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ORIGINAL ARTICLE

Diagnostic accuracy of serum prostate specific antigen and prostate imaging reporting and data system score with gold standard histopathology: a prospective study

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ABSTRACT

Background: Prostate cancer is a considerable health problem. Although serum PSA is a commonly used biomarker, its limitations dictate the need to have more specific diagnostic methods. Multi-parametric MRI, which is interpreted by the use of the PIRADS, has proved to be an attractive modality. Our objective is to compare and contrast the diagnostic validity of PSA and PIRADS scoring for identification of prostate cancer.

Methods: A prospective cross-sectional study was carried out on 300 male individuals who were at the risk of having prostate cancer clinically. Each study subject was subjected to PSA testing and multi-parametric MRI. Patients having a high PSA (≥4 ng/mL) and/or a PIRADS score of 3 or higher underwent transrectal ultrasound-directed biopsy using the histopathology as the gold standard. The parameters of diagnostic accuracy (sensitivity, specificity, PPV, NPV, accuracy) were computed.

Results: The incidence of prostate cancer was 38.7%. Serum PSA had better diagnostic sensitivity of 91.4, specificity of 82.1 and overall accuracy of 85.7 percent respectively. It had a very high negative predictive value (NPV) of 93.8. Conversely, PIRADS scoring (≥3) depicted a moderate sensitivity of 67.2 and specificity of 82.1 and the accuracy was 76.3. Analysis of stratification showed a high level of performance of PSA in all age groups and ethnicities, whereas PIRADS showed mixed sensitivity, especially lower in some ethnic groups.

Conclusion: The results of our study support that due to its exceptional negative predictive value, serum PSA was found to be a sensitive and reliable preliminary test that can exclude the presence of prostate cancer. PIRADS MRI, and scoring system though specific, fail to detect clinically significant cancers. MRI may be used to provide specific biopsy guidance to PSA-positive patients.

Keywords: Diagnostic Accuracy, Prostate Cancer, Prostate Specific Antigen, Multiparametric MRI

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Introduction

Prostate cancer is a health issue that is very significant in the world, especially in the male population. In 2020, it was estimated

that about 1.4 million men across the world were diagnosed with the disease (1). It is highly age-related and post-mortem analysis indicates that 5% of men below 30 years show signs of prostate cancer but this increases drastically to 59 percent in men above 79 years (2). This is a contributing trend to the total cancer burden in the world, which experienced 19.3 million new cases and 10.3 million deaths in 2020. By the year 2040, it is estimated that the annual cancer incidence will increase by 47 percent, which highlights the increasing predicament (3). The prostate cancer is a big problem in the fifth most populated country in the world which is Pakistan. The prevalence rates are presented with differences in the reported prevalence with studies reporting 2.21% (3) and 1.53% (4).

The conventional diagnostic tools are Digital Rectal Examination (DRE), Prostate-Specific Antigen (PSA) blood testing, and Transrectal ultrasound (TRUS)-guided biopsy. PSA is an extremely important serum biomarker and a 2.5 ng/ml or above level makes the patient suspicious of cancer (5). Its application is linked to lower mortality rates specific to cancer. The traditional methods are however limited. TRUS based biopsy although widespread, is invasive, and expensive with the risks of bleeding and sepsis. Moreover, it is not very sensitive to identify low-echoic lesions (17-57%), which results in a substantial proportion of false diagnoses (6,7). Its major limitation is the overdiagnosis of benign tumors exposing the patients to avoidable interventions such as radical prostatectomy which leads to worsening of their lives without enhancing survival (8).

To curb these issues, the European Society of Urogenital Radiology (ESUR) came up with the Prostate Imaging Reporting and Data System (PIRADS) to unify the reporting of Multi-parametric MRI (mpMRI) results. This system measures the likelihood of clinically significant prostate cancer by making use of a scale in the range of 5 (9, 10). Its high diagnostic accuracy has been confirmed by recent studies. A 2017 study established that mpMRI with PIRADS provided a sensitivity of 93% identifying significant cancer, which was large compared to systematic biopsy (sensitivity 48%) (11). It was later confirmed in a subsequent meta-analysis that it has an excellent sensitivity of 95% (12).

