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Prostate Imaging-Reporting and Data System Version 2 and the Implementation of High-quality Prostate Magnetic Resonance Imaging

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1. Introduction

Multiparametric magnetic resonance imaging (mpMRI) is now a well-established tool to improve the diagnosis of prostate cancer (PCa). Several meta-analyses show that the use of mpMRI and mpMRI-targeted biopsy in men with a suspicion of PCa yields higher detection of clinically significant PCa than the current standard using systematic transrectal ultrasound-guided biopsy (TRUS-GB) and reduces the detection of indolent PCa [1,2]. Further support for these concepts has come from the results of the PROMIS project, a large multi-institutional trial in the UK [3]. Therefore, when used as a triage test, mpMRI could be an important contributor in causing a shift in the current paradigm of overdiagnosis and overtreatment of PCa.

However, as pointed out in this issue of *European Urology* by Woo and coworkers [4], there is significant variability in published results. For example, there is a highly variable negative predictive value for the exclusion of clinically significant PCa, ranging from 63% to 98% [5]. Among the possible explanations for these variable results are differences in patient populations, reference standards, image acquisition techniques, image quality, interpretation criteria, reader experience, and inter-reader variability.

Considering the high disease frequency and the growing importance of prostate mpMRI, the entire PCa health care community, including radiologists, urologists, (radiation) oncologists, and pathologists, must speak the same "language" and have access to reliable high-quality mpMRI

exams. To harmonize practices, in 2012 the European Society of Urogenital Radiology (ESUR) published guidelines, including a scoring system, called Prostate Imaging-Reporting and Data System (PI-RADS) version 1 [6].

On the basis of additional experience and rapid progress in the field, PI-RADS version 2 was developed by the ESUR, the American College of Radiology (ACR), and the International Working group of the AdMeTEch foundation, and was published in 2016 [7]. PI-RADSv2 was designed to promote global standardization and diminish variation in the acquisition, interpretation, and reporting of prostate mpMRI examinations. It was intended to be a "living" document that would need to be tested and validated for specific clinical applications. The expectation was that it would continue to evolve as clinical experience and scientific data accrued.

In the excellent systematic review and diagnostic meta-analysis by Woo et al [4], PI-RADSv2 had high pooled sensitivity of 89% and specificity of 73%. In the studies in which head-to-head comparison was possible, the sensitivity of PI-RADSv2 was significantly better than PI-RADSv1 (95% vs 88%) with equal specificity (73% vs 75%), thus supporting the use of PI-RADSv2. On the basis of their findings, the authors propose some areas for improvement in PI-RADS. This adds to the growing literature based on experience and research that has highlighted the strengths of PI-RADSv2 and areas that need refinement, improvement, or additions. Some of these include clarification of PI-RADS assessment category (1-5) cutoff values for different clinical scenarios for detecting PCa (eg, diagnosis in biopsy-naïve

men vs men with previous negative biopsy/biopsies or men on active surveillance), decreasing inter-observer variability, update the system according to new technical developments, use for surveillance, and incorporation of PI-RADS with other relevant information (such as PSA and family history) into nomograms to improve diagnosis and management. Efforts are already underway to incorporate these and other improvements into PI-RADS v3.

2. Experience and training

Despite the heterogeneous level of experience of the radiologists (4–22 yr) who participated in the 21 studies included in the review and meta-analysis, Woo et al did not perform a meta-regression analysis or subgroup analysis of the quality of the reader/reading. This is an important issue, and it may be a major contributor to differences in results from the studies analyzed. The inappropriate and unreliable use of PI-RADSv2 by users who have not had sufficient training or experience may not only result in suboptimal and variable results for research but may also be compromising clinical care [8].

Puech et al [9] proposed three levels of competence in reading prostate MRI:

(1) Level I: the reader can select the appropriate modality and is able to review images and use the results. At this level, the technique is not performed.
(2) Level II: the reader follows an initial training course with practical experience on interpreting prostate MRI, but with a cover of double reading.
(3) Level III: the reader can independently report prostate MRI under all circumstances without double reading.

Of course, several factors influence the learning curve: the dedication and quality of the individual radiologist, the quality of the initial course, the availability of histopathologic and urologic feedback during multidisciplinary meetings, and the learning process during consensus or double readings. Many radiologists may achieve the equivalent of level III competence by completing a recent accredited training program. However, for others who received their training where prostate mpMRI is not routinely performed or who completed their training before prostate mpMRI was a substantial component of a training program, level III competence will be more challenging.

3. Certification and quality criteria

Several authors have advocated for additional training and certification (credentialing) for radiologists who supervise and interpret prostate mpMRI [10].

To improve the current diagnostic pathway for PCa, many lessons can be learned from mammography screening, for which dedicated courses and certification (credentialing) of individual readers are used. Several measures that could be considered to secure high quality

for individual reporting of prostate mpMRI include:

- Make initial continuing medical education courses and yearly hands-on courses mandatory for prostate MRI readers.
- Perform a minimum number of procedures per year.
- Define an upper limit for equivocal diagnoses (PI-RADS 3), depending on the indications and patient population.
- Define a lower limit for PI-RADS 4 and 5 cases that should yield clinically significant PCa.
- Required participation in multidisciplinary meetings to compare PI-RADS findings with histopathology.
- Transparency of institutional clinical outcome data.

Expert panels of the ESUR and ACR should take the lead to further define these criteria to secure high-quality (reading of) prostate MRI and allow further implementation by the urology community.

4. Prostate expertise network

A prerequisite for further development and evolution of high-quality (reading of) prostate MRI is concentration of specific knowledge on this topic. By means of a worldwide network of prostate MRI expert centers—which are sharing their knowledge—the technique can be constantly updated and improved. Internet connectivity of centers with expertise may allow "double reading" of difficult cases, with subsequent better outcomes and diagnoses. Of course, this could be beneficial not only for men with (a suspicion of) PCa but also for fast implementation of newly validated techniques and the development of a large scientific database.

5. Conclusions

It has been shown that PI-RADSv2 is an adequate "language" for assessing the risk of the presence of clinically significant PCa. The sensitivity is significantly better than that of PI-RADSv1. Nonetheless, there is large heterogeneity that could be reduced by an improved PI-RADSv3 and by training and certification of radiologists. Equally important, however, is the training of urologists and other involved physicians in being able to communicate in the same "language".

Conflicts of interest: The authors have nothing to disclose.

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