Materials and Methods: Between 2008 and early 2009, 34 patients with T1−2N0M0 breast cancer were randomised into two groups. Group A (n = 17) received standard radiotherapy with 50 Gy/25f/5w plus boost 10 Gy/5f/1w to tumor bed and Group B (n = 17) 43.2 Gy/16f/22 d plus boost 8.1 Gy/3f/3 d. All patients were tested using spirometry and gas diffusion tests on D0 (before RT), during RT (on D7 and D21) and after completion of RT at 3, 6, 9, 12 months. High resolution CT scans were performed at 6, 9, 12 months after completion of RT. Respiratory symptoms were recorded.
Results: Preliminary results are shown in the table.

Follow-up time (at present)	Treatment group	Uncomplicated	Complicated	Total
6 months	Group-A	7	1	8
	Group-B	2	4	6
	Total	9	5	14
9 months	Group-A	3	1	4
	Group-B	3	1	4
	Total	6	2	8
12 months	Group-A	2	0	2
	Group-B	1	0	1
	Total	3	0	3

The percentance of incidence of radiation-induced pneumonitis for the two treatment groups, is directly derived from the data of the table: **i) Group-A:** 12.5% (6-month follow up) and 25% (9-month follow up), and **ii) Group-B:** 66.7% (6-month follow-up) and 25% (9-month follow-up).
Conclusions: The preliminary results indicate an increase in the incidence of radiation-induced pneumonitis for the patients of group-B (hypofractionated RT regimen) over that for the patients of group-A (conventional fractionation). However, this is an ongoing study and for statistically confident conclusions an investigation of late effects on a larger number of patients is necessary.

5128 POSTER

Optimal radiation field in pathological N0-N1 patients treated with neoadjuvant chemotherapy followed by surgery for locally-advanced breast cancer

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Background: To investigate the treatment results and evaluate the necessity to irradiate the supraclavicular lymph node region (SCN) in pathological N0-N1 patients treated with neoadjuvant chemotherapy followed by surgery and radiotherapy (RT) for locally advanced breast cancer.
Material and Methods: Between 1996 and 2006, 115 patients with initial tumor size >5 cm or clinically positive lymph nodes were treated with neoadjuvant chemotherapy followed by surgery and radiotherapy. Among these patients, we retrospectively reviewed 57 patients with pathological N0 or N1. All patients received anthracycline based neoadjuvant chemotherapy. Thirty patients were treated with modified radical mastectomy and 27 patients with breast conserving surgery. The pathological tumor stage was T0 or Tis in 21%; T1 in 33%: T2 in 28%: T3 in 16% and T4 in 2% of patients. The pathological lymph node stage was N0 in 47% and N1 in 53%. Adjuvant RT was given to all patients; 37 patients to chest wall or breast and supraclavicular area (SCNRT+ group) and 20 patients only to chest wall or breast (SCNRT− group).
Results: Locoregional failure free survival (LRFFS), distant metastasis free survival (DMFS), disease free survival (DFS) and overall survival (OS) at 5 years were 92%, 83.2%, 81.4% and 87.7%, respectively. Pathological tumor stage and hormone treatment were statistically significant factors for DMFS, DFS and OS on multivariate analysis ($p < 0.05$). Radiation field to include supraclavicular area or not did not seem to be any relationship with LRFFS, DMFS, DFS and OS. In pN0 and pN1 patients, 5-year DFS was 86.6% and 68.8% in SCNRT+ group, compared with 80.8% and 100% in SCNRT− group, respectively ($p = 0.9794$, $p = 0.0713$).
Conclusions: In patients with pathological N0 or N1 after neoadjuvant chemotherapy followed by surgery, we might dispense radiotherapy to SCN and give only to chest wall or breast in selected patients according to pathological tumor stage.