The future of prostate cancer diagnostics is the integration of anatomical imaging and the anatomical data with the biomarkers. The data indicate that the use of the PSA density (PSAD) and PIRADS score in conjunction is much more effective in predicting the aggressiveness of the cancer and personalized unnecessary biopsies (13, 14). This combination strategy improves the identification of disease with clinical significance as well as reducing chances of over-diagnosis and overtreatment. Furthermore, rare studies have been conducted in Pakistan regarding the comparative accuracy of PSA and mpMRI PIRADS, so this study would add more evidence on this subject.

Methods

The study was a prospective cross-sectional study that took place at the Dow institute of radiology between the year February 2025 and July 2025 after ethical approval from the institutional review boards of via letter no.IRB3487/DUHA/approval/2024/189.The study population was composed of male adults over 40 years who were referred to evaluate prostate cancer and had a clinical suspicion which was defined by symptoms (e.g., difficulty in urinating, hematuria, night urination), an abnormal digital rectal examination (DRE), a family history of

prostate cancer, or high PSA. A non-probability consecutive sampling method was used to recruit the participants until the sample size was attained. The sample size was calculated using the WHO sample size calculator for diagnostic test evaluation. With an expected sensitivity of 93% (12), specificity of 41% (12), a disease prevalence of 2.2% (12) and a precision (d) of 7%, the initial calculated sample size was 2,353. However, due to the low patient turnover and practical constraints, a final sample size of 300 participants was deemed feasible for this study. Males >40 years referred for screening or biopsy, with suspicious DRE findings, or undergoing mpMRI, and willing to provide informed consent were included in this study. Patients with history of prostate cancer or surgery, active cancer treatment, concurrent UTI or prostatitis, contraindications to MRI or biopsy, inability to consent, significant comorbidities, or incomplete data were excluded. Suspected Prostate Cancer was defined by clinical symptoms (e.g., obstructive urinary symptoms, hematuria), an abnormal DRE (palpable nodule, induration), or a family history in a first-degree relative. A serum level of ≥4 ng/mL was considered elevated and positive for this study. (15) For PIRADS Scoring, lesions on multiparametric MRI (mpMRI) were assigned a score from 1 to 5 by expert radiologists. A score of ≥3 was considered positive for the presence of clinically significant cancer. (16) TRUS-guided biopsy specimens were analyzed by expert pathologists. The existence of adenocarcinoma, which had been scored on the Gleason Score system, was used as the gold standard of assuring the presence of prostate cancer. Following the informed consent, all eligible subjects were subjected to a standardized blood collection and a mpMRI of the prostate. The MRI was interpreted by the radiologists who were blinded to the PSA results and who gave a score on the PIRADS. The subjects whose PSA (4 ng/mL) was higher and/or had a suspicious PIRADS score (3) were further subjected to a TRUS-guided prostate biopsy. The biopsy samples were analyzed by pathologists who were blinded to the PSA and MRI results to establish a histopathological diagnosis. Data were analyzed using SPSS version 25.0. Categorical variables were presented as frequencies and percentages, while continuous variables were expressed as mean ± standard deviation. Diagnostic accuracy parameters, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, for both PSA and PIRADS were calculated using 2x2 contingency tables against the histopathology gold standard. Effect modifiers such as age, family history and ethnicity were controlled through stratification, and the same accuracy parameters were calculated for each subgroup.

Results

We enrolled 300 patients in our study and found that mean age was 65.2±11.9 years. Majority of participants were of Sindhi ethnicity (57.7%). The most common reason for referral was a suspicious digital rectal exam (DRE) (59.3%). Most of the patients had no family history of prostate cancer (82.0%). Serum PSA was elevated in 46.3% of cases, while a positive PIRADS score (≥3) was found in 63.0% of patients. Ultimately, 38.7% of patients had a prostate cancer diagnosis confirmed on histopathology, establishing the disease prevalence in this cohort against which PSA and PIRADS accuracy will be measured (see table 1 for detailed demographic and clinical details).

