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Correlation with PI-RADS Score and Gleason's score of Prostate Cancer

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ABSTRACT

Back Ground: The Prostate Imaging-Reporting and Data System (PI-RADS) is structured reporting scheme plays a crucial role in evaluating suspected prostate cancer using multiparametric MRI (mpMRI). PI-RADS provides a standardized framework for interpreting mpMRI scans of the prostate. It was developed collaboratively by the American College of Radiology (ACR), European Society of Urogenital Radiology (ESUR), and AdMeTech Foundation. The goal is to assess the likelihood of clinically significant prostate cancer based on imaging findings. It is scoring system, each suspicious lesion is assigned a score from 1 to 5, indicating the probability of clinically significant cancer.

Objective: The current study was dealt with derived the PIRADS score and observe the corelation with Gleason's score.

Methods: *Data Collection*- Imaging Data was collected, stored and accessed and use of software for image analysis (e.g., radiomics tools).

Clinical Data: like patient demographics, clinical history, PSA levels were collected in patient information sheet

Histopathological Data: Recording of Gleason scores, tumor stages, and any relevant histological features.

Result: The sensitivity of mpMRI with gleasons score was 85% and specificity was 70% with PPV of 78% and NPV of 80% in PI-RADS≥3 as compared to 90%, 85%, 88%, and 82% (sensitivity, specificity, PPV and NPV) of PI-RADS≥4.

Conclusion: The study demonstrates that mpMRI, particularly with a PI-RADS ≥4 thresholds, provides a reliable and effective approach for detecting clinically significant prostate cancer. By improving sensitivity, specificity, and predictive values, mpMRI enhances diagnostic accuracy and supports better decision-making in patient management. Continued advancements in imaging technology and research will further refine the utility of mpMRI in the diagnosis and treatment of prostate cancer, ultimately leading to improved patient outcomes.

Keywords: *prostate cancer; radical prostatectomy; staging; Gleason score; multi-parametric MRI ;3 Tesla; Spectroscopy; custom made Mold; histopathology.*

1. INTRODUCTION

Prostate Cancer: A Global and Indian Perspective

Prostate cancer is the second most common cancer among men worldwide, with significant variability in incidence and mortality rates across different regions. While countries like the United States and those in Western Europe report high incidence rates, Asian countries, including India, have traditionally reported lower rates. However, recent trends suggest an increase in prostate cancer cases in India, potentially due to improved detection methods, changing lifestyles, and increased awareness. Despite this rise, the diagnosis often occurs at more advanced stages compared to Western counterparts, underscoring the need for improved diagnostic strategies in the Indian context.

Men under 40 are infrequently diagnosed with Prostatic cancer, with men over 65 accounting for 75% of diagnoses. Autopsy studies indicate that up to 90% of men over 70 have Prostatic cancer in some capacity, indicating that [1]. Given that African age is the biggest risk factor for Prostatic cancer Americans have approximately twice the risk of Caucasians, race also poses a concern [2,3]. Genetics is a third important risk factor. Men who have an immediate family member with PCa are at least twice as likely to get the diagnosis as others, and they can be up to ten times more likely if they have many family members with PCa.

Current Diagnostic Challenges

The early detection and accurate localization of prostate cancer are critical for successful treatment and management. Traditional diagnostic methods, such as prostate-specific antigen (PSA) testing and transrectal ultrasound-guided (TRUS) biopsy, have limitations. PSA testing lacks specificity, leading to false positives and unnecessary biopsies, while TRUS-guided biopsy can miss clinically significant cancers due to its random sampling nature. This diagnostic challenge necessitates the exploration of more advanced and reliable imaging techniques.

Another screening technique is transrectal ultrasonography (TRUS), but its low specificity, invasive nature, and high cost have made it less popular. The 2013 AUA guidelines recommend stopping screening for men over 70 or with fewer than ten years to live, and biannual DRE screening for men aged 55 to 69, with shared decision-making about PSA testing. Upon establishing a screening-based suspicion of PCa, a diagnosis is necessary to guide therapy choices. Histopathologic evaluation of TRUS-guided systematic prostate biopsy core samples is the gold standard for screening diagnosis; however, mpMRI is starting to be used in routine clinical treatment, and pressure is growing to reduce the required thresholds for MRI requests.

