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Update of the Standard Operating Procedure on the Use of Multiparametric Magnetic Resonance Imaging for the Diagnosis, Staging and Management of Prostate Cancer

Marc A. Bjurlin[*],
University of North Carolina at Chapel Hill, Winston-Salem, North Carolina

Peter R. Carroll,
University of California San Francisco, San Francisco, California

Scott Eggener,
University of Chicago Medical Center, Chicago, Illinois

Pat F. Fulgham,
Texas Health Presbyterian Hospital of Dallas, Dallas, Texas

Daniel J. Margolis,
Weill Cornell Medical College, New York, New York

Peter A. Pinto,
National Cancer Institute, Baltimore, Maryland

Andrew B. Rosenkrantz,
NYU Langone Medical Center, New York, New York

Jonathan N. Rubenstein,
National Institutes of Health, Bethesda and Chesapeake Urology Associates, Baltimore, Maryland

Daniel B. Rukstalis,
Chapel Hill and Wake Forest Baptist Medical Center, Winston-Salem, North Carolina

Samir S. Taneja,
NYU Langone Medical Center, New York, New York

Baris Turkbey
National Cancer Institute, Baltimore, Maryland

Abstract

[*]Correspondence: Department of Urology, Lineberger Comprehensive Cancer Center, University of North Carolina, 101 Manning Drive, 2nd floor, Chapel Hill, North Carolina (marc_bjurlin@med.unc.edu).

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Purpose: We update the prior standard operating procedure for magnetic resonance imaging of the prostate, and summarize the available data about the technique and clinical use for the diagnosis and management of prostate cancer. This update includes practical recommendations on the use of magnetic resonance imaging for screening, diagnosis, staging, treatment and surveillance of prostate cancer.

Materials and Methods: A panel of clinicians from the American Urological Association and Society of Abdominal Radiology with expertise in the diagnosis and management of prostate cancer evaluated the current published literature on the use and technique of magnetic resonance imaging for this disease. When adequate studies were available for analysis, recommendations were made on the basis of data and when adequate studies were not available, recommendations were made on the basis of expert consensus.

Results: Prostate magnetic resonance imaging should be performed according to technical specifications and standards, and interpreted according to standard reporting. Data support its use in men with a previous negative biopsy and ongoing concerns about increased risk of prostate cancer. Sufficient data now exist to support the recommendation of magnetic resonance imaging before prostate biopsy in all men who have no history of biopsy. Currently, the evidence is insufficient to recommend magnetic resonance imaging for screening, staging or surveillance of prostate cancer.

Conclusions: Use of prostate magnetic resonance imaging in the risk stratification, diagnosis and treatment pathway of men with prostate cancer is expanding. When quality prostate imaging is obtained, current evidence now supports its use in men at risk of harboring prostate cancer and who have not undergone a previous biopsy, as well as in men with an increasing prostate specific antigen following an initial negative standard prostate biopsy procedure.

Keywords

prostatic neoplasms; magnetic resonance imaging; image-guided biopsy; risk assessment

Multiparametric MRI has been proven to be a valuable tool in the diagnostic and management pathway in men at risk for prostate cancer. We update the prior standard operating procedure document on MRI of the prostate by critically appraising the available evidence.[1,2] Practical recommendations are made about how MRI can best be used by clinicians across the spectrum of prostate cancer care, risk assessment and management. Although information on this subject is evolving rapidly, in some instances not enough evidence is available to make definitive recommendations based on data alone. Therefore, the recommendations discussed are based in part on a critical review of the literature and in part on collective expert opinion.

PROSTATE MRI TECHNIQUE

Prostate mpMRI is being increasingly used to guide prostate cancer clinical management but its growing use has been accompanied by significant variation and heterogeneity in image acquisition, interpretation and pre-biopsy image processing, which can hinder patient care. To address these issues, the American College of Radiology, European Society of Urogenital Radiology and AdMeTech Foundation published basic guidelines for mpMRI acquisition

and interpretation in early 2015.[3] This document clearly stated that the technical details of prostate mpMRI, which ultimately affect the imaging protocol, should be tailored to patient needs and the clinical questions raised by the referring physician. An updated version of this document (PI-RADSv2.1) with minor changes was released in March 2019.[4]

Equipment Specifications

Prostate MRI can be obtained with a conventional 1.5 Tesla or high field 3.0 Tesla magnet with or without using an endorectal coil. Although there are some reports comparing these different techniques, there is as yet no prospective and randomized study addressing which equipment is superior for cancer detection and staging.[5,6] Furthermore, multiple factors beyond the magnet strength and coil arrangement influence the resolution and quality of MRI, including the imaging protocol and scan time, making direct comparison difficult.

