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Title

Adjuvant Chemotherapy for Adult Soft Tissue Sarcomas of the Extremities and Girdles: Results of the Italian Randomized Cooperative Trial.[Report]

Source

Journal of Clinical Oncology. 19(5):1238-1247, March 1, 2001.

Abstract

Purpose: Adjuvant chemotherapy for soft tissue sarcoma is controversial because previous trials reported conflicting results. The present study was designed with restricted selection criteria and high dose-intensities of the two most active chemotherapeutic agents.

Patients and Methods: Patients between 18 and 65 years of age with grade 3 to 4 spindle-cell sarcomas (primary diameter >= 5 cm or any size recurrent tumor) in extremities or girdles were eligible. Stratification was by primary versus recurrent tumors and by tumor diameter greater than or equal to 10 cm versus less than 10 cm. One hundred four patients were randomized, 51 to the control group and 53 to the treatment group (five cycles of 4'-epidoxorubicin 60 mg/m2 days 1 and 2 and ifosfamide 1.8 g/m2 days 1 through 5, with hydration, mesna, and granulocyte colony-stimulating factor).

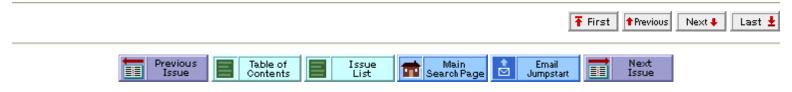
Results: After a median follow-up of 59 months, 60 patients had relapsed and 48 died (28 and 20 in the treatment arm and 32 and 28 in the control arm, respectively). The median disease-free survival (DFS) was 48 months in the treatment group and 16 months in the control group (P = .04); and the median overall survival (OS) was 75 months for treated and 46 months for untreated patients (P = .03). For OS, the absolute benefit deriving from chemotherapy was 13% at 2 years and increased to 19% at 4 years (P = .04).

Conclusion: Intensified adjuvant chemotherapy had a positive impact on the DFS and OS of patients with high-risk extremity soft tissue sarcomas at a median follow-up of 59 months. Therefore, our data favor an intensified treatment in similar cases. Although cure is still difficult to achieve, a significant delay in death is worthwhile,

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also considering the short duration of treatment and the absence of toxic deaths.

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