Advancements in Imaging: The Role of Multi-Parametric MRI (mpMRI)

Multi-parametric MRI (mpMRI) has emerged as a revolutionary tool in the realm of prostate cancer imaging, offering a multi-faceted approach to visualizing the prostate gland. Unlike traditional imaging techniques, mpMRI combines several MRI sequences to provide comprehensive anatomical and functional insights into the prostate [1]

T2-weighted Imaging: Delivers high-resolution images that delineate the prostate's anatomical structures, helping to identify areas of abnormality.

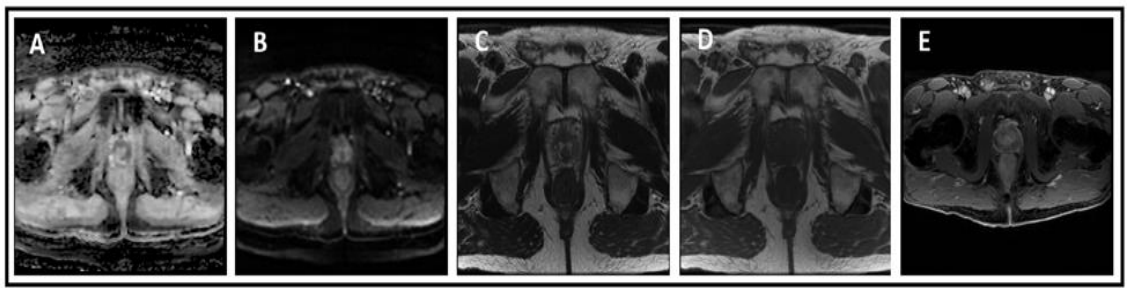
Diffusion-Weighted Imaging (DWI): Detects the restricted diffusion of water molecules, which is often indicative of high cellularity and malignancy.

Dynamic Contrast-Enhanced (DCE) MR: Assesses the vascular properties of tissues by tracking contrast agent kinetics, with malignant tissues typically showing increased perfusion.

Magnetic Resonance Spectroscopy (MRS): Analyzes the biochemical composition of tissues, offering metabolic data that can differentiate benign from malignant lesions.

These sequences, when interpreted together, can significantly enhance the detection, localization, and characterization of prostate cancer, addressing some of the critical limitations of traditional diagnostic methods. [1,2]

Figure 1- Example mpMRI sequences. Taken from the UIC prostate scanning protocol (Appendix C). A. ADC image B. DWI C. T2-weighted image D. T1-weighted image E. DCE image



While MRI has started to demonstrate benefit in the selective identification of high-grade grade PCa , the accuracy of TRUS-guided biopsy in accurately representing the PCa present has come under investigation. The main drawback of TRUS-guided biopsy is its small sample size, which mainly comes from the peripheral zone and impairs accuracy and consistency . On the other hand, the majority of cancers (75%) do occur in the peripheral zone, which is close to the rectal wall [3,4].

Understanding the Gleason Score

The Gleason scoring system is based on the microscopic appearance of prostate cancer tissue, typically obtained through a biopsy. The score is derived from two primary patterns of cancer cell arrangement:

1. Primary Grade: Represents the most common pattern seen in the tissue sample.

2. Secondary Grade: Represents the second most common pattern.

Each pattern is graded on a scale of 1 to 5, with 1 being the least aggressive (most well-differentiated) and 5 being the most aggressive (poorly differentiated). The primary and secondary grades are then added together to form the Gleason score, ranging from 2 to 10.

Clinical Significance of the Gleason Score

1. Prognostic Value: The Gleason score is one of the most significant predictors of prostate cancer prognosis. Higher scores correlate with more aggressive disease, higher likelihood of metastasis, and poorer overall outcomes. Patients with lower Gleason scores generally have a better prognosis and may be candidates for active surveillance rather than immediate treatment.

2. Treatment Planning: The Gleason score helps guide treatment decisions. For instance:

Low Gleason Scores (≤6): Often indicate less aggressive cancer that might be managed with active surveillance or focal therapy.

Intermediate Gleason Scores (7): Typically suggest the need for more aggressive treatment, which could include surgery, radiation therapy, or a combination of treatments.

High Gleason Scores (≥8): Indicate highly aggressive cancer that usually requires a combination of therapies, including surgery, radiation, and hormone therapy.

3. Risk Stratification: The Gleason score, combined with other factors like PSA levels and clinical staging, is used to stratify patients into risk categories (low, intermediate, high). This stratification is crucial for predicting outcomes and tailoring treatment plans.