The 3T magnet systems potentially provide twice the signal-to-noise ratio compared to 1.5T systems which provide increased spatial and temporal resolution, resulting in improved image quality. Despite this difference, prostate mpMRI obtained at 1.5T can still yield diagnostic images sufficient for cancer detection.[3] However, use of an ERC should be considered especially if older 1.5T systems are used or local staging is planned with newer 1.5T magnets. The 1.5T magnets (instead of 3T magnets) can be used when 3T incompatible implanted medical devices or conditionally compatible 3T devices may result in significant susceptibility artifacts (secondary to local magnetic field inhomogeneity). Distortion related to these devices can degrade the quality of prostate MRI.[3]

Per minimum standards, an ERC is not necessary for lesion detection with 3T systems. However, some prostate mpMRI experts consider the ideal technique for tumor detection and staging to be the combination of 3T with endorectal and surface coils. ERC provides 5 times more signal-to-noise ratio compared to surface coil and thus allows improved spatial resolution.[7] Currently, the necessity of ERC at 3T remains uncertain but the improvement in signal-to-noise ratio can also improve the spatial resolution sufficiently so that minimal extraprostatic extension can be detected.[8]

Use of an ERC during image acquisition may not necessarily be enough to obtain an ideal prostate MRI. The current consensus is to use liquid barium or perfluorocarbon instead of air for coil insufflation, since air can induce susceptibility artifacts on diffusion weighted imaging. The ERC can result in patient discomfort, and placement of an ERC requires an on-site physician. Although MRI using an ERC can provide better image resolution in staging, it is more time-consuming and costly.

For nonERC prostate MRI, either at 1.5T or 3T, susceptibility to artifacts secondary to the presence of rectal gas can easily diminish image quality especially during diffusion-weighted MRI. Per minimum standards, patients should be asked to empty the bowel prior to prostate MRI,[3] which is of paramount importance for diagnostic image quality.

MRI Parameters

Prostate MRI is usually called multiparametric MRI because it incorporates the combined use of anatomic and functional pulse sequences. Anatomic pulse sequences include T1 and

T2-weighted mpMRI. The purpose of T1W mpMRI is not for lesion detection, but to document biopsy related residual hemorrhage which can mimic prostate cancer on images. T1W mpMRI should be acquired in the axial plane using spin echo or gradient echo sequences, and its acquisition is inherent for dynamic contrast enhanced imaging.

T2W mpMRI is the workhorse because the anatomic details can best be delineated, mainly in the axial plane. Images should be acquired in 2 or 3 planes (sagittal, axial and coronal) using fast/turbo spin echo sequences. Basic parameters along with technical specifications of image acquisition for diffusion weighted and DCE MRI are shown in Appendix 1.

Functional pulse sequences include diffusion weighted MRI (DW MRI) and dynamic contrast enhanced mpMRI (DCE mpMRI). Magnetic resonance spectroscopy is no longer recommended for clinical purposes, although it may still be used in research settings. DW MRI evaluates the Brownian motion of water molecules within tissue, which is restricted in cancer harboring tissues. The 2 key components of DW MRI are apparent diffusion coefficient maps and high b-value DW MRI, which is a factor related to the degree to which an acquisition is diffusion weighted. Two or more b-values are needed to calculate ADC maps from DW MRI using a mono-exponential decay model. The ADC map and the high b-value DW image are used in conjunction in a qualitative fashion.

DCE mpMRI evaluates the vascularity of the prostate in order to identify permeability changes related to tumor angiogenesis. It consists of T1W gradient echo images obtained before, during and after injection of gadolinium-based contrast agents. Additionally, the importance of detecting hemorrhage on T1W images is to rule out false-positive results on T2W images and, more importantly, to interpret DCE images.

An area of attention in prostate MRI is the relatively narrow role of DCE mpMRI, largely being applied for characterization of indeterminate lesions. Some key studies found that biparametric (T2 and DWI only) MRI can be sufficient to detect clinically significant prostate cancer,[9] while other studies revealed that DCE mpMRI has an important role for better cancer detection.[10] Future research with larger scaled, multi-institutional designs will help to clarify the actual diagnostic efficacy of biparametric MRI in prostate cancer care.

