Multiparametric Magnetic Resonance Imaging Guided Diagnostic Biopsy Detects Significant Prostate Cancer and could Reduce Unnecessary Biopsies and Over Detection: A Prospective Study

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Purpose: Multiparametric magnetic resonance imaging appears to improve prostate cancer detection but prospective studies are lacking. We determined the accuracy of multiparametric magnetic resonance imaging for detecting significant prostate cancer before diagnostic biopsy in men with abnormal prostate specific antigen/digital rectal examination.

Materials and Methods: In this single center, prospective study men older than 40 years with abnormal prostate specific antigen/digital rectal examination and no previous multiparametric magnetic resonance imaging underwent T2-weighted, diffusion-weighted and dynamic contrast enhanced imaging without an endorectal coil. Imaging was allocated alternately to 1.5/3.0 Tesla. Imaging was double reported independently using PI-RADS (Prostate Imaging Reporting and Data System) by specialist radiologists. Transperineal grid directed 30-core biopsy was performed with additional magnetic resonance imaging directed cores for regions of interest outside template locations. Four significant cancer definitions were tested. Chi-square and logistic regression analysis was done. Men undergoing prostatectomy were analyzed.

Results: Of the 165 men who enrolled in the study 150 were analyzed. Median age was 62.4 years, median prostate specific antigen was 5.6 ng/ml, 29% of patients had an abnormal digital rectal examination and 88% underwent initial biopsy. Multiparametric magnetic resonance imaging was positive (PI-RADS 3 to 5) in 66% of patients, 61% had prostate cancer and 30% to 41% had significant prostate cancer (definitions 1 to 4). For significant cancer sensitivity was 93% to 96%, specificity was 47% to 53%, and negative and positive predictive values were 92% to 96% and 43% to 57%, respectively (definitions 1 to 4). Radical prostatectomy results in 48 men were similar. Aggregate PI-RADS (4 to 20)

Abbreviations and Acronyms

DCEI = dynamic contrast enhanced imaging
DRE = digital rectal examination
DWI = diffusion-weighted imaging
ESUR = European Society of Urogenital Radiology
mpMRI = multiparametric magnetic resonance imaging
NPV = negative predictive value
PCa = prostate cancer
PI-RADS = Prostate Imaging Reporting and Data System
PPV = positive predictive value
PSA = prostate specific antigen
ROI = region of interest
RP = radical prostatectomy
T2WI = T2-weighted imaging
TRUS = transrectal ultrasound

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For another article on a related topic see page 252.

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performed similarly to overall PI-RADS (1 to 5). Negative and positive predictive values (100% and 71%, respectively) were similar in men at higher risk, defined as prostate specific antigen greater than 10 ng/ml with abnormal digital rectal examination. On multivariate analysis PI-RADS score was associated with significant prostate cancer ($p < 0.001$) but magnet strength was not. Adding PI-RADS to the multivariate model improved the AUC from 0.810 to 0.913 (95% CI 0.038−0.166, $p = 0.002$). Radiologist agreement was substantial (weighted $\kappa = 0.626$).

Conclusions: Multiparametric magnetic resonance imaging reported by expert radiologists achieved an excellent negative predictive value and a moderate positive predictive value for significant prostate cancer at 1.5 and 3.0 Tesla.

Key Words: prostate, prostatic neoplasms, magnetic resonance imaging, prostate-specific antigen, mass screening

A major limitation of PCa screening with PSA and DRE is poor specificity at acceptable sensitivity thresholds.[1] A 12-core transrectal biopsy is recommended as the initial prostate biopsy despite limited sensitivity and concordance with prostatectomy[2] as well as over detection of insignificant cancer in a third of cases.[3] Saturation templates may improve detection but increase over detection and complication rates.[4]

mpMRI provides anatomical and functional information by combining T2WI with DWI, DCEI and/or spectroscopy. Sensitivity for PCa was 80% to 98% in recent studies[5,6] and reviews.[7,8] mpMRI may improve PCa screening by 1) ruling out significant PCa, and decreasing unnecessary biopsies and over detection, 2) directing biopsy, and increasing sensitivity and grade/volume assessment, and 3) decreasing the number of cores, complications and over detection.