4. Monitoring Disease Progression: For patients under active surveillance, changes in the Gleason score over time can indicate disease progression and necessitate a shift in the treatment approach.

5. Research and Clinical Trials: The Gleason score is a standard parameter in clinical trials for prostate cancer, helping to categorize patient populations and evaluate the efficacy of new treatments.[5,6]

Challenges and Developments

While the Gleason scoring system is widely used and highly valuable, it has some limitations. Inter-observer variability, where different pathologists might assign different scores to the same sample, is a notable challenge. To address this, there have been efforts to refine and standardize the grading process, such as:

- Modified Gleason Grading: Updates to the original system to improve consistency and prognostic accuracy.

The Gleason score remains a cornerstone in the management of prostate cancer, providing critical information that influences prognosis, treatment planning, and monitoring. Its ability to predict the aggressiveness of prostate cancer makes it indispensable for clinicians in delivering personalized and effective care. As technology and research continue to evolve, the accuracy and utility of the Gleason score are expected to improve, further enhancing its role in prostate cancer management.

The advancement of registration techniques between radiologic imaging and histopathology will have a broad impact on how we utilize and optimize imaging in the future and, hopefully, improve patient outcomes through directed early detection efforts. In this work, we devised a methodology and built a program to correlate histopathology to radiologic imaging, using DWI as a proof of concept, to validate PCa detection.[5,6,7]

Specific Focus on the Indian Population

The epidemiology of prostate cancer in India presents unique challenges and opportunities for research. Factors such as genetic diversity, lifestyle differences, and varying healthcare access influence the presentation and progression of prostate cancer in Indian men. [6,7,8]

Significance of the study

The significance of this study lies in its potential to transform prostate cancer diagnostics in India. By leveraging advanced imaging techniques and correlating them with histopathological data, this research aims to improve early detection, reduce invasive procedures, and ultimately enhance patient outcomes. Additionally, the study's findings could contribute to global knowledge, highlighting the importance of tailored diagnostic approaches in diverse populations.[2,9]

2. MATERIAL &METHOD

The study was prospective cohort, conducted for a period of 3 years. The study was conducted at Santosh Medical College in collaboration with Kriti Scanning Centre, Prayagraj & Mahamaya Allopathic Medical College, Ambedkar Nagar. Those

who are between 45 to 70 years and prostate specific antigen range was found to be between 1-19.9ng/ml.

Include all Male patients suspected of having prostate cancer based on clinical symptoms or elevated PSA levels. Patients referred for a multi-parametric MRI (mpMRI) of the prostate that patient who underwent subsequent prostate biopsy.

Those Patients was excluded in this study, with contraindications to MRI (e.g., presence of metallic implants), prior treatment for prostate cancer, Incomplete imaging or histopathological data, Patient should not have any prostatic surgery in previous, cardiac condition such as pacemaker implant, gadolinium history.

This prospective study was conducted on 36 cancer patients who undergo mpMRI exam followed by radical prostatectomy from certain period. The period between prostatectomy after imaging will be 7-30days.

MR imaging Protocol

T2-weighted and DW MR imaging were performed with a 3-T MR imager (Achieva TX; Philips Healthcare) using a cardiac coil (In Vivo; Philips Healthcare, Gainesville, Fla) and an endorectal coil (BPX 30; Medrad, Indianola, Pa). T2- weighted MR imaging has a resolution of 0.27 3 0.27 mm. ADC maps were calculated with monoexponential fitting per voxel of DW images at various b values. High-b-value DW images were acquired with a b value of 2000 sec/ mm2. T2-weighted and high-b-value DW MR imaging are normalized to reduce MR imaging signal inhomogeneity between MR imaging sections and patients per MR imaging section.

Tissue Specimen Preparation

The patient-specific mold (PSM) was created from the presurgical MR images from each patient and by using three-dimensional computer-aided design software (Dassault Systems SolidWorks, Waltham, Mass) and a three-dimensional printer (Dimension Elite 3D Printer; Stratasys, Eden Prairie, Minn). In the PSM, sectioning slots are positioned to match the location of the MR imaging sections (Fig 1). After prostatectomy, whole-mount tissue slices were cut in the mold and were stained with hematoxylin-eosin for histopathologic evaluation. Each tissue slice was digitized on a standard bright-field optical microscope (Aperio Technologies, Vista, Calif) at a magnification of 320 (resolution of 0.504 3 0.504 mm).

