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AUA Policy Statement on the Use of Multiparametric Magnetic Resonance Imaging in the Diagnosis, Staging and Management of Prostate Cancer

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Abstract

Purpose: We summarize the available data about the clinical and economic effectiveness of magnetic resonance imaging in the diagnosis and management of prostate cancer, and provide practical recommendations for its use in the screening, diagnosis, staging and surveillance of prostate cancer.

Materials and Methods: A panel of clinicians with expertise in the diagnosis and management of prostate cancer evaluated the current published literature on the use and effectiveness of

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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: At this time the data support the use of magnetic resonance imaging in patients with a previous negative biopsy and ongoing concerns about increased risk of prostate cancer. The data regarding its usefulness for initial biopsy suggest a possible role for magnetic resonance imaging in some circumstances. There is currently insufficient evidence to recommend magnetic resonance imaging for screening, staging or surveillance of prostate cancer.

Conclusions: Although it adds cost to the management of prostate cancer, magnetic resonance imaging offers superior anatomic detail, and the ability to evaluate cellular density based on water diffusion and blood flow based on contrast enhancement. Imaging targeted biopsy may increase the diagnosis of clinically significant cancers by identifying specific lesions not visible on conventional ultrasound. The clinical indications for the use of magnetic resonance imaging in the management of prostate cancer are rapidly evolving.

Keywords

prostatic neoplasms; magnetic resonance imaging; image-guided biopsy; early detection of cancer

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Multiparametric MRI has proven a valuable diagnostic tool in the management of prostate cancer. The excellent resolution and high signal-to-noise ratio provided by MRI, combined with the functional measurements of water diffusion and contrast enhancement, give an improved insight into the underlying histopathology of the prostate. Enthusiasm in the urology community for prostate MRI is evident in its dramatic increase in use.

While mpMRI offers a positive predictive value of 85% for prostate cancer for index lesions when the Prostate Imaging Reporting and Data System is ≥3, there remains a significant problem with subjective and inconsistent interpretation of lesions and with false-positive results, particularly in the transition zone.[1,2] mpMRI is being extensively promoted for the purpose of directing prostate biopsy either exclusively or as a fused technology in conjunction with transrectal ultrasound.

We evaluate the available evidence and make practical recommendations about how MRI can best be used by clinicians across the spectrum of prostate cancer care and management, including initial diagnosis, pretreatment risk assessment and staging, and active surveillance. The AUA (American Urological Association) Multiparametric Prostate MRI Consensus Panel performed a thorough literature review and examined the potential applications of this imaging modality in the diagnosis, staging and management of clinically localized prostate cancer. Information on this subject is evolving so rapidly that in some instances there is not enough evidence available to make definitive recommendations based on data alone. Therefore, these recommendations are basedin part on a critical review of the literature and in part on collective expert opinion.

TECHNIQUE OF PROSTATE MRI

Prostate MRI has recently been increasingly used to guide prostate cancer clinical management. This growing interest in MRI has led to a significant variation and heterogeneity in image acquisition, interpretation and pre-biopsy image processing, which can easily hinder patient care. To address these issues PI-RADS™ v2 was developed by an international collaboration of the American College of Radiology, European Society of Uroradiology and the AdMetech Foundation. It was published in 2015 and includes basic guidelines for MRI acquisition, interpretation and reporting.[3] This document strongly stated that the technical details of prostate MRI, which ultimately affects the imaging protocol, should be tailored to patient needs and the clinical questions posed by the referring physician. In this section we will cover technical points such as equipment, basic parameters, image interpretation and communication of these findings with urologists.

Equipment Specifications

Prostate MRI can be obtained with a 1.5Tesla or 3.0T magnet with or without using an endorectal coil. Although there are some studies comparing these different techniques, there is as yet no prospective and randomized study addressing which equipment is superior for cancer detection and staging.[4,5] We grouped the technical specifications as minimum and ideal standards.

Minimum Standards.—The 3.0T magnet systems provide twice the signal-to-noise ratio compared to 1.5T systems, providing increased spatial and temporal resolution, which ultimately results in improvement in image quality. Despite this difference, prostate MRI obtained at a 1.5T can still yield diagnostic images for lesion detection.[3] However, use of an endorectal coil should be considered, especially if older 1.5T systems are used or local staging is planned with newer 1.5T magnets.

