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Antiandrogen monotherapy in patients with localized or locally advanced prostate cancer: final results from the bicalutamide Early Prostate Cancer programme at a median follow-up of 9.7 years

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Abstract

OBJECTIVE: To evaluate the efficacy and tolerability of bicalutamide 150 mg once-daily as immediate hormonal therapy in patients with prostate cancer or as adjuvant to radical prostatectomy or radiotherapy.

PATIENTS AND METHODS: In all, 8113 patients with localized (T1-2, N0/Nx) or locally advanced (T3-4, any N; or any T, N+) prostate cancer (all M0) were enrolled in three complementary, double-blind, placebo-controlled trials. Patients were randomized to receive standard care plus either oral bicalutamide 150 mg once-daily or oral placebo. Primary endpoints were progression-free survival (PFS) and overall survival (OS). Data were collated from individual trials and evaluated in a combined analysis.

RESULTS: Overall, at a median follow-up of 9.7 years, bicalutamide significantly improved PFS (hazard ratio 0.85, 95% confidence interval 0.79-0.91; $P=0.001$). Compared with placebo there was no difference in OS (hazard ratio 1.01, $P=0.77$). Patients who derived benefit from bicalutamide in terms of PFS were those with locally advanced disease, with OS significantly favouring bicalutamide in patients with locally advanced disease undergoing radiotherapy ($P=0.031$). Patients with localized disease showed no clinically or statistically significant improvements in PFS; there was a survival trend in favour of placebo in patients with localized disease undergoing watchful waiting ($P=0.054$). The overall tolerability of bicalutamide was consistent with previous analyses, with breast pain (73.7%) and gynaecomastia (68.8%) the most frequently reported adverse events in patients randomized to bicalutamide.

CONCLUSIONS: Bicalutamide 150 mg, either as monotherapy or adjuvant to standard care, improved PFS in patients with locally advanced prostate cancer, but not in patients with localized disease. A pre-planned subset analysis showed a benefit for OS in patients with locally advanced disease undergoing radiotherapy. Bicalutamide 150 mg might represent an alternative for patients with locally advanced prostate cancer considering androgen-deprivation therapy.