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.

5167 POSTER

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	