Renal

Definitive radiotherapy in lieu of systemic therapy for oligometastatic renal cell carcinoma: a single-arm, single-centre, feasibility, phase II trial

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BACKGROUND

The role of radiotherapy in metastatic renal cell carcinoma is controversial. We prospectively tested the feasibility and efficacy of radiotherapy to defer systemic therapy for patients with oligometastatic renal cell carcinoma.

METHODS

This single-arm, phase II, feasibility trial was done at one centre in the USA (The MD Anderson Cancer Center, Houston, TX, USA). Patients (aged ≥18 years) with five or fewer metastatic lesions, an Eastern Cooperative Oncology Group status of 0-2, and no more than one previous systemic therapy (if this therapy was stopped at least one month before enrolment) without limitations on renal cell carcinoma histology were eligible for inclusion. Patients were treated with stereotactic body radiotherapy (defined as ≤5.0 fractions with ≥7.0 Gy per fraction) to all lesions and maintained off systemic therapy. When lesion location precluded safe stereotactic body radiotherapy, patients were treated with hypofractionated intensity-modulated radiotherapy regimes consisting of 60-70 Gy in ten fractions or 52·5-67·5 Gy in 15 fractions. Additional rounds of radiotherapy were allowed to treat subsequent sites of progression. Co-primary endpoints were feasibility (defined as all planned radiotherapy completed with <7.0 days unplanned breaks) and progression-free survival. All efficacy analyses were intention-to-treat. Safety was analysed in the as-treated population. A second cohort, with the aim of assessing the feasibility of sequential stereotactic body radiotherapy alone in patients with low-volume metastatic disease, was initiated and will be reported separately. This study is registered with ClinicalTrials.gov, NCT03575611.

FINDINGS

30 patients (six [20%] women) were enrolled from 13 July 2018, to 18 Sept 2020. All patients had clear cell histology and had a nephrectomy before enrolment. All patients completed at least one round of radiotherapy with less than seven days of unplanned breaks. At a median follow-up of 17·5 months (IQR 13·2-24·6), median progression-free survival was 22·7 months (95% CI 10·4-not reached; 1-year progression-free survival 64% [95% CI 48-85]). Three (10%) patients had severe adverse events: two grade 3.0 (back pain and muscle weakness) and one grade 4.0 (hyperglycaemia) adverse events were observed. There were no treatment-related deaths.

INTERPRETATION

Sequential radiotherapy might facilitate deferral of systemic therapy initiation and could allow sustained systemic therapy breaks for select patients with oligometastatic renal cell carcinoma.