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Quality of Life of Women With Breast Cancer Treated in Adjuvant Setting With Tamoxifen or Aromatase Inhibitors

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Background: To determine the quality of life of women with early breast cancer treated with Tamoxifen, Letrozole, Anastrazole, Exemestane, after 2 years of treatment.
Materials and Methods: A total of 237 women treated in the period 2001–2009 with adjuvant hormonotherapy, were selected to complete the EORTC-C30 and EORTC BR-23 questionnaire. From these women, 115 patients were treated with Tamoxifen and 122 have received aromatase inhibitors: 60 patients have received letrozole, 29 patients anastrazole and 33 patients exemestane. The women had completed the questionnaires after 2 years of hormonal treatment. The primary end point was the comparison of global health status among the groups receiving tamoxifen, letrozole, anastrazole and exemestane. The secondary end point was the analysis of functional scales, emotional scales, cognitive scales and symptom scales of every hormonal treatment group.
Results: The assessments available for analysis were in proportion of 88% from questionnaire completion target. There were no differences between the tamoxifen group and the aromatase inhibitors group (letrozole, anastrazole and exemestane) after 2 years of hormonal therapy. Evaluating separately the scales, there is a superiority of the group receiving aromatase inhibitors (anastrazole, letrozole and exemestane) comparing with tamoxifen group regarding symptom scale (sexual function and fatigability) and emotional scale. Among the three groups treated with letrozole, anastrazole and exemestane, was found a statistically significant difference in symptom scale (nausea, dizziness) in favour of anastrazole compared with letrozole.
Conclusions: After two years of adjuvant hormonal treatment, the treatment with tamoxifen or aromatase inhibitors has a similar overall impact regarding quality of life. The statistic significant differences appears to be related with symptom scale and emotional scale, where aromatase inhibitors are superior.

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Phase II Study of Neoadjuvant S-1 Combined With Paclitaxel Followed by FEC in Patients With Breast Cancer

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Background: Neoadjuvant chemotherapy is a standard procedure to increase the breast-conservation rate, but has a very low response rate in luminal A breast cancer. Adjuvant therapy with oral 5-fluorouracil (5-FU) derivatives has been reported to be effective in estrogen receptor (ER)-positive disease. We performed a phase II study to evaluate the effectiveness of the new oral 5-FU derivative S-1 combined with weekly paclitaxel followed by FEC and report our preliminary results.
Patients and Methods: Patients with operable Stage IIA, IIB, IIIA, IIIB, IIIC breast cancer were enrolled. Weekly paclitaxel 60 mg/m^2 on days 1, 8, 15 q4W, S-1 80 mg/m^2 bid on days 1−14 (4 cycles) followed by FEC (epirubicin 90 mg/m^2, 5-FU 500 mg/m^2, cyclophosphamide 500 mg/m^2 on day 1 q3W (4 cycles) was given. The primary endpoint was the pathological complete response (pCR) rate. The secondary endpoint was the pathological complete and nearly complete response rate. A pCR was defined as no cancer cells or only intraductal cancer cells in the primary tumour. Near pCR was defined as only a few cancer cells remaining at the primary site. Clinical response was evaluated by the RECIST criteria. Adverse events were defined by CTC v3.
Results: Between November 2008 and February 2011, 23 patients were enrolled. Sixteen had ER and progesterone receptor (PR)-positive tumours without Her2 overexpression. Five patients (22%) had pCR. Notably, 3 of 16 (19%) patients with ER/PR-positive, Her2-negative tumours had pCR. All of them were node negative. Near pCR was achieved in 4 patients (25%). Among patients with ER/PR positive tumours, 8 (50%) had clinical complete responses, and 4 (25%) had partial responses. All patients (100%) had Grade 3/4 neutropenia and 2 had febrile neutropenia; however, only 2 (13%) patients had Grade 3/4 neutropenia during the S-1/paclitaxel phase. One patient had grade 3 diarrhea. All other adverse events during the S-1/paclitaxel phase were within grade 2, including numbness (52%), diarrhea (44%), eczema (39%), stomatitis (30%), and liver dysfunction (39%).
Conclusion: Neoadjuvant chemotherapy including S-1combined with paclitaxel followed by FEC appears to be effective and safe especially in patients with ER/PR-positive, Her2-negative breast cancer.