Table 1: Demographic and clinical details of the study subjects (n=300)

Variable	Categories	Frequency (n)	Percent (%)
Ethnicity	Sindhi	173	57.7
	Punjabi	62	20.7
	Pathan	32	10.7
	Balochi	33	11.0
Reason for Referral	Suspicious DRE	178	59.3
	PSA Elevation	63	21.0
	Other	59	19.7
Symptoms	Difficulty urinating	76	25.3
	Hematuria	43	14.3
	Nocturia	51	17.0
	Weak urine flow	32	10.7
	None	98	32.7
Family History of Prostate Cancer	Yes	54	18.0
	No	246	82.0

PSA testing identified 46.3% of cases as positive, whereas PI-RADS MRI classified 37% as suspicious for malignancy. Histopathology, taken as the gold standard, confirmed prostate cancer in 38.7% of patients (table 2).

Table 2: Overall results of PSA Findings, PIRADS-Findings and histopathology in diagnosis of prostate cancer

Variable	Categories	Frequency (n)	Percent (%)
PSA Findings	Positive	139	46.3
	Negative	161	53.7
PI-RADS Findings	Positive	111	37.0
	Negative	189	63.0
Histopathology (Gold Standard)	Positive	116	38.7
	Negative	184	61.3

PSA was more sensitive (91.4%), effective in the detection of prostate cancer with an overall accuracy (85.7%), but likely to produce false positive results because of the lower specificity. PI-RADS had moderate sensitivity (67.2%), but with the same specificity (82.1%) and a general accuracy of 76.3, with fewer false positives, but a greater likelihood of missing true cases. Thus, PSA is more reliable for initial detection, whereas PI-RADS adds value by improving specificity and reducing overdiagnosis (table 3).

Table 3: Diagnostic accuracy of PSA Findings and PIRADS-Findings in diagnosis of prostate cancer keeping histopathology findings as gold standard

PSA Findings	Prostate Cancer on Histopathology		
	POSITIVE	NEGATIVE	TOTAL
POSITIVE	106 (35.3%) (True Positives)	33 (11.0%) (False Positives)	139 (46.3%)
NEGATIVE	10 (3.3%) (False Negatives)	151 (50.3%) (True Negatives)	161 (53.7%)
Total	116 (38.7%)	184 (61.3%)	300 (100.0%)

Sensitivity	Specificity	Accuracy	PPV	NPV
91.4%	82.1%	85.7%	76.3%	93.8%

PIRADS Findings	Prostate Cancer on Histopathology		
	POSITIVE	NEGATIVE	TOTAL
POSITIVE	78 (26.0%) (True Positives)	33 (11.0%) (False Positives)	111 (37.0%)
NEGATIVE	38 (12.7%) (False Negatives)	151 (50.3%) (True Negatives)	189 (63.0%)
Total	116 (38.7%)	184 (61.3%)	300 (100.0%)

Sensitivity	Specificity	Accuracy	PPV	NPV
67.2%	82.1%	76.3%	70.3%	79.9%

PPV: Positive Predictive Value, NPV: Negative Predictive Value

Stratification analysis reflected that PSA performed better in older patients (>60 years) with very high sensitivity (94.3%) and NPV (96.2%), while PIRADS was more consistent across age groups but less sensitive. PSA maintained high accuracy across groups, especially in Balochi and Punjabi patients (>87%), while PIRADS showed moderate sensitivity, with best results in Punjabi and Sindhi populations. Lastly, both PSA and PIRADS performed better in those with a positive family history, with PSA showing excellent sensitivity (94.1%) and PIRADS achieving the highest combined accuracy (77.8%) in this subgroup. Details are illuminated in table 4.

Table 4: Diagnostic accuracy of PSA Findings and PIRADS-Findings in diagnosis of prostate cancer keeping histopathology findings as gold standard (stratification analysis for various effect modifiers)

