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# Phase II trial of non-pegylated liposomal doxorubicin and low-dose prednisone in second-line chemotherapy for hormone-refractory prostate cancer

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ABSTRACT

**Aims and background.** Non-pegylated liposomal doxorubicin (NPLD) (Myocet) has shown marked *in vitro* activity in castration-resistant prostate cancer (CRPC) and also in docetaxel-resistant cells, higher than that shown by pegylated liposomal doxorubicin. Its activity would seem to be due to a high intracellular drug concentration and induction of Golgi-dependent apoptosis. On the basis of these results, a clinical study was designed to assess the activity of NPLD and low-dose prednisone in second-line therapy.

**Methods.** Fifty-four patients were enrolled and evaluated. Eligibility criteria were histologically confirmed CRPC, PSA >20 ng/mL or measurable lesions according to the RECIST criteria, previous docetaxel-based chemotherapy, and adequate cardiac function. Patients were treated with weekly intravenous NPLD 25 mg/m$^2$ and daily prednisone 10 mg until progression.

**Results.** Median patient age was 69 years (range, 52-83) and median baseline PSA concentration was 120 ng/mL (range, 5.35-4350). Sixteen (29.6%) patients had measurable lesions. Objective or PSA responses (>50% reduction) were observed in 8 (14.8%) patients. The median time to progression was 2.8 months and the median overall survival was 11.3 months. Toxicity was generally mild (grade 1-2) and infrequent, with grade 3-4 neutropenia in 12.9% of cases. Grade 3 nonhematological toxicities included nausea in 2 patients (3.7%) and fatigue and stomatitis in 1 case (1.9%). No drug-related serious adverse events were reported.

**Conclusions**. Weekly administration of NPLD is a well tolerated treatment with proven albeit limited activity.

***Key words:*** castration-resistant prostate cancer, liposomal anthracyclines, chemotherapy, translational research.

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