

Prospective Validation of an Artificial Intelligence Model in Guiding Transperineal Prostate Biopsies

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Authors' Contributions Statement

H. Fu for the acquisition of data, analysis and interpretation of data, statistical analysis, and drafting of the manuscript; B. Millan, P. Michael for acquisition of data, technical and material support; P. Pinto for study concept and design, analysis and interpretation of data, drafting of the manuscript, obtained funding and study supervision. Z. Su for technical and material support. B. Coffey for acquisition of data. R. Blachman-Braun, B. Turkbey, S. Harmon, A. Assad, M. Ahmed and S. Gurram for revising the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no potential conflicts of interest.

Background: Prostate MRI interpretation is limited by inter-reader variability and inconsistent detection of clinically significant prostate cancer (csCaP), especially in community settings. Artificial intelligence (AI) models offer the potential to standardize lesion detection and to guide targeted biopsies, but they have been evaluated almost exclusively in retrospective studies. Herein, we prospectively assessed an in-house developed AI model for assessment of prostate MRIs to guide prostate biopsies.

Methods: From May 2024 to April 2025, 202 consecutive men undergoing prostate MRI and biopsy were enrolled in a prospective clinical trial (NCT02594202). For each participant, an expert radiologist first evaluated prostate MRIs for intraprostatic, radiologist-detected (RD) lesions using PI-RADSv2.1. Prior to biopsy, the in-house AI model was applied to biparametric MRI to finalize biopsy targets. Target lesions were grouped into three categories: AI-positive RD (RD+/AI+), AI-negative RD (RD+/AI-), and lesions detected solely by AI (RD-/AI+). All lesions underwent MRI-ultrasound fusion-guided biopsy followed by systematic biopsy. An AI-positive biopsy template (RD+/AI+ lesions, RD-/AI+ lesions, systematic cores) was compared to standard-of-care (SOC) biopsy (RD+ lesions and systematic cores) for non-inferiority in csCaP detection.

Results: Biopsy of RD+/AI+ lesions demonstrated improved csCaP cancer detection rates (CDR) over RD+/AI- lesions (36.6% vs 18.3%, $p<0.001$). False positive rates for csCaP were reduced when comparing all AI-detected lesions to all radiologist-detected lesions (63.8% vs 71.1%, $p<0.001$). RD-/AI+ lesions identified csCaP in 11% of cases and represented the highest-grade lesion in 3%. The AI-positive biopsy template was non-inferior to the SOC template for csCaP detection (0.387 vs 0.412, $p=0.017$) and for overall cancer detection (0.661 vs 0.671, $p=0.003$). Both univariate and multivariate models demonstrated that AI corroboration of MRI lesions was associated with prostate cancer (odds ratio 3.8 and 2.4).

Conclusions: Prospective implementation of a deep learning model for prostate MRI improved lesion-level diagnostic accuracy and supported a non-inferior, AI-guided biopsy template. The model's scanner-agnostic, biparametric design offers a scalable solution to extend expert-level diagnostics to settings without subspecialty radiology expertise.