

Phase II Trial of Paclitaxel monotherapy in Refractory Breast Cancer

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BACKGROUND: We have performed a single institute phase II clinical trial of Paclitaxel to determine its anti-tumor activity in patients with metastatic breast cancer who had failed to anthracycline based combination chemotherapy.

METHOD: Patients were eligible for this study only if there were any disease progression after they had been pre-treated with anthracycline based combination chemotherapy in an adjuvant or metastatic setting. Paclitaxel 175mg/m² was administered as a 3 hour continuous infusion every 3 weeks with a support of prophylactic G-CSF. This treatment was continued until one of the followings occurred: disease progression, unacceptable adverse effect, or treatment refusal by the patient. Intercurrent palliative radiotherapy or concurrent hormonal therapy was permitted depending on each patient's status. All the endpoints were evaluated under the principle of intention to treat analysis. **RESULTS:** A total of 63 patients entered the study and 5 patients were not evaluable because they refused further chemotherapy after the first or second course of treatment before response evaluation. Objective response rate of all the 54 patients who had at least one measurable lesions were 37%(20/54). All the responses were partial. The median response duration was 4 months(range, 2-16 months). The median progression free and overall survival was 4 months(95% CI, 3-5 months) and 18 months(95% CI, 12-24 months), respectively. A 95% of planned dose was delivered. Out of a total 329 cycles administered, about 12% of patients experienced Grade 3 or 4 leukopenia. Other hematologic or non hematologic toxicities were not remarkable. **CONCLUSION:** Paclitaxel was active and tolerable drug in the treatment of metastatic breast cancer patient who had already been treated with anthracycline based combination chemotherapy.

Phase II Trial of Infusional 5-Fluorouracil, Doxorubicin and Cyclophosphamide in advanced breast cancer

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Purpose: We considered a phase II study to estimate the response rate and toxicity of Infusional 5-fluorouracil, doxorubicin and cyclophosphamide treatment in advanced breast cancer.

Patients and Methods: Seventy-one women with stage IV were enrolled in this phase II study. Breast cancer patients with bidimensionally measurable disease or evaluable disease received a 1000 mg/m² intravenous 24 hour infusional 5-fluorouracil (Day 1-5), doxorubicin 40 mg/m² intravenous bolus (Day 1) and cyclophosphamide 600 mg/m² intravenous bolus (Day 1) every 3 weeks.

Results: Overall response rate was 59.1%. The median duration of response was 10.5 months, the median progression free duration was 14.0 months, the median time to response was 4 months and the median overall survival duration was 23.0 months. The median number of cycles per patients was 12. The median cumulative dose of 5-fluorouracil was mg/m²/week, doxorubicin was 11.2 mg/m²/week and cyclophosphamide was 188.0 mg/m²/week. Grade III/IV neutropenia, thromocytopenia, and anemia occured in 59.2 %, 4.2 % and 8.5% of patients, respectively. Grade III/IV nausea, vomiting, musositis, conspitation, diarrhea did not occur. However grade 4 of cardiac toxicity occured 5.6 % of patients.

Conclusion: This chemotherapy regimen, including infusional 5-fluorouracil, doxorubicin and cyclophosphamide was active regimen against advanced breast cancer (Overall response rate: 59.1%) with low non hematologic toxicities.