Prospective Multicenter Randomized Phase III Study of Weekly versus Standard Docetaxel (D2) for First-Line Treatment of Metastatic Breast Cancer

Abstract:
Purpose: Previous phase II studies have indicated a greatly reduced hematotoxicity of docetaxel-based regimens administered on weekly schedules. The present trial was initiated to randomly compare the toxicity and efficacy of weekly docetaxel versus its standard 3-weekly application. Methods: Patients previously untreated with chemotherapy for metastatic disease were recruited. Patients aged >60 years or with a Karnofsky Performance Status (KPS) of 60–80% were eligible for the D2 study. Patients were randomized to receive docetaxel either on a 3-weekly [75 mg/m² every 3 weeks (q3w)] or on a weekly (30 mg/m² on days 1, 8, and 15; q4w) schedule. Treatment was continued until a maximum of 8 cycles, unacceptable toxicity, or disease progression. All patients received standard corticosteroid prophylaxis. Results: Since statistical significance for the primary endpoint (toxicity) was achieved in the interim analysis, the study was closed according to the study protocol (102 of 162 patients). Compared to the standard arm, leukopenia grade 3 was a rare event in the weekly arm of the D2 study (per-patient analysis: 4.2% q1w vs. 51.9% q3w; p < 0.0001). No difference was observed between the 2 schedules regarding the occurrence of anemia or
thrombocytopenia. With regard to nonhematological toxicity, there was a higher incidence of skin/nail and hepatic toxicity with the weekly schedule, whereas neurotoxicity was observed more often in the standard arm. The rate of omitted doses was significantly increased in the weekly arm (8.6% q1w vs. 0% q3w). The overall response rate was 22.9% in the weekly arm compared to 42.6% in the standard arm (p = 0.039). Time to progression was 5.4 (q1w) versus 6.3 (q3w) months (p = 0.91), and overall survival was 22.7 (q1w) versus 15.8 (q3w) months (p = 0.24). Conclusion: The present data support the feasibility of both weekly and 3-weekly application of docetaxel. As expected, severe leukopenia seems avoidable in weekly scheduled single-agent docetaxel and may serve as an important treatment option, particularly in elderly patients and patients with a reduced performance status.

Stichwörter: Docetaxel; Weekly application; Metastatic breast cancer; Combination chemotherapy

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