Reporting of Findings

Reporting and PI-RADSv2.1.—Current guidelines strongly encourage radiologists to use PI-RADSv2.1 to report prostate mpMRI findings.[4] This system is designed to evaluate treatment naïve patients and aims to standardize the MRI interpretation. PI-RADSv2.1 defines criteria for scoring each zone of the prostate on each pulse sequence. Once scoring for each lesion is completed for each pulse sequence, a final overall PI-RADSv2.1 score should be given for each lesion. The PI-RADS assessment is show in Appendix 2.

Marking and processing of MRI for reporting and biopsy purposes.—In contemporary practice prostate mpMRI is more commonly used for guiding biopsies rather than local staging. PI-RADSv2.1 guidelines provide a 41 sector map that divides the prostate into a total of 38 sectors at apical, mid and base levels along with 2 additional sectors for the

seminal vesicles and 1 sector for the membranous urethra. PI-RADSv2.1 recommends mapping of up to 4 suspicious lesions on this sector map.

Image processing in advance of the biopsy session is mandatory for transrectal ultrasound/MRI fusion guided approaches. This processing includes the 2 important steps of 1) segmentation of the prostate within axial T2W mpMRI and 2) labeling the target lesion within the prostate on axial T2W mpMRI. For segmentation of the prostate, manual, semiautomated or fully automated approaches can be used by radiologists or trained technologists under the supervision of radiologists. For labeling the index lesion, a radiologist should manually delineate intraprostatic target lesion(s) on axial T2W mpMRI using information from all pulse sequences.

There are several key points of the MRI technique. 1) For optimal scanning technique, a 3T surface coil should be used but the need for an endorectal coil remains debated. An endorectal coil may be necessary for older 1.5T scanners, although diagnostic quality prostate MRI has been reported without an endorectal coil using newer 1.5T systems. 2) Identification and reporting of putative tumors require anatomic and functional images. Image quality (especially avoiding air or stool in the rectum) and reader experience are paramount for accurate reporting. 3) The radiographic report should identify up to 4 suspicious lesions with each individual lesion reported and characterized using PI-RADSv2.1 criteria.

ROLE OF MRI IN PROSTATE CANCER SCREENING

Limited studies have evaluated mpMRI as a primary screening test in a PSA naïve population, and the data suggest that it is a more sensitive and specific screening tool than PSA.[11] Cost is a major consideration in the adoption of mpMRI based screening,[12] although cost may be offset by reducing the number of biopsies compared to PSA.

There are several significant impediments to the adoption of mpMRI as a stand-alone, population based screening strategy. 1) The performance of PI-RADS is specifically trained and validated on an at-risk population consisting of men with elevated PSA levels. The performance of PI-RADS and the thresholds for biopsy in a screening population with lower prevalence of occult prostate cancer are largely untested. 2) The widespread use of community based PSA screening may make it difficult to study MRI alone as a screening intervention without the use of concomitant PSA based risk stratification. Identification of a PSA naïve population may be difficult in most developed countries. 3) The cost of mpMRI may not be supportable as a generalized stand-alone screening strategy unless proven to reduce downstream costs associated with reduction in unnecessary biopsies and treatment.

INITIAL EVALUATION OF BIOPSY NAÏVE PATIENTS SUSPECTED OF HAVING PROSTATE CANCER

Prebiopsy Risk Stratification

As an increasingly useful tool for prostate cancer detection and risk stratification, mpMRI allows noninvasive assessment of the prostate gland from an anatomic and a functional

perspective. The MRI suspicion score has been shown to be the most important determinant of prostate cancer risk. mpMRI has been reported to predict more aggressive disease[13] and is positively correlated with the Gleason score of lesions at biopsy or surgery.[14]

There are several key points to consider. 1) MRI suspicion score correlates well with the likelihood of clinically significant cancer, potentially allowing prebiopsy risk stratification for individualized decision making. 2) Clinically, MRI suspicion scores (based on ADC value and diffusion weight imaging) correlate with the risk of adverse pathology on radical prostatectomy, risk of biochemical relapse following surgery and the likelihood of progression on active surveillance. 3) Implementation of mpMRI based risk stratification in clinical practice, particularly for guiding clinical decision making, is predicated upon the availability of high quality images and experienced readers. 4) Data derived from prebiopsy mpMRI can enhance the predictive ability and overall diagnostic accuracy of currently available clinical prediction tools.

