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were demonstrated by Kaplan-Meier analysis and Cox proportional hazard model for disease free survival (DFS) and overall survival (OS).

Results: Among the 135 TNBC patients, median age was 54 years old, median tumor diameter on palpation was 4.5 cm (Min-Max; 1-15 cm), and there were 2 UICC stage I, 50 stage IIA, 40 stage IIB, 21 stage IIIA, 20 stage IIIB, and 2 stage IIIC patients. Seventeen out of 135 patients had family history of breast cancer within second-degree relatives. Body mass index of the 135 patients were classified into 97 normal (18.5-25), 10 underweight (<18.5), 28 overweight and obese (>25) patients. One hundred twenty three patients underwent both anthracycline and taxane containing regimen, 5 patients had anthracycline only, and 7 patients had taxane only. It was demonstrated that clinical response rate was 76% including 44 patients (32%) of clinical complete response (CR) and 59 patients (44%) of partial response (PR) and pCR was observed in 24 (18%) patients. Median disease free survival (DFS) was 44.4 months and median overall survival (OS) was 49.2 months. Univariate analysis showed that completion of chemotherapy, good clinical response, low histological grade, small pathological invasive size (pT), less positive node, no lymphatic invasion (ly-), no vascular invasion (v-), and pCR were the significant factors for both favorable DFS and OS. Multivariate analysis demonstrated that completion of chemotherapy, good clinical response, low histological grade, less positive nodes, and v- were the significant factors for favorable DFS and OS. The pCR was not a significant prognostic factor for TNBC patients receiving PST.

**Conclusions:** Our data demonstrated that pCR was not independent favorable prognostic factor among TNBC patients receiving PST. Clinical response, histological grades, nodal status, and vascular invasion, instead of pCR, were significant factors for the patients' prognosis.

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## Neoadjuvant Endocrine Therapy: Retrospective Analysis of Some Mechanisms of Resistance

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**Background:** At least three randomized trials of neoadjuvant endocrine therapy were conducted in our cancer centers and published (Semiglazov et al. Proc. Am Soc. Clin. Oncol. 2004; 22(145): 519: J Clin. Oncol 2005: 23; 530; Cancer 2007: 110; 244–254).

Patients and Methods: A total of 440 postmenopausal women with ER-positive and/or PgR-positive breast cancer (T2N1-2, T3N0-1, T4N0M0), previously (2001–2007) received neoadjuvant endocrine therapy of aromatase inhibitors [IA] (anastrazole, letrozole, exemestane; n = 211) or tamoxifen (TAM) [n = 229], were included into retrospective analysis.

On the basis of immynohistochemical (IHC) analysis of the archive pathological material we reevaluated the levels of expression of ER/PgR, HER2 and cyclin D1 expression (Histocore-Labvision) before neoadjuvant therapy (cut biopsy material) and after surgery (surgical specimens).

**Results:** There was a higher overall rates of clinical objective response (ORR) among patients of both arm with high levels of ER (Allred score ≥ 6) [ORR = 53% in TAM group vs 70% in Al group].

Co-expression of hormone receptors (HR) and HER2 was revealed in 17% of 440 patients. Our data confirm previously results (Ellis et al, 2001) that TAM is less effective than Al in HER2 + and HR+ tumors (ORR=23% in TAM arm vs 47.7% in Al arm; p = 0.052).

Over-expression of cyclin D1 has been linked to breast cancer growth, as well as development of resistance to hormone therapy.

Cyclin D1 low level (less than 30%) was revealed in 79 of 142 patients (55.6%), moderate level (>30–70%) in 53 patient (37.3%), high level (>70%) in 26 patient (18.3%). More than 60% patient with low level of cyclin D1 expression responded to endocrine therapy (ORR = 65% in TAM group vs 76% in A1 group, p = 0.072). There was clinical response with AI (ORR = 46.6%) but not with TAM in patient whose tumor expresse high level cyclin D1. Striking down regulation in cyclin D1 and PgR were seen only in the AI arm.

After a mean follow up 60 months distant recurrences were observed in 25.5% of patients in TAM arm vs 12.0% in Al arm when tumors have moderate or high levels cyclin D1 expression (p = 0.054).

