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### **Key Words**

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## **Original**

# Phase-II Study of Three-hour Infusion Paclitaxel for Metastatic Breast Cancer after Failed Adjuvant Therapy of Anthracycline-containing Regimens

#### **ABSTRACT**

**Background.** In previous phase I and II trials, paclitaxel (Anzatax) exerts novel cytotoxic effect on ovarian, lung, and head and neck cancers. Further information is required on using paclitaxel in breast cancer.

**Aim.** To evaluate the efficacy and toxicity of paclitaxel as first line chemotherapy by 3-h infusion to patients after failed adjuvant chemotherapy with anthracycline-containing regimens.

Methods. Between November 1995 and November 1996, a total of 25 eligible women with metastatic breast cancer were enrolled in this study; and all patients had to have measurable lesions. The median age of the patients was 46.9 years (range 30–65). All of them were definitely evidenced as metastatic breast cancer and received six courses of anthracycline-containing agents as adjuvant chemotherapy for at least 1 year before applying paclitaxel. The protocol utilized paclitaxel in the moderate dosage of 175 mg/m² by 3-h intravenous infusion every 3 weeks.

**Results.** A total of 117 cycles were administered on these 25 patients with median delivered cycles of 4 (4–10) and response rate was 36% (95% CI: 17.2%–54.8%) including 2 complete response, 7 with partial response, 6 with stable disease, 10 with progressive disease. The median time to progression was 2.5 (range 0.5-7.6) months and the median survival was 7 months. Twelve percent showed grade 3 anemia and 24% showed grade III–IV leukopenia, while only 4% grade II thrombocytopenia. Grade III sensory neuropathy was seen in 4% of these patients, and 8% had grade III myalgia.

**Conclusions.** This study shows that paclitaxel exerts moderate activity as first-line chemotherapy on patients after failed adjuvant chemotherapy with anthracycline containing regimens and the toxicities are acceptable.

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