Epirubicin and vinorelbine are considered active drugs in metastatic breast cancer. The optimal duration of a chemotherapy regimen for metastatic breast cancer patients is still unknown. Nevertheless, epirubicin has a dose-limiting cardiotoxicity. Vinorelbine is also available as oral formulation. In a multicenter phase II study, we analyzed the feasibility and the efficacy of a maximum of six cycles of i.v. epirubicin plus vinorelbine, followed by oral vinorelbine. We enrolled 30 patients with metastatic breast cancer. Each patient received epirubicin (75 mg/m² on day 1) and vinorelbine (25 mg/m² on days 1-8), every 3 weeks, for three cycles or six cycles in case of objective response or stable disease. When a clinical benefit was obtained, patients received oral vinorelbine (60 mg/m² on days 1-8 every 3 weeks for three cycles). The regimen demonstrated to be active and well tolerated in metastatic breast cancer, and 6-8 months represented the optimal treatment duration. Maintenance therapy with oral vinorelbine was feasible, effective, safe and well accepted by the patients.

Key words: chemotherapy, maintenance chemotherapy, metastatic breast cancer, oral vinorelbine.