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Editorial on "Head-to-Head Comparison of PI-RADS Version 2 and 2.1 in Transition Zone Lesions for Detection of Prostate Cancer"

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The role of multiparametric magnetic resonance imaging (mpMRI) in prostate cancer has evolved from a primary staging tool to one used for detection and monitoring. This evolution was in part prompted by a paradigm shift in prostate cancer management away from overdiagnosis and over-treatment of clinically insignificant disease.[1] Lower-grade cancers are quite common and unlikely to impact overall survival or result in significant morbidity during a man's life-time. However, the treatment for prostate cancer comes with significant morbidity.

In order to serve as a tool for detection, a standardized approach to acquisition and interpretation of mpMRI is essential. The Prostate Imaging Reporting and Data System (PI-RADS) was developed to improve consistency and communication, and to facilitate research advances. The first edition, PI-RADS version 1 (PI-RADS v1), was released in 2012 and an update, PI-RADS v2, was released in 2015.[2,3] PI-RADS emphasizes identification of clinically significant cancer, which is defined as Gleason ≥7 (3 + 4) and a volume of at least 0.5 cc and/or cancer with extracapsular extension. Based on features derived from T_2-weighted, diffusion-weighted (DWI), and dynamic contrast-enhanced images, lesions are assigned a score of PI-RADS category 2 through 5, reflecting the level of suspicion for clinically significant cancer. If there are no suspicious lesions, a category of 1 is assigned to the whole prostate.

While PI-RADS v1 and v2 were based on expert consensus and the best available evidence, scant peer-reviewed publications were available at the time of conception. Since the release of PI-RADS v2, evidence has accumulated, prompting the release of an update, PIRADS v2.1, in 2019[4].

One specific criticism of PI-RADS v2 related to its relatively poor performance in the transition zone (TZ)—relatively poor accuracy, ambiguous lexicon descriptions for T_2 scoring, and worse reader agreement—compared to the peripheral zone (PZ). The majority of prostate cancers are located in the PZ, and about 20–30% are located in the TZ. Detection of TZ cancers is made more difficult by the heterogeneous architecture of glandular and stromal tissue and due to benign prostatic hyperplasia (BPH) that is nearly ubiquitously

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present in the TZ. Improving the performance of TZ lesion categorization was the primary goal of the recent PI-RADS v2.1 update. The changes comprised the following:

1. The lexicon clarified that circumscribed nodules which are incompletely or almost completely encapsulated (the so-called atypical nodules) warrant a score of 2 on T_2-weighted images.
2. DWI score of 4 or 5 (focal markedly restricting) can now upgrade these atypical nodules to category 3 (formerly DWI was only used to upgrade category 3 to 4).
3. The downgrade of insignificant disease (ie, fully encapsulated BPH nodules) to PI-RADS category 1 (formerly reserved for negative/normal MRI).

The general framework of PI-RADS assessment for both PZ and TZ has not significantly changed, and T_2 remains the dominant sequence in the assessment of PI-RADS category assignment in the TZ.

In the present article Byun et al[5], *Head-to-head comparison of PI-RADS version 2 and 2.1 in transition zone lesions for detection of prostate cancer,* the authors aimed to critically evaluate and compare the performance and interreader agreement of PI-RADS v2 and v2.1 for TZ nodules. Two readers retrospectively evaluated 201 nodules in 142 patients and assigned PI-RADS v2 and PI-RADS v2.1 category scores to annotated images. In the current study, eight lesions were upgraded to PI-RADS category 3 for DWI features and 46 lesions were downgraded to PI-RADS category 1 or 2 according to the PI-RADS v2.1 criterion. The authors found trends towards improvements in sensitivity (91.8% for PI-RADS v2 vs. 94.5% for PI-RADS v2.1), specificity (56.3% for PI-RADS v2 vs. 60.9% for PI-RADS v2.1), and interreader agreement ($k = 0.451$ for PI-RADS v2 vs. $k = 0.509$ for PI-RADS v2.1) for the detection of clinically significant cancer in PI-RADS category ≥3. One strength of the current study was the use of prostatectomy specimens for the reference standard.

A recent article published in *European Radiology* similarly compared interreader agreement and diagnostic performance for clinically significant TZ cancer using PI-RADS v2 and PI-RADS v2.1.[6] That study included a smaller cohort of 58 patients who received fusion-guided targeted biopsies, rather than prostatectomy, and showed a similar improvement in interreader agreement ($k = 0.580$ for PI-RADS v2 vs. $k = 0.645$ for PI-RADS v2.1) and possible slight improvements in diagnostic performance.

The diagnostic accuracy results of the current article by Byun et al and the findings of Tamada et al should be considered preliminary in nature, as neither study was likely sufficiently powered to detect differences, a fact that highlights the relative rarity of TZ cancer, and which renders it a challenging topic to study. Additionally, caution is advised in considering the results with regards to diagnostic accuracy. In the current study by Byun et al, the authors constructed a retrospective enriched cohort, impacted by selection bias, provided no PI-RADS 1 prostates to serve as controls, and failed to provide data regarding incidental cancers on prostatectomy. Hence, the results related to specificity and sensitivity must be taken in the context of these limitations.

Despite these limitations, the findings from these studies, if confirmed, may be particularly relevant in determining management for men with TZ nodules who are upgraded to category 3 based on DWI features of PI-RADS v2.1 (formerly PI-RADS v2 category 2). These men may wish to undergo biopsy or at least enroll in active surveillance. Likewise, confirmation that none of the downgraded lesions were clinically significant cancers is a potentially relevant finding of the current study. This may allow more men to comfortably enroll in active surveillance and may avoid unnecessary biopsy, depending on the institutional threshold for biopsy. Both findings seem to indicate that PI-RADS v2.1 provides incremental improvements over PI-RADS v2, although the clinical impact may be marginal, given the rarity of TZ cancer and the focus on low to intermediate probability categories.

Beyond diagnostic accuracy, the authors also aimed to evaluate and compare the interreader agreement. They found higher agreement for scores of ≥3 with v2.1 compared to v2. The agreement values for the qualitative lexicon terms remained disappointing (ranging from 0.029–0.457). Hence, while the authors found some improvement, there remains work to be done to achieve the goal of standardization across interpretation. Of note, the use of annotated images in the current article likely inflates the kappa values for agreement (ie, agreement may be much worse in practice where readers may not even agree on the presence of scoreable nodules).

In conclusion, the results of the current study by Byun et al are consistent and reflect the intent of the v2.1 PI-RADS update. Future multicenter studies may provide sufficient power to validate these preliminary findings, and to offer additional refinements.

Acknowledgments

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