

Histopathological Correlation of Current Prostate Imaging Reporting and Data System Scores with 3 Tesla Multiparametric Prostate Magnetic Resonance Imaging in Detecting Prostate Cancer

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Abstract

Objective: This study aimed to evaluate the effectiveness of multiparametric prostate magnetic resonance imaging findings by scoring with the current guideline and correlating these scores with histopathology results in patients who underwent 3 T multiparametric prostate magnetic resonance imaging with the suspicion of prostate cancer and then underwent biopsy and/or radical prostatectomy.

Methods: Between January 2017 and January 2020, 399 patients who underwent imaging with the suspicion of prostate cancer and then biopsy due to elevated prostate specific antigen on the 3 T magnetic resonance imaging device were included in the study. Each patient's multiparametric prostate magnetic resonance imaging findings were scored independently by 2 readers using Prostate Imaging Reporting and Data System v2.1. We used appropriate statistical methods to examine the correlation between Prostate Imaging Reporting and Data System v2.1 scores and Gleason scores for 399 patients.

Results: The study included 399 patients ranging in age from 24 to 89 years; mean prostate specific antigen level was 17.2 ng/mL; mean prostate gland volume was 77.2 mL; and mean prostate specific antigen density was 0.35. Spearman correlation analysis revealed a positive correlation between the increase in Prostate Imaging Reporting and Data System v2.1 scores and the pathology Gleason scores.

Conclusion: In Prostate Imaging Reporting and Data System 1 or 2 lesions, biopsy should be avoided because the risk of clinically significant cancer is low. In Prostate Imaging Reporting and Data System 3 scores, the presence of clinically significant cancer is uncertain and biopsy is required because of suspicion of prostate cancer. Lesions classified as Prostate Imaging Reporting and Data System 4 or 5 have a high sensitivity, specificity, and negative predictive value for clinically significant cancer diagnosis. Histopathological examinations of these lesions should be performed.

Keywords: MpMRI, Prostate cancer, PIRADS

INTRODUCTION

Prostate cancer is the most prevalent type of cancer in Europe's elderly male population and the second leading cause of death, after lung cancer.¹ Prostate cancer is a serious health problem in countries with a large elderly population. Around 1 in every 6 men will be diagnosed with prostate cancer at some point in their lives, and approximately 1 in every 36 men will die of prostate cancer.² The Gleason score and clinical stage at the time of diagnosis are the most important predictors of prognosis in prostate cancer. When prostate cancer is contained within the prostate gland at the time of diagnosis, there is a chance of cure; however, as the disease progresses, the cost of treatment increases. Additionally, it results in a high rate of mortality and morbidity.

Prostate cancer diagnosis is based on a combination of digital rectal examination, prostate specific antigen (PSA), and multiple prostate biopsy guided by transrectal ultrasonography (TRUS).³ The PSA test is not a specific test and may be above normal limits for reasons such as prostatitis, prostate biopsy, globe vesicle, ejaculation, and prostate massage, apart from prostate cancer. Additionally, a PSA level within normal range does not rule out prostate cancer. Transrectal ultrasonography-guided biopsy is not a targeted procedure and is associated with a high rate of false-negative results.⁴ The current situation has prompted researchers to look for noninvasive methods that will reduce the number of biopsy procedures, which are invasive, assist in performing targeted biopsies, and even enable the diagnosis of prostate cancer without biopsy.

Magnetic resonance imaging (MRI) has been used in this regard since the 1980s, especially in the last 10 years. The European Society of Urogenital Radiology published the "Prostate Imaging Reporting and Data System" (PIRADS) for the first time in 2012 to standardize image interpretation and reporting. Prostate Imaging Reporting and Data System version 2.1 (PIRADS v2.1) was published in 2019 as a result of research conducted in 2019.

