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Tolerance of concurrent adjuvant trastuzumab and radiotherapy, involving in most cases the internal mammary chain, for breast cancer: results from a prospective study

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Background: To evaluate the tolerance of a concurrent adjuvant trastuzumab (T)–radiotherapy (RT) for breast cancer (BC), especially in the case of internal mammary chain (IMC) irradiation.

Material and Methods: Prospective study of 106 patients (pts) treated at the Institut Curie (IC) between 06/2003 and 03/2007 by concurrent T-RT for non-metastatic BC. The perfusion of T started either with or after chemotherapy. RT consisted of either whole breast (+/− boost) or chest wall normo-fractionated irradiation. When indicated, IMC and supra/infra-clavicular lymph nodes were also irradiated. Left ventricular ejection fractions (LVEF) were assessed at baseline, before start of RT (pre-RT), after completion of RT and then every 4−6 months with either echocardiography or multiple gated acquisition scanning. All toxicities were evaluated using CTCAEV3.

Results: Median age was 52 years (range: 25−70). Chemotherapy with anthracycline was administered in 92% (97 pts), with an epirubicine median total dose of 496 mg/m^2. All but two pts (treated weekly) received T every three weeks (8 mg/kg followed by 6 mg/kg) for a median duration of 11 months (3−40). LVEF at pre-RT was $\geqslant$50% in 99 pts (100%, 7 missing data). The treated breast was the left one in 44% (47 pts). The IMC was irradiated in 83% (88 pts) and the left side IMC in 38% (40 pts).

After a median follow-up of 28 months (range: 14−60 months), 105 pts (99%) were alive and 1 had died of cancer progression.

Acute skin reactions occurred in 103 pts: 87 grade 1, 14 grade 2 and 2 grade 3. Acute esophagitis occurred in 13 pts: 10 grade 1; 2 grade 2, and 1 grade 3; all had received concurrent radio-chemotherapy.

A grade $\geqslant$2 left ventricular systolic dysfunction occurred in 5 pts: 3 asymptomatic grade 2 (i.e. LVEF 40%-50%), 1 reversible grade 2 with myocardial infarction and 1 reversible grade 3 (i.e. LVEF 20%-40%). Of 101 pts with sequelae and toxicity assessments after 6 months, late telangiectasia grade 1 occurred in 5 pts, local pain in 22 (19 grade 1 and 3 grade 2), fibrosis grade 1 in 16, and grade 1 dyspnoea in 1 pt.

Conclusion: In this prospective study of breast cancer patients treated with, in most cases, anthracycline-based chemotherapy and IMC irradiation, concurrent trastuzumab-radiotherapy was deemed acceptable. Further follow-up is still needed.

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The physical activity level after the treatment for breast cancer: one-year follow-up

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Background: The physical activity level after the treatment for breast cancer becomes more and more important because of the increasing number of breast cancer survivors. The pattern of change of the physical activity level over time among breast cancer patients is not investigated in many studies. In addition, there is a limited amount of information about the predictive factors for a decreased physical activity level twelve months after the surgery in comparison with the preoperative level.

Material and Methods: Patients with a primary breast cancer (N = 267) filled in the Physical Activity Computerized Questionnaire before the breast surgery and 1, 3, 6 and 12 months after the surgery. This questionnaire collects information about the occupational, sport and household activities of the patient. It registers also patient-related factors, as age, body weight, body height, marital status and educational level. Disease-related factors, as tumour stage and lymph node stage, and treatment-related factors, as type of breast surgery, surgery at the dominant side, type of axillary surgery, level of axillary surgery, radiotherapy, chemotherapy and hormonal therapy, were abstracted from the medical file of the patient. In addition, 12 months after the surgery the arm volume and the shoulder mobility was measured of both arms.

Results: The total activity level of the breast cancer patients was decreased with 14% (34 MET-hours/week) the first month after surgery and respectively with 12% and 9% after 3 and 6 months. After one year, the activity level was still significantly decreased with 6% (14 MET-hours/week). At 12 months, only 79 of 145 preoperatively employed patients (54%) were working and 119 of 144 preoperatively sporting patients (83%) were doing some sport. Furthermore, the household activities were still decreased with 16% (6 MET-hours/week). At 12 months after the surgery, a higher decreased physical activity level compared with the preoperative level was associated with a lower age of the patient (<60 year) and having received chemotherapy. No association could be found with the other patient, disease and treatment-related factors.

Conclusions: The study shows that one year after the surgery for breast cancer, the physical activity level is still significantly decreased. Breast cancer patients and in particular those at risk for a decreased physical activity level should be detected and stimulated to increase their activities.

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Consumption of tranquilisers, chemotherapy and long term cognitive impairment in French young breast cancer women

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Background: Cognitive impairment (CI) is common just after cancer treatments, but little is known about long term effects of chemotherapy on cognitive function

Materiel and Methods: since July 2005, all consecutive women included in the registry of the National Health Insurance Fund (NHIF) for a diagnosis of primary breast cancer, aged 18−40 years and living in South Eastern France have been asked to participate in a 5 years follow-up, including a mailed self-questionnaire in the month after diagnosis and then telephone interviews. Medical record is yearly collected from physicians, and data about psychotropic and hormonal therapy drugs delivery are collected through the NHIF database. Until March 2009, 153 women answered the 10, 16, and 28 months interviews. At each interview, cognitive impairment (CI) was defined as self-report of frequent memory loss and attention deficits.

