Aim: Nab-paclitaxel, which consists of human albumin stabilized nanoparticle formation, is one of chemotherapy drugs for metastatic breast cancer. In pivotal Phase III trial of metastatic breast cancer, triweekly regimen of nab-paclitaxel was significantly greater efficacy than triweekly regimen of paclitaxel. However, weekly administration of paclitaxel is regarded as standard regimen for metastatic breast cancer. We tend to avoid using triweekly regimen of paclitaxel for metastatic breast cancer. The candidate dosage of weekly nab-paclitaxel treatment is 100, 125 or 150 mg/m², but we could not determine which becomes the standard regimen. We will confirm the safety of weekly nab-paclitaxel dosed at 100 mg/m² in Japanese women with HER2 negative metastatic breast cancer and subsidiarily evaluate the effectiveness of this regimen.

Methods: Patients with metastatic breast cancer were pathologically confirmed adenocarcinoma of the breast. Less than 3 regimens for metastatic breast cancer were eligible for inclusion. Patients received nab-paclitaxel dosed at 100 mg/m² with 3.3 mg of dexamethasone as premedication on day 1, 8 and 15 of 28 day cycle. The primary endpoint was safety, which was defined as the percentage of patients who achieved 2 cycle of this regimen. Secondary endpoint was efficacy.

Results: Thirty-nine patients were enrolled in this trial from plural facilities in Hokkaido, Japan. The mean age of patients was 60 years old (range : 43-77). Seventy-four % of patients have ER positive breast cancer and 41 % of patients have taken adjuvant chemotherapy. We defined the ratio of achieving two cycle of this regimen as the safety. Eighty-seven % of the patients were treated not less than two cycle of this regimen safely. The mean of relative dose intensity was 91.6 %. The most frequent adverse event was neutropenia. Grade 3 or 4 neutropenia was occurred in 44.7 % of the patients. There was no grade 3 or 4 neuropathy.

Conclusions: Weekly nab-paclitaxel dosed at 100 mg/m² proved to be a safety regimen in this trial. The choice of this regimen is appropriate not only for first-line therapy of metastatic breast cancer but also for heavily pretreated metastatic breast cancer.

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