An open label, non-comparative phase II study of topotecan as salvage treatment for patients with soft tissue sarcoma.

BACKGROUND: The number of effective cytotoxic agents for the treatment of patients with metastatic soft tissue sarcoma (STS) is limited, especially when patients have failed anthracycline-based chemotherapy. PATIENTS AND METHODS: Between 1999 and 2000 a total of 16 patients with histologically proven STS progressing during or after first-line anthracycline-based chemotherapy were entered into this open-label, noncomparative study. Topotecan was administered as a 30-min infusion at a dosage of 1.5 mg/m² on five consecutive days every 3 weeks. All patients had received an anthracycline- or ifosfamide-based first-line chemotherapy. RESULTS: None of the 16 included patients achieved an objective response to topotecan. Six patients achieved stable disease (38%), lasting for at least 6 weeks in four patients (25%) and for less than 6 weeks in two patients (13%). Ten patients (62%) had progressive disease. The median time to progression was 79 days calculated from the start of topotecan therapy (range, 28-230). The treatment was well tolerated; however, both anemia and thrombopenia grade III/IV occurred in 25% of the patients as well as severe neutropenia in 69% of the patients. Nonhematologic toxicities grade III/IV such as diarrhea and severe bleeding occurred only in one patient each (6%). DISCUSSION: Topotecan is well tolerated in...
anthracycline-resistant patients with metastatic STS, but no objective response has been observed in this trial.

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