Despite promising results most MRI studies have had methodological limitations. Studies using prostatectomy as the reference standard may be confounded (if MRI is performed after biopsy) by radiologist awareness of PCa in participants (reporting bias), by biopsy artifact and by exclusion of men with negative biopsy/alternative treatments (selection bias). Studies using 12-core biopsy as the reference standard may have high false-negative and cancer underestimation rates. Other common methodological limitations include retrospective design, small sample size, heterogeneous scan protocols, inadequate functional parameters and single reporting. A mpMRI scoring system was recently validated and higher scores correlated strongly with more significant cancer.[9] In 2012 the PI-RADS system was proposed by the ESUR[10] but it requires external validation, as discussed in a recent review of standardized mpMRI reporting.[11]

We determined the accuracy of mpMRI for significant cancer detection before diagnostic biopsy in a prospective cohort with abnormal PSA/DRE.

MATERIALS AND METHODS

This prospective study was done at St. Vincent's Clinic, Sydney, Australia. Institutional review board approval was granted and informed consent was obtained. Two urologists (PDS and PB) invited all men who met selection criteria to participate in the study. Selection criteria were age greater than 40 years, planned biopsy for abnormal PSA/DRE, life expectancy greater than 10 years, as assessed by age, family longevity and comorbidity, and no previous prostate MRI. No PSA/DRE criteria were set to maximize finding generalizability.

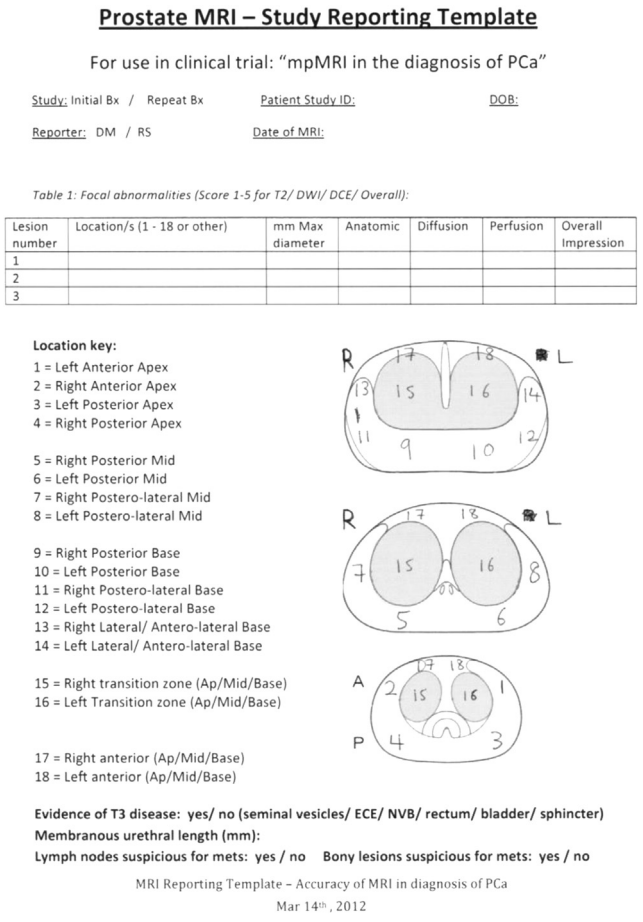
MRI Protocol

All mpMRIs were performed at 2 centers using a standardized protocol (Appendix 1). A 1.5 Tesla magnet was used at 1 center and a 3 Tesla magnet was used at the other. Participants were allocated alternately to center 1 or 2 in order of enrollment.

Reporting Protocol

Two radiologists (DM at center 1 and RS at center 2) double reported in independent fashion while blinded to each other. Each radiologist had reported more than 1,000 prior prostate mpMRIs. A total of 20 pretrial mpMRIs were reviewed together using the PI-RADS system[10] to establish consensus. Radiologists received clinical data (PSA, DRE and family history) according to routine practice. Standardized PI-RADS reporting comprised a 5-point scale on which the presence of clinically significant cancer is 1—extremely unlikely, 2—unlikely, 3—equivocal, 4—likely or 5—extremely likely.

