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Applicability of the SelectMDx Test in Identifying Clinically Significant Prostate Cancer: Insights from an Eastern European Cohort

Petrino-Cristian Călinoiu[1,2], Daniel Liviu Bădescu[1,2]*, Ovidiu-Cătălin Nechita[1,2]*, Cristian-Valentin Toma[1,2], Cosmin-George Radu[1,2], Diana Neculai[2], Ștefan Rașcu[1,2], Razvan-Cosmin Petca[1,2], Justin Aurelian[1,2], Cristian-Sorin Sima[1,2], Viorel Jinga[1,2,3]

[1]Department of Urology, Carol Davila University of Medicine and Pharmacy, Bucharest, Romania
[2]Department of Urology, Prof. Dr. Th. Burghele Clinical Hospital, Bucharest, Romania
[3]Medical Sciences Section, Academy of Romanian Scientists, Bucharest, Romania

***Corresponding author:**
Daniel Liviu Bădescu, MD
E-mail: daniel.badescu@umfcd.ro
Ovidiu-Cătălin Nechita, MD
E-mail: ovidiu-catalin.nechita@drd.umfcd.ro

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Rezumat

Aplicabilitatea testului SelectMDx în identificarea cancerului de prostată semnificativ clinic: date dintr-o cohortă est-europeană

Context: Cancerul de prostată reprezintă o problemă majoră de sănătate la nivel global, iar metodele actuale de diagnostic, inclusiv testarea antigenului specific prostatic, prezintă limitări semnificative. SelectMDx este un test bazat pe biomarkeri urinari utilizat pentru stratificarea riscului de cancer de prostată clinic semnificativ, având potențialul de a reduce biopsiile inutile.
Metode: Acest studiu retrospectiv a inclus 126 de pacienți evaluați într-un spital universitar din România în perioada ianuarie 2022 - decembrie 2023. Toți pacienții prezentau PSA >3 ng/mL şi/sau rezultate anormale la tuşeul rectal şi au fost supuşi testului SelectMDx, urmat de biopsie ghidată prin ecografie transrectală. Au fost calculate sensibilitatea, specificitatea, valoarea predictivă pozitivă şi valoarea predictivă negativă, iar performanța diagnostică a fost evaluată utilizând curbe ROC.
Rezultate: SelectMDx a demonstrat o sensibilitate de 90,6%, o specificitate de 70,4% şi o valoare predictivă negativă de 94,3% în cohorta cu PSA < 10 ng/mL. Testul a avut rezultate promițătoare la pacienții cu tuşeul rectal negativ sau scoruri PI-RADS ≤ 3, contribuind la reducerea biopsiilor inutile.
Concluzii: SelectMDx s-a dovedit a fi un instrument valoros în stratificarea riscului de cancer de prostată clinic semnificativ, contribuind la îmbunătățirea deciziilor clinice şi la reducerea biopsiilor inutile. Cu toate acestea, sunt necesare studii suplimentare pentru a valida performanța sa în diferite populații.

Cuvinte-cheie: cancer de prostată, SelectMDx, biomarkeri urinari, diagnostic neinvaziv, biopsie, PSA, stratificarea riscului, PI-RADS

Abstract

Background: Prostate cancer is a major global health concern, and current diagnostic methods, including prostate-specific antigen testing, have significant limitations. SelectMDx is a urinary biomarker test used for risk stratification of clinically significant prostate cancer, with the potential to reduce unnecessary biopsies.

Methods: This retrospective study included 126 patients evaluated in a Romanian university hospital between January 2022 and December 2023. All patients had PSA >3 ng/mL and/or abnormal digital rectal examination findings and underwent the SelectMDx test followed by transrectal ultrasound-guided biopsy. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated, and diagnostic performance was assessed using ROC curves.

Results: SelectMDx demonstrated a sensitivity of 90.6%, specificity of 70.4%, and NPV of 94.3% in the cohort with PSA < 10 ng/mL. The test performed optimally in patients with negative DRE or PI-RADS ≤ 3 scores, reducing unnecessary biopsies.

