Oligometastases

Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of Oligometastatic Cancers: Long-Term Results of the SABR-COMET Phase II Randomised Trial

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J Clin Oncol. 2020 Sep 1;38(25):2830-2838. doi: 10.1200/JCO.20.00818.

PURPOSE

The oligometastatic paradigm hypothesises that patients with a limited number of metastases may achieve long-term disease control, or even cure, if all sites of disease can be ablated. However, long-term randomised data that test this paradigm are lacking.

METHODS

We enrolled patients with a controlled primary malignancy and one to five metastatic lesions, with all metastases amenable to stereotactic ablative radiotherapy (SABR). We stratified by the number of metastases (one to three vs. four to five) and randomised in a 1:2 ratio between palliative standard-of-care (SOC) treatments (arm 1) and SOC plus SABR (arm 2). We used a randomised phase II screening design with a primary end point of overall survival (OS), using an α of 0.20 (wherein $P < 0.20$ indicates a positive trial). Secondary end points included progression-free survival (PFS), toxicity, and quality of life (QOL). Herein, we present long-term outcomes from the trial.

RESULTS

Between 2012 and 2016, 99 patients were randomly assigned at 10 centres internationally. The most common primary tumour types were breast (n = 18), lung (n = 18), colorectal (n = 18), and prostate (n = 16). Median follow-up was 51 months. The five-year OS rate was 17.7% in arm 1 (95% CI, 6% to 34%) versus 42.3% in arm 2 (95% CI, 28% to 56%; stratified log-rank P = 0.006). The five-year PFS rate was not reached in arm 1 (3.2%; 95% CI, 0% to 14% at four years with last patient censored) and 17.3% in arm 2 (95% CI, 8% to 30%; P = 0.001). There were no new grade 2-5 adverse events and no differences in QOL between arms.

CONCLUSION

With extended follow-up, the impact of SABR on OS was larger in magnitude than in the initial analysis and durable over time. There were no new safety signals, and SABR had no detrimental impact on QOL.