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Prostate cancer diagnostics: the independent and combined roles of SelectMDx and mpMRI

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Introduction Prostate cancer is a major global health concern, affecting one in every eight men over the course of their lives. Early detection and precise risk stratification are essential for distinguishing indolent types from aggressive cancer that necessitates immediate treatment. Prostate-specific antigen (PSA), although its widespread use in prostate cancer screening, lacks specificity, resulting in unnecessary biopsies and overtreatment of clinically insignificant malignancies. The SelectMDx test, a non-invasive molecular diagnostic tool, and multiparametric magnetic resonance imaging (mpMRI) have shown promise in enhancing diagnostic precision. This study compares the independent and combination diagnostic performance of SelectMDx and mpMRI in patients with intermediate PSA levels.

Material and methods A retrospective analysis of 126 patients was conducted in an academic hospital in southern Romania from 2022 to 2023. The requirements for inclusion included PSA values ≥3 ng/ml, SelectMDx evaluation, mpMRI, and a prostate biopsy. SelectMDx used mRNA expression levels of *HOXC6* and *DLX1*, in addition to clinical data, to create a risk score for clinically significant prostate cancer (PCa) (grade group ≥2). PI-RADS version 2.1 was used to rate mpMRI images. Lesions with a grade of ≥3 were considered suspicious. Logistic regression models were used to determine the predictive power of SelectMDx, PI-RADS, and their combination. The diagnostic performance was assessed using sensitivity, specificity, positive predictive value, and negative predictive value. The medical relevance of reducing unnecessary biopsies has been studied using decision curve analysis.

Results SelectMDx showed a sensitivity of 89.2%, a specificity of 61.8%, a PPV of 49.25%, and an negative predictive value (NPV) of 93.22%. Patients with positive SelectMDx results had a 13.35-fold greater risk of clinically severe PCa ($p < 0.001$). Using mpMRI with PI-RADS scoring improved detection of high-grade PCa. A PI-RADS score of ≥4 corresponded to a 7.13-fold higher probability of aggressive cancer ($p < 0.001$). In multivariate analysis, adjusting for SelectMDx and patient age reduced the predictive value of PI-RADS ≥4 (adjusted OR = 1.49; $p = 0.555$). Standalone SelectMDx outperformed its combination with mpMRI in terms of diagnostic accuracy, as shown by higher AUC values and better DCA results.

Conclusions The SelectMDx test is a highly effective and reliable diagnostic tool for predicting clinically severe PCa in individuals with intermediate PSA levels. Its high NPV avoids unnecessary biopsies and their associated morbidity. While integrating SelectMDx with mpMRI provides new diagnostic insights, the molecular test revealed superior accuracy when used alone, confirming its importance in precision medicine.

Key Words: PSA ‹› prostate cancer ‹› risk assessement ‹› molecular diagnostic tehniques

INTRODUCTION

Prostate cancer (PCa) constitutes a considerable worldwide health challenge, being one of the most prevalent cancers in males and associated with a lifetime risk of 1 in 8 [1]. Early diagnosis and precise risk evaluation are essential for enhancing patient outcomes, especially considering the various characteristics of prostate cancer, which varies from indolent types requiring no therapy, to aggressive forms that require prompt treatment [2].

The serum prostate-specific antigen (PSA) is fundamental in the diagnostic plan, serving as a biomarker for prostate cancer screening [3]. Although widely utilized, PSA is not specific to cancer and can be influenced by various factors, including age, prostate inflammation, benign prostatic hyperplasia, and particular drugs [4]. Consequently, increased PSA levels often lead to high false-positive rates and unnecessary biopsies, resulting in overdiagnosis and overtreatment of clinically insignificant prostate cancer [5]. To address these limitations, new diagnostic modalities have been developed, integrating molecular biomarkers and imaging technology to improve specificity and predictive accuracy. Among these recent advances, the SelectMDx test was identified as a promising non-invasive technique for detecting people at risk for clinically severe PCa.

