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Re: Use of Prostate Systematic and Targeted Biopsy on the Basis of Multiparametric MRI in Biopsy-naive Patients (MRI-FIRST): A Prospective, Multicentre, Paired Diagnostic Study

Rouvière O, Puech P, Renard-Penna R, et al

Lancet Oncol 2019;20:100–9

Experts' summary:

Multiparametric magnetic resonance imaging (mpMRI) before prostate biopsy has become increasingly common with the growing scientific evidence that it increases the likelihood of finding clinically significant prostate cancer [1–3]. However, whether a negative mpMRI scan obviates the need for systematic biopsy in biopsy-naïve men is controversial. Most studies in support of this concept have been conducted in specialized centers with expertise in the interpretation of mpMRI and/or in performing mpMRI-targeted prostate biopsy. Rouvière and colleagues [3] conducted a well-designed, prospective, real-world study (MRI-FIRST) across 16 centers in France and compared the sensitivity of systematic versus targeted biopsy in patients with a clinical suspicion of prostate cancer undergoing mpMRI. Combining both techniques improved the detection of clinically significant prostate cancer and omitting systematic biopsy reduced the detection of indolent disease (from 19.5% to 5.6%). However, for every three additional clinically significant prostate cancers detected by adding targeted biopsy, two were missed by omitting systematic biopsy.

Experts' comments:

Avoiding unnecessary prostate biopsy is crucial. Complications from prostate biopsy are not trivial (especially infectious complications if biopsy is performed using a transrectal approach) and systematic biopsy clearly drives overdiagnosis. Overtreatment is a concern and some men drop out of active surveillance because of anxiety. Identification of a diagnostic pathway that can accurately stratify risk and avoid the need for prostate biopsy in men with a low risk of harboring clinically significant prostate cancer is urgently needed. Undoubtedly, a pathway that includes mpMRI followed by targeted biopsy in the case of positive mpMRI improves risk stratification and increases the detection of clinically significant disease. However, the MRI-FIRST trial adds to the body of literature [4] indicating that a negative mpMRI scan does not preclude the need for systematic biopsy owing to the high miss rate for clinically significant cancer: the negative predictive value in the PROMIS trial was 76% [1]. To be successful, prebiopsy mpMRI requires access to high-quality mpMRI studies, a robust training program for radiologists to mitigate interobserver variability, and access to high-quality mpMRI-targeted biopsy, which has a learning curve. One way forward to combining the advantages of mpMRI and targeted biopsy (ie, detecting more clinically significant prostate cancer while reducing the number of biopsies and overdiagnosis) could be to perform systematic biopsy only in men in whom the clinical suspicion is high. Prostate-specific antigen (PSA) testing alone has proven inadequate in selecting men for prostate biopsy. While the "best" approach has yet to be defined, a multistep, multivariable approach is logical: risk assessment (age, family history, race); repeating measurement of PSA for men with elevated levels; clinical examination (digital rectal examination, prostate volume assessment/PSA density); and likely additional biomarker testing such as percentage free/total PSA, 4Kscore, Prostate Health Index, or SelectMDx. Should this assessment result in a recommendation for a prostate biopsy, then mpMRI should be performed, followed by systematic biopsy plus targeted biopsy should the mpMRI identify a lesion [5].

Conflicts of interest: Sigrid V. Carlsson has received a lecture honorarium and travel support from Astellas Pharma unrelated to the current study. James A. Eastham has nothing to disclose.

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Re: Optimizing Patient's Selection for Prostate Biopsy: A Single Institution Experience with Multi-parametric MRI and the 4Kscore Test for the Detection of Aggressive Prostate Cancer

Punnen S, Nahar B, Soodana Prakash N, et al

PLoS One 2018;371:e0201384

Experts' summary:
This retrospective study included a consecutive cohort of patients for whom both multiparametric magnetic resonance imaging (mpMRI) and the 4Kscore test were carried out for prostate cancer (PC) diagnosis. Of the 300 patients identified, 149 (49%) were biopsied and 49 (33%) had significant PC (Gleason score $\geq$7). The diagnostic value of mpMRI and 4Kscore was examined. The authors found that the area under the receiver operating characteristic curve was superior when using 4Kscore and mpMRI together (0.82; 0.75 $\pm$ 0.89) compared using 4Kscore (0.70; 0.62 $\pm$ 0.79) or mpMRI (0.74; 0.66 $\pm$ 0.81) alone (p = 0.001). The likelihood of clinically significant PC was best predicted by combining mpMRI and 4Kscore. The 4Kscore test provided a more accurate level of risk within each mpMRI Prostate Imaging-Reporting and Data System (PI-RADS) category. The authors concluded that both mpMRI and 4Kscore have independent and additive prognostic value for predicting significant PC.

Experts' comments:
In the past, the main clinical dilemma facing a patient with elevated prostate-specific antigen (PSA) was whether to have a prostate biopsy. Today, the clinical dilemma has expanded from a simple yes/no biopsy decision to a more sophisticated question of whether to perform another test, where to aim the biopsy needle, and what technology to use.

Several PC biomarkers are now available for blood (phi, 4Kscore, IsoPSA), urine (PCA3, SelectMDx), and tissue (ConfirmMDx). For all of these biomarkers, an advantage over PSA has been demonstrated [1,2]. The biomarkers are noninvasive and the results are reproducible. However, unlike mpMRI, they can only assist in the question of whether or not to perform a biopsy. Furthermore, none of these have been tested in a randomized control trial.

We now have level 1 evidence from the PROMIS study showing that mpMRI used as a triage test before biopsy could both identify a quarter of men who might avoid biopsy and improve the detection of clinically significant PC [3]. The PRECISION trial went a step further and demonstrated that MRI-ultrasound fusion biopsies are superior to systemic biopsies [4]. Thus, prebiopsy mpMRI provides answers to all three questions: do we need a biopsy, where to aim, and how to carry out the biopsy. However, mpMRI is costly and unavailable in many centers, and results are subject to the operator's experience.

The current study is one of the first to look at a combination of biomarkers and mpMRI. The authors demonstrated that their combination can improve the accuracy of predicting significant PC. While performing the 4Kscore test and mpMRI before biopsy for all patients might be too expensive, several clinical scenarios may be cost-effective. For example, one approach could be to triage all patients using MRI, and then observe patients with normal MRI findings, biopsy all PI-RADS 4/5 lesions, and refer PI-RADS 3 lesions for further biomarker analyses. Another possibility would be to triage patients using biomarker analyses, observing men with normal values and referring patients with abnormal values for MRI before biopsy. All such strategies would need to be tested in well-designed studies.

Emerging from these studies is the fact that an abnormal PSA finding alone may not be enough to trigger a biopsy.

Conflicts of interest: The authors have nothing to disclose.

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