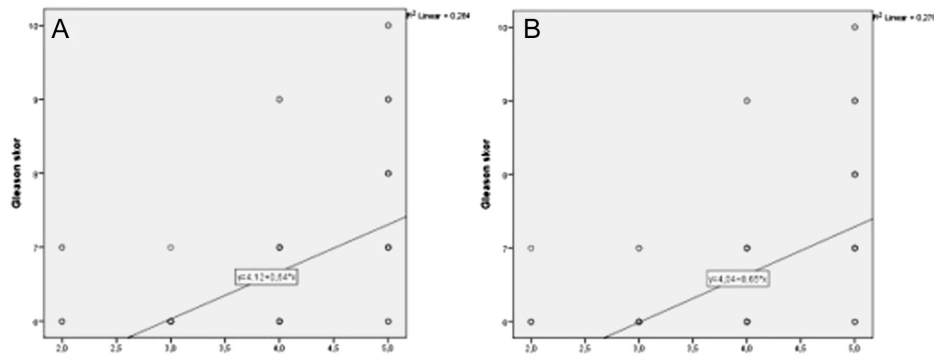


Figure 1. Correlation of PIRADS v2.1 score and Gleason score according to Readers 1 (A) and 2 (B).

The purpose of this study is to determine the correlation between PIRADS scores obtained in accordance with PIRADS v2.1 recommendations and the pathology results of prostate biopsy samples taken from patients with suspected prostate cancer who underwent MpMRI.

METHODS

The Institutional Review Board approved this retrospective study (Protocol number: atauni-kaek-19-568, Atatürk University Faculty of Medicine, January 22, 2019). Because of the retrospective nature, informed consent was waived.

Between January 2017 and January 2020, patients who underwent 3T MRI imaging for prostate cancer screening due to an elevated PSA level at the Radiology Department of Atatürk University Medical Faculty Hospital were included in our study. A total of 532 patients who provided informed consent and underwent MR imaging were examined in our prospective study; 27 patients were excluded from the study due to a prior prostate cancer diagnosis, and 106 patients due to a lack of histopathological correlation. When the remaining imaging findings are analyzed, 399 patients underwent conventional 12-quadrant biopsy and/or radical prostatectomy. The relationship between the Gleason score derived from these patients' pathology results and the PIRADS score was investigated.

All prostate images in our study were acquired using a pelvic coil and axial-coronal-sagittal T2 weighted imaging (WI), axial diffusion weighted imaging (DWI), axial dynamic contrast examination, and pelvic postcontrast T1 WI to evaluate pelvic lymph nodes.

MAIN POINTS

- The clinical behavior of prostate cancer can range from low-grade silent tumors that do not progress to invasive, aggressive fatal disease that progresses rapidly and becomes metastatic.
- Distinguishing the silent and aggressive forms of prostate cancer is very important in terms of treatment chances and management. Prostate specific antigen (PSA) and transrectal ultrasonography (TRUS)-guided biopsy is still the most widely used method for diagnosis. The PSA test is not a specific test. A TRUS-guided conventional biopsy is not a targeted examination and may miss the diagnosis of clinically significant cancer in a significant number of patients.
- Multiparametric prostate magnetic resonance imaging stands out as an imaging method that reduces overdiagnosis/overtreatment rates and can diagnose more clinically important cancers.

The prostate MR images were evaluated by a radiology assistant in her fourth year of education and a specialist radiologist with abdominal imaging experience, and the readers' compatibility was determined. Each patient was scored according to the PIRADS v2.1 guidelines. Following that, using an appropriate statistical method, the correlation between the double-blind PIRADS v2.1 scores and the Gleason scores obtained from the pathology was examined.

Statistical Analysis

Standard deviation values were used to calculate patient ages, PSA values, and prostate volume mean. Cohen's kappa analysis was used to assess inter-investigator consistency in PIRADS scoring following MpMRI examination. The statistical analysis was performed using the Statistical Package for the Social Sciences 23.0 program (IBM SPSS Inc., Chicago, Ill, USA).

RESULTS

The study included 399 patients aged 24-89 (63.1 ± 9.3); the mean PSA value was 17.2 ± 86.8 ng/mL; the mean prostate gland volume was 77.2 ± 45.1 mL; and the mean PSA density was 0.35 ± 2.3 .

The Kappa value among readers was 0.826 for the PIRADS v2.1 scores of 399 patients who underwent histopathological examination. There was statistical significance ($P = .01$) and significant agreement.

Spearman correlation analysis revealed a positive correlation between the increase in PIRADS v2.1 scores and the pathology Gleason scores. According to the first and second readers, the correlation value is 0.585 ($P = .01$) and 0.579 ($P = .01$), respectively (Figure 1).