The SelectMDx analysis utilizes reverse-transcription polymerase chain reaction (RT-PCR) to evaluate the expression levels of *HOXC6* and *DLX1* – genes implicated in prostate cancer growth and cell proliferation – along with *KLK3*, the gene encoding PSA production. By merging these molecular information with clinical data like as age, digital rectal examination (DRE) findings, PSA levels, and prostate volume, SelectMDx presents a revised risk assessment model. This test, performed using urine samples collected post-DRE, has shown utility for identifying the presence of high-grade PCa (Gleason score >7) and assisting clinical decision-making regarding biopsy requirement [6, 11].

In addition, advancements in imaging, specifically multiparametric magnetic resonance imaging (mpMRI), have changed PCa diagnoses. mpMRI, guided by the Prostate Imaging Reporting and Data System (PI-RADS), differentiates lesions depending on their risk of malignancy. This method enables targeted biopsies of suspicious areas, improving detection of clinically important malignancies while decreasing the identification of indolent ones [7]. However, mpMRI is not without disadvantages as well, including variability in interpretation and the possibility of missing up to 18% of significant PCa cases[8]. Consequently, the integration of mpMRI with molecular biomarkers such as SelectMDx is gaining interest as a way to boost diagnostic precision.

The combination of SelectMDx and mpMRI has the potential to transform PCa management, in particular among patients with intermediate PSA levels (4–10 ng/ml). Combining molecular and imaging data could help clinicians better distinguish between indolent and aggressive disease, potentially reducing unnecessary interventions and enabling timely medical care for high-risk individuals.

MATERIAL AND METHODS

The current study is a retrospective analysis of patients evaluated for PCa at an academic hospital in southern Romania between 2022 and 2023. The inclusion criteria were as follows: patients aged 40 to 80 years with serum PSA levels ≥3 ng/ml, who underwent SelectMDx testing, multi-parametric MRI (mpMRI), and subsequent prostate biopsy. Patients with a history of prior prostate procedures (e.g., transurethral resection of the prostate), those receiving androgen deprivation therapy, or those with incomplete clinical data were excluded from the analysis.

Each patient underwent a detailed clinical evaluation, including an assessment of age, family history of PCa, and a DRE. PSA levels were analyzed using validated immunoassay techniques, and prostate volume was measured through mpMRI.

The SelectMDx risk score, developed and performed by MDxHealth B.V. (Nijmegen, The Netherlands), is calculated using a first-void urine sample collected after a DRE. The test integrates mRNA expression levels of the genes *HOXC6* and *DLX1* with clinical parameters such as age, DRE findings, PSA levels, and prostate volume. The resulting score ranges from –6 to 6, with higher scores indicating a greater likelihood of high-grade PCa. This score is then translated into a percentage likelihood of detecting high-grade PCa in a subsequent biopsy. A score of –2.8 or higher is considered positive, reflecting a 13% probability of identifying high-grade PCa during follow-up testing.

All patients underwent mpMRI of the prostate using a 3 Tesla Siemens Magnetom Vida (Siemens Healthineers, Erlangen, Germany). The protocol included T2-weighted imaging, diffusion-weighted imaging (DWI) with b-values of 0, 500, and 1,000 s/mm², and dynamic contrast-enhanced (DCE) sequences, following the Prostate Imaging Reporting and Data System (PI-RADS) version 2.1 guidelines. The images were evaluated by a single,

experienced radiologist. Lesions with a PI-RADS score of 3 to 5 were considered suspicious for high-grade PCa. In cases with multiple suspicious lesions on mpMRI, the highest PI-RADS score was designated as a reference lesion.

Each patient underwent a systematic prostate biopsy guided by transrectal ultrasound (TRUS). For lesions with PI-RADS scores of ≥3, fusion MRI-guided biopsies were performed, with 2–5 cores obtained from each suspicious lesion to enhance lesion-specific sampling accuracy. The collected specimens were analyzed histopathologically and classified using the International Society of Urological Pathology (ISUP) Grade Group system, with grade groups ≥2 defined as clinically significant.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics 25. The distribution of quantitative variables was assessed using the Shapiro-Wilk test and reported as means ± standard deviations for normally distributed data or medians with interquartile ranges (IQR) for non-normally distributed data. Categorical variables were summarized as frequencies and percentages.

Group comparisons were conducted using the Student's t-test for normally distributed data, the Mann-Whitney U test for non-normally distributed data, and the χ^2 test or Fisher's exact test for categorical variables, as appropriate.