Evaluation of Biopsy Naïve Patients using mpMRI

In men presenting for an initial prostate biopsy the potential advantages of mpMRI and targeted biopsy are to improve detection of high grade cancer and to avoid detection of low grade disease by selectively targeting tumor foci that are more likely to be clinically significant. Randomized clinical trial evidence supports the use of MRI in men at risk for prostate cancer presenting for initial prostate biopsy.[15–17] Taken together, these trials provide strong evidence for the benefit of prebiopsy mpMRI in men with no previous biopsy but questions remain regarding whether it is safe to avoid a biopsy in men at risk for prostate cancer with a low risk mpMRI (PI-RADS regions of interest less than 2). Individual institutional experience with mpMRI and an active quality assurance program assessing mpMRI targeted biopsy outcomes are necessary to determine the validity of this approach as a learning curve for MRI and biopsy has been demonstrated.[18,19]

There are several key points. 1) Randomized clinical trials have provided evidence to support the recommendation of mpMRI prior to biopsy for all men without a history of biopsy who are under consideration for prostate biopsy. 2) mpMRI targeted prostate biopsy in men suspicious of having prostate cancer with no history of prostate cancer detects more clinically significant cancer when combined with systematic biopsy and less clinically insignificant cancer than systematic biopsy alone. 3) The use of mpMRI targeted biopsy alone in men suspicious of having prostate cancer with no history of biopsy risks missing a small number of clinically significant cancers identified by systematic biopsy alone. Therefore, the performance of systematic biopsy in conjunction with mpMRI targeted sampling is advisable until a low risk of missed clinically significant cancers is documented. Continued use of systematic biopsy will increase the risk of over detection. 4) Image quality, experience of the interpreting radiologist, cost and availability of alternate biomarkers should be considered before performing prebiopsy MRI. 5) Defer systematic biopsy in men when the risk of missing clinically significant cancers is 15%. If biopsy is deferred, further risk stratification with secondary biomarkers or careful followup of subsequent PSA kinetics is advisable.

mpMRI Evaluation of Men with Previous Negative Biopsy

Among men with persistent suspicion of prostate cancer despite a previous negative biopsy the rationale for prebiopsy mpMRI is the detection of occult cancers missed by previous systematic sampling. In this setting prebiopsy MRI and MRI targeted biopsy detect more cancers than systematic sampling alone.[20] Several strategies to increase optimization in a prior negative biopsy setting have been published previously.[21] When high quality prostate MRI acquisition and interpretation by individuals with sufficient experience and skill in the area are available, it should be used in the prebiopsy setting of men with a prior negative biopsy.

STAGING AND TREATMENT PLANNING FOR PROSTATE CANCER

Role of mpMRI in Staging Prostate Cancer

Before being studied for localizing prostate cancer and guiding biopsies, mpMRI was used for staging.[22] Specifically it was used to assess the presence/absence of significant cancer and seminal vesicle invasion, to predict organ confined disease and extraprostatic/extracapsular extension of cancer, and to improve overall diagnostic accuracy over conventional T2W MRI alone.[23] Despite the improvements, mpMRI carries low sensitivity and high specificity for the detection of extracapsular extension. Secondary findings, such as capsular bulge, capsular irregularity or significant length of capsular contact, can improve sensitivity, as these findings correlate strongly with extracapsular extension. Results of mpMRI can be integrated into currently available clinical staging systems for risk stratification.

Role of mpMRI in Selecting Local Management, Surgical Choice and Technique

Identification of pathological features of cancer is important to help guide therapy. Results from mpMRI can be integrated into currently available clinical staging systems, and the information can be extrapolated to help risk stratify patients, guide therapy choice and inform surgical technique. Therapeutic technique, including surgical approach, radiation planning and antiandrogen use, may be modified based on the improved accuracy of radiological staging over clinical staging. The addition of mpMRI and mpMRI fusion biopsies has been recently studied in regard to patient selection for focal therapy but there are concerns as mpMRI typically underestimates tumor volume.[24] Although MRI provides a tool for identification of dominant regions or tumor, at present, proper selection of patients and planning for focal therapy require a combination of imaging and extended biopsy techniques.