Use of 1.5T magnets (instead of 3.0T) can be recommended for particular situations in which 3.0T incompatible implanted medical devices or conditionally compatible 3.0T devices may result in significant susceptibility artifacts (secondary to local magnetic field inhomogeneity). Distortion related to these devices can easily degrade the quality of prostate MRI.[3] Minimum standard prostate MRI, if performed carefully, can be used to detect lesions and be helpful for staging within its limitations.

Preferred/Ideal Standards.—Prostate MRI obtained at 3.0T with combined use of endorectal and surface coils currently stands as the most ideal technique for tumor detection and staging. ERC provides 5 times more signal-to-noise ratio compared to surface coil which results in improved spatial resolution and image quality.[6] Currently, the necessity of ERC at 3.0T remains uncertain but it is documented that the improved signal-to-noise ratio can also improve the spatial resolution sufficiently so that capsular invasion can be detected.[7]

Use of an ERC during image acquisition may not necessarily be enough to obtain ideal prostate MRI. The current consensus is to inflate the coil with liquid barium or perfluorocarbon instead of air, since air can easily induce susceptibility artifacts on

diffusion-weighted imaging.[3] It should be noted that ERC can result in patient discomfort and placement of an ERC may require a physician to assist if necessary. Although the ideal MRI can provide more optimum lesion detection and staging, it can cost more due to the use of ERC.

MRI Parameters

Prostate MRI is usually referred to as multiparametric MRI since it incorporates the combined use of anatomic and functional pulse sequences. Anatomic pulse sequences include T1 and T2-weighted images. T1W MRI is not used for lesion detection but the purpose of its acquisition is to document biopsy related residual hemorrhage that can mimic prostate cancer on mpMRI. T1W MRI should be acquired in the axial plane using spin echo or gradient echo sequences. T2W MRI is the workhorse of mpMRI since the anatomic details can best be delineated on T2W MRI, mainly in the axial plane. T2W MRI should be acquired in 3 planes (sagittal, axial and coronal) using spin echo sequences. The basic MRI parameters are shown in the table.

Functional pulse sequences include diffusion-weighted MRI and dynamic contrast enhanced MRI. DCE-MRI 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. The technical specifications of image acquisition for diffusion-weighted MRI and DCE-MRI are shown in the table.

DCE-MRI is the most invasive component of prostate mpMRI since gadolinium based contrast injection is used. Patients at risk for renal insufficiency (eg history of severe hypertension, diabetes or a history of solitary kidney) should have renal function evaluated to reduce the risk of nephrogenic systemic fibrosis.[8] It should be noted that magnetic resonance spectroscopy is no longer recommended for clinical purposes but its use is encouraged for research purposes only.

Reporting of Findings

Current guidelines strongly encourage radiologists to use the PI-RADS™ v2 to report prostate mpMRI findings.[3] It is clear that prostate mpMRI is more commonly used for guiding biopsies rather than local staging. Accurate lesion mapping and dimension measurement are key steps in communicating the results to the referring physicians. PI-RADS™ v2 guidelines provide a sector map that divides the prostate into 12 sectors at apical, mid and base levels of the prostate. Detected lesions can be mapped on this sector map along with their estimated size. PI-RADS™ v2 recommends mapping of the most suspicious 4 lesions on this sector map and such an approach can enhance communication of the prostate mpMRI findings to referring physicians efficiently.[3] Documentation of specific imaging series number and image number (e.g. Series 4, Image 15) of index lesions with those lesions clearly marked on the image is crucial to the physician performing subsequent biopsies.

Key points are 1) for optimal scanning technique use 3.0T surface coil plus or minus endorectal coil, 2) for 1.5T use an endorectal coil with older scanners, whereas a surface coil

can be sufficient with newer 1.5T systems, and 3) the radiographic report should identify the 4 most suspicious lesions, with each individual lesion identified using PIRADS™ v2 criteria.

