

A prospective, blinded comparison of magnetic resonance (MR) imaging-ultrasound fusion and visual estimation in the performance of MR-targeted prostate biopsy: the PROFUS trial

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Abstract

Background: Increasing evidence supports the use of magnetic resonance (MR)-targeted prostate biopsy. The optimal method for such biopsy remains undefined, however.

Objective: To prospectively compare targeted biopsy outcomes between MR imaging (MRI)-ultrasound fusion and visual targeting.

Design, setting, and participants: From June 2012 to March 2013, prospective targeted biopsy was performed in 125 consecutive men with suspicious regions identified on prebiopsy 3-T MRI consisting of T2-weighted, diffusion-weighted, and dynamic-contrast enhanced sequences.

Intervention: Two MRI-ultrasound fusion targeted cores per target were performed by one operator using the ei-Nav|Artemis system. Targets were then blinded, and a second operator took two visually targeted cores and a 12-core biopsy.

Outcome measurements and statistical analysis: Biopsy information yield was compared between targeting techniques and to 12-core biopsy. Results were analyzed using the McNemar test. Multivariate analysis was performed using binomial logistic regression.

Results and limitations: Among 172 targets, fusion biopsy detected 55 (32.0%) cancers and 35 (20.3%) Gleason sum ≥ 7 cancers compared with 46 (26.7%) and 26 (15.1%), respectively, using visual targeting ($p=0.1374$, $p=0.0523$). Fusion biopsy provided informative nonbenign histology in 77 targets compared with 60 by visual ($p=0.0104$). Targeted biopsy detected 75.0% of all clinically significant cancers and 86.4% of Gleason sum ≥ 7 cancers detected on standard biopsy. On multivariate analysis, fusion performed best among smaller targets. The study is limited by lack of comparison with whole-gland specimens and sample size. Furthermore, cancer detection on visual targeting is likely higher than in community settings, where experience with this technique may be limited.

Conclusions: Fusion biopsy was more often histologically informative than visual targeting but did not increase cancer detection. A trend toward increased detection with fusion biopsy was observed across all study subsets, suggesting a need for a larger study size. Fusion targeting improved accuracy for smaller lesions. Its use may reduce the learning curve necessary for visual targeting and improve community adoption of MR-targeted biopsy.

Keywords: Magnetic resonance imaging; Prostate biopsy; Prostate cancer; Targeted biopsy.

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