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A Phase II Study of the Combination of Gemcitabine Plus Carboplatin as the Neoadjuvant Treatment in Locally Advanced Breast Cancer

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Abstract

Objective: Although anthracycline-based regimen is standard neoadjuvant chemotherapy (NAC) for locally advanced breast cancer (LABC), there is some concern over its toxicities such as alopecia and cardiotoxicity. Gemcitabine is another active agent in metastatic breast cancer after failure to anthracycline with less toxicity. The objective of the present study is to evaluate the efficacy and safety of the combination of gemcitabine and carboplatin as NAC in LABC.

Material and Method: Patients with histologically confirmed LABC (T3, T4 or N2 and M0) were included. Patients were scheduled to receive 3 cycles of neoadjuvant GC (gemcitabine 1,000 mg/m² D1, D8 and carboplatin AUCx5 D1) every 21 days. Patients with clinical response underwent surgery and additional 3 cycles of adjuvant GC. Primary end point was clinical response rate whereas secondary end points included pathological response, DFS, OS and toxicity.

Results: Between 2004 and 2007, 40 LABC patients were enrolled. Of 40 patients, 35 were evaluable for efficacy and 40 for toxicity. Twenty-three out of 35 patients (65%) obtained cPR. Among 22 patients who had clinical response and who underwent surgery, overall pathological response rate was 51.5% with 1-pCR (2.9%) and 17-pPR (48.5%). All 7 triplenegative patients had pathological response (1-pCR, 6-pPR). At median follow-up of 59 months, median DFS and OS were not reached. Five-year OS and DFS were 67% and 62%, respectively. Major adverse effect was myelosuppression without fatal complications.

Conclusion: The combination GC was feasible and well-tolerated for LABC in neoadjuvant setting. Triple-negative subgroup seems to have high response to GC.

Keywords: Carboplatin, Chemotherapy, Gemcitabine, Locally advanced breast cancer, Neoadjuvant therapy

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