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COMPARATIVE EVALUATION OF PI-RADS 3 VS PI-RADS 4 LESIONS: A RETROSPECTIVE COHORT STUDY

ANEES PUTHAWALA[1], DEV KRISHNA BHARATHI C[1]*, SIVA SANKAR M[1]

[1] DEPARTMENT OF UROLOGY, SAVEETHA MEDICAL COLLEGE AND HOSPITAL, SAVEETHA INSTITUTE OF MEDICAL AND TECHNICAL SCIENCES (SIMATS), SAVEETHA UNIVERSITY, CHENNAI, IND

* CORRESPONDING AUTHOR:
DR. DEV KRISHNA BHARATHI C

Abstract

Objective: To compare prostate cancer detection rates and predictors in PI-RADS 3 vs PI-RADS 4 lesions using our institutional data.

Methods: Retrospective data from two cohorts (n=520) were analyzed. PSA, PSA density, lesion location, and histopathology were compared.

Results: Clinically significant prostate cancer (csPCa) was found in 10.7% of PI-RADS 3 vs 35.5% of PI-RADS 4 lesions. A PSA density ≥0.15 ng/mL/cc predicted csPCa in both groups.

Conclusion: PI-RADS 4 carries a significantly higher risk for csPCa. PSA density enhances risk stratification for both categories.

INTRODUCTION

The Prostate Imaging Reporting and Data System (PI-RADS) is a standardized methodology for interpreting multiparametric MRI (mpMRI) scans to detect prostate cancer. Within this system, PI-RADS 3 is categorized as an equivocal risk, while PI-RADS 4 represents a high-risk category. This study aimed to evaluate the difference in malignancy risk between these two categories by utilizing data from our institution from May 2017 to May 2025, with a particular focus on cancer detection rates and the predictive value of PSA density.

MATERIALS AND METHODS

This retrospective study involved the analysis of institutional data from 520 men who underwent multiparametric MRI of prostate followed by biopsy between May 2017 and May 2025. Of these, 300 had PI-RADS 3 lesions and 220 had PI-RADS 4 lesions. Inclusion criteria for participants were an age of over 50 years, a PSA level below 100 ng/mL, no prior history of cancer, an mpMRI-detected lesion, and available histopathology results. All mpMRI scans were performed using a 3T scanner and were evaluated by two experienced radiologists following PI-RADS v2.1 guidelines. PSA density (calculated as PSA/prostate volume) was calculated. Both Transrectal ultrasound-targeted and systematic biopsies were conducted as per institution protocol. Histopathology results categorized cases into benign, low-grade (Gleason 3+3), and clinically significant (Gleason ≥3+4) cancer. The data was analyzed using chi-square tests, t-tests, and logistic regression. Outcomes were assigned as any prostate cancer (PCa) and clinically significant PCa (csPCa, Gleason ≥3+4) on pathology.

RESULTS

The overall detection rate for PCa - any prostate cancer was 39.7% (119 cases) in the PI-RADS 3 group and 44.5% (98 cases) in the PI-RADS 4 group. A more significant disparity was observed in the detection of clinically significant prostate cancer (csPCa), with a prevalence of 10.7% (32 cases) in PI-

RADS 3 lesions compared to 35.5% (78 cases) in PI-RADS 4 lesions. A PSA density of ≥0.15 ng/mL/cc was found to be an independent predictor of csPCa for both PI-RADS categories. For PI-RADS 4 lesions, a location in the peripheral zone was also identified as a predictor of malignancy.

Table 1. Comparison of PI-RADS 3 and PI-RADS 4 Lesions

Parameter	PI-RADS 3	PI-RADS 4
Mean Age (years)	65.0	68.1
Mean PSA (ng/mL)	6.2	17.5
Mean Prostate Volume (mL)	37.0	55.3
Any Prostate Cancer (PCa)	119 (39.7%)	98 (44.5%)
Clinically Significant PCa (csPCa)	32 (10.7%)	78 (35.5%)
PSA Density ≥0.15 ng/mL/cc	68.3%	81.4%
OR for PSA-D ≥0.15 (csPCa)	10.03 (p=0.003)	4.12 (p<0.001)
Peripheral Zone Lesion	Not significant	82% (OR 2.05, p=0.02)