5129 POSTER

Surfactant protein D as a serological marker of lung inflammation in breast cancer patients under radiation treatment

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Background: Surfactant protein D (SP-D), a potential specific marker of lung disease, and C-reactive protein (CRP), an established inflammatory marker, are evaluated to assess radiation-induced lung inflammation in breast cancer patients.
Material and Methods: SP-D and CRP levels were measured prospectively by ELISA in 40 patients with primary breast cancer, aged 29−71 years, and 20 healthy controls. Serum samples were collected prior to initiation, during, and at completion of radiation therapy and throughout a follow-up period of 7 months (90, 140 and 240 days after the initiation).
Results: According to their median SP-D and CRP serum levels, patients were categorized into three groups. Regarding SP-D, patients of the first group exhibited levels within normal range compared to healthy controls (<110 ng/ml) at all time points. Patients within the second group exhibited increased levels at the end of radiation therapy and during follow-up (At the end: 123.57 ng/ml, Follow-up: 90th day: 113.86 ng/ml, 140th day: 116.22 ng/ml), whereas patients of the third group expressed highest levels, above normal range, at all time points. Considering CRP, serum levels were within normal range at all time points for patients of the first and second group compared to healthy controls (114.2–3832.6 ng/ml) whereas increased levels (4946.2 ng/ml) were observed only prior to radiation therapy for the patients of the third group. No disease progression was observed according to clinical evaluation and tumor marker measurements (CEA and CA 15−3).
Conclusions: Increased levels of SP-D and CRP prior to radiotherapy, in the patients of the third group, indicate the presence of an inflammatory condition not associated with radiation treatment. The sustained elevated SP-D expression at all time points suggests that this molecule may be a more sensitive marker of lung inflammation than CRP. Regarding patients of the second group, the increased SP-D serum expression at the end of radiotherapy and during follow-up may be suggestive of radiation-induced lung inflammation. However, CRP does not appear to reflect these effects since no corresponding increase was detected. Concluding SP-D seems to be indicative of lung inflammation in breast cancer patients under radiation therapy, serving as a specific noninvasive serological marker.

5130 POSTER

Short-term outcome of prospective trial for Japanese breast cancer patients treated with accelerated partial breast irradiation using 3D Conformal Radiotherapy

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Purpose: We present our clinical trial utilizing 3D-conformal radiation therapy (3D-CRT) to deliver accelerated partial breast irradiation (APBI) in patients with early-stage breast cancer treated with breast conserving therapy.
Methods and Materials: Between Janualy 2008 and March 2009, 51 patients with Stage 0−2 breast cancer were enrolled at National Cancer Center Hospital, Japan, institutional review board-approved. Eligibility criteria included pathological tumor size <3 cm, invasive ductal and lobular histologies as well as ductal carcinoma in situ, lumpectomy with negative surgical margins, $\leqslant$3 positive axillary nodes, unifocal lesion, and written patients consent. Patients receiving chemotherapy before operation were excluded. The clinical target volume consisted of the lumpectomy cavity with surgical clips plus a 10 mm margin; the planning target volume (PTV) was calculated from the CTV using uniform 3-D expansions. The prescribed dose was 38.5 Gy in 10 fractions given over 2 weeks. All patients were treated once a day.
Results: The median follow-up after radiotherapy was 248 days (range, 35–456). The clinical stage distribution was as follows: 0 in 7 patients, 1 in 33, and 2 in 20. The median tumor size was 16 mm (range, 5−30 mm). The median age was 58 year (range, 32−79). 15 patients underwent chemotherapy before entering trial. Adverse event information according to CTCAE V3.0 is presented in table. No local or distant recurrences developed.
Conclusion: 3D-CRT for APBI is feasible for Japanese breast cancer patients in short follow up. Additional follow-up will be needed to assess the long-term feaibility and efficacy of APBI using 3D-CRT.