Sixty-four (59.2%) of malignant lesions are located in the peripheral zone, 28 (26%) in the transitional zone, and 16 (14.8%) in both.

None of the ten PIRADS 1 lesions described by Reader 1 had a pathology result of CSC. Clinically significant cancer was detected in 2 patients as a result of the pathology of 149 PIRADS 2 lesions. As a result of the pathology of 144 PIRADS 3 lesions, CSC was reported in 1 patient. Clinically significant cancer was detected in 14 patients as a result of the pathology of 67 PIRADS 4 lesions. Clinically significant cancer was detected in 25 patients as a result of the pathology of 29 PIRADS 5 lesions (Table 1).

No CSC were identified in the pathology report of Reader 2's 6 PIRADS 1 lesions. One CSC was reported as a result of pathology in 149 PIRADS 2 lesions, 2 CSCs were reported as a result of pathology

Table 1. Pathology Result Corresponding to PIRADS Scores and PIRADS Scores Described by Reader 1

Reader 1	PIRADS 1	PIRADS 2	PIRADS 3	PIRADS 4	PIRADS 5	Total
Other	10	147	143	53	4	357
CSC	0	2	1	14	25	42
Total	10	149	144	67	29	399

CSC, clinically significant cancer; PIRADS, Prostate Imaging Reporting and Data System.

Table 2. Pathology Result Corresponding to PIRADS Scores and PIRADS Scores Described by Reader 2

Reader 2	PIRADS 1	PIRADS 2	PIRADS 3	PIRADS 4	PIRADS 5	Total
Other	6	148	145	54	4	357
CSC	0	1	2	14	25	42
Total	6	149	147	68	29	399

CSC, Clinically significant cancer; PIRADS, Prostate Imaging Reporting and Data System.

in 147 PIRADS 3 lesions, 14 CSCs were reported as a result of pathology in 68 PIRADS 4 lesions, and 25 CSCs were reported as a result of pathology in 29 PIRADS 5 lesions (Table 2).

When those with Gleason 7 and higher scores according to the pathology result are grouped and evaluated as high-risk (PIRADS 4 and 5) and non-high-risk (PIRADS 1, 2 and 3) according to the PIRADS v2.1 score, the positive predictive value in the analysis of Reader 1 is 0.40, negative predictive value was 0.99, sensitivity 0.92, and specificity 0.84 (Table 3).

When those with Gleason 7 and above according to the pathology result were grouped and evaluated as high-risk and non-high-risk according to the PIRADS v2.1 scores, the positive predictive value was 0.40, the negative predictive value was 0.99, the sensitivity was 0.92, and the specificity was 0.83 in the analysis of Reader 2 (Table 4).

DISCUSSION

Prostate cancer is the most frequently diagnosed type of cancer in men.⁵ Digital rectal examination, serum PSA, and conventional

Table 3. Analysis of CSC and Other Lesions as a Result of Pathology According to Reader 1 for High-Risk or Non-High-Risk Lesions According to PIRADS v2.1

Reader 1	Not High Risk (PIRADS 1, 2, and 3)	High Risk (PIRADS 4 and 5)	Total
Others	300	57	357
CSC	3	39	42
Total	303	96	399

CSC, clinically significant cancer; PIRADS, Prostate Imaging Reporting and Data System.

Table 4. Analysis of CSC and Other Lesions as a Result of Pathology According to Reader 2 for High-Risk or Non-High-Risk Lesions According to PIRADS v2.1

Reader 2	Not High Risk (PIRADS 1, 2, and 3)	High Risk (PIRADS 4 and 5)	Total
Others	299	58	357
CSC	3	39	42
Total	302	97	399

CSC, Clinically significant cancer; PIRADS, Prostate Imaging Reporting and Data System.