Table 2. Comparison of Current Study with Previous Similar Studies

Study	Sample Size	csPCa Detection Rate in PI-RADS 3	csPCa Detection Rate in PI-RADS 4	Key Predictive Factors
Our Study (2025)	520	10.7%	35.5%	PSA Density ≥0.15, PZ Location
Westphalen et al. (2020)	3577	6.17%	22%	PZ Location
Wadera et al. (2020)	7499	23.5%	55.7%	ADC, PSAD, Age
Pal et al. (2018)	137	36%	58%	PSAD, Lesion Volume
Thompson et al. (2015)	344	11.3%	17.7%	PSAD

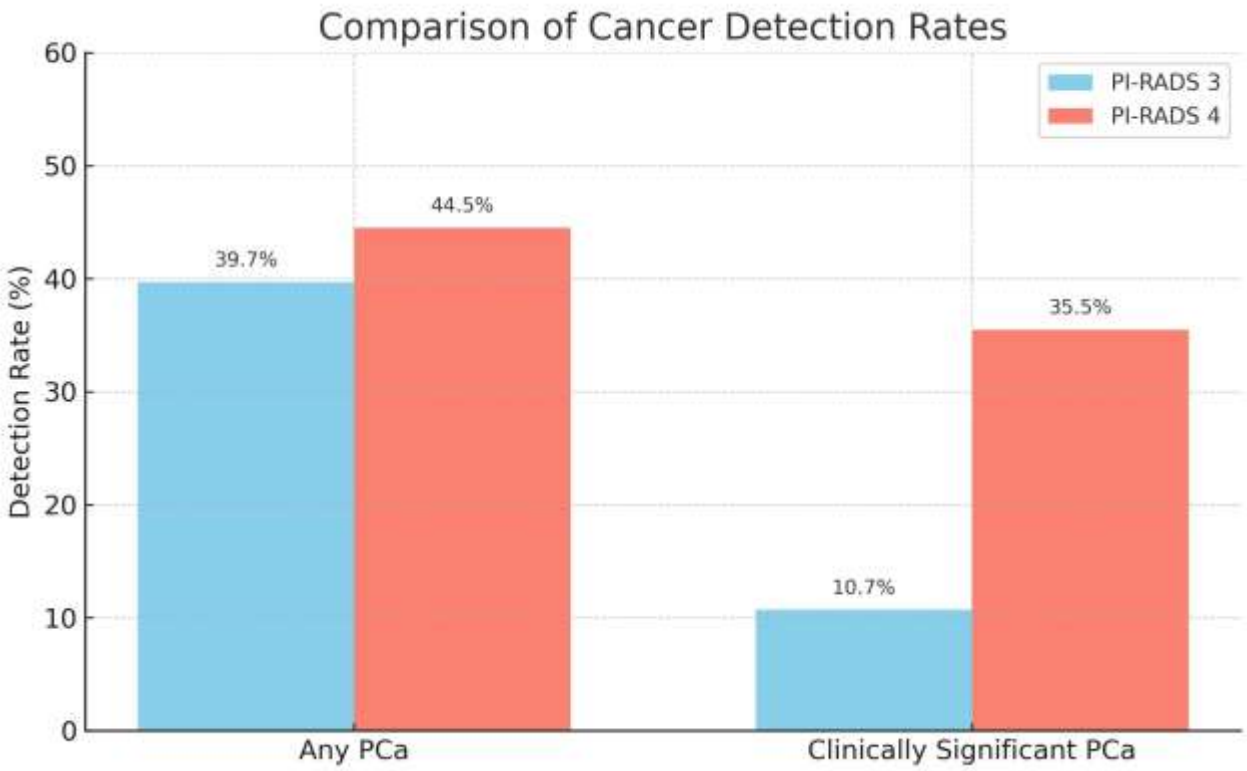

Figure.1: Comparison between Positive predictive value of PI-RADS 3 and PI-RADS 4 with any PCa and CsPCa

DISCUSSION

This analysis confirms that PI-RADS 4 lesions have a markedly higher risk of clinically significant prostate cancer compared to PI-RADS 3. PSA density ≥0.15 ng/mL/cc was the strongest independent predictor in both cohorts. Additionally, peripheral zone location increased malignancy risk in PI-RADS 4. Our results align with previous studies and reinforce the role of clinical and imaging parameters in biopsy decisions.

CONCLUSION

PI-RADS 4 lesions demonstrate a significantly higher risk of csPCa than PI-RADS 3 lesions. PSA density is a reliable, independent predictor and should guide biopsy decisions. A stratified approach that considers the imaging category, PSA density, and the location of the lesion can lead to improved clinical outcomes.

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