Prospective Evaluation of the Prostate Imaging Reporting and Data System Version 2 for Prostate Cancer Detection

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Abbreviations and Acronyms

AC = all cancers
CDR = cancer detection rate
CS = clinically significant
csPCa = clinically significant prostate cancer
DCE = dynamic contrast enhanced
DWI = diffusion weighted imaging
FgBx = fusion guided biopsy
FP = false-positive
GL = Gleason
mpMRI = multiparametric magnetic resonance imaging
MRI = magnetic resonance imaging
PCa = prostate cancer
PI-RADS = Prostate Imaging Reporting and Data System
PZ = peripheral zone
Sbx = systematic biopsy
T2W = T2-weighted imaging
Tbx = targeted biopsy
TP = true positive
TRUS = transrectal ultrasound
TZ = transition zone

Purpose: Prostate Imaging Reporting and Data System version 2 (PI-RADSv2) was developed to standardize the interpretation and reporting of multiparametric prostate magnetic resonance imaging and provide guidelines for biopsy of multiparametric magnetic resonance imaging findings. We prospectively evaluated the cancer detection rate at each overall PI-RADSv2 score.

Materials and Methods: This prospective study included 62 consecutive patients with 116 lesions who underwent multiparametric prostate magnetic resonance imaging at 3T with PI-RADSv2 evaluation and subsequent targeted magnetic resonance imaging/transrectal ultrasound fusion guided biopsy and concurrent 12-core systematic prostate biopsy between May and September 2015. Median patient age and prostate specific antigen values were 65.5 years (range 50.3 to 76.6) and 7.10 ng/ml (range 0.47 to 863.0), respectively. Mean lesion size was 12.7 mm overall. Lesion based cancer detection rates for all tumors and for Gleason 3+4 or greater tumors at each PI-RADSv2 score were calculated. Univariate analysis was performed to assess differences in the cancer detection rate among PI-RADSv2 scores.

Results: A total of 116 lesions in 62 patients were evaluated prospectively (0 PI-RADS 1, 18 PI-RADS 2, 19 PI-RADS 3, 47 PI-RADS 4, 32 PI-RADS 5), and the patients underwent magnetic resonance/transrectal ultrasound fusion guided biopsy and systematic biopsy. Histopathology revealed 55 of 116 (47.4%) cancers (17 Gleason 3+3, 16 Gleason 3+4, 6 Gleason 4+3, 12 Gleason 4+4, 3 Gleason 4+5 and 1 Gleason 5+4). Based on targeted biopsy on a per lesion basis, the overall cancer detection rates of PI-RADS 2, 3, 4 and 5 scores for all tumors was 22.2%, 15.8%, 29.8% and 78.1%, respectively. The cancer detection rate of PI-RADS 2, 3, 4 and 5 scores for Gleason 3+4 or greater tumors was 5.6%, 0%, 21.3% and 75%, respectively. Differences in the cancer detection rate between overall PI-RADS 4 and 5 scores were significant ($p < 0.001$ for Gleason greater than 3+3 and Gleason 3+4 or greater cancers).

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Conclusions: A PI-RADS score of 5 had the highest prospective cancer detection rate (78%). A PI-RADS score of 4 had only a 30% cancer detection rate, which is lower than expected. Surprisingly, no or few significant cancers were detected at a PI-RADS score of 3 (16%). These early prospective data suggest that current criteria result in a high false-positive rate that lowers the cancer detection rate. Therefore, stricter criteria may be needed in the future to decrease false-positives and increase the cancer detection rate for PI-RADS scores of 3, 4 and 5.

Key Words: prostate, magnetic resonance imaging, diffusion magnetic resonance imaging

PROSTATE cancer is the second leading cause of cancer death among American men. It is estimated that 26,120 men will die of the disease this year in the United States.[1] Traditionally PCa has been diagnosed by increased prostate specific antigen values, abnormal digital rectal examination and 12-core systematic ultrasound guided biopsy. However, this approach often leads to over diagnosis and under diagnosis of PCa.[2–4]

Multiparametric MRI has become an important part of the management of localized PCa. Specifically, mpMRI is commonly used in the detection, localization and staging of PCa.[5] The information obtained from mpMRI is co-registered with real-time TRUS and known as MRI/TRUS fusion guided biopsy, which preferentially detects clinically significant tumors as opposed to random biopsies that tend to detect more indolent cancers.[6]

A limitation of mpMRI has been the lack of a standardized nomenclature and scoring system with which to communicate results among imaging technicians, clinicians and patients. This has made comparisons of studies from different institutions difficult. In 2012 the ESUR (European Society of Urogenital Radiology) developed the Prostate Imaging Reporting and Data System,[7,8] whose purpose was to provide common guidelines in assessing mpMRI of the prostate and assess the clinical significance of a mpMRI visible lesion in a standardized manner.[8] However, several practical problems were encountered with this initial version and the technical advances necessitated a revision.

Thus, in early 2015 PI-RADS version 2 was developed as a collaboration of the American College of Radiology, ESUR and the AdMeTech Foundation. Like the original, PI-RADSv2 was developed to standardize the interpretation and reporting of mpMRI of the prostate and improve risk stratification. In this new version the scoring system was changed from a 15 to a 20-point scale. The new scale assesses the likelihood that csPCa (GL 7 or greater, and/or volume 0.5 cc or greater, and/or extraprostatic extension) exists in each detected lesion based on mpMRI evaluation. Accordingly a PI-RADSv2 score of 1 represents a low likelihood that the detected prostatic lesion contains CS cancer and a PI-RADSv2 score of 5 represents a high likelihood that csPCa is present in the lesion.[7]

The testing of new scoring systems such as PI-RADSv2 is challenging. A common method is to retrospectively identify previously verified lesions and score them with the new system. However, this introduces bias because only lesions specifically identified are available for re-review. This limits the ability to test the new system of scoring in a fair manner. For instance, retrospective evaluations of PI-RADSv2 have shown that the scoring system performs well in identifying PCa.[9,10] However, in both studies the lesions were scored according to PI-RADSv2 only after pre-selection using another scoring system. This dramatically reduces the potential number of false-positives and yields results that might not have been seen if the study had been done in a prospective manner.

To our knowledge the cancer detection rates for each PI-RADS score have not been prospectively evaluated. In this study we prospectively evaluated the PCa detection rates for each overall PI-RADSv2 score in a cohort of patients undergoing MRI/TRUS FgBx for prostate cancer.

MATERIALS AND METHODS

Study Population and Design

This prospective, single institution study was approved by the local institutional review board and is compliant with the Health Insurance Portability and Accountability Act of 1996. Starting in May 2015 PI-RADSv2 was used as the scoring system to evaluate prostate MRI. From May 2015 to early September 2015, 247 consecutive patients underwent mpMRI of the prostate. Inclusion criteria for this study were having mpMRI of the prostate with PI-RADS scoring and subsequent systematic plus targeted MRI/TRUS FgBx. Overall 185 patients were excluded on the basis of prior prostate therapy (51) (radical prostatectomy, transurethral prostate resection, radiation therapy etc), limited or suboptimal MRI (13), no biopsy due to a PI-RADS score of 1 (35) or biopsy pending (86) (fig. 1). The final patient population consisted of 62 patients with a median age of 65.5 years (range 50.3 to 76.6) and a median prostate specific antigen of 7.10 ng/ml (range 0.47 to 863.0).