

stratified sample, and results were projected to reflect the total population in each country using known population incidences – US: gender, age, race/ethnicity, and educational distribution from 2003 Current Populations Survey Annual Demographic File; Europe: gender, age, and education distribution from the International Data Base of the US Census Bureau and Organization for Economic Cooperation and Development.

Results: 67,198 adults completed the National Health and Wellness Survey (Table). In the 6 months preceding the survey, in all countries, those with breast cancer more often than those without visited a general practitioner/family practitioner (GP/FP) and an oncologist; in the US, UK, and Germany, an internist; and in France and Germany, a gynecologist (women). In the UK, breast cancer respondents visited rheumatologists more often than oncologists. Visits to GP/FPs and oncologists (all countries) and internists (US, Germany) were variably higher for breast cancer respondents than for those without breast cancer. More respondents with breast cancer than without visited an emergency room or were hospitalized in the prior 6 months in the US, UK, and Germany. In the US, breast cancer respondents frequently used a doctor as a source of medical information, followed by the Internet, pharmacist, nurse/nurse practitioner, and family/friend (Table). Other countries also used these sources, but to differing degrees. Breast cancer respondents in all countries ranked medical professionals (doctors, pharmacists, nurse/nurse practitioners) as most trustworthy and media (newspaper/magazine, TV/radio) as least trustworthy sources of medical information.

Demographics and selected results of the National Health and Wellness Survey

Breast cancer status	US (n = 40,730)	UK (n = 8,393)	France (n = 9,011)	Germany (n = 9,064)
No, n	40,137	8,329	8,938	9,005
Mean age, y	44	47	47	47
Female, %	51.2	51.3	50.6	50.9
Yes, n (%)	593 (1.5)	64 (0.7)	73 (0.8)	59 (0.7)
Mean age, y	61	64	61	67
Female, %	99.7	96.2	99.2	95.5
Top 5 frequently used sources (%)	Doctors (48.4) Internet (26.3) Pharmacists (21.2) Nurse/NP (17.3) Family/friend (14.0)	Doctors (36.3) Nurse/NP (20.7) Family/friend (19.1) Pharmacists (16.7) Internet (10.0)	Doctors (50.6) Pharmacists (22.3) Nurse/NP (13.0) Family/friend (10.5) Internet (8.9)	Doctors (30.4) Internet (23.6) Pharmacist (21.9) Family/friend (19.0) Health insurance (23.6)

NP = nurse practitioner.

Conclusions: Overall, there were no substantial differences in consultation patterns between breast cancer and non-breast cancer respondents in the countries investigated; however, there were country-specific differences in how medical information was obtained by those with breast cancer.

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POSTER

Locoregional recurrence after conservative treatment for invasive breast carcinoma: the effect on survival and distant metastasis

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Background: Patients with invasive breast cancer submitted to conservative treatment must be followed for a long period of time to ensure the efficacy of the procedure regarding locoregional control. This study was performed to analyze the outcome and the relationships between locoregional recurrence (LRR) and, distant metastasis (DM) and survival.

Material and methods: Fifteen-year prospective study including 470 patients with early breast cancer, stage I and II, who underwent breast conservative treatment. Tumor size, nodal status, age, menopausal status, histological grade and LRR were analyzed for their ability to predict overall survival, disease-specific survival and distant disease-free survival.

Results: With a median follow-up time of 6.6 years (3 months–19.1 years), there were 19 LRR at their first site of recurrence and 53 distant metastasis. On univariate analysis, patients with LRR had a lower 10-year overall survival and DM-free survival: $61 \pm 12\%$ vs. $85 \pm 2\%$ (log rank = 8.06, $p < 0.005$) and $62 \pm 11\%$ vs. $87 \pm 2\%$ (log rank = 10.94, $p < 0.001$), respectively. Tumor size > 2 cm, positive lymph nodes and histological grade III were also significantly related to lower overall survival and DM-free survival. On multivariate analysis, nodal status, histological grade III and LRR (either as a categorical or as a time-dependent variable) were significantly related to overall, specific and DM-free survival, whereas tumor size had only a borderline effect on specific and distant disease-free survival.