ROLE OF mpMRI IN SCREENING FOR PROSTATE CANCER

The concept of finding a malignancy in the earliest stages of development which could then allow treatment to eradicate the cancer is inherently attractive to patients and their physicians. The European Randomized Study of Screening for Prostate Cancer, the largest prospective clinical trial to evaluate the effect of population based screening for prostate cancer, noted a statistically significant reduction in cancer related mortality for treated men in the screening arm, further supporting the concept of early detection.[9] However, this large study found the overall positive effect of screening with prostate specific antigen and digital rectal examination to be small and without any change in overall mortality.[10] Therefore, the current recommendations of the AUA and the American Cancer Society are for each man to review the risks and benefits of screening with his physician, and to reach an individual shared decision.

The significance of abnormal mpMRI findings varies by biopsy indication, largely due to the underlying prevalence of disease within studied cohorts. In a screening cohort, not risk stratified by PSA, the prevalence of disease would be low, potentially making it difficult to establish thresholds for abnormality on mpMRI. While provocative, mpMRI as a standalone screening application should be considered purely investigational. The key point is that there is no current evidence that mpMRI should be routinely used in population based screening for prostate cancer.

INITIAL EVALUATION OF BIOPSY NAÏVE PATIENTS SUSPECTED OF HAVING PROSTATE CANCER

Pre-Biopsy Risk Stratification

In general, the problems of over diagnosis and overtreatment of prostate cancer are not associated with imaging modalities but, rather, patient selection. Using standard transrectal ultrasound directed biopsies and appropriate selection criteria, positive biopsy rates may be as high as 60% with only 20% to 25% of patients diagnosed by that modality having low stage, low grade disease. More restrictive selection criteria for biopsy will result in the increased diagnosis of clinically significant cancers and a decrease in the diagnosis of low volume low stage disease, independent of the imaging modality used.

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. A recent meta-analysis demonstrated sensitivity ranging from 44% to 87% for the detection of clinically significant prostate cancer and a negative predictive value ranging from 63% to 98% for exclusion of clinically significant prostate cancer.[11] There is increasing interest in using a negative mpMRI to avoid biopsy. The use of mpMRI in clinical practice is critically dependent upon the availability of high quality mpMRI interpreted by radiologists experienced in the technique.

The key points are 1) MRI suspicion score correlates well with the likelihood of clinically significant cancer, potentially allowing pre-biopsy risk stratification for individualized decision making; 2) clinically, MRI suspicion scores (based on apparent diffusion coefficient 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 in guiding clinical decision making, is predicated upon the availability of high quality mpMRI and experienced readers; and 4) data derived from pre-biopsy mpMRI can enhance the predictive ability and overall diagnostic accuracy of currently available clinical prediction tools.

Initial Biopsy of Biopsy-Naïve Patients using mpMRI

In men presenting for a first prostate biopsy the potential advantages of mpMRI and targeted biopsy are to 1) improve detection of high grade cancer and 2) avoid detection of low grade disease by selectively targeting tumor foci that are more likely to be clinically significant. The performance characteristics of mpMRI targeted biopsy vary with the clinical indication, in part, due to the variable prevalence of disease in the study cohort. As such, the absolute rates of detection, when not stratified by suspicion score, may vary among series but trends remain similar. Several studies reporting outcomes of combined MRI targeted biopsy and systematic biopsy among men with no previous biopsy have suggested the potential to achieve these goals using mpMRI in the primary biopsy setting.[12–15] Most series to date suggest a persistent, low rate of clinically significant cancer detection on systematic biopsy among men with no history of prostate biopsy, drawing concerns about routine avoidance of systematic biopsy in this cohort.

Further refinements in imaging and MRI targeting strategies may be required before routine use of MRI targeted sampling in all men presenting for prostate biopsy is considered. Ongoing randomized trials, such as PROMIS (Prostate MR Imaging Study) and PRECISION (Prostate Evaluation for Clinically Important Disease: Sampling Using Image Guidance or Not), will offer further insight into its use and adoption.

There are 5 key points to consider. 1) In men suspected of prostate cancer with no history of mpMRI targeted prostate biopsy detects less clinically insignificant and more clinically significant prostate cancer than systematic biopsy alone. Combining targeted and systematic biopsies further increases detection of both clinically significant and insignificant cancers.

2) The use of mpMRI targeted biopsy alone in men suspected of having prostate cancer with no history of biopsy risks missing a small number of clinically significant cancers identified by systematic biopsy alone. Therefore, use of systematic biopsy in conjunction with MRI targeted sampling is advised in this group if MRI targeting is used.