The diagnostic performance of SelectMDx, PI-RADS, and their combination was evaluated against biopsy results, with metrics including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy.

Logistic regression models were used to determine the independent predictive value of PI-RADS and SelectMDx for detecting aggressive PCa, with results reported as odds ratios and 95% confidence intervals. Receiver operating characteristic (ROC) curves and area under the curve (AUC) values were calculated to assess diagnostic accuracy.

Decision curve analysis (DCA) was employed to evaluate the clinical utility of the diagnostic tools in reducing unnecessary biopsies. Statistical significance was set at $\alpha = 0.05$.

RESULTS

Patient demographics and clinical characteristics

A total of 126 patients were included in the study. The mean age was 63.2 ±7.24 years, with a median age of 64 years (range: 42–80 years). The mean prostate volume was 54.78 ±25.91 ml, while the median PSA level was 5.75 ng/ml (IQR: 4.17–8.71 ng/ml). Intermediate PSA levels (4–10 ng/ml) were observed in 60.3% of patients (Table 1).

A family history of prostate cancer was reported in 7.9% of cases; however, this factor was not significantly associated with the presence of cancer (p = 0.722; Suppl. Table 1).

SelectMDx accuracy in prostate cancer detection

SelectMDx positivity was identified in 53.2% of patients. Among these, 89.2% were found to have clinically significant prostate cancer (grade group ≥2), whereas only 10.8% of patients with negative SelectMDx results fell into this category (p <0.001; Suppl. Table 2). As reported in Figure 1, these findings correspond to a sensitivity of 89.2%, specificity of 61.8%, a positive predictive value of 49.25%, and a negative predictive value of 93.22%.

Table 1. *Distribution of patients according to PSA levels*

PSA level [ng/ml]	Number	Percentage (%)
< 4	27	21.4
4–10	76	60.3
>10	23	18.3

PSA – prostate-specific antigen

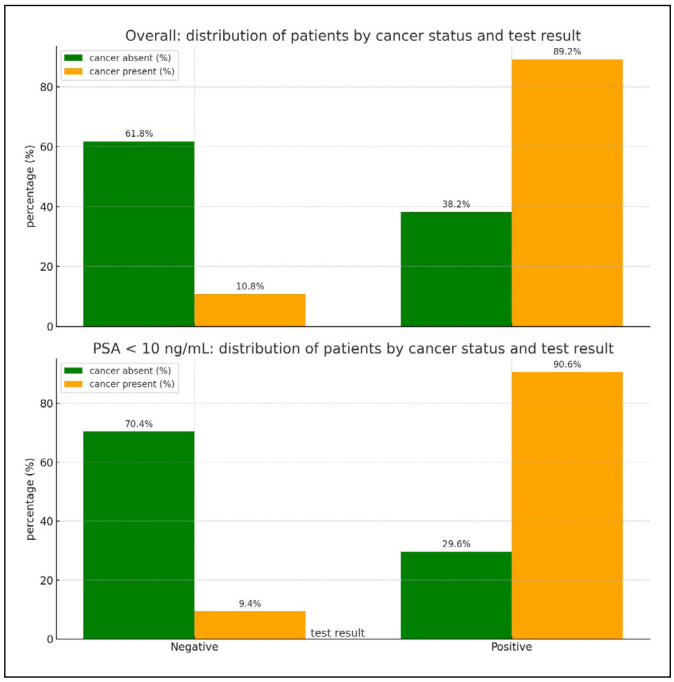

Figure 1. *Distribution of patients based on the presence of prostate cancer and SelectMDx test results.*

SelectMDx demonstrated even greater efficacy in the subgroup with intermediate PSA levels (Suppl. Table 3). The overall diagnostic accuracy was 76.7%, with a sensitivity of 90.62%, specificity of 70.42%, and positive and negative predictive values of 58% and 94.34%, respectively.