Conclusions: SelectMDx has proven to be a valuable tool in the risk stratification of clinically significant prostate cancer, contributing to improved clinical decision-making and reducing unnecessary biopsies. However, further studies are needed to validate its performance across different populations.

Keywords: prostate cancer, SelectMDx, urinary biomarkers, non-invasive diagnosis, biopsy, PSA, risk stratification, PI-RADS

Introduction

Being the second most common type of cancer in men and one of the main causes of cancer-related death worldwide, prostate cancer (PCa) is a major public health concern (1). Improving oncological prognosis for patients depends on the early and accurate detection of clinically significant prostate cancer (2). However, current diagnostic approaches face considerable limitations, particularly due to drawbacks associated with prostate-specific antigen (PSA) testing. When PSA serum levels range between 4 and 10 ng/mL, the rate of negative biopsies reaches 70%, and up to 30% of repeat biopsies are also negative (3). Moreover, approximately 70% of men diagnosed with prostate cancer following elevated PSA levels prove to have a Gleason Score of 6 on prostate biopsy, highlighting the challenges in distinguishing clinically significant cases (4).

In recent years, there has been significant interest in developing biomarker-based diagnostic techniques to improve or complement existing protocols for prostate cancer detection. One of these strategies is the SelectMDx test (MDxHealth, Nijmegen), a commercially available molecular test designed to predict the presence of high-grade prostate cancer (Gleason Score ≥ 7) on biopsy. This urinary RNA biomarker test stratifies prostate cancer risk in men with elevated PSA levels by assessing molecular markers associated with aggressive prostate cancer (5).

The SelectMDx prediction model integrates a molecular risk score based on urinary mRNA levels of the HOXC6 and DLX1 genes detected after digital rectal examination (DRE), in addition to clinical data such as DRE findings, age, and PSA density. By identifying individuals who are more likely to benefit from prostate biopsy, the test reduces the rate of potentially negative biopsies, which otherwise have limited clinical utility in low-risk patients (6).

Although clinical studies have demonstrated the potential of the SelectMDx test to improve the detection of clinically significant prostate cancer, its performance appears to vary across different populations, highlighting the need for local validation studies (7). Despite its increasing adoption in clinical practice, data regarding its applicability in Eastern European populations, including Romania, remain limited. Differences between populations in terms of genetic profiles, environmental factors, and healthcare system structures may influence the test's performance and clinical utility, underscoring the importance of cohort-specific evaluations to ensure its effectiveness across various clinical settings (8).

While other diagnostic techniques, such as multiparametric magnetic resonance imaging (mpMRI) for detecting clinically significant prostate cancer, have significantly advanced, SelectMDx represents a less invasive and potentially more accessible alternative that requires independent evaluation (9).

This study aims to assess the diagnostic accuracy and clinical utility of the SelectMDx test within a Romanian patient population. The primary objective is to determine its effectiveness in predicting clinically significant prostate cancer and its potential to reduce unnecessary biopsies without compromising diagnostic accuracy. Importantly, this study emphasizes an independent evaluation of SelectMDx, deliberately avoiding direct comparisons with imaging modalities such as mpMRI or classification systems like PIRADS. This approach seeks to highlight the independent value of SelectMDx in routine clinical practice.

Materials and Methods

This retrospective study was conducted at a university hospital in Romania between January 15, 2022, and December 15, 2023, aiming to evaluate the diagnostic performance of the SelectMDx urinary biomarker test in identifying clinically significant prostate cancer. The institutional ethics committee provided ethical approval, and each participant provided written informed consent for the use of their clinical and diagnostic data.

The study cohort consisted of male patients evaluated for suspected prostate cancer based on elevated PSA levels (> 3 ng/mL) and/or abnormal findings on DRE. Inclusion criteria required that patients underwent SelectMDx testing followed by histopathological confirmation through transrectal ultrasound-guided prostate biopsy. Exclusion criteria included a previous history of prostate cancer or related treatments, as well as incomplete clinical or diagnostic data (*Fig. 1*).