Image Registration

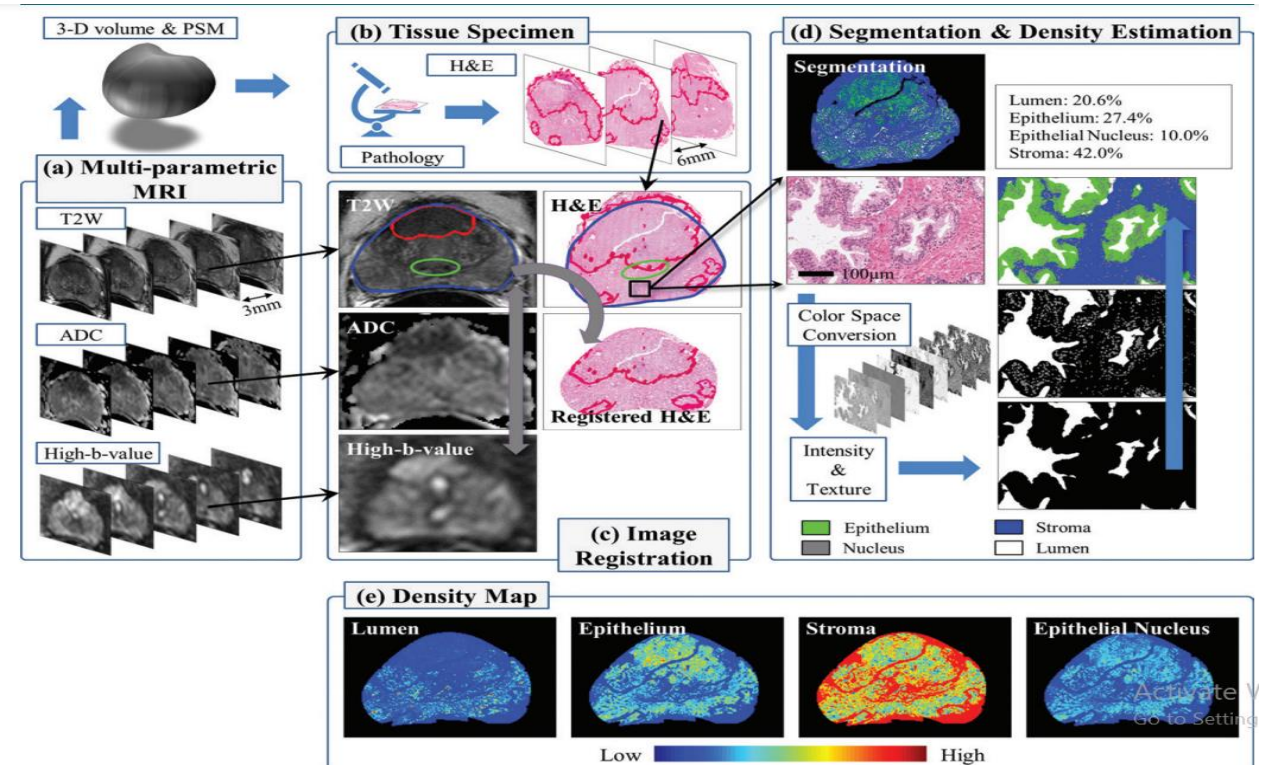
Image Registration The PSM helps orient the tissue specimen and maintain the shape of the prostate, but tissue preparation (eg, fixation) introduces deformation. The endorectal coil also deforms the prostate during MR imaging (absent in the specimen). In-house semiautomated registration software, implemented in OncoNav software (Center for Interventional Oncology, National Institutes of Health, Bethesda, Md), enables accurate registration based on the outer contours and internal fiducial structures within the prostate (Fig 1). The registration result is visually inspected to ensure that the overall shape and anatomic landmarks (urethra, ejaculatory ducts, benign prostatic hyperplasia nodules) at histology match the identified regions (peripheral zone [PZ], transition zone [TZ], and tumor). Also, ADC and high-b-value DW images undergo rigid registration with T2-weighted MR images using the MR imaging coordinate information.