Conclusions: LRR appears to be a significant predictor of DM and survival and patients who sustain early LRR tend to display a more aggressive clinical course

Publication

Breast cancer – early disease

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PUBLICATION

Biochemical markers of the risk for cardiovascular disease in women with early breast cancer treated with anastrozole

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Background: Endocrine therapy for breast cancer targets estrogen – one of the major regulators of lipid metabolism. Newer generation aromatase inhibitors, such as anastrozole, actively suppress synthesis of estrogens from androgenic substrates. In some previous studies the effect of anastrozole on lipid profile was analyzed in patients with advanced/metastatic disease and/or pretreated with tamoxifen, both of which may interfere with lipid metabolism. In this study we evaluate the effect of anastrozole on lipoprotein / lipid profiles of patients with early breast cancer when used in adjuvant setting.

Material and methods: Fasting blood samples were taken from 54 postmenopausal women (median age: 64, range: 41–83 years). Serum concentrations of apolipoprotein A-I (APO-A-I), apolipoprotein-B (APO-B), triglycerides, total cholesterol (T-CH), high density lipoprotein cholesterol (HDL-CH), low density lipoprotein cholesterol (LDL-CH) as well as body mass index (BMI) values were prospectively measured at baseline and 1, 3, 6, 12 months afterwards. All the patients completed 12 months anastrozole administration.

Results: We did not observe any statistically significant changes in apolipoproteins and lipid profiles as well as the BMI values during anastrozole therapy. Moreover, the risk of cardiovascular diseases as measured by atherogenic ratios (TCH/HDL-CH, LDL-CH/HDL-CH and APO-A-I/APO-B) remained unchanged throughout anastrozole administration.

Conclusion: Anastrozole – when used in the adjuvant setting in women with early breast cancer – did not have any detrimental influence on biochemical markers of cardiovascular risk.

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PUBLICATION

Neoadjuvant capecitabine (X) plus docetaxel (T) for patients (pts) with locally advanced breast cancer (LABC): preliminary safety and efficacy data

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Background: The 3-weekly XT combination has significant activity in metastatic breast cancer, resulting in significantly superior survival, time to progression and response rate compared with T alone. Both drugs are synergistic with trastuzumab in HER2-positive tumours. This single-centre phase II study evaluated the efficacy and safety of weekly XT as neoadjuvant therapy for LABC.

Materials and methods: Pts with newly diagnosed invasive stage III inoperable breast cancer (cT4 and/or cN2–3) received X (900 mg/m² orally bid d1–14) plus T (36 mg/m² i.v. d1&8) every 3 weeks for 6 cycles, followed by surgery and radiotherapy. Pts with HER2-positive tumours (IHC 3+ or FISH+) also received trastuzumab (8 mg/kg on d1 of the first 3-weekly cycle and 6 mg/kg on d1 of subsequent cycles). Safety was evaluated after each cycle, clinical response after 3 and 6 cycles, and pathological complete response (pCR) postoperatively. pCR was defined as no residual invasive tumour in breast and axilla.

Results: To date, 19/34 pts have completed neoadjuvant chemotherapy and surgery. Baseline characteristics are as follows: median age 50 years (range 25–74), median ECOG PS 0 (range 0–1), ER/PR/HER2+ status 68/59/21%. The most common treatment-related adverse events (all grades) were diarrhoea (63%), hand-foot syndrome (HFS, 63%), nail changes (63%), peripheral neuropathy (58%) and lacrimation (56%). The most frequent grade 3/4 treatment-related events were diarrhoea (21%), HFS (10%) and anorexia (10%). Dose reductions were applied because of grade 2/3 adverse events (mucositis, HFS, diarrhoea, peripheral neuropathy and skin rash) in 5 pts and because of neutropenic fever in 1 pt. Therapy was prematurely interrupted because of disease progression (1 pt), capillary leak syndrome (1 pt), psychological intolerance (1 pt) and infection (1 pt). Median and mean dose intensities were 100% and 97% for T and 100% and 93% for X. The overall response rate was 79%, including 2 CRs and 13 PRs. A further 2 pts had stable disease. pCR was achieved in 2 pts who completed 6 cycles of XT. Most pts (75%) received postoperative anthracycline-based chemotherapy (4–6 cycles of FEC100) without unexpected toxicity. All pts with hormone receptor-positive tumours received locoregional radiotherapy and adjuvant hormonal therapy.

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 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.

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PUBLICATION

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;