A Decade of Active Surveillance in the PRIAS Study: An Update and Evaluation of the Criteria Used to Recommend a Switch to Active Treatment.


Abstract

BACKGROUND: The Prostate Cancer Research International Active Surveillance (PRIAS) study was initiated a decade ago to study the most optimal selection and follow-up of men on active surveillance (AS).

OBJECTIVE: We report on 10 yr of follow-up of men on AS in the PRIAS study and evaluate if criteria used to recommend a switch to active treatment truly predict unfavorable outcome on subsequent radical prostatectomy (RP).

DESIGN, SETTING, AND PARTICIPANTS: Men with low-risk prostate cancer were included and followed prospectively on AS. Follow-up consisted of regular prostate-specific antigen (PSA) tests, digital rectal examinations, and biopsies. Men with Gleason >3+3, more than two positive biopsy cores, or stage higher than cT2 were advised to switch to active treatment (until 2014, a PSA doubling time [PSA DT] of 0-3 yr was also used).

OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS: Reclassification rates, treatment after discontinuation, and outcome on RP after discontinuing AS were reported. Regression analysis on the outcome of RP was used to evaluate the predictive value of criteria currently used to recommend a switch to active treatment. Kaplan-Meier and competing risk analysis were used to report discontinuation rates over time and long-term oncologic end points.

RESULTS AND LIMITATIONS: A total of 5302 men were included in PRIAS across 18 countries. Reclassification rates remained stable on all subsequent biopsies, with 22-33% of men having either Gleason >3+3 or more than two positive cores on any repeat biopsy. At 5 and 10 yr of follow-up, 52% and 73% of men, respectively, had discontinued AS, most of them because of protocol-based reclassification. A third of men undergoing subsequent RP had favorable pathologic tumor features (Gleason 3+3 and pT2). Of the criteria used to recommend a switch to active treatment, more than two positive cores and a PSA DT of 0-3 yr were not predictive of unfavorable pathologic outcome on RP.

CONCLUSIONS: A substantial group of men discontinued AS without subsequent unfavorable tumor features on RP; therefore, we propose Gleason upgrading and cT3 as the only indicators for an immediate switch to active treatment. Surrogate indicators (eg, more than two positive...
cores and a fast-rising PSA) should not trigger immediate active treatment but rather further investigation to confirm the suspicion of higher risk disease.

**PATIENT SUMMARY:** We confirmed the safety of active surveillance as a treatment option for men with low-risk prostate cancer; however, some changes could be made to the follow-up protocol to safely increase the number of men who remain on active surveillance.

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**KEYWORDS:** Active surveillance; Disease progression; MRI; Prostate biopsy; Prostate-specific antigen; Prostatic neoplasms

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