Results: Of the 153 women, 9% had a stage 0 tumour, 32% a stage I, 43% a stage II and 16% a stage III. All had surgery, 79% chemotherapy and 90% radiotherapy. Hormonal adjuvant therapy was prescribed to 54.2%, 64.1% and 64.1% during the respective periods: in the 10 months after diagnosis, 10 to 16 months after diagnosis and 16 to 28 months after diagnosis. In parallel, 60.1%, 31.4% and 34.0% were delivered tranquilisers during the same three periods. CI was reported by 40.5%, 38.2% and 39.2% at the 10^h, 16th and 28th month's interview respectively. Tranquilisers delivery was associated with CI self-report at each interview, chemotherapy was only associated with CI self-report at the 28th month interview. In the 28 months multivariate analysis, besides chemotherapy and tranquillisers consumption, a low level of education, and not being a French native woman were also associated with CI. Age, pre-existing cognitive troubles, and hormonal adjuvant therapy were unrelated to self-report of CI.

Conclusion: More than one third of young women report CI in the 2 years after breast cancer diagnosis. In the first months after diagnosis, CI self-report is mostly associated with psychological factors and tranquillisers consumption. Two years after, women who received chemotherapy are more likely to complain about CI, irrespective of their consumption of tranquillisers. Physicians should better consider long-term complains about CI in women who received chemotherapy, as CI may compromise the return to a "normal life" especially among those who suffer from psycho-social vulnerabilities.

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Prevalence of lymphoedema 5 years after breast cancer surgery

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Background: Lymphoedema is a frequent complication after breast cancer surgery. Lymphoedema can be defined as a volume difference of more than two hundred millilitres between affected and unaffected arm, a difference between the sum of arm circumferences of more than five centimetres, or a positive answer to the question whether patients have complaints of lymphoedema. Also bio-impedance spectroscopy can be performed to compare the affected side with the non-affected side. The objective of this study was to determine the prevalence of lymphoedema five years after breast cancer surgery.

Material and Methods: One hundred forty-five patients, operated on for breast cancer minimally five years ago, between January 2001 and December 2003, were included. All the above mentioned methods to establish lymphoedema were performed.

Results: Prevalence of lymphoedema varies with the different methods: with water displacement volumetry and a cut-off value of 200 mL or 150 mL results were respectively a prevalence of 7% and 10%. 18% with a circumference difference of >2 cm and 19% using the sum of arm circumferences with a cut-off value of 5 cm. Self-reported lymphoedema yields a prevalence of 17%. Bio-impedance spectroscopy resistance of extracellular water (Recw) ratio is significantly smaller in the subjective oedema group ($p = 0.033$), the sum of arm circumferences (SOAC) >5 cm group ($p = 0.005$) and volume >200 mL group ($p = 0.003$), but was not able to detect lymphoedema patients. Of those patients with self-reported lymphoedema, 56% tested positive with the SOAC method, and only 36% tested positive using the water displacement method. Ninety percent of the patients with an arm volume difference of more than 200 mL reported lymphoedema. So a smaller volume difference does not exclude the presence of subjective lymphoedema.

Conclusions: When measuring lymphoedema 5 years after surgery for breast cancer, different methods result in a prevalence varying from 0.7% to 19%. Water displacement volumetry resulted in a much higher prevalence than Bio-impedance spectroscopy, in contrast with acute phase studies where BIS and volumetry yield comparable results. In this study there was a relatively high prevalence of subjective lymphoedema when compared with water displacement volumetry. These findings support the hypothesis that after 5 years the consistency of lymphoedema has changed drastically.

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Side effects of treatment

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Long-term cause specific mortality in patients treated for DCIS; a population based study

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Background: Since the introduction of the national breast cancer screening program in the Netherlands in 1990, incidence of ductal carcinoma in situ (DCIS) has increased dramatically. DCIS is treated by surgery and, in case of breast conserving therapy, radiotherapy is also frequently used. The prognosis of DCIS is very good. However, it is still unclear what proportion of these in situ tumours would have progressed into invasive breast cancer if left untreated. Because of potential overdiagnosis, treatment-related late health effects after DCIS may be of even greater importance than late effects of invasive breast cancer treatment. Currently, there is no information on treatment-related excess mortality following treatment for DCIS.

Treatment-related late health effects after breast cancer include second tumours and cardiovascular disease. Previous studies have indeed shown increased mortality after treatment of invasive breast cancer with radiotherapy. However, most of these studies are based on outdated treatment regimens. Therefore it is still unclear to what extent contemporary radiotherapy regimens used to treat DCIS also increase the risk of cardiovascular disease and second tumours.