The SelectMDx test, performed on urine samples collected after DRE, assessed messenger RNA expression levels of two key biomarkers - HOXC6 and DLX1 - normalized to KLK3 (10). The results were classified as "positive" or "negative" based on predefined thresholds indicating the probability of detecting clinically significant prostate cancer (7). Transrectal ultrasound-guided prostate biopsy, serving as the diagnostic reference standard, involved systematic sampling of 12 prostate tissue cores. Clinically significant prostate

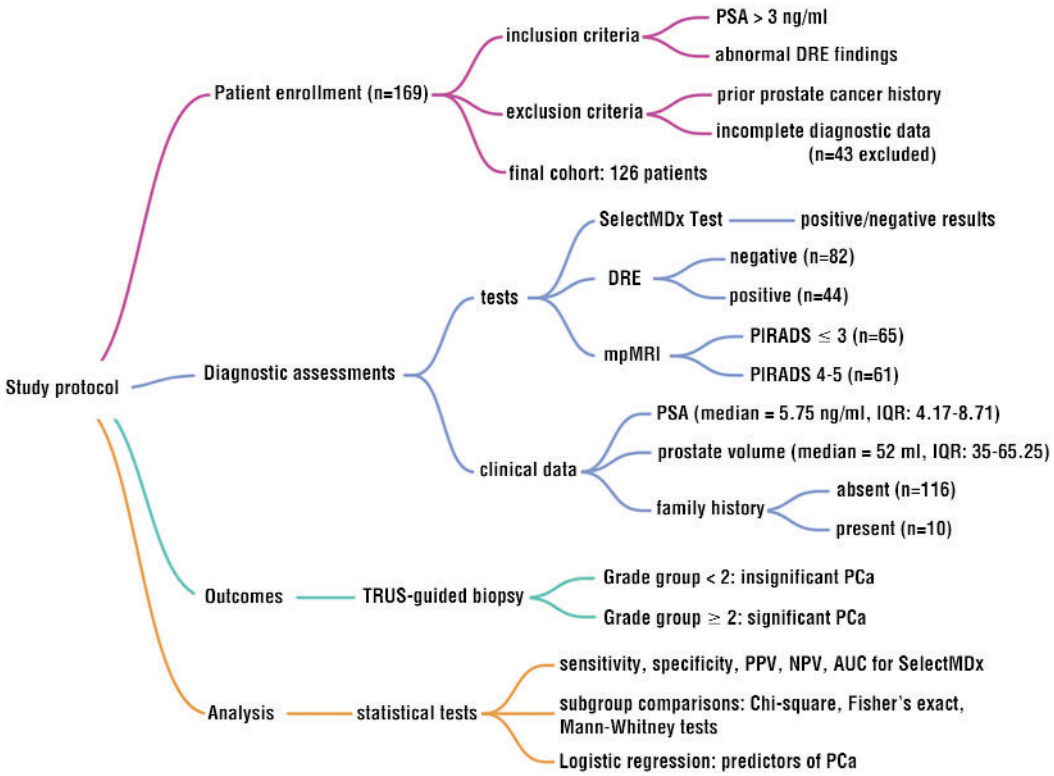

Figure 1. Overview of the study protocol: patient enrollment, diagnostic assessments, outcomes, and statistical analyses

cancer was defined as Grade Group ≥2 according to the grading system of the International Society of Urological Pathology (11).

Demographic, clinical, and diagnostic data were obtained from the medical documents of patients included in the analysis. Variables collected included age, PSA levels, prostate volume, digital rectal examination findings, family history of prostate cancer, SelectMDx test results, and biopsy outcomes. Additionally, when available, mpMRI results were reviewed to provide supplementary context, although these data were not a primary focus of this study.

