted as reference value. Body mass index (BMI) was calculated for all patients. None of them had hypothyroidism, hyperthyroidism, diabetes mellitus and alcohol abuse. Level above 200 mg/dL for serum total cholesterol was defined as hypercholesterolemia.

Results: Characteristics of patients are listed in Table 1. BMI was found significantly associated with age, menopausal status and total cholesterol level ($p = 0.0001$, $p = 0.012$, $p = 0.038$; respectively). There was no correlation between serum total cholesterol level and number of resected axillary lymph nodes ($p = 0.069$). Number of positive axillary lymph nodes was inversely correlated with serum total cholesterol level ($r = -0.189$, $p = 0.022$). Serum total cholesterol level was determined as an independent prognostic factor for evaluating number of positive axillary lymph nodes in multivariate analysis ($p = 0.01$). The relationship between high serum total cholesterol level and number of positive axillary lymph nodes is shown in Table 2 ($p = 0.05$).

Table 1: Characteristics of patients (median values)

Age (year)	51
Tumor size (cm)	3
Total number of resected axillary lymph nodes	17
Number of positive axillary lymph nodes	1
BMI (kg/m^2)	28.4
Serum total cholesterol level (mg/dL)	208
Premenopausal/postmenopausal (%)	56/44

Table 2: The relationship between serum total cholesterol level and number of positive axillary lymph nodes.

axillary Lymph node status (N)	Rate of high serum total cholesterol level (%)
0	61.9
1–3	72.2
4–9	59.1
≥ 10	38.5

Conclusions: Despite small number of patients in this study, we found an inverse correlation between serum total cholesterol level and number of positive axillary lymph nodes. The effect of BMI in breast cancer is known. But relation with total cholesterol level, axillary involvement and the effect on survive, should experienced by large number of studies.

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PUBLICATION

Diagnostic trends over 15 years in patients with breast cancer. Importance of having a computerised clinico-pathological database

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Introduction: To be able to conduct effectively a clinical or basic research study on cancer patients, an easy access to the maximum information of the patients is needed.

Objectives: To create a centralised computerised database from the clinical histories of breast cancer patients.

Design: Review of the clinical histories of all the patients with breast cancer diagnosed and treated at the 3 University Hospitals of Las Palmas de Gran Canaria, Canary Islands, Spain. From each clinical chart we collected more than 70 variables and arranged them in 5 major groups: antecedents, clinical diagnosis, anatomical and pathological diagnosis, treatment, and clinical course of the disease.

Results: Between Jun 2003 and May 2005, 2150 cases were incorporated into the database, corresponding to patients diagnosed after January 1975. Here we want to highlight 2 aspects about the variables behaviour during part of the diagnostic period: 1) the detection by mammography increased progressively from 9.6% in 1990–94, to 27.4% in 95–99, and to 53.9% in