3) The clinical impact of mpMRI targeted biopsy in men with no history of prostate biopsy remains controversial due to an unclear magnitude of clinical impact relative to cost. Quality of mpMRI, experience of the interpreting radiologist, cost of mpMRI and availability of alternate biomarkers should be considered before its use.

4) There may be added value to pre-biopsy MRI in selected biopsy naïve patients when technical challenges prevent good prostate visualization by ultrasound (eg absent or restricted anal access, large prostate or extensive calcification of prostate preventing evaluation of the anterior gland, risk of bleeding or infection when a negative MRI might obviate biopsy, presence of a nodule when pretreatment staging/planning is anticipated).

5) There are insufficient data to recommend routine MRI in every biopsy naïve patient under consideration for prostate biopsy. Its use may be considered in men for whom clinical indications for biopsy are uncertain (eg minimal PSA increase, abnormal digital rectal examination with normal PSA or marginal indications based on age).

mpMRI OF MEN WITH PREVIOUS NEGATIVE BIOPSY

Among men with persistent suspicion of prostate cancer despite a previous negative biopsy the rationale for pre-biopsy mpMRI is the detection of occult cancers missed by previous systematic sampling. These cancers are often located in the anterior transition zone or fibromuscular stroma, extreme apex or baseand wouldlikely bemissedby routine systematic sampling. There is minimal consensus on the indication for repeat biopsy in clinical practice and, as a result, the cancer detection rates vary widely among reported series. The AUA collaborated with the Society of Abdominal Radiology to develop a consensus statement on prostate MRI and MRI targeted biopsy in patients with a prior negative biopsy.[16]

STAGING OF AND TREATMENT PLANNING FOR PROSTATE CANCER

Role of mpMRI in Staging Prostate Cancer

Even before it was being studied for localizing prostate cancer and guiding prostate biopsies, mpMRI was used for staging prostate cancer.[17] mpMRI is useful for assessing the presence/absence of significant cancer, predicting organ confined disease and extraprostatic extension/extracapsular extension of cancer, and assessing seminal vesicle invasion. Results of mpMRI can be integrated into currently available clinical staging systems for risk stratification.

Role of MRI in Selecting Therapy (Local Management, Surgical Choice and Technique)

Identification of pathological features of cancer is important to help guide therapy in an individual patient. Results of MRI 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 procedures, radiation planning and antihormonal therapy, may be modified based on the improved accuracy of radiological staging over clinical staging.

Role of MRI in Evaluating Regional Lymphatics

Currently available imaging modalities for the evaluation of lymph nodes in patients with intermediate to high risk prostate cancer have high specificity and accuracy but only low to moderate sensitivity. MRI appears to be equivalent to computerized tomography and positron emission tomography in this regard.

The key points are 1) staging prostate cancer using MRI to evaluate possible lymph node metastasis can be considered in select patients (T3/T4 and T1/T2 disease) with nomograms predicting the risk of lymph node metastasis >10%, and 2) mpMRI/transrectal ultrasound may offer valuable staging information when performed before definitive local therapy. However, the current staging accuracy has not demonstrated the capability to rule out microscopic capsular extension or positive margins.

Evaluation for Local Recurrence

mpMRI can be of value in men with biochemical failure after radical prostatectomy and radiation therapy to help evaluate for local recurrence vs systemic recurrence, to help guide biopsies and to help inform therapy choice. Suspicion of recurrence in the setting of biochemical failure is a valid reason for clinicians to request mpMRI.

The key point is that it is possible that mpMRI may be useful for followup evaluation of men treated with radical prostatectomy or in situ ablative therapies (cryoablation or high intensity focused ultrasound and radiation therapy). However, current information is not available to determine the diagnostic accuracy of this imaging modality in these settings.

MRI for Surveillance of Prostate Cancer

The concept of observation as a therapeutic option for clinically localized prostate cancer has been well established and is associated with excellent long-term progression-free survival in men with favorable malignancy on prostate biopsy. Chodak demonstrated in a large multi-institutional pooled analysis of 828 men that conservative therapy, also known as watchful waiting, resulted in an 87% disease specific survival at 10 years for men with either grade 1 (equivalent Gleason sum 5,6) or grade 2 (likely equivalent Gleason sum 7) cancer.[18] The finding that the metastasis-free survival for men with grade 2 adenocarcinoma was only 58% at 10 years suggested that there was a role for a more active monitoring strategy in some men.