Fig. 1 provides a schematic representation of the study protocol, detailing patient enrollment, diagnostic assessments, outcomes, and statistical analyses.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics (v25). The Shapiro-Wilk test was used to check for normality in continuous variables, and the results were given as either the mean ± standard deviation (SD) or the median with the interquartile range, depending on data distribution. Categorical variables were presented as frequencies and percentages. Student's t-test or the Mann-Whitney U test were used to compare groups with continuous variables, and the Fisher's exact test or Chi-square test were used to compare groups with categorical variables.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated to assess the SelectMDx test's diagnostic performance, and overall accuracy, with prostate cancer confirmed by biopsy serving as the reference standard. ROC curves were constructed to assess diagnostic accuracy, with the area under the curve (AUC) serving as a summary metric. Binary logistic regression models were employed to evaluate the predictive value of SelectMDx alongside clinical variables such as PSA levels, prostate volume, and age, with odds ratios (OR) and 95% confidence intervals reported for univariate and multivariate analyses. Clinical utility was assessed using decision curve analysis (DCA), which quantified the net benefit of reducing unnecessary biopsies across various probability thresholds, assuming a prostate cancer prevalence of 30%.

Ethics Approval

This investigation was conducted in line with the principles outlined in the Declaration of Helsinki, ensuring ethical research practices and protection of patient confidentiality. To safeguard participants' privacy, all data were anonymized prior to analysis.

Results

A total of 126 patients were included in this study, all undergoing the SelectMDx urinary biomarker test followed by ultrasound-guided prostate biopsy. The median age of the cohort was 64 years (IQR: 58-68.25), with a mean prostate volume of 54.78 ± 25.91 ml and a median PSA value of 5.75 ng/mL (IQR: 4.17-8.71)(*Fig. 2*).

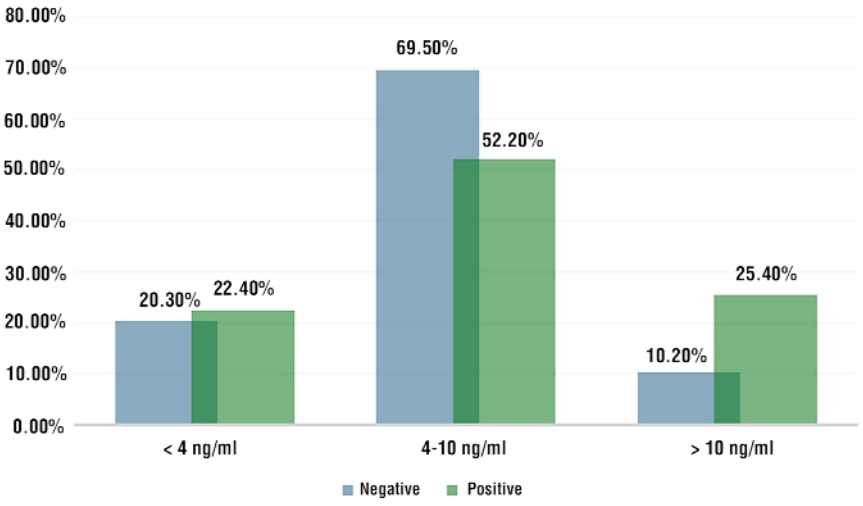

Figure 2. Distribution of patients according to PSA levels and SelectMDx test results

Of these patients, 53.2% (n=67) had a positive SelectMDx test result, and 29.4% (n=37) were diagnosed with clinically significant prostate cancer (Grade Group ≥ 2) based on histopathological assessment, summarized in *Table 1*, which outlines the main clinical parameters of this patient cohort.

Given the heterogeneous presentation of prostate cancer and the need for improved risk stratification, we further analyzed the performance of SelectMDx within specific patient subgroups defined by clinical and imaging characteristics. By evaluating its predictive value in relation to digital rectal examination (DRE) findings, PI-RADS scores from mpMRI, and family history of prostate cancer, we aimed to assess its utility in identifying high-risk patients while minimizing unnecessary biopsies. The following results provide a detailed evaluation of SelectMDx performance within these distinct subgroups, offering insights into its potential role in clinical decision-making.

