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Surveillance or Metastasis-Directed Therapy for Oligometastatic Prostate Cancer Recurrence: A Prospective, Randomized, Multicenter Phase II Trial.

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Purpose Retrospective studies suggest that metastasis-directed therapy (MDT) for oligorecurrent prostate cancer (PCa) improves progression-free survival. We aimed to assess the benefit of MDT in a randomized phase II trial. Patients and Methods In this multicenter, randomized, phase II study, patients with asymptomatic PCa were eligible if they had had a biochemical recurrence after primary PCa treatment with curative intent, three or fewer extracranial metastatic lesions on choline positron emission tomography-computed tomography, and serum testosterone levels > 50 ng/mL. Patients were randomly assigned (1:1) to either surveillance or MDT of all detected lesions (surgery or stereotactic body radiotherapy). Surveillance was performed with prostate-specific antigen (PSA) follow-up every 3 months, with repeated imaging at PSA progression or clinical suspicion for progression. Random assignment was balanced dynamically on the basis of two factors: PSA doubling time (≤ 3 v > 3 months) and nodal versus non-nodal metastases. The primary end point was androgen deprivation therapy (ADT)-free survival. ADT was started at symptomatic progression, progression to more than three metastases, or local progression of known metastases. Results Between August 2012 and August 2015, 62 patients were enrolled. At a median follow-up time of 3 years (interquartile range, 2.3-3.75 years), the median ADT-free survival was 13 months (80% CI, 12 to 17 months) for the surveillance group and 21 months (80% CI, 14 to 29 months) for the MDT group (hazard ratio, 0.60 [80% CI, 0.40 to 0.90]; log-rank P = .11). Quality of life was similar between arms at baseline and remained comparable at 3-month and 1-year follow-up. Six patients developed grade 1 toxicity in the MDT arm. No grade 2 to 5 toxicity was observed. Conclusion ADT-free survival was longer with MDT than with surveillance alone for oligorecurrent PCa, suggesting that MDT should be explored further in phase III trials.

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