A Magnetic Resonance Imaging-Based Prediction Model for Prostate Biopsy Risk Stratification.

Mehralivand S1,2,3, Shih JH4, Rais-Bahrami S5,6, Oto A7, Bednarova S8,9, Nix JW6, Thomas JV6, Gordetsky JB10, Gaur S3, Harmon SA11, Siddiqui MM12, Merino MJ13, Parnes HL14, Wood BJ9, Pinto PA2, Choyke PL3, Turkbey B3.

1 Department of Urology and Pediatric Urology, University Medical Center, Mainz, Germany.
2 Urologic Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland.
3 Molecular Imaging Program, National Cancer Institute, National Institutes of Health, Bethesda, Maryland.
4 Division of Cancer Treatment and Diagnosis: Biometric Research Program, National Cancer Institute, National Institutes of Health, Rockville, Maryland.
5 Department of Urology, University of Alabama at Birmingham.
6 Department of Radiology, University of Alabama at Birmingham.
7 Department of Radiology, University of Chicago Medical Center, Chicago, Illinois.
8 Institute of Diagnostic Radiology, Department of Medical and Biological Sciences, University of Udine, Udine, Italy.
9 Center for Interventional Oncology, National Cancer Institute and Radiology and Imaging Sciences, Clinical Center, National Institutes of Health, Bethesda, Maryland.
10 Department of Pathology, University of Alabama at Birmingham.
11 Clinical Research Directorate/Clinical Monitoring Research Program, Leidos Biomedical Research, Inc, National Cancer Institute Campus at Frederick, Frederick, Maryland.
12 University of Maryland Medical Center, Baltimore.
13 Laboratory of Pathology, National Cancer Institute, National Institutes of Health, Bethesda, Maryland.
14 Division of Cancer Prevention, National Cancer Institute, National Institutes of Health, Bethesda, Maryland.

IMPORTANCE: Multiparametric magnetic resonance imaging (MRI) in conjunction with MRI-transrectal ultrasound (TRUS) fusion-guided biopsies have improved the detection of prostate cancer. It is unclear whether MRI itself adds additional value to multivariable prediction models based on clinical parameters.

OBJECTIVE: To determine whether an MRI-based prediction model can reduce unnecessary biopsies in patients with suspected prostate cancer.

DESIGN, SETTING, AND PARTICIPANTS: Patients underwent MRI, MRI-TRUS fusion-guided biopsy, and 12-core systematic biopsy in 1 session. The development cohort used to derive the prediction model consisted of 400 patients from 1 institution enrolled between May 14, 2015,
and August 31, 2016, and the validation cohort included 251 patients from 2 independent institutions who underwent biopsies between April 1, 2013, and June 30, 2016, at 1 institution and between July 1, 2015, and October 31, 2016, at the other institution. The MRI model included MRI-derived parameters in addition to clinical variables. Area under the curve of receiver operating characteristic curves and decision curve analysis were performed.

**MAIN OUTCOMES AND MEASURES:** Risk of clinically significant prostate cancer on biopsy, defined as a Gleason score of 3 + 4 or higher in at least 1 biopsy core.

**RESULTS:** Overall, 193 (48.3%) of the 400 patients in the development cohort (mean [SD] age at biopsy, 64.3 [7.1] years) and 96 (38.2%) of the 251 patients in the validation cohort (mean [SD] age at biopsy, 64.9 [7.2] years) had clinically significant prostate cancer, defined as a Gleason score greater than or equal to 3 + 4. By applying the model to the external validation cohort, the area under the curve increased from 64% to 84% compared with the baseline model (P < .001). At a risk threshold of 20%, the MRI model had a lower false-positive rate than the baseline model (46% [95% CI, 32%-66%] vs 92% [95% CI, 70%-100%]), with only a small reduction in the true-positive rate (89% [95% CI, 85%-96%] vs 99% [95% CI, 89%-100%]). Eighteen of 100 fewer biopsies could have been performed, with no increase in the number of patients with missed clinically significant prostate cancers.

**CONCLUSIONS AND RELEVANCE:** The inclusion of MRI-derived parameters in a risk model could reduce the number of unnecessary biopsies while maintaining a high rate of diagnosis of clinically significant prostate cancers.

*PMID: 29470570  PMCID: PMC5885194  DOI: 10.1001/jamaoncol.2017.5667*