Table 1. Baseline characteristics of the patients

Characteristic	Value
Age (years, median [IQR])	64 (58–68.25)
PCa family history	7.9% (10/126)
PSA (ng/mL, median [IQR])	5.75 (4.17–8.71)
Prostate volume (mL, median [IQR])	52 (35–65.25)
PSA density (ng/mL/cm^3, median [IQR])	0.10 (0.07–0.14)
Pathological rectal examination	34.9% (44/126)
Previous negative biopsy	21.4% (27/126)
mpMRI performed	50.8% (64/126)
PIRADS 4–5	48.4% (61/126)
PIRADS ≤ 3	51.6% (65/126)

Patients with Negative Digital Rectal Examination

Of the 82 patients with negative DRE findings, 46 (56.1%) had a positive SelectMDx result. Among these, 22 patients (47.8%) were diagnosed with clinically significant prostate cancer (Grade Group ≥ 2) on biopsy. Conversely, 36 patients (43.9%) had a negative SelectMDx result, and only 2 (5.6%) of these patients were diagnosed with clinically significant prostate cancer. In this subgroup, SelectMDx demonstrated a sensitivity of 91.7%, specificity of 57.1%, and negative predictive value (NPV) of 94.4% ($p < 0.001$).

Patients with PI-RADS ≦ 3

Among the 65 patients with mpMRI findings classified as PI-RADS ≤3 (clinically indeterminate), 31 (47.7%) had elevated SelectMDx biomarker scores. Of these, 8 patients (25.8%) were subsequently diagnosed with clinically significant prostate cancer confirmed by biopsy. Of the 34 patients (52.3%) with negative SelectMDx results, only one patient (2.9%) was diagnosed with clinically significant cancer. SelectMDx sensitivity in this subgroup was 88.9%, specificity 58.6%, and NPV 97.1% ($p = 0.002$) (*Fig. 3*).

Patients Without Family History of Prostate Cancer

Of the 116 patients without a family history of prostate cancer, 60 (51.7%) had a positive SelectMDx result, and 28 of these patients (46.7%) had biopsy-confirmed clinically significant cancer. Among the 56 patients (48.3%) with negative SelectMDx results, 3 patients were diagnosed with clinically significant cancer. The test's sensitivity in this subgroup was 90.3%, specificity was 56.4%, and NPV was 94.6% ($p < 0.001$).

Patients with Positive Digital Rectal Examination

Of the 44 patients with positive DRE results, 27 (61.4%) had a positive SelectMDx result, and 21 were diagnosed with clinically significant prostate cancer. Among the 17 patients (38.6%) with negative SelectMDx results, 5 were diagnosed with significant cancer. Sensitivity was 80.8%, specificity 50.0%, and NPV was 70.6% ($p = 0.016$).

Patients with a Family History of Prostate Cancer

Of the 10 patients with a family history of prostate cancer, 7 had a positive SelectMDx result, and 5 were confirmed with clinically significant prostate

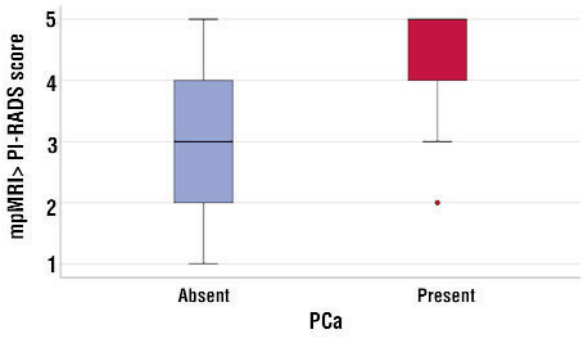

Figure 3. Comparison of mpMRI-PI-RADS score values according to the presence of prostate cancer

cancer. Among the 3 patients with negative SelectMDx results, none were diagnosed with significant cancer. SelectMDx achieved a sensitivity of 100%, specificity of 40.0%, and NPV of 100% in this subgroup (p = 0.034).

