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# A Phase II Trial of 5-Day Neoadjuvant Radiotherapy for Patients with High-Risk Primary Soft Tissue Sarcoma

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## Abstract

**Purpose:** In a single-institution phase II study, we evaluated the safety of a 5-day dose-equivalent neoadjuvant radiotherapy (RT) regimen for high-risk primary soft tissue sarcoma.

**Patients and methods:** Patients received neoadjuvant RT alone (30 Gy in five fractions) to the primary tumor with standard margins. The primary endpoint was grade  $\geq 2$  late-radiation toxicity. Major wound complications, local recurrences, and distant metastases were also examined. In exploratory analysis, we evaluated germline biomarkers for wound toxicity and the effects of the study on treatment utilization.

**Results:** Over 2 years, 52 patients were enrolled with median follow-up of 29 months. Seven of 44 evaluable patients (16%) developed grade  $\geq 2$  late toxicity. Major wound complications occurred in 16 of 50 patients (32%); a signature defined by 19 germline SNPs in miRNA-binding sites of immune and DNA damage response genes, in addition to lower extremity tumor location, demonstrated strong predictive performance for major wound complications. Compared with the preceding 2-year period, the number of patients treated with neoadjuvant RT alone at our institution increased 3-fold, with a concomitant increase in the catchment area.

**Conclusions:** A shorter 5-day neoadjuvant RT regimen results in favorable rates of wound complications and grade  $\geq 2$  toxicity after 2-year follow-up. Five-day RT significantly increased utilization of neoadjuvant RT at our high-volume sarcoma center. With further validation, a putative germline biomarker for wound complications may guide safer RT utilization.