Table. adverse events (CTCAE v3.0)

	Grade0	1	2−4	Grade 1 (%)
fatigue	31	20	0	39.2%
nausea	48	3	0	5.9%
vomiting	51	0	0	0
anorexia	45	6	0	11.8%
dermatitis	4	47	0	92.2%
dry skin	48	3	0	5.9%
skin pigmentation	35	16	0	31.4%
Skin depigmentation	51	0	0	0
edema	30	21	0	41.2%
pain	32	19	0	37.3%
pneumonitis	51	0	0	0

5131 POSTER

Hypofractionated radiotherapy after conservative surgery for breast cancer: analysis of acute and late toxicity in a mono-institutional series

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Background: To assess acute and late toxicity after hypofractionated radiotherapy (RT) following breast conserving surgery in a mono-institutional series.
Materials and Methods: A group of 85 women operated by conservative surgery for breast cancer (pT1−2 pN0−1 M0) was treated with postoperative hypofractionated RT to a total dose of 45 Gy in 20 fractions of 2.25 Gy to the whole breast followed by 9 Gy boost in 3 fractions (BED = 55 for acute toxicity, alfa/beta = 10; BED = 78 for late toxicity, alfa/beta = 3). Acute and late toxicity were scored according to the RTOG/EORTC criteria. These results were analyzed and compared with those observed in a group of 70 patients with similar characteristics and treated with RT to the same treatment volumes to a total dose of 50 Gy in 25 fractions followed by 10 Gy boost in 5 fractions (BED = 60 for acute toxicity, alfa/beta = 10; BED = 83 for late toxicity, alfa/beta = 3). Statistical analysis was performed using the chi-square test to compare acute and late toxicity between patients treated with hypofractionation and those treated with conventional fractionation.
Results: Early reactions were observed in 72/85 (85%) patients treated with hypofractionation and in 67/70 (96%) patients treated with conventional fractionation. Acute toxicity was classified as grade 1 in 60%, as grade 2 in 22% and as grade 3 in 2% of patients in the group treated with hypofractionation. Early reactions were classified as grade 1 in 49%, as grade 2 in 41% and as grade 3 in 5% of patients in the group treated with conventional fractionation. The difference between the two fractionation groups resulted to be statistically significant ($p = 0.01$).
Late toxicity was observed in 8 patients (10%) in the group treated with hypofractionation with a mean of follow up of 435 days and in 10 patients (15%) in the group treated with conventional fractionation with a mean follow up of 854 days, respectively. The difference in frequency of late toxicity was not statistical significant ($p = 0.4$).
Conclusions: In our experience, a radiation hypofractionated schedule delivering 45 Gy in 20 fractions offered a significant reduction of skin acute toxicity ($p = 0.01$) and not significant difference of late effects ($p = 0.4$) compared to the conventional schedule. The reduction in acute toxicity in patients treated with hypofractionated RT could be explained by the BED values and by the dosimetric data that are still under analysis and could differ in the two treatment groups.

5132 POSTER

Targeted intraoperative radiotherapy and sentinel node biopsy enable breast and axillary lymph node preservation