Patients with PI-RADS ≥ 4

In the group of 61 patients with mpMRI scores of PI-RADS 4-5, 40 (65.6%) had positive SelectMDx results, and 30 of these were diagnosed with clinically significant cancer. Among the 21 patients (34.4%) with negative SelectMDx results, 6 had clinically significant cancer. In this high-risk subgroup, SelectMDx demonstrated a sensitivity of 83.3%, specificity of 36.4%, and NPV of 71.4% (p = 0.004) (*Fig. 4*).

Additional Analysis of SelectMDx Performance

Beyond basic diagnostic performance indicators, further analysis revealed significant correlations between SelectMDx results and key clinical factors. Patients with positive SelectMDx results were significantly older (mean age: 65.16 ± 6.95 years) compared to those with negative results (mean age: 60.97 ± 6.96 years; p = 0.001). Similarly, PSA levels were significantly higher in the SelectMDx-positive group (median PSA: 7.1 ng/mL, IQR: 4.2-10.1) compared to the negative group (median PSA: 5.14 ng/mL, IQR: 4.09-7; p = 0.012) (*Fig. 5A + 5B*).

No statistically significant difference was observed in prostate volume between SelectMDx groups (p = 0.266), although a trend towards smaller prostate volumes in SelectMDx-positive patients suggests a potential inverse relationship warranting further investigation.

A stratified analysis of SelectMDx performance in patients with PSA levels below 10 ng/mL showed improved diagnostic accuracy. In this cohort, the test demonstrated a sensitivity of 90.62%,

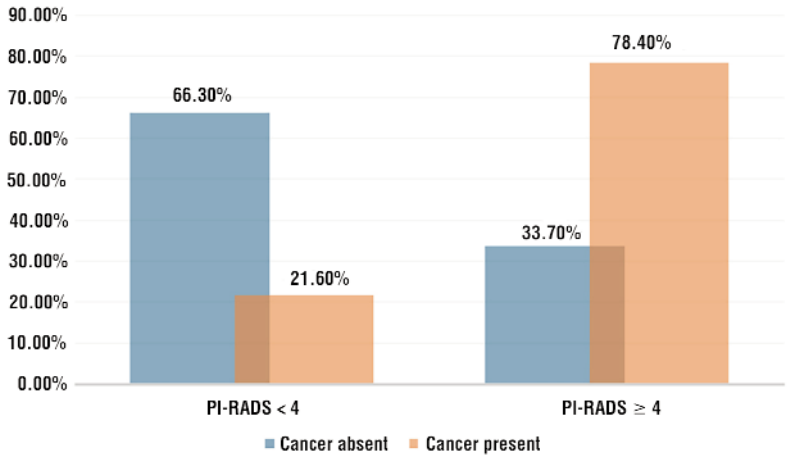

Figure 4. Distribution of patients according to the presence of prostate cancer and a PI-RADS score ≥ 4

