Phase II pilot study of weekly Docetaxel as Neoadjuvant Chemotherapy for operable Breast Cancer

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Abstract

Purpose: In this study of weekly docetaxel in the neoadjuvant treatment of stage II breast cancer, we evaluated the efficacy and safety of docetaxel and analyzed the correlation between the response observed and the expression of c-*erb*B2, ER status.

Patients and Methods: This study included patients with previously untreated, stage II & III breast cancer. Docetaxel was given as a 30-min i.v. infusion at a dose of 40 mg/m2 weekly for 6 weeks, followed by 2 weeks rest. Patients received two 8-week cycles of treatment. Patients achieving a CR or partial response or who had stable disease at the end of treatment proceeded directly to surgery.

Results: A total of 40 patients were evaluated by intention-to-treat analysis for efficacy and safety. The overall clinical response rate was 65% (complete and partial response, 25 and 40%, respectively). Six patients (15%) achieved a pathological complete response. There was no correlation between response to docetaxel and the expression of molecular markers, however, the majority of the pathological complete responses were observed in patients with c-*erb*B2-negative tumors. Non-hematological toxicity was more common than hematological toxicity, with alopecia and asthenia were the most frequently reported adverse events. Severe hematological toxicity was rare.

Conclusion: Weekly docetaxel appears to be very effective in the neoadjuvant setting. A high pathological response rate was achieved with tolerable toxicity