Prospective Multicenter Randomized Phase III Study of Weekly versus Standard Docetaxel plus Doxorubicin (D4) 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 compare the toxicity and efficacy of weekly docetaxel versus its standard 3-weekly application in combination with doxorubicin.

Methods: Patients previously untreated with chemotherapy for metastatic disease were recruited. Inclusion criteria were age 0.05). Grade 3 and grade 4 fever, diarrhea, and infections occurred more frequently in the standard arm, whereas neurotoxicity and skin/nail disorders were observed more frequently in the weekly arm. Except for fever, none of these differences reached a level of significance. Dose delays, dose reductions, and the rate of omitted doses were increased in the weekly arm. The overall response rate was 44.2% in the weekly arm compared to 52.4% in the standard arm (p = 0.52). Time to progression was 6.2 (q1w) versus 10.3 (q3w) months (p = 0.36), and overall survival was 20.5 (q1w) versus 28.7 (q3w) months (p = 0.98).

Conclusion: The present data support the feasibility of both weekly and 3-weekly application of docetaxel in combination with doxorubicin. Nevertheless, given that leukopenia was similar in both arms and the
efficacy parameters were at least numerically inferior with the weekly schedule, standard 3-weekly application seems to be preferable for patients requiring combination chemotherapy.

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

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