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Clinical Use of OncotypeDX Recurrence Score as an Adjuvant-Treatment Decision Tool in Early Breast Cancer Patients

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Background: The 21-gene Recurrence Score® (RS) is a clinically validated assay that predicts the risk of distant recurrence and the likelihood of chemotherapy benefit in early breast cancer patients (pts) with estrogen receptor positive (ER+) tumours. It can be used as an adjuvant-treatment decision tool according to St. Gallen recommendations and the National Comprehensive Cancer Network guidelines, including pts with lymph node micrometastases (Nmic). During the last 3 years, we used Oncotype*DX* RS in 5 centers of the *HBSS* in a selected group of pts with favorable or intermediate characteristics to identify those who need chemotherapy.
Methods: RS was evaluated in 101 women with a mean age of 51.4 years (range 35−84). 57 pts were premenopausal and 44 postmenopausal. Tumour type was invasive lobular in 21 and ductal in 80 pts. Tumour size was $\leqslant$2 cm in 88 and >2 cm in 13 pts. Lymph nodes were negative in 85 pts; twelve pts had Nmic in 1 node, 2 pts in two and 2 pts in three nodes. All pts but one had ER+ tumours and PgR was also positive in 83% of them. Tumour grade was III in 12 pts, II in 51 pts and I in 17 pts (21 lobular carcinomas were not graded). Ki67 score was 1 (<10%) in 40 pts, 2 (10−20%) in 29 and 3 (>20%) in 20 pts (not measured in 12 cases). Her2-new expression was positive in 4 pts. All pts had a combination of favorable prognostic factors making them candidates for adjuvant treatment with hormonal therapy only or favorable prognostic factors combined with at least one unfavorable characteristic (either T-size >2 cm, Grade II-III, Ki67=2−3, Nmic or her2-new positive).
Results: OncotypeDX RS result was <18 (low risk of recurrence) in 60 pts (59.4%), 18−30 (intermediate risk) in 27 pts (26.7%) and $\geqslant$31 (high risk) in 14 pts (13.9%). Based on the RS result and following discussion with each patient on the risk and benefit of chemotherapy, 29 out of the 41 pts with RS $\geqslant$18 received additional chemotherapy before starting adjuvant hormonal treatment. Seven more patients with RS < 18 decided to receive chemotherapy. Overall, RS resulted in treatment decision of additional adjuvant chemotherapy in 29/101 (28.7%) of pts.
Conclusions: The 21-gene RS helped in treatment decision for this group of patients with favorable characteristics or on “intermediate risk” of recurrence due to the presence of at least one unfavorable factor; for those patients, it is not clear if hormonal therapy only or chemotherapy plus hormonal therapy is the optimal adjuvant treatment.

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PT1a,bN0M0 Breast Carcinoma Characteristics and Management: the French ODISSEE Cohort

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Background: The incidence of infra-centimetric breast cancer (BC) is increasing due to early diagnosis by mammographic screening. Although most of these tumours have favorable issue, controversy surrounds the prognosis of these patients with locoregional therapy only and the need for adjuvant systemic therapy. The objective of the prospective ODISSEE study was to describe the disease management in daily practice, the outcome of these patients over a 10-year follow-up period and to identify prognosis biomarkers.
Methods: Clinical data, pathological characteristics, treatments and outcome were collected in routine visits. Centralized pathological analysis of tumours is ongoing. From May 2009 to March 2010, 618 women with infiltrating, unifocal pT1a,bN0M0 BC who underwent surgery were recruited by 116 centers. Preliminary results are described below.
Results: 401 (65%) patients were included in private clinic, 181 (29%) in hospital, 36 (6%) in cancer centers. Median age at diagnosis was