PI-RADS score and its predictive value

The mean PI-RADS score for the entire cohort was 3.48 ±1.27, with a median score of 3 (IQR: 3–5). A PI-RADS score of ≥4 was strongly associated with aggressive prostate cancer, as 78.4% of patients in this category had grade group ≥2 disease, compared to 21.6% of those with a PI-RADS score <4 (p <0.001). On univariate analysis, patients with a PI-RADS score of ≥4 had 7.13 times higher odds of being diagnosed with aggressive cancer (OR = 7.13; 95% CI: 2.90–17.49; p <0.001; Table 2). However, in a multivariate logistic regression analysis that included SelectMDx results and patient age, the independent predictive value of a PI-RADS score ≥4 was diminished (adjusted OR = 1.49; 95% CI: 0.39–5.65; p = 0.555, Table 2).

Utility of PI-RADS score and SelectMDx combination in biopsy prediction

The data presented in Figure 2 illustrate the distribution of patients based on the presence of prostate cancer and the combination of PI-RADS ≤2 criteria and a negative SelectMDx test result. Statistically significant differences were observed between the groups (Fisher's exact test, p = 0.001). Patients with both a negative SelectMDx test result and a PI-RADS score ≤2 were significantly more likely to have a negative prostate biopsy result (29.2% vs 2.7%). In contrast, patients with a PI-RADS score >2 and either a positive or negative SelectMDx test result were significantly more likely to have a positive biopsy result (97.3% vs 70.8%; Suppl. Table 4).
This diagnostic combination, however, is less effective than using the SelectMDx test alone, primarily due to the high rate of false-positive results. Its efficacy relies in the precise identification of negative cases, consequently reducing unnecessary biopsies.
The diagnostic performance showed a sensitivity of 97.3% and a specificity of 29.21%. The positive predictive value was 36.36%, while the negative predictive value reached 96.3%. Overall, the diagnostic accuracy was 49.21%.
The data presented in Table 3 and Figures 3–5 compare the diagnostic performance of the SelectMDx test alone versus its use in combination with other diagnostic tools for detecting prostate cancer. Two scenarios were analyzed: conditional combinations (where all included diagnostic tests must be positive or negative for the combination to yield a corresponding result) and joint combinations (where a positive result is generated if at least one test is positive, and vice versa for negative results).
The predictive performance of each diagnostic test and combination was assessed using ROC curves. These curves were constructed based on the predicted probability of clinically significant prostate cancer, calculated using a binary logistic regression model with the presence of csPCa as the dependent variable and the diagnostic test or combination as the independent variable.
As shown in Table 2, the SelectMDx test alone had the highest diagnostic accuracy, reflected

Table 2. *Logistic regression models for prostate cancer prediction*

Parameter	Univariate OR (95% CI)	p	Multivariate OR (95% CI)	p
PSA	1.007 (0.927–1.094)	0.869	–	–
Prostate volume	0.983 (0.966–1.0002)	0.053	–	–
PI-RADS ≥4	7.129 (2.905–17.494)	<0.001	1.493 (0.395–5.646)	0.555
Age	1.072 (1.012–1.136)	0.019	1.036 (0.971–1.105)	0.283
Family history	0.579 (0.117–2.864)	0.503	–	–
SelectMDx +	13.346 (4.344–40.997)	<0.001	8.487 (1.738–41.444)	0.008

PI-RADS – Prostate Imaging Reporting and Data System; PSA – prostate-specific antigen

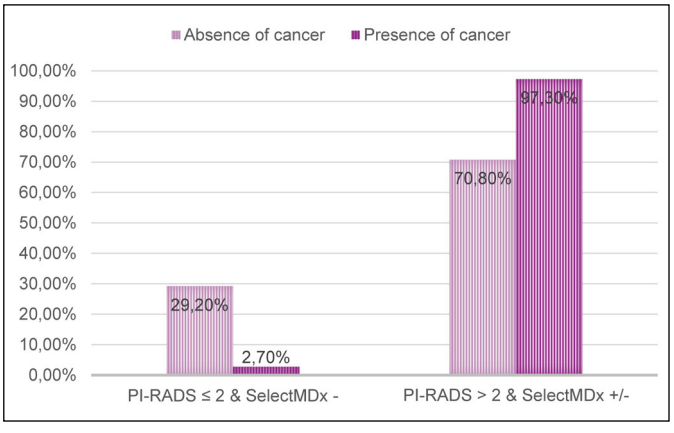

Figure 2. *Distribution of patients based on the presence of prostate cancer and the combination of PI-RADS score with a negative SelectMDx test result.*
PI-RADS – Prostate Imaging Reporting and Data System

by the largest area under the ROC curve. Combining the SelectMDx test with other diagnostic tools consistently reduced the AUC and overall diagnostic accuracy.