MRI FOR PROSTATE CANCER SURVEILLANCE

Although current evidence is inadequate to establish that mpMRI guided biopsy is a required step in the pathway for active surveillance, it is strongly recommended that it be performed in men considering active surveillance if they have not already undergone imaging before biopsy in order to allow more accurate baseline risk stratification.[25,26] Targeted and systematic biopsies before mpMRI are recommended in men on active surveillance because disease may progress outside the target in a small but significant number of men.[27] Although

in many men undergoing confirmatory targeted biopsy upgraded disease may be demonstrated, the clinical significance of upgrade on MRI targeted biopsy remains to be explored.

Once men select active surveillance as a management option for low risk prostate cancer, the specific details of followup imaging and testing intensity represent an area of ongoing debate. A normal mpMRI (PI-RADS 1) is predictive of a lower risk of future progression than an abnormal mpMRI. However, despite normal mpMRI, disease upgrade has been demonstrated on confirmatory biopsy, suggesting that this imaging modality alone cannot be used to select active treatment in men who are on active surveillance.[28,29] Guidelines for the use of mpMRI in men on active surveillance have been established.[30]

There are several key points. 1) mpMRI improves the identification of occult intermediate risk and high risk prostate cancer. 2) Patients with MRI suggestive of occult clinically significant disease should undergo repeat MRI targeted and systematic biopsies before considering active surveillance. However, current information about mpMRI is not sufficient to support a role for repeat mpMRI in the absence of any confirmatory prostate biopsy for monitoring men on active surveillance. 3) mpMRI may be used in conjunction with other risk stratification techniques such as PSA density and genomic profiling to enhance the use and safety of active surveillance regimens.

CONCLUSION

Information obtained by mpMRI represents a significant addition to traditional imaging techniques for the management of prostate cancer. When a quality prostate MRI is obtained, current evidence now supports its use in men at risk for harboring prostate cancer prior to the initial biopsy as well as in men with an increasing PSA following an initial negative standard prostate biopsy procedure. It is likely that mpMRI can be beneficial for men with presumed clinically localized prostatic cancer before selecting definitive therapy or surveillance. The information obtained from mpMRI appears to offer some useful guidance for surgical planning of extirpative and ablative treatments.

Appendix 1.

MRI parameters and technical specifications

Basic parameters for T2W MRI
•Slice thickness: 3mm without gap. Imaging planes should be the same as those used for DWI and DCE
•Field of view (FOV): 12–20cm covering entire prostate and seminal vesicles
•In plane dimension: ≤0.7mm (phase) x ≤0.4mm (frequency)

Technical specifications of image acquisition for DW MRI
•Echo time (TE): ≤90 msec; Repetition time (TR): ≥3,000 msec,
•Slice thickness: ≤4 mm without gap. Imaging planes should be the same as those used for T2W and DCE
•FOV: 16—22 cm covering entire prostate and seminal vesicles
•In-plane dimension: ≤2.5 mm (phase and frequency)

Technical specifications of image acquisition for DCE MRI
•TR/TE: <100 msec/<5msec
•Slice thickness: 3mm without gap. Imaging planes should be the same as those used for T2W and DWI
•FOV: 12—20 cm covering entire prostate and seminal vesicles
•In plane dimension: ≤2 mm (phase and frequency)
•Temporal resolution: ≤15 sec
•Total scanning time: ≥2 min

•Gadolinium based contrast agent dose: 0.1 mmol/kg, injection rate: 2—3 cc/sec
• Injection rate: 2–3 cc/sec starting with continuous image data acquisition

Appendix 2.

PI-RADS Assessment

Peripheral Zone			
DWI	T2W	DCE	PI-RADS
1	Any	Any	1
2	Any	Any	2
3	Any	-	3
		+	4
4	Any	Any	3
5	Any	Any	4
Transition Zone			
T2W	DWI	DCE	PI-RADS
1	Any	Any	1
2	≤3	Any	2
	≥4	Any	3
3	≤4	Any	3
	5	Any	4
4	Any	Any	4
5	Any	Any	5

Abbreviations and Acronyms

ADC	apparent diffusion coefficient
DCE	dynamic contrast enhanced
DW	diffusion weighted
DWI	diffusion weighted imaging
ERC	endorectal coil
mpMRI	multiparametric MRI
MRI	magnetic resonance imaging
PI-RADS	Prostate Imaging Reporting and Data System
PSA	prostate specific antigen
T1W	T1-weighted
T2W	T2-weighted

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