	Neoadjuvant chemotherapy			Neoadjuvant endocrine therapy		
	low Ki-67 (n = 8)	moderate Ki-67 (n = 11)	high Ki-67 (n = 16)	low Ki-67 (n = 11)	moderate Ki-67 (n = 8)	high Ki-67 (n = 7)
Clinical Response*						
CR	0 (0.0%)	1 (9.1%)	3 (18.7%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
PR	7 (87.5%)	8 (72.7%)	12 (75.0%)	4 (36.4%)	5 (62.5%)	0 (0.0%)
SD	1 (12.5%)	2 (18.2%)	1 (6.3%)	7 (63.6%)	2 (25.0%)	5 (71.4%)
PD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (14.3%)
Pathological Response**						
Grade 0	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (12.5%)	0 (0.0%)
Grade 1a	0 (0.0%)	1 (9.1%)	4 (25.0%)	5 (45.5%)	2 (25.0%)	4 (57.1%)
Grade 1b	7 (87.5%)	6 (54.5%)	5 (31.3%)	4 (36.4%)	5 (62.5%)	3 (42.9%)
Grade 2	1 (12.5%)	4 (36.4%)	4 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Grade 3	0 (0.0%)	0 (0.0%)	3 (18.8%)	1 (9.1%)	0 (0.0%)	0 (0.0%)

*Clinical Response evaluated by RECIST; CR: complete response, PR: partial response, SD: stable disease, PD: progressive disease.

**Pathological Response evaluated by response criteria of Japanese Breast Cancer Society; Grade 0: no response, Grade 1: slight response (Grade 1a: mild response, Grade 1b: moderate response), Grade 2: marked response, Grade 3: complete response.

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Significantly Higher Pathologic Complete Response Rate with Weekly Compared with Three-weekly Paclitaxel and Carboplatin Plus Trastuzumab Neoadjuvant Therapy − Results of a Randomized Trial in Human Epidermal Growth Factor Receptor 2-positive Breast Cancer

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Background: Paclitaxel works synergistically with trastuzumab in HER2 positive breast cancer. But few trials have studied the combination of a paclitaxel-containing regimen and trastuzumab in the neoadjuvant setting. We conducted a phase III randomized trial to compare the efficacy and safety of weekly and 3-weekly paclitaxel (P) and carboplatin (C) plus trastuzumab (H) for the neoadjuvant treatment of HER2 positive breast cancer.

Material and Methods: 38 patients (pts) with stage IIB to IIIC disease and HER2 positive (IHC3+ and/or FISH+) were randomized to receive neoadjuvant treatment with four cycles of weekly PCH (P: 80 mg/m^2, C: AUC=2, d1, 8, 15, q4w and H: 2 mg/kg every week with loading dose of 4 mg/kg), or 3-weekly PCH (P: 175 mg/m^2, C: AUC=6, q3w and H: 6 mg/kg every 3 weeks with loading dose of 8 mg/kg). Primary endpoint was pathological complete response (pCR) rate. Secondary endpoints included response rate, lymph node downstage rate, disease free survival (DFS) and safety.

Results: 19 pts were treated in each arm and pretreatment characteristics were similar in the two groups. All pts completed the 4 planned cycles of neoadjuvant treatment and received mastectomy or breast conserving surgery. The overall combined pCR rate was 60.5% (73.7% in weekly group and 47.4% in 3-weekly group, p = 0.091, Fisher's test). Subgroup analysis indicated a higher pCR rate in the weekly PCH group (10/14; 71.4%) than in the 3-weekly PCH group (3/12, 25%) for luminal B type patients (p = 0.047). Axillary lymph node downstage rates were similar in each group. No cardiac side effects was found in either group. If we add 15 cases preliminary weekly PCH neoadjuvant therapy data into the analysis, the pCR rate of combined weekly PCH group is 76.5% (26/34), which is significantly higher than that of 3-weekly group (p = 0.018). In luminal B subgroup analysis, weekly PCH maintains its superior efficacy over 3-weekly PCH (70.8% vs. 25%, P = 0.014).

Conclusion: Neoadjuvant treatment with a weekly PCH regimen achieved higher pCR rates compared with a 3-weekly PCH regimen for HER2 positive, especially luminal B type, breast cancer, with good cardiac safety profile and without exposure to anthracyclines. Preliminary results are encouraging and further cases are needed to be enrolled to confirmed the statistically significant differences between the groups.