DCA was also performed to evaluate the net benefit and biopsy reduction rates for each diagnostic test and combination. Figure 3 presents a simplified DCA comparing SelectMDx alone, SelectMDx + PI-RADS, and a biopsy-all strategy, while additional combinations are provided in Figures 4, 5. In all scenarios, the SelectMDx test consistently demonstrated the highest net benefit and biopsy reduction rate, as represented in purple on the graphs.

In conclusion, the diagnostic performance of the SelectMDx test alone, demonstrated by its superior AUC values and supported by the DCA findings, surpassed all proposed combinations with other diagnostic tools. Instead of improving diagnostic accuracy, the combinations diminished the effectiveness of the SelectMDx test, emphasizing its strength and reliability as a standalone diagnostic tool.

DISCUSSION

Prostate cancer remains a major concern in urological oncology, demanding diagnostic strategies that precisely identify clinically significant malignancies

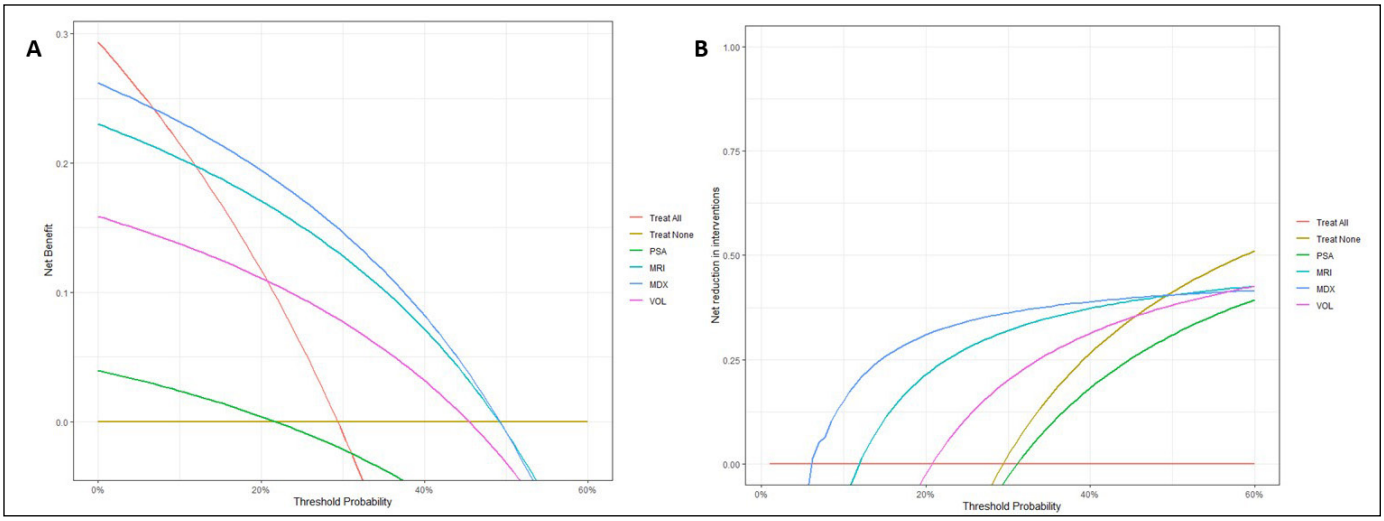

Figure 3. A) *DCA analysis using each diagnostic test for prostate cancer detection.* **B)** *Biopsy reduction rates for each diagnostic test.*