Conclusion: HR+ breast cancers with co-expression of HER2, cyclin D1, low level HR – less sensitive to neoadjuvant endocrine therapy a, namely, to TAM.

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## Feasibility Study of Adjuvant Chemotherapy with S-1 for Advanced Breast Cancer After Primary Systemic Chemotherapy

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Background: Primary systemic chemotherapy (PSC) for advanced breast cancer has been performed preoperatively as standard treatment in late years. Although in cases which were pathological complete response (pCR), they might be better in survival benefit, we often experience non-pCR cases, and they have higher risk to recur postoperatively. Therefore, the new therapeutic strategy that could expect the improvement of treatment effect is mandatory for advanced breast cancer. In this study, we conducted a feasibility study using S-1 as postoperative adjuvant chemotherapy for curatively resected advanced breast cancer patients after PSC.

Material and Methods: Patients with stage II or III breast cancer who underwent anthracycline and/or taxan based PSC followed by surgery were enrolled in this study. Adjuvant chemotherapy consisted of eighteen courses (2-week administration and 1-week withdrawal) of S-1, at 100–120 mg/body per day. From September 2007 to April 2010, forty patients from 2 institutions were enrolled in this pilot study. In cases judged to require postoperative radiotherapy, the concurrent administration was permitted. If they were estrogen and/or progesterone receptor positive, endocrine therapy was permitted concurrently, and if they were human epidermal growth factor receptor 2 positive, trastuzumab was also administered concurrently. The primary end point was successful execution rate of the administration of S-1 for eighteen courses (one year).

Results: Thirty-eight patients were eligible. In 5 patients, S-1 administration was discontinued due to recurrence. Among the 33 patients without recurrence, the planned eighteen courses of S-1 were administered to 21 patients (63.6%). In 7 patients, S-1 administration was discontinued due to subjective symptoms, such as nausea or anorexia. Adverse reactions such as neutropenia, leukopenia, thrombocytopenia, anemia, elevated liver function, anorexia, general fatigue, diarrhea, nausea, and stomatitis were comparatively frequent. Although grade 3 neutropenia (10.0%), leukopenia (7.5%), and diarrhea (5.0%) were observed, no grade 4 adverse effects appeared.

**Conclusions:** Postoperative administration of S-1 for one year seems feasible as adjuvant chemotherapy for advanced breast cancer after PSC.

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## Comparative Study of Breast MRI and Ultrasonography for the Residual Tumor Extent and Response Monitoring in Breast Cancer Patients Undergoing Neoadjuvant Chemotherapy

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**Background:** To decide the surgical procedure and postoperative treatment clinically, it is necessary to assess the response to cytotoxic drugs acurrately in breast cancer patients undergoing neoadjuvant chemotherapy (NAC).

Materials and Methods: We examined 49 patients undergoing NAC for locally advanced breast cancer between July, 2008 and February, 2011. All underwent MRI and USG prior to NAC and after NAC. We compared residual tumor extent on MRI and USG, with pathological results, to investigate effectiveness of MRI rather than USG. The residual tumor response on MRI and USG was based on RECIST (version 1.1). Analysis was performed using T-test and Spearman's correlation coefficient.

Results: MRI examination of patients completing NAC revealed that 7 patients had complete remission(CR), 25 patients had partial remission(PR), 8 patients had stable disease(SD), and 9 with progressive disease(PD). 4 patients had CR, 32 patients had PR, 8 patients had SD, 5 with PD on USG. Specificity was 90.8%, sensitivity was 81.6%, and accuracy was 86.2% on MRI. Specificity was 72.7%, sensitivity was 86.8%, and accuracy was 79.8% on USG. Spearman's correlation coefficient were 0.731 on MRI, and it was 0.271 on USG. There is no statistical significance in comparison residual tumor extent MRI and USG, compared with pathological results on t-test(p > 0.05).

Conclusions: Accuracy and Spearman's correlation coefficient on MRI were higher than USG during comparing pathologic results on the residual tumor size after NAC. MRI tends to be more precise for the assessment of residual tumor extent in advanced breast cancer receiving NAC.