Tissue Segmentation and Density Mapping

Tissue Segmentation and Density Map We convert each digitized specimen image into three different color forms: histogram equalization, HSV (H, hue; S, saturation; V, value), and La*b* (L, lightness; a*, between red-magenta and green; b*, between yellow and blue). Intensity and texture features are extracted at seven different scales and are integrated in a multiview boosting scheme to construct classifiers (lumen vs non-lumen, nuclei vs non-nuclei, and epithelium vs stroma). By using these classifiers, a tissue specimen image is segmented into lumen, nucleus, epithelium, and stroma in a cascaded fashion (Fig 1). A threshold value of 0.4–0.6 is used for classifier output, and the size and shape of segments are examined to identify and remove artifacts The density (ie, percentage area of tissue components [lumen, nuclei, epithelium, and stroma]) per voxel is estimated by drawing a window of 540 3 540 pixels (approximately equal to an MR imaging voxel) around the location and calculating the ratio of the size of the tissue component to the size of the window.

Figure 1 suggests Multi-parametric MR imaging and tissue specimen image processing. (a) Pre-surgical MR images are acquired and used to construct a three-dimensional (3-D) volume of the prostate and a PSM. (b) Whole-mount tissue specimens are cut in the mold and stained with hemotoxylin-eosin (H&E) for histopathologic evaluation. (c) Image registration is performed (T2-weighted MR images to DW images, MR images to digitized tissue specimen images). (d) Tissue specimen images are segmented into four tissue components. By using segmentation, the tissue component densities are estimated per MR imaging voxel and then (e) whole-density maps are computed.

Figure 1:



Results: Table 1- Characteristics of Patient Cohort

Variables		Overall	PZM	PZB	TZM	TZB
T2-weighted imaging	…	41	90	22	103	
ADC/high-*b*-value imaging	…	40	87	22	103	
Gleason score	…	3+4	4+3	4+4	4+5	
PZ and TZ	…	32	5	17	9	
PZ	…	24	3	8	6	
TZ	…	8	2	9	3	

As per table 1 There are notable

differences between malignant and benign areas in the peripheral zone (PZ) and transition zone (TZ) in terms of both digital histopathologic metrics (lumen, epithelium, stroma, and epithelial nucleus) and magnetic resonance imaging signals (T2-weighted MR imaging, ADC maps, high-b-value DW imaging). A total of 256 ROIs from 128 tissue sections (36 patients) were selected.

To create tissue component density maps, 36 patients' digital specimen photos and MP MR images were registered and analyzed. We found and analyzed 256 ROIs (n = 240 for the cancer group; 91 PZ and 103 TZ ROIs; benign group, 90 PZ and 103 TZ ROIs; Gleason score 3+4, n = 8; Gleason score 4+3, n = 2; Gleason score, 4+4, n = 9; Gleason score 4+5, n = 6]. Due to the lack of an ADC or high-b-value DW picture, three PZ benign ROIs and one PZ cancer ROI were removed.

Figure 2- Distribution of PI-RADS Scores

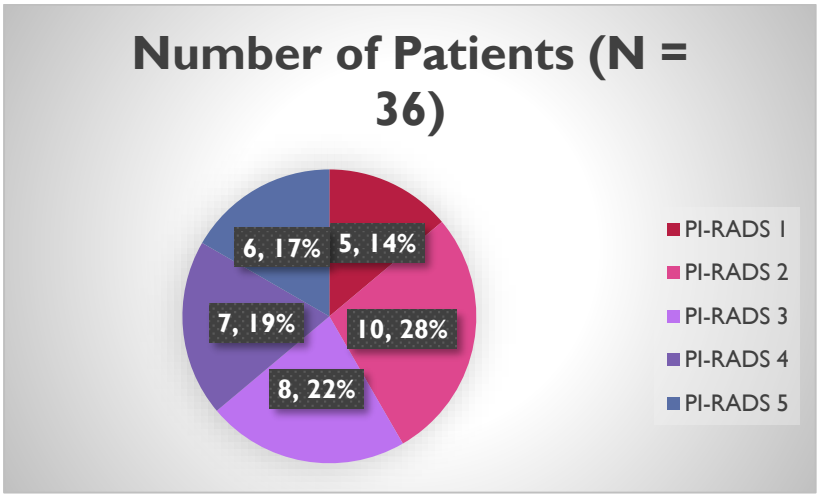


Figure 3- A 55-year-old man with prostate cancer (T2b, gleason score (GS): 8). A, Axial T2W MRI; B, Prostate sample. Arrows show prostate cancer in the right peripheral zone