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Prognostic Value of a Positive-to-negative Change in Hormonal Receptor Status Following Neoadjuvant Chemotherapy in Patients with Luminal-type Breast Cancer

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Background: This study investigated the prognostic value of positive-to-negative changes in hormonal receptor (HR) status after neoadjuvant chemotherapy in patients with luminal-type breast cancer.

Patients and Methods: Data from 224 stage II-III breast cancer patients with positive hormonal receptor (HR) status prior neoadjuvant chemotherapy (NCT) was collected, and the HR status of the residual tumors was retested after NCT. A survival analysis was performed in 214 patients with adjuvant endocrine therapy regardless of post-NCT HR status. The survival analysis also examined other clinical and pathological variables.

Results: In total, 15.2% of patients had a positive-to-negative change in HR status following NCT, and this change was observed more frequently in HER-2 positive tumors than HER-2 negative tumors (P = 0.001). Pre-NCT tumor stage (T2 *vs.* T3 *vs.* T4, P = 0.015), post-NCT node metastasis (0 *vs.* 1−3 *vs.* 4+, P = 0.006), and post-NCT HR (negative *vs.* positive, P = 0.026) were identified as independent predictive factors for DFS and significant predictors of OS (P = 0.004, P = 0.001, P < 0.001, respectively) in 214 patients who had been treated with adjuvant endocrine therapy regardless of post-NCT HR status. The 5-year DFS and OS rates were 43.5% and 59.8%, respectively, in patients with HR status conversion and 67.8% and 82.5%, respectively, in patients whose HR status remained positive (log-rank test P = 0.003 and P = 0.001). Besides, a relatively high proportion of high Ki-67 indexes were observed in tumors with HR alteration compared to tumors in which HR status remained positive (62.5% *vs.* 29.5%, P = 0.004).

Conclusion: Our results indicated that the switch of HR status after NCT is not negligible for luminal-type tumors. An HR-negative switch may lead to a poor outcome regardless of adjuvant endocrine therapy.

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The Role of Iodine-125 Seed Localization in Breast Conserving Therapy After Neo-adjuvant Chemotherapy in Breast Cancer

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Background: Neo-adjuvant chemotherapy (NAC) is increasingly used, especially in the treatment of large unifocal and multifocal breast cancer, in the framework of breast conserving therapy (BCT). Complete pathological response (CPR) is seen more often after newer chemotherapy regimes. If BCT is a surgical option, localization of the initial tumour, before initiation of NAC, is essential to guide the surgical resection. We studied the use of radioactive I-125 seeds in breast cancer patients treated with BCT following NAC. Our main objective was to analyze its value with regard to obtainment of tumour free surgical resection margins.

Material and Methods: Between January 2009 and December 2010, 85 patients were treated with NAC after I-125 seed localization. Tumours were unifocal and multifocal in 53 (63%) and 32 (38%) patients, respectively. During the chemotherapy course tumour response was monitored by magnetic resonance imaging (MRI). Definitive pathological examination was evaluated. Student t-Test and chi-square analysis were used to evaluate differences in surgical resection margins between patients with unifocal and multifocal tumours. P values of $\leqslant$ 0.05 were considered significant.

Results: After NAC, all patients underwent a lumpectomy without any secondary local excision. Nineteen patients (36%) with an unifocal tumour and 7 patients (22%) with a multifocal tumour had a CPR (p = 0.176). Overall tumour free resection margins were obtained in 78 patients of which 50 patients (94%) with unifocal tumours and 28 patients (88%) with multifocal tumours (p = 0.266). Focally involved margins were seen in 2 patients (4%) with an unifocal tumour and in 2 patients (6%) with a multifocal tumour (p = 0.273). Extensively involved margins were seen in 1 (2%) and 2 (6%) patients respectively (p = 0.291), subsequently followed in all 3 patients by a mastectomy.

Conclusions: To our experience, the I-125 radioguided lumpectomy proves to be very feasible providing an optimal per-operative three dimensional image of the tumour bed. A very high rate of microscopically complete lumpectomy was obtained in both uni- and multifocal tumours, with only 3 out of 85 patients requiring a mastectomy. Therefore, radioactive I-125 seed implantation increases the surgical opportunities for BCT following NAC, especially in the treatment of large unifocal and multifocal breast cancers.