Retroperitoneal

Preoperative radiotherapy plus surgery versus surgery alone for patients with primary retroperitoneal sarcoma (EORTC-62092: STRASS): a multicentre, open-label, randomised, phase III trial.

Bonvalot S, Gronchi A, Le Péchoux C, Swallow CJ, Strauss D, Meeus P, van Coevorden F, Stoldt S, Stoeckle E, Rutkowski P, Rastrelli M, Raut CP, Hompes D, De Paoli A, Sangalli C, Honoré C, Chung P, Miah A, Blay JY, Fiore M, Stelmes JJ, Dei Tos AP, Baldini EH, Litière S, Marreaud S, Gelderblom H, Haas RL.

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BACKGROUND

Unlike for extremity sarcomas, the efficacy of radiotherapy for retroperitoneal sarcoma is not established. The aim of this study was to evaluate the impact of preoperative radiotherapy plus surgery versus surgery alone on abdominal recurrence-free survival.

METHODS

EORTC-62092 is an open-label, randomised, phase III study done in 31 research institutions, hospitals, and cancer centres in 13 countries in Europe and North America. Adults (aged ≥18 years) with histologically documented, localised, primary retroperitoneal sarcoma that was operable and suitable for radiotherapy, who had not been previously treated and had a WHO performance status and American Society of Anesthesiologists score of two or lower, were centrally randomly assigned (1:1), using an interactive web response system and a minimisation algorithm, to receive either surgery alone or preoperative radiotherapy followed by surgery. Randomisation was stratified by hospital and performance status. Radiotherapy was delivered as 50·4 Gy (in 28 daily fractions of 1·8 Gy) in either 3D conformal radiotherapy or intensity modulated radiotherapy, and the objective of surgery was a macroscopically complete resection of the tumour mass with en-bloc organ resection as necessary. The primary endpoint was abdominal recurrence-free survival, as assessed by the investigator, and was analysed in the intention-to-treat population. Safety was analysed in all patients who started their allocated treatment. This trial is registered with ClinicalTrials.gov, NCT01344018.

FINDINGS

Between 18 Jan 2012 and 10 April 2017, 266 patients were enrolled, of whom 133 were randomly assigned to each group. The median follow-up was 43·1 months (IQR 28·8-59·2). 128 (96%) patients from the surgery alone group had surgery, and 119 (89%) patients in the radiotherapy and surgery group had both radiotherapy and surgery. Median abdominal recurrence-free survival was 4·5 years (95% CI 3·9 to not estimable) in the radiotherapy plus surgery group and 5·0 years (3·4 to not estimable) in the surgery only group (hazard ratio 1·01, 95% CI 0·71-1·44; log rank p=0·95). The most common grade 3-4 adverse events were lymphopenia (98 [77%] of 127 patients in the radiotherapy plus surgery group vs one [1%] of 128 patients in the surgery alone group), anaemia (15 [12%] vs ten [8%]), and hypoalbuminaemia (15 [12%] vs five [4%]). Serious adverse events were reported in 30 (24%) of 127 patients in the radiotherapy plus surgery group, and in 13 (10%) of 128 patients in the surgery alone group. One (1%) of 127 patients in the radiotherapy plus surgery group died due to treatment-related serious adverse events (gastropleural fistula), and no patients in the surgery alone group died due to treatment-related serious adverse events.

INTERPRETATION

Preoperative radiotherapy should not be considered as standard of care treatment for retroperitoneal sarcoma.