Effect Modifier	Test	Sensitivity	Specificity	Accuracy	PPV	NPV
Age Groups						
Age ≤60 yrs	**PSA**	87.0%	77.3%	81.2%	72.7%	89.5%
	PIRADS	76.1%	77.3%	76.8%	70.0%	82.3%
Age >60 yrs	**PSA**	94.3%	84.7%	88.3%	78.6%	96.2%
	PIRADS	61.4%	84.7%	75.5%	70.5%	78.7%
Ethnicity						
Balochi	**PSA**	100.0%	78.9%	87.9%	77.8%	100.0%
	PIRADS	64.3%	78.9%	72.7%	69.2%	75.0%
Pathan	**PSA**	81.8%	85.7%	84.4%	75.0%	90.0%
	PIRADS	36.4%	85.7%	68.8%	57.1%	72.0%
Punjabi	**PSA**	92.6%	85.7%	88.7%	83.3%	93.8%
	PIRADS	66.7%	85.7%	77.4%	78.3%	76.9%
Sindhi	**PSA**	90.6%	80.7%	85.0%	73.4%	93.6%
	PIRADS	73.4%	80.7%	77.5%	69.1%	83.8%
Family History of Prostate Cancer						
No Family History of Prostate CA	**PSA**	90.9%	81.0%	85.4%	76.3%	93.0%
	PIRADS	66.7%	81.0%	75.0%	70.2%	78.3%
Family History of Prostate CA	**PSA**	94.1%	86.5%	88.9%	76.2%	97.0%
	PIRADS	70.6%	86.5%	77.8%	70.6%	86.5%

PPV: Positive Predictive Value, NPV: Negative Predictive Value

Discussion

The proposed study critically analyzed the diagnostic performance of Prostate-Specific Antigen (PSA) and the Prostate Imaging Reporting and Data System (PIRADS) in a given cohort of patients and present critical understanding of the roles these diagnostic systems play in the diagnostic pathway of prostate cancer. In our study the NPV of PSA (93.8percent) is high and confirms the high level of usefulness of PSA in ruling out disease and, possibly, avoiding needless invasive procedures in a substantial group of patients. Our results are an interesting variation when put in the context of the literature available. This high sensitivity and specificity of PSA with our cohort, compared with the well-reported limitations of PSA screening in the Western population (specificity is much lower in Western populations, because of high prevalence of benign situations including prostatitis and benign prostatic hyperplasia (BPH) (17). The high disease prevalence in our cohort (38.7) or demographic diversity could be the reason behind the difference. However, our findings on the performance of PIRADS align more closely with its recognized pitfalls. The sensitivity of 67.2% and Positive Predictive Value (PPV) of 70.3% in our study are lower than those reported in many international studies. For instance, the landmark PROMIS trial by Ahmed et al. reported a sensitivity of 93% for mp-MRI in detecting clinically significant cancer (11). This significant difference could be influenced by our use of systematic TRUS-biopsy as the reference standard, which is known to miss a substantial number of clinically significant cancers (up to 15-45%) that a more robust reference like template mapping might have identified (11,19). Many of our false negative PIRADS cases may have harbored such missed tumors. The comparative low

sensitivity of mpMRI with respect to identifying clinically significant prostate cancer can be attributed to small size lesions, diffuse infiltration, discrete nodules, or arise in the transition zone where it is lost in benign prostatic hyperplasia, leading to insignificant restricted diffusion or early enhancement. Tumors that contain limited components of Gleason pattern 4 could also be a reason for this limitation.