12-quadrant TRUS-guided biopsy are all used to diagnose prostate cancer.⁶ Although the PSA test is not specific for prostate cancer, its normal range does not exclude it.⁷ While TRUS-guided biopsy is standardized, it is not a targeted examination and thus may result in overdiagnosis/overtreatment and miss the diagnosis of CSC in a significant proportion of patients.⁸ Prognosis prediction for prostate cancer is critical for individualizing treatment and determining the applicability of more effective treatment methods. After radical prostatectomy, the histopathological features of the disease provide critical information for predicting the disease's prognosis. Correlations between the PIRADS scoring system and final histopathology may also provide prognostic information. Thus, MpmRI data can also be used as a prognostic factor and can actually be used to modify patient treatment with appropriate risk stratification.⁹

In a study by Chen et al.¹⁰ the agreement of PIRADS v2 scores between readers ($\kappa=0.74$) was found to be moderate. Similarly, there are additional studies in the literature that demonstrate moderate reader agreement.¹¹⁻¹³ Apart from these, when all lesions were considered in the study by Greer et al.¹⁴ inter-reader agreement ($\kappa=0.37$) was found to be weak. This situation may vary according to the readers' knowledge and experience. The Kappa value for PIRADS v2.1 scores among readers was 0.826 in our study. There was statistical significance ($P=.01$) and significant agreement.

In the study published by Daun et al.¹⁵ the area under the Receiver Operating Characteristic (ROC) curve between PIRADS v2 score and Gleason scores was found to be 0.79. In our study, similar to this study, the area under the ROC curve was found to be 0.81 (good) and 0.80 (good) according to the first and second reader, respectively.

According to current guidelines, PIRADS 1 and PIRADS 2 lesions have a very low/low risk of CSC. Clinically significant cancers were not detected in any of the 3 patients with a PIRADS 1 score and 33 patients with a PIRADS 2 score in a study of 137 patients with a PIRADS v2 score and histopathological result published in 2019 by Daun et al.¹⁵ According to Park et al's study, CSC could not be detected in approximately one-third of patients using MpmRI prior to biopsy, and approximately 60% of missed cancers had a PIRADS score of 1 or 2. In this study, when the retrospective MpmRI was re-evaluated, it was stated that 63.6% of the lesions were normal or could not be reliably distinguished from other structures, but 71.4% of these tumors were CSC. Additionally, this study stated that missed CSCs were smaller in size than other lesions detected, and the pathology outcome was cancers of lower grade.¹⁶ Along with inconsistent findings in the literature, Reader 1 identified 10 PIRADS 1 and 144 PIRADS 2 lesions in our study. While PIRADS 1 lesions were benign, 2 PIRADS 2 lesions were reported to be CSC. On the other hand, Reader 2 described 6 PIRADS 1 lesions and 144 PIRADS 2 lesions. While all PIRADS 1 lesions were found to be benign, 1 PIRADS 2 lesion was found to be CSC. Additionally, when MpmRI images were evaluated retrospectively in patients who were classified as PIRADS 1 and 2 by the readers and had a pathology result of CSC, no focus suggestive of prostate cancer could be detected in the prostate gland. The positive predictive value of Readers 1 and 2 was determined to be 0.16-0.16 for the diagnosis of PIRADS 1 and 2 lesions and CSC, respectively. The negative predictive value was determined to range between 0.98 and 0.99. Additionally, the sensitivity ranged between 0.95 and 0.97 and the specificity ranged between 0.43 and 0.43. Inter-reader agreement for lesion identification is significant ($\kappa=0.82$ and $P=.01$). The pathology result reported as CSC for lesions described by readers as PIRADS 1 and 2 indicates

lesions outside the PIRADS v2.1 criteria or outside MpMRI detection limits. Furthermore, because the PIRADS score 1 and 2 lesions included in this study were those with pathology following biopsy, and there were PIRADS 1 and 2 lesions excluded from the study due to a lack of pathology results, it should be considered that there will be a relative increase in those reported as CSC with pathology results.