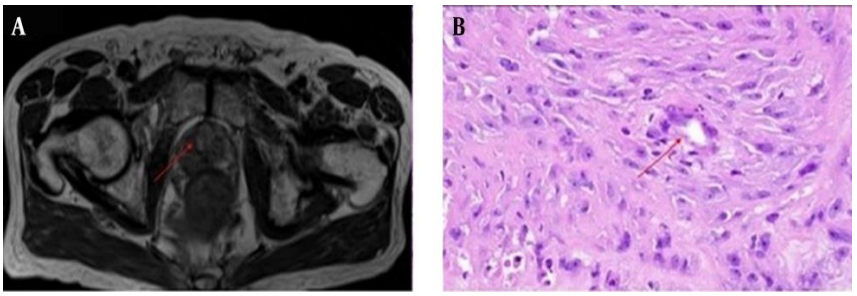


Figure-4

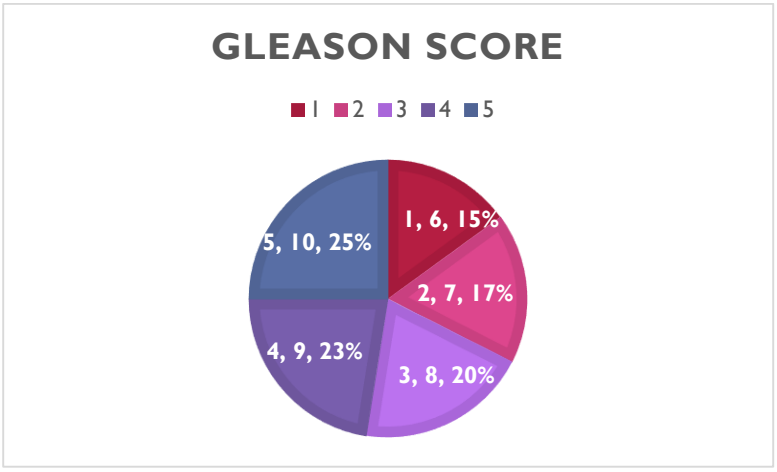


Table-2 Sensitivity and Specificity of mpMRI for Detecting Clinically Significant Prostate Cancer

PI-RADS Cut-off	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
PI-RADS ≥ 3	85	70	78	80
PI-RADS ≥ 4	90	85	88	82

As per table 2 the sensitivity of mpMRI was 85% and specificity was 70% with PPV of 78% and NPV of 80% in PI-RADS≥3

as compared to 90%, 85%, 88%, and 82% (sensitivity, specificity, PPV and NPV) of PI-RADS≥4.

3. DISCUSSION

In the present study, we observed that the mean age of the patients was 58 years, which is consistent with the typical age range for prostate cancer diagnosis. This finding aligns with other studies conducted in the Indian population, such as the one by study which reported a mean age of 60 years in their cohort of prostate cancer patients. The relatively younger mean age in our study could be indicative of earlier detection trends in the Indian population, possibly due to increased awareness and screening practices.[5]

The correlation between Gleason scores and MRI findings was another critical aspect of our study. Higher Gleason scores were associated with more pronounced changes in MRI signal characteristics, particularly in ADC and high-b-value DW imaging. This observation is supported by study who found that higher Gleason scores, indicative of more aggressive cancer, corresponded to lower ADC values and higher signal intensity on DW imaging. Our study's findings contribute to the growing body of evidence that MRI can be a valuable non-invasive tool for assessing tumor aggressiveness and guiding clinical decisions.[6,7]

In this study, we investigated the association between the Gleason score—a key prognostic indicator in prostate cancer—and various MRI parameters, including Diffusion-Weighted Imaging (DWI) and Digital Histopathological Analysis (DHA). The findings reveal a complex and nuanced relationship between Gleason scores and MRI metrics, particularly when considering the different anatomical zones of the prostate, namely the Peripheral Zone (PZ) and Transition Zone (TZ).

In our study, we observed that multi-parametric MRI (mpMRI) demonstrated a sensitivity of 85% and specificity of 70% for detecting clinically significant prostate cancer using the PI-RADS ≥3 threshold. In comparison, the PI-RADS ≥4 threshold yielded higher diagnostic performance with sensitivity of 90%, specificity of 85%, positive predictive value (PPV) of 88%, and negative predictive value (NPV) of 82%.

