



European Association of Urology



Letter to the Editor

Re: Ofer Yossepowitch, Anders Bjartell, James A. Eastham, et al. Positive Surgical Margins in Radical Prostatectomy: Outlining the Problem and Its Long-Term Consequences. Eur Urol 2009;55:87–99

We very much welcome the recent paper by Yossepowitch and colleagues [1] on the management of men with margin-positive disease at radical prostatectomy. We strongly support their conclusion that “a randomized trial comparing adjuvant RT [radiotherapy] immediately after surgery to salvage RT at the earliest onset of PSA [prostate-specific antigen] relapse is critically needed.” The recently opened Radiotherapy and Androgen Deprivation in Combination after Local Surgery (RADICALS) trial (ISRCTN40814031) [2] currently is addressing this issue.

RADICALS is a large intergroup phase III trial, with two randomizations and a pragmatic design. Where there is uncertainty about the need for adjuvant RT after radical prostatectomy, patients may enter the RT timing randomization between adjuvant RT and a surveillance strategy. Patients in the surveillance arm will receive early salvage RT at the earliest onset of PSA relapse.

Patients who are to receive postoperative RT, whether adjuvant or salvage and whether in the RT timing randomization or not, may enter a second randomization, which tests different durations of hormone therapy. This is a three-way randomization among RT alone, RT plus 6 mo of hormone therapy, and RT plus 24 mo of hormone therapy. Patients may elect to be randomized between two hormone duration arms rather than among all three.

The RADICALS trial is designed to recruit >4000 men, with a goal of reliably detecting any improvement in 10-yr disease-specific survival and to balance this against long-term patient-reported

morbidity. It is led by the Medical Research Council (MRC) Clinical Trials Unit for the UK National Cancer Research Institute and is run in collaboration with the National Cancer Institute (NCI) Canada Clinical Trials Group. Recruitment opened in December 2007 and is anticipated to take 5 yr. Other trial groups are invited to join this intergroup collaboration.

Conflicts of interest: The authors have nothing to disclose.

References

- [1] Yossepowitch O, Bjartell A, Eastham JA, et al. Positive surgical margins in radical prostatectomy: outlining the problem and its long-term consequences. *Eur Urol* 2009; 55:87–99.
- [2] Parker C, Sydes MR, Catton C, et al. Radiotherapy and androgen deprivation in combination after local surgery (RADICALS): a new Medical Research Council/National Cancer Institute of Canada phase III trial of adjuvant treatment after radical prostatectomy. *BJU Int* 2007;99: 1376–9.

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