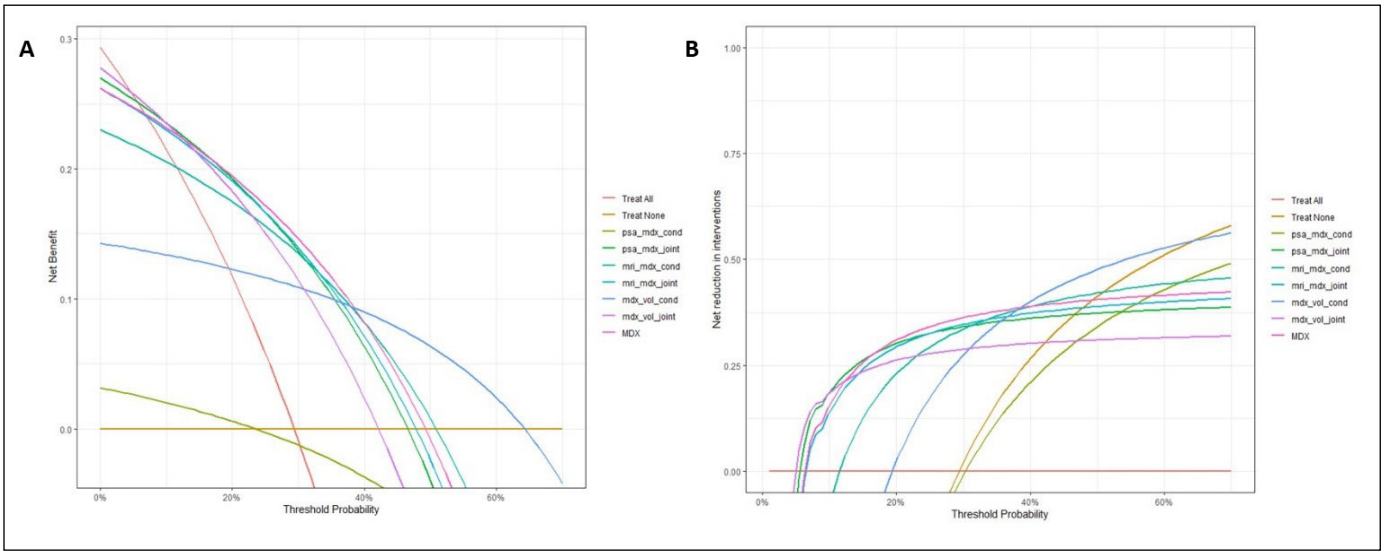

Figure 4. A) *DCA analysis of diagnostic tests combined with SelectMDx in prostate cancer detection.* **B)** *DCA illustrating biopsy reduction rates for diagnostic tests combined with SelectMDx in prostate cancer detection.*

while reducing unnecessary procedures. Current efforts seek to overcome the limitations of PSA testing, specifically its inability to distinguish between indolent and aggressive disease.

Table 3. *Comparison of the diagnostic performance of the SelectMDx test used alone and in combination with other diagnostic tools for detecting prostate cancer*

Prediction	AUC (95% CI)	Std. Error	p
SelectMDx	0.755 (0.667–0.843)	0.045	<0.001
SelectMDx + PSA (conditional)	0.519 (0.409–0.629)	0.056	0.738
SelectMDx + PSA (joint)	0.740 (0.652–0.828)	0.045	<0.001
SelectMDx + PI-RADS (conditional)	0.735 (0.639–0.830)	0.049	<0.001
SelectMDx + PI-RADS (joint)	0.744 (0.655–0.833)	0.045	<0.001
SelectMDx + volume (conditional)	0.687 (0.577–0.797)	0.056	0.001
SelectMDx + volume (joint)	0.703 (0.612–0.794)	0.047	<0.001
SelectMDx + PSA + PI-RADS (conditional)	0.527 (0.418–0.636)	0.056	0.635
SelectMDx + PSA + PI-RADS (joint)	0.729 (0.640–0.819)	0.046	<0.001
SelectMDx + PSA + PI-RADS + volume (conditional)	0.516 (0.403–0.628)	0.057	0.781
SelectMDx + PSA + PI-RADS + volume (joint)	0.681 (0.587–0.775)	0.048	0.001

PI-RADS – Prostate Imaging Reporting and Data System; PSA – prostate-specific antigen

The EAU guidelines recommend applying risk calculators or imaging tools to evaluate men with elevated PSA values (2–10 ng/ml) and a normal DRE [9]. Among these, mpMRI has emerged as a key tool for evaluating risk prior to prostate biopsy. MpMRI and PI-RADS scoring offer highly important imaging information, particularly for lesions defined as PI-RADS ≥4, which are strongly linked with clinically significant PCa [10]. Our study found that lesions with a PI-RADS score of ≥4 had a 7.13-fold increased risk of aggressive PCa. However, the inherent variability in mpMRI interpretation, including inter-reader variances and subjectivity in PI-RADS rating, is a significant restriction that may affect diagnostic accuracy and consistency.