Using objective criteria ROIs were assigned a score of 1 to 5 for each parameter (T2WI, DCEI and DWI) and then an overall ROI score (mean of parameter scores). The highest overall ROI score was termed the overall study score. The aggregate of the 4 scores was calculated for each ROI and the highest aggregate score was considered the overall aggregate score. The mean of the 2 overall study scores (1 per radiologist) was calculated and a binary variable was defined, including 1 to 2—negative and 2.5 to 5—positive. ROIs were indicated on a topographic map with 18 regions corresponding to biopsy template locations (fig. 1). Anterior and transition zones were subdivided into apex/mid/base to create 26 ROI locations. Color mpMRI images



Prostate MRI – Study Reporting Template

For use in clinical trial: "mpMRI in the diagnosis of PCa"

Study: Initial Bx / Repeat Bx Patient Study ID: DOB:

Reporter: DM / RS Date of MRI:

Table 1: Focal abnormalities (Score 1-5 for T2/ DWI/ DCE/ Overall):

Lesion number	Location/s (1 - 18 or other)	mm Max diameter	Anatomic	Diffusion	Perfusion	Overall Impression
1						
2						
3						

Location key:

1 = Left Anterior Apex
2 = Right Anterior Apex
3 = Left Posterior Apex
4 = Right Posterior Apex

5 = Right Posterior Mid
6 = Left Posterior Mid
7 = Right Postero-lateral Mid
8 = Left Postero-lateral Mid

9 = Right Posterior Base
10 = Left Posterior Base
11 = Right Postero-lateral Base
12 = Left Postero-lateral Base
13 = Right Lateral/ Antero-lateral Base
14 = Left Lateral/ Antero-lateral Base

15 = Right transition zone (Ap/Mid/Base)
16 = Left Transition zone (Ap/Mid/Base)

17 = Right anterior (Ap/Mid/Base)
18 = Left anterior (Ap/Mid/Base)

Evidence of T3 disease: yes/ no (seminal vesicles/ ECE/ NVB/ rectum/ bladder/ sphincter)
Membranous urethral length (mm):
Lymph nodes suspicious for mets: yes / no Bony lesions suspicious for mets: yes / no

MRI Reporting Template – Accuracy of MRI in diagnosis of PCa
Mar 14th, 2012

Figure 1. Standardized PI-RADS based reporting template for study mpMRIs. *Bx,* biopsy. *Ap,* apex. *ECE,* extracapsular extension. *NVB,* neurovascular bundle. *mets,* metastasis.

indicating ROIs in multiple planes and sequences accompanied reports.

Biopsy and Prostatectomy Methodology

Participants underwent transperineal, grid directed biopsy (median of 30 cores and adjusted for volume) from 18 template locations with the patient under general anesthesia. Urologists reviewed the MRI report and images, and collected another 2 targeted cores from all ROIs potentially under sampled by template biopsy using 2 methods. 1) MRI/TRUS fusion biopsy was performed with a floor mounted, transperineal grid TRUS platform (BK Medical, Herlev, Denmark) combined with Biojet rigid MRI/TRUS fusion software (Meditron, Melbourne, Victoria, Australia) for ROIs potentially missed by cognitive targeted biopsy due to a diameter of less than 10 mm and a site outside the template, eg midline, junction of peripheral and transitional/anterior fibromuscular zones, extreme anterolateral horn or adjacent to bladder/seminal vesicles. 2) Cognitive (manual MRI informed) transperineal grid directed, TRUS guided biopsy was done for ROIs with a diameter of 10 to 15 mm at an easily accessible location but that were potentially under sampled by template biopsy. Such ROIs were generally visible on TRUS as a hypoechoic area, aiding cognitive targeted biopsy.

Targeted biopsy was unnecessary for large ROIs greater than 15 mm in diameter that spanned multiple template locations since they were covered by more than 3 or 4 template cores. Biopsies and RPs were processed and reported according to ISUP (International Society of Urological Pathology) protocols by a subspecialist uropathologist (WD).

Statistical Analysis

Analysis was performed using SAS®, version 9.3. Binary overall PI-RADS (1 or 2—negative and 3 to 5—positive), aggregate PI-RADS (1 to 8—negative and 9 to 20—positive), biopsy (primary end point) and prostatectomy (secondary end point) significant cancer variables were defined for chi-square analysis. Due to controversy regarding the biopsy definition of significant PCa 4 definitions were selected prospectively based on strict criteria (definitions 1 and 3) from older studies[12] and less restrictive criteria based on newer studies (Appendix 2).[13,14] Definition 4 was selected prospectively as the primary end point. Alternatives accounted for controversy and facilitated comparison with other studies. Significant cancer at RP was defined based on a recent study as any of 1) Gleason 7-10 with greater than 5% grade 4 and 0.7 cc or greater, 2) Gleason 6 and 1.3 cc or greater, 3) pT stage 3a or greater and 4) nodal metastasis (pN1).[13]

