breast cancer, metastatic

SAFETY AND EFFICACY OF VINORELBINE PLUS LOW-DOSE METRONOMIC CYCLOPHOSPHAMIDE IN PATIENTS WITH METASTATIC BREAST CANCER PREVIOUSLY TREATED WITH ANTHRACYCLINES AND TAXANES

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Aim: Metronomic chemotherapy has recently gained attention as a promising experimental strategy, involving alternative or complementary ways of using old and new anticancer chemotherapeutic agents. This study aimed to determine the toxicity, safety, and efficacy of a combination of vinorelbine and low-dose metronomic cyclophosphamide (CPA) in patients with metastatic breast cancer (MBC) previously treated with anthracyclines and taxanes.

Methods: Eligibility criteria were as follows: human epidermal growth factor receptor (EGFR) 2-negative MBC previously treated with anthracyclines and taxanes, ECOG PS 0–1, and adequate bone marrow and organ function. Prior hormone therapy for MBC was permitted. In this study, patients received vinorelbine (40 mg/m²) intravenously on days 1 and 8, and CPA (100 mg) orally once daily on days 1–14, every third week. The primary endpoints were the objective response rate (ORR) at 6 months and median time to progression (TTP). Secondary endpoints included safety and tolerability.

Results: Between July 2010 and March 2014, 15 patients (median age 54.8 years [range, 37–67 years]) were enrolled. 80% were estrogen receptor and/or progesterone receptor positive, and 20% were triple negative. Sites of metastasis included the lymph nodes (53%), lungs (47%), liver (47%), and bone (47%). Five patients (33%) had ≥3 sites of metastasis. A total of 179 cycles of chemotherapy were administered (median, 11 cycles; range, 1–29 cycles). The ORR at 6 months was 73.3%, including 6 (40%) patients with partial responses and 5 (33%) with stable disease. The median TTP was 9.2 months (95%CI). The most common hematologic toxicity was grade 2 neutropenia (30%); no grade 3/4 hematologic toxicity was observed. The most common non-hematologic toxicities were grade 1 hair loss (30%) and grade 2 neuropathy (20%). Discontinuation to adverse events did not occur.

Conclusions: The combination of vinorelbine and low-dose cyclophosphamide is safe, with minimal adverse effects; it shows promising antitumor activity in patients with MBC refractory to anthracyclines and taxanes. Further clinical evaluation of this combination is warranted.

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