The performance of PIRADS in our study finds a closer parallel in the work by Obino et al., who also reported a high sensitivity of 92.2% but a low specificity of 47.8% in an East African population (20). Although our research indicated more specificity to PIRADS (82.1%), both studies point to a major issue, which is the high rate of false-positive with MRI. Obino et al. explained this by the BPH nodules and prostatitis simulating cancer on the imaging, (20) a fact that is also echoed by our results, and is a known limitation of mp-MRI. The fact that this pattern is observed in various populations also indicates the urgency not to use PIRADS as a positive diagnosis, but as a marker to focus biopsy. Our study has stratification analysis to add further to this discussion. The better results of both tests in patients, when aged more than 60 years agree with those found by Obino et al, and can be attributed to the larger probability of pre-test disease in older age groups (20). The difference in test accuracy between ethnic subgroups of our Pakistani cohort is critical finding and it should be explored further. It proposes that the biology of disease and imaging features may be impacted by genetic, anatomical, or environmental factors, which supports the assumption made by Obino et al. that the population-specific diagnostic accuracy data is necessary and the values available in another area cannot be directly extrapolated (20). Conclusively, it is our study that in our clinical situation, serum PSA is one of the most significant first tests because of its superior sensitivity and excellent NPV in the elimination of disease. Specific but showing an alarming lack of sensitivity with TRUS-biopsy as a reference, the PIRADS score proved to be concerning. This does not undermine the usefulness of mp-MRI but explains its utility. A sequential diagnostic approach with the use of PSA to provide risk stratification followed by the use of mp-MRI to visual localization of suspicious features in patients with increased values of PSA may seem to be the most appropriate diagnostic route and is supported by our data and literature, in general (11,20,22). This method applies both the high NPV of PSA and the guiding capacity of PIRADS to make sure that later biopsies are focused, and consequently, more clinically significant cancerous findings are made and less indolent disease is over-diagnosed. These findings are enriched by the stratification analysis. The higher sensitivity of the two tests in patients aged more than 60 years is consistent with the higher prevalence or incidence of the disease among this group of patients, a fact already proven in epidemiology. The inter-ethnic difference in tests performance, especially the low sensitivity of PIRADS in Pathan subgroup is a curious observation that should be followed-up by researches on the possible genetic, anatomical, or access-to-care differences. The fact that PSA has been able to remain as highly accurate in all these subpopulations supports its credibility as a universal initial biomarker. Such findings reinforce the suggested diagnostic algorithm according to which PSA is the key screening instrument to use in the first line because of its high sensitivity and excellent rule-out

capability. After a PSA elevation, multi-parametric MRI and PIRADS scoring then have their desired part as a form of a triage test to enhance diagnostic specificity as they help direct targeted biopsies and minimize unnecessary procedures that PSA false positives will cause. This progressive method uses the benefits of each test and reduces the shortcomings of each test.

The current study showed discordance between mpMRI (PI-RADS) and histopathology in a sub-set of cases. False-negative MRI were mostly in small-sized or diffusively infiltrative significant tumors or those in the transition-zone which are obscured by BPH. On the other hand, the false-positive outcome was largely explained by inflammatory conditions (prostatitis), stromal BPH nodules, post-biopsy hemorrhage, and overcalling of equivocal PI-RADS 3 foci, which in its nature has low PPV for clinically significant cancer. These discrepancies were further caused by technical factors, the experience of the reader, and sampling errors that may occur as a result of fusion biopsy, which should be regarded as an excellent but imperfect screening tool requiring to be interpreted in combination with clinical parameters and systematic biopsy whenever it is necessary.

Limitations

This research has a number of limitations that should be noted. To begin with, the single-center design can restrict the possibility of generalizing the results to other populations with varying ethnic composition or clinical practices. Second, the study population was a group of referred patients with clinical suspicion of prostate cancer (e.g., suspicious DRE), which induces a high-prevalence environment and overinflates the PPV when compared to a general screening population. Third, a central, blinded review might not be done on PIRADS scoring which might lead to inter-observer variability which is a well-known problem with this scoring system. Fourth, the standard cutoff was employed without age and prostate volume adjustment to the PSA levels and could have affected its specificity. Importantly, the authors calculated a required sample size of 2353, but conducted the study on 300 due to time constraint and resource limitations. Lastly, spectrum bias might exist in any study on diagnostic accuracy since it only included patients who had gone through biopsy, thus may have left out men with very low or very high PSA that had not gone through histopathological confirmation.

Conclusion

The results of our study support that in the given clinical context, the PIRADS scoring system was found to lack sensitivity, which was verified against systematic biopsy, meaning that it may fail to detect clinically significant cancers. Conversely, serum PSA has remained to play a significant and important role as a strong screening tool. This is well supported by the fact that a streamlined pathway will be followed, as PSA would be used in the pre-identification of patients at risk by the use of high reliability in various groups of people and then followed by multi-parametric MRI which would be used to visualize lesions that might be suspected of malignancy and to map guide biopsies. The combination of the respective advantages of each test, better rule-out of PSA and MRI guidance to accurately guide exactly where the intervention is necessary, effectively utilizes the capabilities of these two tests to improve the ability to diagnose clinically significant prostate cancer as well as reduce the risks of

over-diagnosis and unnecessary invasive therapy.

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