The comparison between the PI-RADS ≥3 and PI-RADS ≥4 thresholds highlights the impact of threshold selection on diagnostic accuracy. The increased sensitivity and specificity observed with the PI-RADS ≥4 threshold suggest that this higher threshold may be more effective in identifying clinically significant prostate cancers, which are crucial for guiding treatment decisions.

Sensitivity: The higher sensitivity (90%) of PI-RADS ≥4 compared to PI-RADS ≥3 (85%) indicates that using the PI-RADS ≥4 threshold is more effective in identifying patients with clinically significant prostate cancer, thus reducing the risk of false negatives.[7]

Specificity: While the sensitivity is higher for PI-RADS ≥4, the specificity (85%) is also improved compared to PI-RADS ≥3 (70%). Higher specificity at the PI-RADS ≥4 threshold suggests a reduced rate of false positives, which can help avoid unnecessary biopsies and reduce the risk of overtreatment. This is consistent with study who demonstrated that a higher PI-RADS score improves specificity and helps to more accurately distinguish between benign and malignant lesions[8].

Positive Predictive Value (PPV) and Negative Predictive Value (NPV): The PPV of 88% and NPV of 82% for PI-RADS ≥4 further support its efficacy in predicting clinically significant prostate cancer. A high PPV indicates that patients with a PI-RADS ≥4 score are likely to have significant disease, while a high NPV suggests that a negative PI-RADS ≥4 result is reliable in ruling out significant cancer.

The findings from our study emphasize the importance of using appropriate PI-RADS thresholds to optimize the diagnostic performance of mpMRI. For clinicians, adopting the PI-RADS ≥4 threshold can enhance the accuracy of detecting clinically significant prostate cancers, thereby improving patient management and treatment planning.

Ahmed et al. (2016) highlighted that adopting higher PI-RADS thresholds can reduce unnecessary biopsies and improve the targeting of clinically significant lesions. This is particularly important in the context of active surveillance and personalized treatment approaches, where accurate detection of high-risk tumors is crucial.[1]

Our results are in line with several studies that have investigated the diagnostic performance of mpMRI with different PI-RADS thresholds. For instance few studies both reported that higher PI-RADS scores are associated with improved sensitivity and specificity for detecting clinically significant prostate cancer, supporting the use of PI-RADS ≥4 in clinical practice.[9,10]

While the study demonstrates the utility of mpMRI with PI-RADS thresholds, it is essential to consider potential limitations such as variations in MRI protocols and reader experience. Future research should focus on standardizing imaging protocols and validating the performance of mpMRI with PI-RADS thresholds in larger, diverse populations. Additionally, exploring the integration of mpMRI with other diagnostic modalities, such as molecular imaging and biopsy techniques, could further enhance the accuracy of prostate cancer detection.

The higher sensitivity and specificity of mpMRI with PI-RADS ≥4 compared to PI-RADS ≥3 emphasize the importance of selecting appropriate thresholds to optimize diagnostic accuracy. By improving the detection of clinically significant prostate

cancer and reducing the risk of false positives and negatives, the PI-RADS ≥4 threshold offers a more effective approach for guiding clinical decision-making and patient management. Continued research and advancements in imaging technology will further enhance the role of mpMRI in the diagnosis and treatment of prostate cancer.

Conclusion: This study provides valuable insights into the effectiveness of multi-parametric MRI (mpMRI) in the diagnosis and characterization of clinically significant prostate cancer. The findings from our analysis highlight the strengths and limitations of mpMRI, particularly in relation to the PI-RADS scoring system and its correlation with histopathological findings.

1. Diagnostic Performance of mpMRI:

- The sensitivity of mpMRI for detecting clinically significant prostate cancer was 85% with a PI-RADS ≥3 threshold and improved to 90% with a PI-RADS ≥4 threshold.

- Specificity increased from 70% at PI-RADS ≥3 to 85% at PI-RADS ≥4.

- The positive predictive value (PPV) and negative predictive value (NPV) also demonstrated improved performance with PI-RADS ≥4, with PPV reaching 88% and NPV at 82%.

LIMITATIONS

Sample size of our study is a limitation and all PIRADS scoring was done by a particular diagnostic center by different consultant. so multiple radiologists reviewing and given same scoring which is bettered scoring of PI-RADS.

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