The Cochran-Armitage trend test was used to assess the association between PI-RADS score and significant cancer at biopsy and RP. Analysis was stratified by prebiopsy risk with lower risk defined as PSA less than 10 ng/ml and normal DRE, and higher risk defined as PSA 10 ng/ml or greater, or abnormal DRE. Stepwise logistic regression and AUC analysis were done to explore the relationship between overall PI-RADS score (1 to 5) and significant cancer (yes/no) adjusting for age, PSA, DRE (normal/abnormal), family history (yes/no), magnet strength (1.5/3.0 Tesla) and radiologist (1/2). We assessed radiologist agreement via the κ statistic[15] with quadratic weighting using the square of the difference between the PI-RADS score of each radiologist, thus, weighting widely discordant scores more heavily.

RESULTS

Of 165 men enrolled in the study between April 2012 and April 2013, 15 had insufficient data and 150 were included in study. Table 1 lists baseline characteristics. The rate of significant PCa was 36%, 30%, 41% and 34% according to biopsy definitions 1, 2, 3 and 4, respectively.

Table 2 shows the relationship between PI-RADS score and cancer risk category at biopsy. Significant cancer was noted in none of the 11% of men with PI-RADS 1 (NPV 100%, 95% CI 82–100), 6% of 23% with PI-RADS 2 (NPV 94%, 95% CI 81–93), 26% of 38% with PI-RADS 3 (NPV 74%, 95% CI 61–83 and PPV 26%, 95% CI 17–39), 73% of 20% with PI-RADS 4

Table 1. *Baseline characteristics of analyzed study population of 150 patients*

Median age (IQR)	62.4	(55.0–66.4)
Median ng/ml PSA (IQR)	5.6	(4.5–7.5)
% abnormal DRE (%)	29.3	
% First-degree relative with PCa (%)	30.7	
% Diagnostic biopsy:		
Initial	88	
Repeat	12	
% Magnet strength (Tesla):		
1.5	47	
3.0	53	
Median cm^3 MRI vol (IQR)	40	(30–57)
% Pos MRI PI-RADS 3–5 (%)	66	
% Biopsy pos for prostate Ca (%)	61.3	
Median No. cores (IQR):		
Collected	30	(26–33)
Pos	2	(0–7)

(PPV 73%, 95% CI 56–86) and all of 8% with PI-RADS 5 (PPV 100%, 95% CI 76–100). Table 3 lists chi-square and AUC accuracy estimates for mpMRI by significant cancer definition. Supplementary table 1 (http://jurology.com/) lists clinical, MRI, biopsy and RP data for 4 false-negative mpMRIs.

Accuracy

Aggregate PI-RADS score. Compared to the binary overall PI-RADS variable, using the binary maximal aggregate PI-RADS variable at the lower (4 to 8 vs 9 to 20) or higher (4 to 9 vs 10 to 20) cutoff did not significantly alter NPV and PPV, which were 98% and 47% for the lower cutoff vs 96% and 51%, respectively, for the higher cutoff.

mpMRI in men at lower vs higher risk before biopsy. Stratifying by prebiopsy risk demonstrated superior accuracy in 53 men at higher risk vs 97 at lower risk (NPV and PPV 100% and 71% vs 96% and 28%, respectively).

Analysis

Logistic regression. PSA, DRE, age and PI-RADS score were strongly associated with significant PCa on univariate analysis (each $p < 0.005$) while magnet strength ($p = 0.080$) and family history ($p = 0.938$) were not. On multivariate analysis PI-RADS ($p < 0.001$), PSA ($p = 0.042$) and DRE ($p = 0.032$) were independent predictors. Age ($p = 0.406$) and magnet strength ($p = 0.176$) were not and, therefore, they were removed from the final model. Adding PI-RADS to the base model of PSA and DRE increased the AUC for predicting significant cancer from 0.810 to 0.913 for definition 4 ($p = 0.002$, 95% CI 0.038–0.166, fig. 2). Results for definitions 1 to 3 were similar (table 3).