The aim of the current study is to assess long-term cause-specific mortality in patients treated for DCIS in a population-based design.

Materials and Methods: Data on all incident DCIS cases in the Netherlands between 1989 and 2004 were obtained from the population-based Netherlands Cancer Registry. The Netherlands Cancer Registry was established in 1989 and also collects treatment information. Date and cause of death were acquired through linkage with Statistics Netherlands until January 2009.

Results: At the EBCC, results will be presented on the evaluation of mortality rates (including the three main outcomes breast cancer, other cancer, and cardiovascular disease) in comparison with the general population. In addition, we will compare mortality rates between DCIS patients treated with surgery and radiotherapy, and those treated with surgery alone. For cardiovascular disease we will also compare mortality after radiotherapy for left-sided and right-sided DCIS.

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Prophylactic use of H1 and H2 antagonists may prevent hypersensitivity reactions and skin toxicity to docetaxel with cyclophosphamide in early breast cancer patients

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Background: US oncology 9735 study demonstrated significant improvement in DFS and OS for Docetaxel/Cyclophosphamide (TC) compared with Doxorubicin/cyclophosphamide (AC). We previously evaluated tolerability and safety of TC regimen and reported this regimen was feasible for Japanese patients with early breast cancer (Takabatake et al. Jpn J Clin Oncol 2009). In this feasibility study, relatively high incidence of hypersensitivity reactions (HSRs) or rashes were observed. Therefore, to reduce these side effects patients were premedicated with H1 and H2 antagonists in our institution. The aim of this study is to compare the rates of HSRs and rashes when TC is administered with and without prophylactic H1 and H2 antagonists.

Patients and Methods: This study was a retrospective cohort study evaluating the rates of HSRs and rashes in patients receiving TC regimen for early breast cancer at Shikoku Cancer Center from June 2006 to August 2009. Until October 2008, patients received 8 mg of iv dexamethasone (DEX) for prophylaxis: Group H(−). From November 2008, patients received H1 and H2 antagonists (50 mg of oral diphenhydramine and 20 mg iv famotidine, respectively), 30 min prior to docetaxel in addition to intravenous DEX: Group H(+). All patients received oral 8 mg of DEX day2 and day3. Medical records from all patients were reviewed to evaluate demographics, drug administration and incidence of HSRs and rashes. The chi-squared test was used for statistical analyses.

Results: Fifty eight patients received only iv DEX and 69 received H1 and H2 antagonists with DEX. Of the 58 patients in group H(−), 26 had HSRs (44.8%) and 33 had rashes (56.9%). In contrast, of the 69 patients in group H(+), 21 had HSRs (30.4%) and 26 had rashes (37.7%). There were statistically significant differences in both HSRs and rashes ($p = 0.042$ and 0.031, respectively).

Conclusion: Our study suggests that prophylactic use of H1 and H2 antagonists may prevent hypersensitivity reactions and skin toxicity to Docetaxel with Cyclophosphamide in early breast cancer patients.

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Musculoskeletal pain in the FEC-D regimen is common and frequently severe − experiences in an outer metropolitan oncology unit

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Background: The FEC-D regimen is a commonly used adjuvant chemotherapy regimen for node positive early breast cancer in our oncology unit. It has demonstrated considerable toxicity in terms of febrile neutropenia (FN) but also fatigue, myalgias and arthralgias. G-CSF can decrease the risk of FN but as the main side effect of G-CSF treatment is bone pain, there is a possible risk that it may compound the musculoskeletal side effects of docetaxel.

Materials and Methods: A retrospective analysis of the medical records of all clinic patients who had completed treatment with FEC-D between July 2007 and October 2009 was performed. Parameters measured were rates of use of G-CSF (pegylated filgrastim, Neulasta®), incidence of FN and occurrence and NCI-CTC grade musculoskeletal (MSk) pain.

Results: Of the 37 patients included, six (16%) had an episode of FN. None of these were receiving G-CSF at the time of the episode. The majority of FN occurred in either Cycle 1 of FEC or Cycle 1 of docetaxel. 25 patients (68%) received some treatment cycles with G-CSF. There were two chemotherapy discontinuations during the docetaxel treatment due to severe side effects. MSk symptoms are listed in the table.

		MSk pain			
		All grades		Grades 2 and 3	
Treatment cycle	No. treated (no. also receiving GCSF)	n (%)	receiving GCSF (% of all GCSF)	(% of total cases)	receiving GCSF (% of all cases also receiving GCSF)
FEC1	37 (6)	2 (5%)	0 (0%)	0 (0%)	0 (0%)
FEC2	37 (13)	2 (5%)	2 (15%)	0 (0%)	0 (0%)
FEC3	37 (15)	2 (5%)	0 (0%)	0 (0%)	0 (0%)
D1	**37(19)**	**26 (70%)**	**17 (89%)**	**16 (62%)**	**10 (59%)**
D2	36 (25)	19 (53%)	15 (60%)	7 (37%)	5 (33%)
D3	35 (25)	10 (28%)	8 (32%)	5 (50%)	5 (62%)