61 years (range [22−89] years). 569 were ECOG 0 (93%) and 519 diagnosed from imagery (84%). Majority of patients had conservative surgery 592 (96%) with sentinel node biopsy in 547 (88.5%) and axillary dissection in 90 (15%). Median tumour size was 8 mm (range [0−10] mm) with 114 (18%) pT1a/504 (82%) pT1b. Most of tumours were SBR I and II, 326 (53%) and 37 (38%) respectively, 50 (8%) were grade III. 333 (54%) of tumours were pure invasive carcinoma and 285 (46%) presented associated in situ carcinoma. Almost all tumours were HR (hormone receptors) positive status (562 (91%)) and 5.6% were HER2 positive (HER2+). 522 patients were HR+/HER2− (89%), 32 HR−/HER2− (5%), 18 HR+/HER2+ and 13 HR−/HER2+). 557 patients (95%) received radiotherapy (RT) and 443 (76%) received adjuvant therapy. Decision of chemotherapy (CT) was associated with HER2+ or triple negative status (63.3% and 45.2%). 61.3% of HER2+ patients received trastuzumab.
Conclusions: The ODISSEE patients with pT1a,bN0M0 BC were mainly SBR I or II with pT1b HR+/HER2− tumour. In routine practice majority had conservative surgery followed by RT. More patients have been recommended a CT when a HER2+ or triple negative status was diagnosed. Biomarkers centralized analysis and long term follow up will provide further prognosis data.

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A Multicenter Randomized Phase II Study of KRN125 (Pegfilgrastim) to Determine the Optimal Dosage in Japanese Breast Cancer Patients Receiving TAC Treatment

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Background: KRN125 (Pegfilgrastim) is a sustained duration form of Filgrastim, a human granulocyte colony-stimulating factor (G-CSF). KRN125 has been shown to decrease the risk of febrile neutropenia in non-Japanese cancer patients whose immune response was severely weakened by chemotherapy. Here, we report results of the phase II study of KRN125 in Japanese breast cancer patients.
Material and Methods: To confirm efficacy and safety of KRN125 and determine the optimal KRN125 dose, Japanese patients were administered KRN125 at 1.8 mg, 3.6 mg or 6.0 mg once per TAC chemotherapy cycle (docetaxel 75 mg/m^2, doxorubicin 50 mg/m^2, and cyclophosphamide 500 mg/m^2). TAC chemotherapy was allowed both as neoadjuvant and adjuvant chemotherapy. The primary endpoint was the duration of severe neutropenia (DSN) in the first TAC cycle.
Patients eligible to enter the study were at least 20 and under 65 years of age with stage II/III invasive carcinoma, were chemo-naivë, and were expected to receive TAC therapy as prescribed dosage above. Patients randomized to each KRN125 dosage group received TAC on day 1 followed by administration of KRN125 on day 2 at least 24 hours after TAC completion. From day 3 onwards, neutrophil count was taken daily and the time taken to exceed 1000 cells/μL was recorded.
Results: Between November 2009 and April 2010, 90 patients were enrolled, with 30 randomized to each KRN125 dosage group. In total, 87 patients were administered KRN125. Patient baseline characteristics included a median age of 47.0 (40.0–54.0) years and a median BSA of 1.52 (1.43–1.60) m^2. Patients characteristics were balanced in the three dosage groups.
DSN in the first cycle was 2.2±0.9 days, 1.5±0.9 days and 1.4±0.7 days in the 1.8 mg, 3.6 mg and 6.0 mg groups, respectively. Comparing the dose response analysis profile with three possible contrast shapes − 'linear reduction', 'reduction at 6.0 mg' and 'plateau at 3.6 mg' − revealed a dose response most similar to that of 'plateau at 3.6 mg'. P-values for the response patterns were 0.005, 0.092 and 0.001, respectively. From this result, P-value in contrast shape of plateau at 3.6 mg was the smallest which showed that efficacy of KRN125 had saturated at 3.6 mg. The optimal dose of KRN125 was therefore set as 3.6 mg/body. Safety of KRN125 was confirmed at 6.0 mg.
Seventy-eight percent of patients completed six cycles of TAC with KRN125. FN rate was 10.3% in each KRN125 dosage groups and TAC chemotherapy was able to be administered together with KRN125.
Conclusion: In this study, the optimal KRN125 dosage for Japanese patients was determined to be 3.6 mg/body, which differs from the approved dosage of 6.0 mg in other countries.

