Abstract

**Purpose:** Patients with biochemical failure (BF) after radical prostatectomy may benefit from dose-intensified salvage radiation therapy (SRT) of the prostate bed. We performed a randomized phase III trial assessing dose intensification.

**Patients and Methods:** Patients with BF but without evidence of macroscopic disease were randomly assigned to either 64 or 70 Gy. Three-dimensional conformal radiation therapy or intensity-modulated radiation therapy/rotational techniques were used. The primary end point was freedom from BF. Secondary end points were acute toxicity according to the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.0) and quality of life (QoL) according to the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaires C30 and PR25.

**Results:** Three hundred fifty patients were enrolled between February 2011 and April 2014. Three patients withdrew informed consent, and three patients were not eligible, resulting in 344 patients age 48 to 75 years in the safety population. Thirty patients (8.7%) had grade 2 and two patients (0.6%) had grade 3 genitourinary (GU) baseline symptoms. Acute grade 2 and 3 GU toxicity was observed in 22 patients (13.0%) and one patient (0.6%), respectively, with 64 Gy and in 29 patients (16.6%) and three patients (1.7%), respectively, with 70 Gy (P = .2). Baseline grade 2 GI toxicity was observed in one patient (0.6%). Acute grade 2 and 3 GI toxicity was observed in 27 patients (16.0%) and one patient (0.6%), respectively, with 64 Gy, and in 27 patients (15.4%) and four patients (2.3%), respectively, with 70 Gy (P = .8). Changes in early QoL were minor. Patients receiving 70 Gy reported a more pronounced and clinically relevant worsening in urinary symptoms (mean difference in change score between arms, 3.6; P = .02).

**Conclusion:** Dose-intensified SRT was associated with low rates of acute grade 2 and 3 GU and GI toxicity. The impact of dose-intensified SRT on QoL was minor, except for a significantly greater worsening in urinary symptoms.

**Trial Registration:** ClinicalTrials.gov NCT01272050.

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