Table 2. *PI-RADS MRI score and biopsy risk category in 150 men*

PI-RADS Score*	% No Ca	% Any Ca	% Low Risk	% Moderate Risk	% High Risk
1	8	3.3	3.3	0	0
2	15.3	7.3	6	1.3	0
3	12	26	16	8	2
4	3.3	16.7	2	12	2.7
5	0	8	0	3	5
Totals	38.7	61.3	27.3	24.3	9.7

*With definition 4 as prospectively selected primary end point definition.

Mean overall PI-RADS score. Using the binary mean overall PI-RADS variable (1 to 2 vs 2.5 to 5) on chi-square analysis the NPV, sensitivity, specificity and PPV for significant PCa using definition 4 were 100%, 100%, 43% and 51%, respectively. Adding the mean PI-RADS score (1 to 5) to the multivariate base model resulted in an AUC of 0.944.

Radiologist Accuracy and Agreement

The accuracy of the 2 radiologists was similar (supplementary table 2, http://jurology/com/). General agreement (each scoring PI-RADS 1 or 2, or 3 to 5) was 75%. Quadratic weighted κ was 0.626 (95% CI 0.523–0.716), indicating substantial agreement.[15]

RP Cohort Analysis

A total of 48 men underwent RP. None with overall PI-RADS 1 underwent RP and 4 with PI-RADS 2 underwent RP, of whom patient 2 (25%) had borderline significant PCa (supplementary table 1, http://jurology.com/). Of the remaining men 14 with PI-RADS 3 underwent RP, of whom 11 (79%) had significant cancer; 23 with PI-RADS 4 underwent RP, of whom 23 (96%) had significant cancer; and 7 with PI-RADS 5 underwent RP, all of whom had significant cancer. Using the binary overall PI-RADS and RP significant cancer variables in chi-square analysis resulted in 98% sensitivity, 43% specificity, 91% PPV and 75% NPV. If borderline findings in patient 2 were defined as negative, sensitivity and NPV were 100% each (supplementary table 1, http://jurology.com/). The correlation between PI-RADS score and significant PCa was highly significant ($p < 0.001$).

DISCUSSION

These results demonstrate that mpMRI has high NPV and moderate PPV, indicating potential usefulness as a second line screening test to guide biopsy decisions in men with abnormal PSA/DRE. Biopsy analysis results were almost identical to RP analysis results, suggesting that our reference test was robust. These findings are consistent with those of previous studies showing high NPV and

Table 3. *MRI accuracy estimates by definition of significant cancer at biopsy*

Accuracy Estimates	1 (more strict grade only)	2 (less strict grade only)	3 (more strict grade + vol)	4 (less strict grade + vol)*
% Chi-square:†				
Sensitivity	94	96	93	96
Specificity	50	47	53	50
NPV	94	96	92	96
PPV	52	43	58	50
AUC:‡				
1 (PSA + DRE base model)	0.837	0.803	0.794	0.810
2 (base + PI-RADS model)	0.921	0.897	0.888	0.913
1 vs 2 Difference (95% CI)	0.084 (0.027–0.139)	0.094 (0.027–0.160)	0.094 (0.036–0.151)	0.103 (0.038–0.166)
p Value	0.004	0.005	0.001	0.002

* Prospectively selected primary end point definition based on recent evidence.[15,16]
† Based on binary overall PI-RADS definition (negative—1 and 2, and positive—3 to 5).
‡ Based on categorical overall PI-RADS variable (1 to 5) on multivariate logistic regression analysis.

moderate PPV for significant cancer compared to standard TRUS biopsy[5,6,16,17] and transperineal template mapping biopsy.[18] Unlike a recent study that showed poor diagnostic usefulness for mpMRI in men at higher risk (PSA greater than 10 ng/ml or abnormal DRE)[17] our study revealed high NPV but with decreased PPV and in a limited number of patients (53).

If biopsy had been deferred in men with PI-RADS 1 or 2, 50% without significant PCa would have avoided biopsy, over detection of low risk cancer would have decreased by 34%, a diagnosis of Gleason 3 + 4 would have been delayed in 1% of patients and no patient with Gleason 4 or greater + 3 PCa would have been missed.