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Male Breast Cancer (MBC): Optimal Treatment and Diagnosis Factors − Analysis of 636 Cases

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Background: MBC represents 1% of all male cancers. Our study details clinic-pathological features, treatments and prognostic factors according to age in a multicentric French cohort.
Material and Methods: From 1990 to 2005, 636 patients were treated. Median age was 65 years (11% <50 y, 54% 50−70 y and 35% >70 y). There was at least one chronic disease in 50% of the patients (<50: 26%, 50−70: 46% and >70: 63%). Median FU was 55 months. All patients were M_0. According to T/N, we found T_1: 44.5%, T_2: 43.7% and T_3T_4: 11.8%, and N_{1-2}: 27%. Lumpectomy and mastectomy were performed in 6% and 94% of the cases. Axillary dissection (AD), sentinel node biopsy or both were performed in 90.4%, 1.6% and 4.3% of the cases, respectively. 95% of tumours were ductal carcinomas; 45% were pT_1, 19% pT_2 and 36% pT_3-T_4. Axillary nodal involvement was found in 54.5% of the cases. ER and PgR were positive in 92% and 89% of the cases. Radiotherapy (RT), chemotherapy (CT) and hormonal treatment (HT) were delivered in 84.4%, 34% and 70% of the patients, respectively. Tamoxifen, aromatase inhibitors or both were delivered in 87%, 9% and 4% of the cases. Various hormonal treatments also seem to be efficient.
There were wide differences in treatments according to age (Table 1).
Results: Local recurrences (LR), nodal recurrences and metastases occurred in 22.2%, 4.9% and 22.2% of the cases, respectively. Contralateral BC and other cancers occurred in 1.8% and 11.8% of the cases. The 5 and 10-year overall survival (OS) rates were 78% and 54%; disease-specific survival (DSS) rates were 88% and 74%. Death causes were BC, 2nd cancer, intercurrent or unknown disease in 51%, 11.4%, 15.6% and 18.6%, but with wide differences according to age (Table 1). In a multivariate analysis, metastatic risk factors were T stage ($p = 0.006$), pN status ($p < 0.0001$), SBR grading ($p = 0.016$) and presence of locoregional recurrence ($p < 0.0001$).
Conclusions: Earlier diagnosis and wide use of adjuvant treatments (RT/HT/CT) widely decreased relapses and increased survival rates in MBC, reaching the female ones. Prognostic factors were also similar to female ones.

Table 1: Treatments and results according to age (%)

	Age <50 (n = 69)	Age 50−70 (n = 343)	Age >70 (n = 224)	Total (n = 636)	p
Therapy					
RT	84	89	78	84	0.0034
CT	56	44	12	34	<0.0001
HT	62	71	73	70	0.25
Recurrences					
LR	−	3.2	1.4	2.2	0.2
LRR	7.6	5	4	5	0.48
M	32.4	26	13	22	0.0001
Causes of death					
BC deaths	90	60	27	51	
2nd cancer death	−	12	14	11.5	
Interc. Death	−	12	25	16	0.0001
Unknown death	5	12	31	19	