To overcome the difficulties of limited mpMRI availability and variability, molecular testing techniques like the SelectMDx test offer a complementary alternative. SelectMDx aims to help identify the risk of clinically significant prostate cancer in patients with intermediate PSA levels who have not yet undergone a biopsy.

Notably, the diagnostic performance of SelectMDx with its standard cut-off value (≥13%) aligns closely with its intended purpose of detecting high-grade prostate cancer, as evidenced by its high sensitivity (89.2%) and negative predictive value (93.22%), reinforcing its clinical utility in identifying patients who can safely avoid unnecessary biopsies [11]. Our results confirm previous findings, demonstrating that SelectMDx achieved a sensitivity of 90.62% and a negative predictive value of 94.34% in patients with intermediate PSA levels. SelectMDx ef-

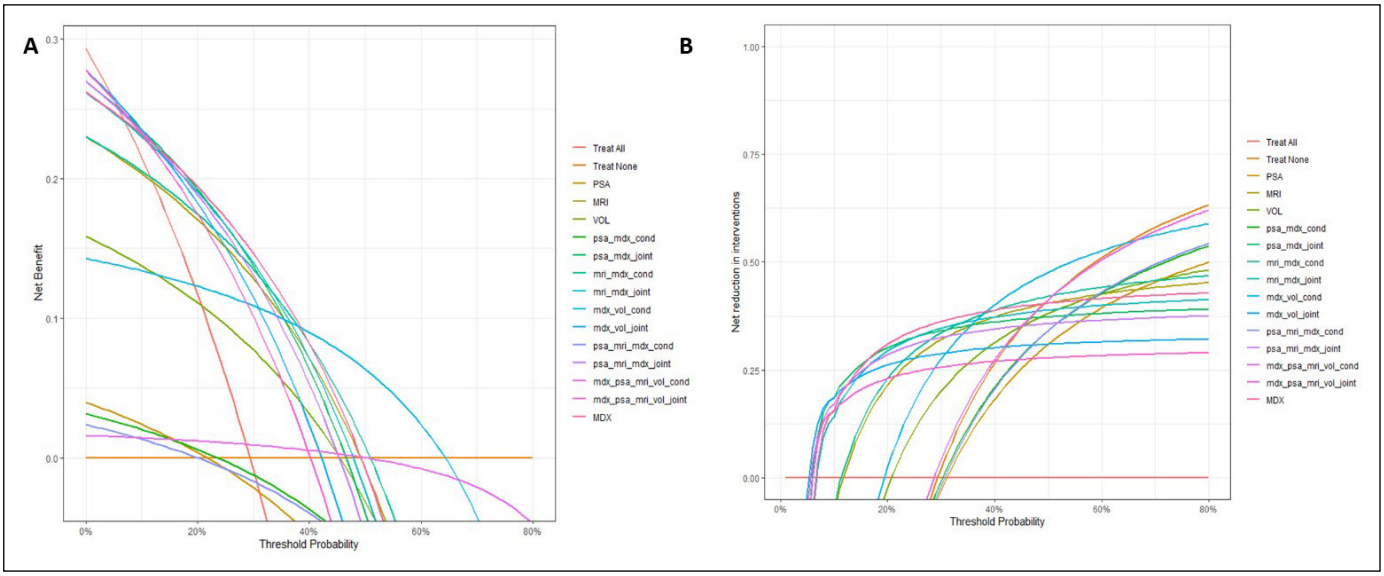

Figure 5. A) *DCA analysis of each proposed combination in prostate cancer detection.* **B)** *DCA analysis of each proposed combination in prostate cancer detection illustrated biopsy reduction rates.*

fectively reduces the need for unnecessary prostate biopsies by accurately identifying individuals with a low likelihood of clinically significant prostate cancer, thereby decreasing procedure-related morbidity and associated healthcare costs.

