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### **Prostate**

## Short Androgen Suppression and Radiation Dose Escalation in Prostate Cancer: 12-Year Results of EORTC Trial 22991 in Patients With Localised Intermediate-Risk Disease

Bolla M, Neven A, Maingon P, Carrie C, Boladeras A, Andreopoulos D, Engelen A, Sundar S, van der Steen-Banasik EM, Armstrong J, Peignaux-Casasnovas K, Boustani J, Herrera FG, Pieters BR, Slot A, Bahl A, Scrase CD, Azria D, Jansa J, O'Sullivan JM, Van Den Bergh ACM, Collette L; EORTC Radiation Oncology Group.

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#### PURPOSE

The European Organisation for Research and Treatment of Cancer (EORTC) trial 22991 (NCT00021450) showed that 6 months of concomitant and adjuvant androgen suppression (AS) improves event- (EFS, Phoenix) and clinical disease-free survival (DFS) of intermediate- and high-risk localised prostatic carcinoma, treated by external-beam radiotherapy (EBRT) at 70-78 Gy. We report the long-term results in intermediate-risk patients treated with 74 or 78 Gy EBRT, as per current guidelines.

#### PATIENT AND METHODS

Of 819 patients randomly assigned between EBRT or EBRT plus AS started on day one of EBRT, 481 entered with intermediate risk (International Union Against Cancer TNM 1997 cT1b-c or T2a with prostate-specific antigen (PSA)  $\geq$  10 ng/mL or Gleason  $\leq$  7 and PSA  $\leq$  20 ng/mL, NOMO) and had EBRT planned at 74 (342 patients, 71.1%) or 78 Gy (139 patients, 28.9%). We report the trial primary end point EFS, DFS, distant metastasis-free survival (DMFS), and overall survival (OS) by intention-to-treat stratified by EBRT dose at two-sided  $\alpha$  = 5.0%.

#### RESULTS

At a median follow-up of 12.2 years, 92 of 245 patients and 132 of 236 had EFS events in the EBRT plus AS and EBRT arm, respectively, mostly PSA relapse (48.7%) or death (45.1%). EBRT plus AS improved EFS and DFS (hazard ratio [HR] = 0.53; CI, 0.41 to 0.70; P < .001 and HR = 0.67; CI, 0.49 to 0.90; P = .008). At 10 years, DMFS was 79.3% (CI, 73.4 to 84.0) with EBRT plus AS and 72.7% (CI, 66.2 to 78.2) with EBRT (HR = 0.74; CI, 0.53 to 1.02; P = .065). With 140 deaths (EBRT plus AS: 64; EBRT: 76), 10-year OS was 80.0% (CI, 74.1 to 84.7) with EBRT plus AS and 74.3% (CI, 67.8 to 79.7) with EBRT, but not statistically significantly different (HR = 0.74; CI, 0.53 to 1.04; P = .082).

#### CONCLUSION

Six months of concomitant and adjuvant AS statistically significantly improves EFS and DFS in intermediate-risk prostatic carcinoma, treated by irradiation at 74 or 78 Gy. The effects on OS and DMFS did not reach statistical significance.