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Background: The purpose of the study is: 1) to analyse results of the breast conserving treatment (BCT) in patients with breast carcinoma using both intraoperative radiotherpy (IORT) and sentinel node biopsy (SNB) simultaneously; and 2) to estimate breast and axillary lymph nodes preservation with this approach.
Material and Methods: The treatment protocol was approved by Ethical Committee. The BCT using combined SNB, wide local excision (WLE) and IORT was performed in 138 patients who signed the informed consent. Patients with primary tumour $\leqslant 2$ cm and clinically negative axillary lymph nodes were eligible. The SNB was done using isotope-dye technique with preoperative lymphoscintigraphy. The INTRABEAM® PRS 500 system (Carl Zeiss, Oberkochen, G) was used for irradiation of the tumour bed with the dose of 20 Gy (boost; energy 18 keV). After completion of the adjuvant treatment, whole breast external beam irradiation was performed with a total dose of 50 Gy, omitting the tumour bed. Objective computerized aesthetic effect assessment was done using BCCT.core® software (University of Porto, PT). Follow-up time ranged from 9 to 38 months (mean 22 months).
Results: Minor early postoperative complications (reddening of the skin wound; seroma) did not prolong hospitalization. In 14 patients (10%), surgical specimen pathology revealed positive margin. Re-excision of the margins was performed all in of these patients. In one patient mastectomy was necessary because neoplastic cells in re-excison specimen. In 27 (20%) patients (selective) lymphadenectomy was performed following positive SNB. In one patient both positive SNB and positive margins necessitated mastectomy; whereas in another patient after selective lymphadenectomy, mastectomy was necessary because of margins' infiltration by comedo type carcinoma. Altogether breast and axillary lymph node preservation was possible in 108 (78%) of patients. Fifteen patients (11%) had fibrosis of the treated breast quadrant. In patients after breast conservation who reached 1 year follow-up, the BCCT.core® general aesthetic score was excellent in 52%, good in 42%, and fair in 6% of patients. There was neither poor aesthetic outcome. In one patient pulmonary metastases were detected prior to local recurrence in the breast.
Conclusions: The combination of SNB, WLE and IORT is a safe surgical procedure leading both to breast and axillary lymph nodes preservation with improved patients' satisfaction by excellent or good aesthetic effect and shortening the time of treatment in majority of patients.

5133 POSTER

Incidence of distant metastasis (DM) in elderly postmenopausal women with operable breast cancer treated with tamoxifen (TAM)

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Background: Breast cancer recurrence risk is greatest during the first 2 years following surgery, and DM recurrences predominate during this early peak (Mansell J et al. *Breast Cancer Res Treat.* 2008; Dec [Epub ahead of print]). DM has been associated with poor survival and breast cancer-related death (Lamerato L et al. *J Clin Oncol*. 2005;23(16S):62s. Abstract 738). Elderly women ($\geqslant 75$ yr) with early breast cancer are often less likely to receive chemotherapy (CT) due to comorbid conditions (pulmonary, cardiovascular), yet they remain at risk for early DM and are good candidates for adjuvant hormonal treatment (Crivellari D et al. *J Clin Oncol.* 2008;26:1972−9; Rao VSR et al. *Int J Cancer.* 2007;120:1155−60).
Methods: We stratified a cohort of 3614 women treated with TAM following surgery for early breast cancer by age, identified CT status, and the incidence of DM and calculated the Kaplan-Meier-estimated 2.5- and 5-year recurrence rates.

	N	Patients with DM, n (%)	CT received, n (%)	CT status unknown, n (%)
All pts	3614	344 (9.5)	713 (21.9)	360 (10)
<75 yr	2992	272 (9.1)	690 (25.1)	248 (8.3)
$\geqslant$75 yr	622	72 (11.6)	23 (4.5)	112 (18.0)

Results: Elderly patients (pts) $\geqslant 75$ yr were less likely to receive CT, and the incidence of DM was higher than in younger pts <75 yr (Table). The 2.5-yr and 5-yr cumulative DM (95% CI) for pts <75 yr vs $\geqslant 75$ yr, respectively, were 4.0% (3.2−4.8) and 8.7% (8.5−10.9) versus 9.0% (6.5−11.5) and 14.8% (11.3−18.3). Of the 344 pts with DM, 75.6% died during follow-up.
Conclusions: Elderly pts with breast cancer are frequently undertreated for their disease, despite being at risk for DM, and are good candidates for adjuvant hormonal therapy. The aromatase inhibitors are superior to TAM, and results from the BIG 1−98 trial show that letrozole (LET) significantly reduces recurrences, regardless of age (Crivellari et al 2008). Early reductions in DM recurrence, as observed with initial adjuvant LET (Thurlimann B et al. *N Engl J Med.* 2005;353:2747−57; Mauriac L et al. *Ann Oncol.* 2007;18:859−67] may translate to the observed survival advantage