Place of short-term androgen deprivation therapy in intermediate-risk prostate cancer treated with radiotherapy: A phase III trial.

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Abstract Disclosures

Abstract

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Background: The place of short term androgen deprivation therapy (STADT) in combination with radiation therapy (RT) for patients with intermediate risk prostate cancer (IRPC) remains controversial. The purpose of this prospective, randomized trial was to compare outcomes between patients with IRPC treated with different doses of RT with or without STADT, (PCS III trial, Clinical Trials.gov, NCT00223145).**Methods:** From December 2000 to September 2010, 600 patients with IRPC were randomized to 6 months of STADT and two levels of prostate RT doses of 70 (arm 1) or 76 Gy (arm 2) versus prostate dose-escalated RT alone at 76 Gy (arm 3). STADT consisted of bicalutamide and gosereline for six months. RT (2 Gy per fraction) started four months after the beginning of STADT. Biochemical failure and disease-free survival (DFS) were primary end-points, with overall survival (OS) as secondary endpoint. DFS and OS rates were estimated with Kaplan-Meier and compared with log rank test and Cox regression. **Results:** Patient's characteristics were well balanced among the 3 arms (median age 71 years, median PSA 10 ng/ml, median Gleason score 7). At a median follow-up of 75.4 months, biochemical failure occurred in 84 (14%) patients (arms 1 to 3: 12.5%, 8.0%, 21.5%) with statistical difference between arm 1 and 3 ($p = 0.023$) and arm 2 and 3 ($p < 0.001$). There was no significant difference between arm 1 and 2. A total of 113 (19%) patients had died with only 6 deaths (1%) attributed to prostate cancer. The 5-/10-year DFS rates were 93%, 97.5% and 86%, and 77%, 90% and 64.5%, respectively. Significant differences in DFS between the treatment arms were observed at 5 years but at 10 years it was observed only between arm 1 and 3 ($p=0.01$) and arm 2 and 3 ($p<0.001$). The 5-/10-year OS rates were 91%, 95% and 93%, and 64%, 70% and 78%, respectively. There was no statistical difference in OS between arms at 5 and 10 years. **Conclusions:** In patients with IRPC, the use of STADT in association with RT, even at lower doses, leads to a superior biochemical control and DFS as compared to dose-escalated RT alone. These outcomes did not translate into an improved OS. Source of Funding: AstraZeneca Pharmaceuticals Grant. Clinical trial information: NCT00223145.