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Abstract

**Background:** The predominant pattern of failure of retroperitoneal sarcoma (RPS), frequently associated with subsequent death, is locoregional recurrence. Unlike in limbs, the efficacy of radiotherapy (RT) combined with surgery is not established. **Methods:** STRASS is a randomized, multicentre, international trial. Eligible patients had histologically-proven localized primary RPS, operable and suitable for radiotherapy. Patients were randomized 1:1 to preoperative RT (3D-CRT or IMRT) 50.4 Gy followed by surgery (RT/S group)
or surgery alone (S group), stratified by hospital and performance status (0-1 vs 2). Primary endpoint is abdominal recurrence-free survival (ARFS; local relapse after complete resection, peritoneal sarcomatosis, R2 surgery, progressive disease during RT or unresectable disease). IDMC recommended a sensitivity analysis in which local progression on RT is not regarded as an event for patients who subsequently achieve complete surgical resection. Secondary endpoints were recurrence-free survival, overall survival, acute toxicity profile of RT, perioperative and late complications, and QoL. The study was designed to provide 90% power to show an increase of 20% in the 5-year ARFS rate, from 50% to 70% (corresponding to a HR of 0.52) at 2-sided 5% significance level. **Results:** 266 patients from Europe, USA and Canada were randomized between January 2012 and April 2017; 198 patients (74.5%) had liposarcoma (LPS). Eighteen patients were designated ineligible. Overall rate of re-operation for any complication was 10.1%: 13 (10.9%) and 12 (9.4%) patients in RT/S versus S groups. 19 pts (14%) progressed during RT, 4 of whom did not undergo surgery. 3-year ARFS was 60.4% (95% Confidence interval (CI) 51.4-68.2%) and 58.7% (49.5-66.7%) (HR = 1.01, 95%CI 0.71-1.44, p=0.954) in RT/S versus S groups. In the sensitivity analysis, 3-year ARFS was 66.0% (57.1-73.5%) and 58.7% (49.5-66.7%) in RT/S versus S groups (HR = 0.84, 95% CI 0.58-1.21, p=0.340). In the LPS subgroup, 3-year ARFS (sensitivity analysis) was 71.6% (61.3-79.6%) and 60.4% (49.8-69.5%) in RT/S versus S groups (HR = 0.64, 95%CI 0.40-1.01, p =0.049). **Conclusion:** STRASS failed to demonstrate a benefit of pre-operative RT for RPS. In the exploratory analysis, preoperative RT may benefit the LPS subgroup. Funding Source: EORTC and EUROSARC FP7 278472. Clinical trial information: EORTC 62092.

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