Several diagnostic modalities are currently being evaluated for enhanced performance of active surveillance. A simple change from a transrectal approach for prostate biopsy to transperineal biopsy has been found to more accurately predict clinical risk category but with similar risk of pathological upgrading.[19,20] Similarly, use of MRI-fusion biopsy techniques may better identify high risk disease.

Once men select active surveillance as an option for low risk prostate cancer the specific details of followup represent important costs and treatment intensity concerns. A negative MRI has been found to be associated with upgrading (>Gleason 6) in 27% of men, suggesting that this imaging modality alone cannot be used to monitor men on active surveillance.[21] An unchanged MRI has also been associated with an 80% negative predictive value for biopsy upgrading during an active surveillance investigation.[22] Again, the variability of treatment intensity and the lack of standardization for MRI findings suggest that this modality may be useful for the initial categorization of men as candidates for active surveillance but is not sufficient for use as a primary test during surveillance.[23]

Despite this conclusion, significant opportunities exist for further refinement of active surveillance protocols to better risk stratify men at initial entry into these protocols and to better target the regions of the prostate that could harbor a malignancy that would require a delayed therapeutic intervention. The combination of advanced imaging with MRI, altered biopsy approaches (eg transperineal) and the use of molecular markers may ultimately improve the outcomes of non-curative therapies beyond those established with traditional watchful waiting.

The key point is that prostate mpMRI has been demonstrated to improve the diagnosis of intermediate risk and high risk prostate cancer on targeted prostate biopsy which could be beneficial for identifying candidates for active surveillance protocols. However, the current information about MRI is not sufficient to support a role for repeat MRI without a prostate biopsy for monitoring men on active surveillance.

CONCLUSION

The information obtained by mpMRI represents a significant addition to traditional imaging techniques for the management of prostate cancer. mpMRI has the potential to improve the timely identification of clinically significant prostate cancer. Enhanced targeting approaches have the potential to reduce the cost of care through the reduction of unnecessary or inaccurate prostate biopsy procedures.

Current evidence supports the performance of mpMRI in men with an increasing PSA following an initial negative standard prostate biopsy procedure. It is likely that a targeted biopsy, using a combination of mpMRI and ultrasound guided transrectal or transperineal biopsy, will become the preferred method for an initial prostate biopsy in a biopsy naïve man with an abnormal digital rectal examination or elevated PSA. It is also likely that mpMRI before selecting definitive therapy can be beneficial for men with a presumed clinically localized prostatic adenocarcinoma. Advanced imaging appears to offer some useful information for planning extirpative and ablative treatments.

Current enthusiasm for the potential benefit of mpMRI suggests that more evidence will be forthcoming regarding the role of this modality in men on active surveillance and possibly in population based screening programs for prostate cancer. These applications should be considered investigational at this time.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Abbreviations and Acronyms

DCE-MRI	dynamic contrast enhanced MRI
ERC	endorectal coil
mpMRI	multiparametric magnetic resonance imaging

MRI	magnetic resonance imaging
PI-RADS™	Prostate Imaging Reporting and Data System
PSA	prostate specific antigen
W	weighted

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Table.

MRI parameters and specifications

Basic MRI parameters
• Slice thickness 3 mm without gap
• Field of view 12–20 cm covering entire prostate and seminal vesicles
• In plane dimension ≤0.7 mm (phase) × ≤0.4 mm (frequency)[3]
Technical specifications of image acquisition for DW MRI
• Echo time ≤90 msec, repetition time ≥3,000 msec
• Slice thickness ≤4 mm without gap
• Field of view 16–22 cm covering entire prostate and seminal vesicles
• In plane dimension ≤2.5 mm (phase and frequency)[3]
Technical specifications of image acquisition for DCE MRI
• Repetition time/echo time <100 msec/<5 msec
• Slice thickness 3 mm without gap
• Field of view 12–20 cm covering entire prostate and seminal vesicles
• In plane dimension ≤2 mm (phase and frequency)
• Temporal resolution ≤10 sec (<7 sec preferred)
• Total scanning time ≥2 mins
• Gadolinium based contract agent dose 0.1 mmol/kg, injection rate 2–3 cc/sec[3]