According to the current guideline, PIRADS 3 lesions are those with an uncertain presence of CSC, making clinical management difficult. The probability of malignancy of PIRADS 3 lesions in the literature has been described between 6.5% and 34% in the published PRECISION study.¹⁷ Schlenker et al published a study in 2019 in which they performed targeted prostate MR-TRUS fusion biopsy on 41 PIRADS 3 lesions using the PIRADS v2 scoring system and found that 6 of them were CSC.¹⁷ In a 2017 study published by Osses et al.¹⁸ only 1 of 29 PIRADS 3 lesions was diagnosed as CSC. In our study, Reader 1 described 144 PIRADS 3 lesions. Of these, only 2 (1.3%) came from CSC. Reader 2 described 147 PIRADS 3 lesions. Of these, only 2 (1.3%) were reported as CSC. According to Readers 1 and 2, the percentage of patients defined as PIRADS 3 and reported as CSC with pathology results is relatively low compared to the literature, but the probability of these lesions being CSC was found to be higher than PIRADS 1 and 2 lesions and lower than PIRADS 4 and 5 lesions.

PIRADS 4-5 lesions are lesions with high/very high CSC presence according to current guidelines. In a 2017 study published by Osses et al. 38 (45%) of 84 PIRADS 4 lesions had a pathology result of CSC. In the same study, 24 (66%) of 36 PIRADS 5 lesions had a pathology result of CSC.¹⁸ The rates of CSC for PIRADS 4 and 5 lesions were found to be 43%-67% in a multicenter study published in 2020 by Kızılay et al.⁹ Apart from these, CSC rates ranged from 34% to 45% for PIRADS 4 lesions and 67% to 84% for PIRADS 5 lesions in 3 separate studies.¹⁸⁻²⁰ According to eader 1, in our study, 14 (20.9%) of 67 PIRADS 4 lesions had a pathology result of CSC. According to Reader 2, 14 (20.6%) of 68 PIRADS 4 lesions had a pathology result of CSC. According to Readers 1 and 2, 25 (86.2%) of 29 PIRADS 5 lesions were diagnosed as CSC, which is consistent with the literature. The positive predictive value was 0.41, the negative predictive value was 0.98, the sensitivity was 0.72, and the specificity was 0.93 in a study conducted by Mathur et al²¹ in 2019 using the PIRADS v2 score system. The positive predictive value of Readers 1 and 2 was found to be 0.40-0.40 in our study for the diagnosis of PIRADS 4 and 5 lesions and CSC, respectively. The negative predictive value was determined to range between 0.99 and 0.99. Sensitivity and specificity were 0.92-0.92 and 0.84-0.83, respectively. Although the data are similar to the literature, PIRADS 4-5 lesions are likely to be CSC.

There are few studies in the literature examining the correlation between PIRADS and Gleason scores, and the results are inconsistent.^{22,23} There is a need for further research into the prognostic value of MpMRI by examining the correlation between current PIRADS scores and histopathological factors. As a result, it is critical to diagnose clinically significant lesions, to assess the disease stage at the time of diagnosis and to assess the risk of progression during disease management.

The primary limitation of our study is that we obtained biopsies using the conventional method and did not compare the lesion in one-to-one MRI to the result of targeted biopsy and/or radical prostatectomy. Additionally, by increasing the readership, the diagnostic values of PIRADS v2.1 scores can be investigated in greater detail based on reader experiences.

Although MpMRI is the most sensitive and specific noninvasive procedure for early detection, localization, grading, and staging of prostate cancer,²⁴ the contribution of MpMRI to clinical practice is still unclear⁹ and deserves further evaluation.

CONCLUSION

Multiparametric prostate magnetic resonance imaging does not yet have a high enough positive predictive value to be used in place of systemic biopsy alone. According to the current PIRADS guidelines, there are insufficient studies in the literature.

The radiology component of prostate cancer diagnosis consists of imaging quality, a PIRADS guide, and an experienced radiologist. It is obvious that the problem arising from any of these 3 is reflected in the quality of the report.

Currently, there is a need for imaging and diagnostic methods that decrease prostate cancer overdiagnosis/overtreatment rates and can detect more CSCs. Multiparametric prostate magnetic resonance imaging may fill a portion of this unmet need.

Ethics Committee Approval: Ethical committee approval was received from Atatürk University Faculty of Medicine Institutional Review Board (Date: January 22, 2019, Decision No: atauni-kaek-19-568).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – G.T., D.C.Ş.; Design – D.C.Ş.; Supervision – G.T.; Materials – G.T., D.C.Ş.; Data collection – G.T.; Analysis – G.T.; Literature Review – G.T.; Writing – G.T., D.C.Ş.; Critical Review – D.C.Ş.

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