**Hypofractionated Radiation Therapy After Mastectomy for the Treatment of High-Risk Breast Cancer: 5-Year Follow-Up Result of a Randomized Trial**

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**Purpose/Objective(s):** Randomized trials testing hypofractionated radiotherapy (HFRT) after breast conservative surgery in women with early breast cancer have reported similar results compared with conventional fractionated radiotherapy (CFRT). We conducted a phase III non-inferior randomized trial to evaluate the efficacy and toxicity of HFRT after mastectomy. In this analysis, we report the 5-year result.

**Materials/Methods:** From 2008 to 2016, 820 high-risk patients mainly with stage III breast cancer were enrolled. Patients were randomly assigned after mastectomy to receive either HFRT (43.5 Gy/15f/3w) or CFRT (50 Gy/25f/5w) to the chest wall and supraclavicular nodal region. The primary endpoint was locoregional recurrence (LRR). The recurrence and survival rates were calculated by using the Kaplan-Meier method and compared by log-rank test. Acute and late toxicities were scaled with CTC3.0 criteria, and Chi-squire test was used to compare the differences

**Results:** Of 811 eligible patients, there were 400 in HFRT and 411 in CFRT group. The median age was 49 years (range, 24-74). 767 (94.6%) patients had stage III and 44 (5.4%) had stage II diseases. All received chemotherapy. 139 (17.1%) patients received trastuzumab targeted therapy. Out of 644 patients with ER and/or PR positive, 603 (93.6%) received hormonal therapy. The baseline characteristics were well balanced be- tween the two groups. With a median follow-up of 52 months (IQR, 39-79) for surviving patients, the 5-year cumulative incidence of LRR was 92.8%. The 5-year distant metastasis (DM), disease-free survival (DFS) and overall survival (OS) were 22.7%, 74.9%, and 86%. There were no significant differences in 5-year LRR (8.4% vs. 6.0%, P = 0.396), DM (21.3% vs. 24.3%, P = 0.530), DFS (75.1% vs. 74.6%, P = 0.841), and OS (84.9% vs. 87.1%, P = 0.562) between HFRT and CFRT group. The incidences of symptomatic radiation pneumonitis, lymphedema, and shoulder disorder were similar between the two groups, but there was less grade 3 acute skin toxicity in HFRT group. Four patients developed ischemic heart disease with 1 in HFRT and 3 in CFRT group. No brachial plexopathy occurred during follow-up.

**Conclusion:** In patients with high-risk breast cancer after mastectomy, 43.5 Gy delivered in 15 fractions over 3 weeks has comparable efficacy and toxicity at 5 years with standard fractionation. Long-term follow-up is required.