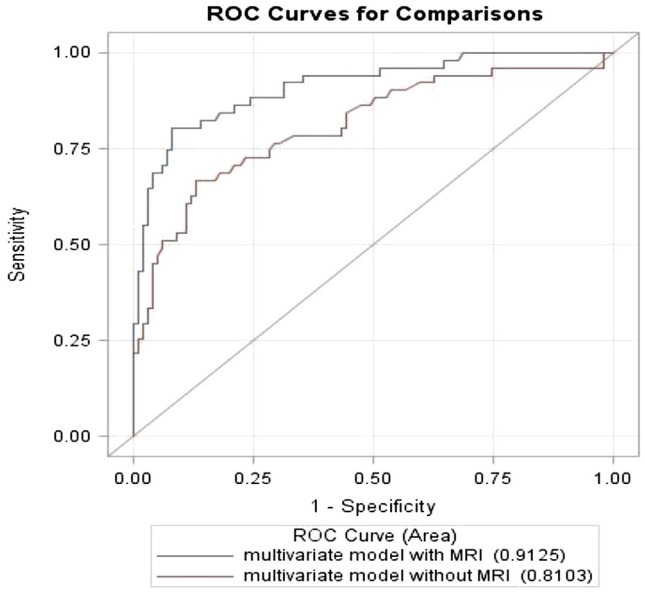


Figure 2. AUCs of multivariate base model with PSA plus DRE and base plus PI-RADS model to predict significant PCa at biopsy based on definition 4.

To our knowledge this study also represents the first external validation of the ESUR PI-RADS scoring system[10] in a predominately initial biopsy cohort using a saturation template biopsy reference test, complementing recent validation in smaller repeat biopsy[19] and MRI/TRUS fusion biopsy[20] cohorts. The latter investigators assessed overall (1 to 5) and aggregate (4 to 20) PI-RADS scores, noting superior performance for the aggregate score. However, overall and aggregate scores performed similarly in this study. Each group reported lower accuracy using PI-RADS than in our series, which may relate to the biopsy reference test used, the cancer end point definition chosen, the inclusion of multiple ROIs per patient instead of only the most suspicious ROI as in our study, and scanning/reporting factors.

Alternate MRI scoring/reporting systems have been validated, such as that proposed by the NCI (National Cancer Institute) in the United States, with higher scores also correlating strongly with higher grade and volume cancer.[9] Furthermore, prebiopsy mpMRI provides anatomical localization of ROIs that can be targeted using in-gantry MRI guided, MRI/TRUS fusion or cognitive (manual) techniques. Targeted cores consistently and selectively detect higher grade and volume cancers with greater core efficiency and better correlation with radical prostatectomy compared to 12-core and transperineal template biopsies.[21–25] The comparative accuracy of template vs MRI directed biopsy was discussed in recent systematic reviews.[8,26]

Despite encouraging results our findings suggest room for improvement in specificity and consistency among radiologists with the PI-RADS system. For example, we observed a subset of men with ROIs that were likely benign but are currently classified as overall PI-RADS 3, or aggregate PI-RADS 9 or 10 since malignancy cannot be excluded. These

men may benefit from followup mpMRI rather than immediate biopsy, comprising a new PI-RADS 2F category equivalent to Bosniak 2F for renal cystic disease. This would include diffuse abnormalities typical of prostatitis and a small ROI in the transition zone with background nodular benign prostatic hyperplasia, likely a hyperplastic nodule. Followup mpMRI in 6 to 12 months for patients with PI-RADS 2F may decrease the number with PI-RADS 3 who require biopsy, increasing PPV without compromising NPV.

A number of validated nomograms were developed to predict PCa, eg those of the ERSPC (European Randomized Study of Screening for Prostate Cancer) and PCPT (Prostate Cancer Prevention Trial), although uptake has been poor due to limited predictive accuracy.[27] The high AUC values in this study suggest that a novel nomogram combining the PI-RADS score, PSA and DRE could be developed to guide biopsy decisions with higher accuracy than existing models. Internal and external validation with AUC above 0.90 would be required before routine clinical use.

The biopsy definition of significant cancer remains controversial and exacerbated by recent changes in pathological reporting such that some cancers previously classified as Gleason grade 3 are now 4 and multiple cancer foci in a core with intervening normal stroma are now classified as continuous, increasing reported cancer core lengths.[28] A recent large study using ERSPC data recommended that the volume threshold for significant Gleason 6 cancer be 1.3 cc (14 mm diameter)[13] rather than 0.5 cc.[12] Another study of 15,000 radical prostatectomies showed that Gleason 6 lacked metastatic potential in the absence of higher grade disease.[29] Despite this controversy our results show similar sensitivity and specificity across biopsy definitions and the RP subset cohort.

