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Prostate

Focal Boost to the Intraprostatic Tumour in External Beam Radiotherapy for Patients With Localised Prostate Cancer: Results From the FLAME Randomised Phase III Trial

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J Clin Oncol. 2021 Jan 20;JCO2002873. doi: 10.1200/JCO.20.02873. Online ahead of print.

PURPOSE

This study investigates whether focal boosting of the macroscopic visible tumour with external beam radiotherapy increases biochemical disease-free survival (bDFS) in patients with localised prostate cancer.

PATIENTS AND METHODS

In the phase III, multicenter, randomised controlled Focal Lesion Ablative Microboost in Prostate Cancer trial, 571 patients with intermediate- and high-risk prostate cancer were enrolled between 2009 and 2015. Patients assigned to standard treatment received 77 Gy (fractions of 2.2 Gy) to the entire prostate. The focal boost arm received an additional simultaneous integrated focal boost up to 95 Gy (fractions up to 2.7 Gy) to the intraprostatic lesion visible on multiparametric magnetic resonance imaging. Organ at risk constraints were prioritised over the focal boost dose. The primary end point was 5-year bDFS. Secondary end points were disease-free survival (DFS), distant metastases-free survival, prostate cancer-specific survival, overall survival, toxicity, and health-related quality of life.

RESULTS

Median follow-up was 72 months. Biochemical DFS was significantly higher in the focal boost compared with the standard arm (hazard ratio 0.45, 95% CI, 0.28 to 0.71, $P < .001$). At five-year follow-up bDFS was 92% and 85%, respectively. We did not observe differences in prostate cancer-specific survival ($P = .49$) and overall survival ($P = .50$). The cumulative incidence of late genitourinary and GI toxicity grade ≥ 2 was 23% and 12% in the standard arm versus 28% and 13% in the focal boost arm, respectively. Both for late toxicity as health-related quality of life, differences were small and not statistically significant.

CONCLUSION

The addition of a focal boost to the intraprostatic lesion improved bDFS for patients with localised intermediate- and high-risk prostate cancer without impacting toxicity and quality of life. The Focal Lesion Ablative Microboost in Prostate Cancer study shows that a high focal boost strategy to improve tumour control while respecting organ at risk dose constraints is effective and safe.