The integration of SelectMDx with mpMRI substantially improves diagnostic precision. Lesions defined as PI-RADS ≥4 in patients with a positive SelectMDx test indicate a considerably higher chance of high-grade PCa, demonstrating the associated roles of molecular and imaging evaluations [12]. Additionally, our data indicate that patients with both a negative SelectMDx result and a PI-RADS score ≤2 were highly unlikely to have clinically severe disease, with a negative predictive value of 96.3%. However, the benefit of combination techniques must be carefully considered.

A key strength of this study is the combined use of SelectMDx and mpMRI in a well-defined cohort with intermediate PSA levels, demonstrating a high sensitivity (89.2%) and negative predictive value (93.22%) for detecting clinically significant prostate cancer (csPCa). However, limitations include the retrospective design, which may introduce selection bias, and the focus on a PSA range of 4–10 ng/ml, potentially limiting applicability to patients with PSA levels starting from 3 ng/ml. Our findings align with those of Hendriks et al. [15], who reported similarly high sensitivity and negative predictive value for SelectMDx in detecting high-grade prostate cancer. Unlike their study, which focused solely on SelectMDx, our analysis extends to its combination with mpMRI, revealing a synergistic potential that enhances diagnostic precision, albeit with a reduced independent predictive value for PI-RADS ≥4 in multivariate analysis.

Despite their promise, integrating advanced diagnostics such as SelectMDx and mpMRI into standard clinical practice is not without limitations. Economic factors, including the cost and resource requirements of these technologies, remain significant challenges, particularly in low-resource countries [13]. Additionally, the diagnostic performance of SelectMDx relies on a standard cut-off value (≥13%), which may need adjustment to balance the goals of detecting high-grade PCa, avoiding unnecessary biopsies, and minimizing the overdetection of low-grade disease. Personalized interpretation of SelectMDx outcomes within shared decision-making processes may enhance its clinical value, enabling individualized approaches to patient care. Furthermore, advancements in machine learning and artificial intelligence hold promise for improving the integration of genetic and imaging data, opening the door to highly individualized diagnostics in prostate cancer care [14].

CONCLUSIONS

The conclusions of the present study confirm the SelectMDx test as a very accurate and reliable diagnostic tool for predicting clinically relevant prostate cancer in individuals with intermediate PSA levels, particularly when used independently. Its high negative predictive value enables accurate identification of low-risk individuals, consequently decreasing the need for unnecessary biopsies and reducing associated morbidity and healthcare costs.

The integration of SelectMDx with mpMRI improves diagnostic value; however, the molecular test's standalone results showed superior accuracy. These findings emphasize how important it is in precision medicine, supporting early identification and individualized care strategies for individuals at a higher risk of aggressive prostate cancer.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The ethical approval was not required.

SUPPLEMENTARY MATERIALS

Suppl. Table 1. *Distribution of patients based on the presence of prostate cancer and family history*

Cancer/History	Absent	(%)	Present	(%)	p*
No family history	81	91	35	94.6	0.722
With family history	8	9	2	5.4	

*p: Fisher's Exact Test

Suppl. Table 2. *Distribution of patients based on cancer presence and test results*

Cancer/Result	Absent	(%)	Present	(%)	p*
Negative	55	61.8	4	10.8	<0.001
Positive	34	38.2	33	89.2	

Suppl. Table 3. *Distribution of patients with low or borderline PSA values (4–10 ng/ml) based on the presence of prostate cancer and SelectMDx test results*

Cancer/Result	Absent	(%)	Present	(%)	p*
Negative	50	70.4	3	9.4	<0.001
Positive	21	29.6	29	90.6	

*p: Fisher's Exact Test

Suppl. Table 4. *Patient distribution by prostate cancer status, PI-RADS score, and SelectMDx results*

Cancer/Test	Absent		Present		p*
	No.	%	No.	%	
PI-RADS ≤2 & SelectMDx –	26	29.2	1	2.7	0.001
PI-RADS >2 & SelectMDx +/–	63	70.8	36	97.3	

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