Our finding of equivalent accuracy for 1.5 and 3 Tesla validates similar findings in a study using RP as the reference test.[30] This has major implications since most MRI devices in radiology practices globally are 1.5 Tesla and endorectal coils are expensive and invasive. While 3 Tesla has advantages, including decreased acquisition time and improved anatomical resolution for T staging, to our knowledge no study has shown an advantage over 1.5 Tesla for detection.

Our study has certain limitations. We used biopsy as the reference test, creating the risk of missing or misclassifying some cancers. However, biopsy analysis results were almost identical to RP analysis results, suggesting that our reference test was accurate. A second limitation was sample size. This created the potential for error in accuracy estimates, particularly in secondary end point analysis (1.5 vs 3 Tesla), although the data showed no trend toward significance to suggest a type 1 error due to inadequate sample size. We did not perform comparative analysis of the accuracy of template vs targeted biopsies since this study was not designed for that purpose. Thus, targeted biopsy was performed selectively, as described. We plan to extend the trial by enrolling a sample size of 300 patients to perform fully powered 1.5 vs 3.0 Tesla analysis, fully powered stratified analysis of men at lower vs higher risk, anatomical correlation analysis and subset analysis using RP as the reference test in 100 men to validate biopsy results. In conclusion, mpMRI has potential to improve the selection of men for biopsy, decreasing unnecessary biopsies and over detection of insignificant cancers while maintaining a low rate of missed significant cancers.

APPENDIX 1

Four proposed definitions of biopsy based risk categories

Definition	PCa Risk Category		
	Low	Moderate	High
1—More strict, grade only criteria	Gleason score 6	Gleason score 7	Gleason score 8-10
2—Less strict, grade only criteria	Gleason score 6-7 with 5% or less Gleason grade 4	Gleason score 7 with greater than 5% Gleason grade 4	Gleason score 8-10
3—More strict grade + vol criteria	Gleason score 6 + less than 20% of cores pos + less than 5 mm max core length PCa	Gleason score 7 + less than 50% of cores pos or Gleason score 6 + either 20% or greater of cores pos or 5 mm or greater max core length of PCa	Gleason score 7 and greater than 50% of cores pos or Gleason score 8-10
4—Less strict grade + vol criteria	Gleason score 6-7 with 5% or less Gleason grade 4 + less than 30% of cores pos + less than 8 mm max core length PCa	Gleason score 7 with greater than 5% Gleason grade 4 + less than 50% of cores pos or Gleason score 6-7 with 5% or less Gleason grade 4 + either 30% or greater of cores pos or 8 or greater mm max core length of PCa	Gleason score 7 + greater than 5% Gleason grade 4 + greater than 50% of cores pos or Gleason score 8-10

APPENDIX 2

Study mpMRI Standardized Protocol According to ESUR Guidelines

T2WI with 3 mm slice thickness, 0.5 × 0.5 mm anatomical resolution; axial, sagittal, coronal plane reconstructions

DWI with axial 4 mm slice thickness; derived ADC (apparent diffusion coefficient) maps (B-values 0, 400 to 800 and 1,400 s/mm^2 (note: 1,400 used only for 3 and not 1.5 Tesla)

DCEI with intravenous gadolinium diethylenetriaminepentaacetic acid bolus (10 ml at 3 ml per second) followed by rapid sequences with temporal resolution of 4 to 6 seconds; continued for 5 minutes for washout; quantitative analysis using K-trans color maps and curve morphological analysis

Allocated consecutively (alternate) on enrollment to 1.5 or 3 Tesla field strength

A 32-channel system (14-channel spine and 18-channel pelvic phased array coils)

No endorectal coils or magnetic resonance spectroscopy (as per ESUR guidelines for detection)

Dedicated MRI technician present for all MRIs to optimize protocols

Greater than 10 scans per week performed at each center

Mean scan time 30 minutes

All scans double reported via a standardized 18-region reporting tool using PI-RADS criteria, providing a score of 1 to 5 for each MRI parameter and overall (mean), repeated for each discrete lesion; radiologists blinded to each other

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