Reduced incidence of severe palmar-plantar erythrodysesthesia and mucositis in a prospective multicenter phase II trial with pegylated liposomal doxorubicin at 40 mg/m² every 4 weeks in previously treated patients with metastatic breast cancer.

Abstract:

PURPOSE: The aim of this study was to assess whether the reduction in the total dose of pegylated liposomal doxorubicin (PLD) per cycle from 50 mg/m² every 4 weeks to 40 mg/m² every 4 weeks can effectively lower the incidence of treatment-related palmar-plantar erythrodysesthesia (PPE) and mucositis. METHODS: Patients received PLD 40 mg/m² every 4 weeks, and were evaluated for toxicity prior to each treatment and for response every 8 weeks. RESULTS: All patients were previously treated with at least one chemotherapy regimen for metastatic disease, and 72% of the patients had a prior exposure to an anthracycline. Forty-six evaluable patients received a median of four PLD cycles, with a median dose intensity of 10 mg/m²/week and a median cumulative dose of 160 mg/m². No National Cancer Institute Common Toxicity Criteria (NCI-CTC) grade 3 or 4 PPE was observed in these patients. NCI-CTC grade 3 or 4 mucositis occurred in 4.3% of patients, only. Response rates and survival results observed here were comparable to those observed with PLD 50 mg/m² every 4 weeks in a matched patient population. However, patients treated with PLD 40 mg/m² every 4 weeks experienced less PPE and mucositis.
and required clearly less dose reductions and treatment delays. CONCLUSION: The favorable safety profile observed in this study leads us to recommend the use of PLD 40 mg/m(2) every 4 weeks for patients with advanced breast cancer.