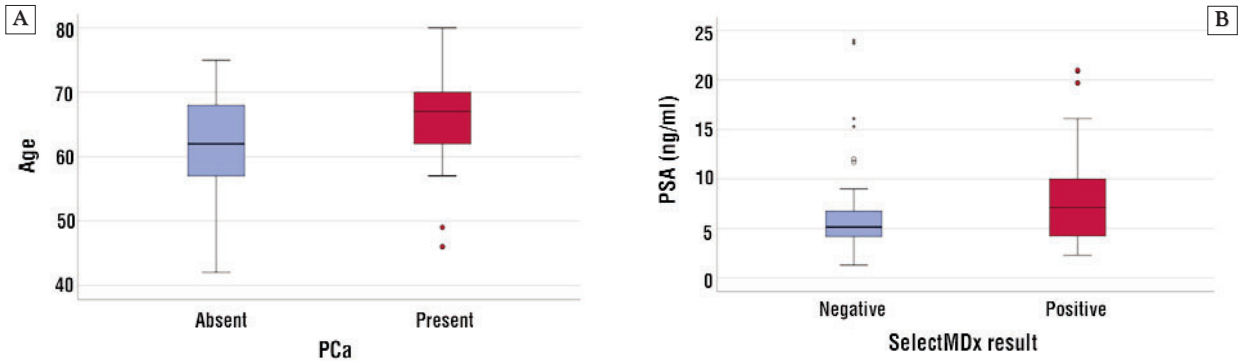

Figure 5. **(A)** Comparison of patient age according to SelectMDx test results; **(B)** Comparison of PSA values according to SelectMDx test results.

specificity of 70.42%, and an NPV of 94.34% (*Table 2*), surpassing its overall performance in the entire cohort and highlighting its potential to enhance risk stratification in patients with low or borderline PSA values, reducing unnecessary biopsies while maintaining high sensitivity for clinically significant prostate cancer.

Table 2. Distribution of patients with low or borderline PSA levels (<10 ng/mL)

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

Discussion

The findings of this study highlight the potential value of SelectMDx as a non-invasive tool for enhancing prostate cancer risk stratification, particularly when traditional biomarkers, such as PSA, lack the desired specificity. While previous research consistently demonstrates that SelectMDx can reduce unnecessary biopsies (12), its optimal clinical application remains a topic of ongoing debate, especially regarding its integration into established diagnostic pathways. Several validation studies, including a prospective, multicentric investigation by Hendriks et al (13) and a prospective diagnostic accuracy study by Lendínez-Cano et al., have reported similar performance patterns for SelectMDx (14). These findings support the test's ability to identify high-risk individuals while protecting those at lower risk from invasive procedures. Nevertheless, interpopulation variability remains significant, considering that genetic predisposition (15), healthcare access, and differences in biopsy thresholds may influence test outcomes across various patient cohorts.

One of the primary challenges in prostate cancer diagnosis is achieving the appropriate balance between sensitivity and specificity - enabling early detection while minimizing overdiagnosis. The moderate specificity observed in this study aligns with previous research, indicating that although SelectMDx effectively excludes clinically insignificant disease, it may still yield a considerable number of false-positive results (12). This concern has been emphasized in a prospective multi-institutional study by Maggi et al., which underscores the necessity of multiparametric risk models (16). By integrating SelectMDx with additional predictive factors - such as PSA kinetics, prostate volume, and genomic markers - these models may enhance overall diagnostic accuracy.

Another critical aspect in biomarker integration is cost-effectiveness within routine clinical practice. A cost-effectiveness analysis by Govers suggests that biomarker-driven decision-making could significantly reduce healthcare expenditures by limiting unnecessary biopsies and associated complications (17). However, real-world cost-effectiveness data remain limited, particularly within Eastern European healthcare systems, where resource allocation strategies might differ from those in Western Europe or North America. Therefore, future research should explore the economic implications of SelectMDx across various healthcare settings, especially where routine access to mpMRI is restricted.

Additionally, the potential utility of SelectMDx in guiding treatment decisions warrants further investigation. Although primarily employed as a biopsy triage tool, its capability to refine risk assessment within active surveillance protocols remains inadequately explored. Emerging evidence indicates that incorporating urinary biomarkers into surveillance algorithms could optimize patient selection for deferred intervention, reducing overtreatment without compromising oncological safety. In a recent review, Fiorella et al. highlighted the role of SelectMDx, among other biomarkers, in enhancing risk stratification among men under active surveillance, emphasizing the need for further prospective validation (18).

Large-scale, multicenter future studies are needed to refine biomarker thresholds and validate SelectMDx performance across diverse patient populations. Moreover, prospective studies integrating SelectMDx into multimodal diagnostic approaches - such as combinations with PSA density, clinical nomograms, or emerging machine learning-based predictive models - could provide a more comprehensive framework for risk-adapted prostate cancer management.

While this study offers valuable insights into the diagnostic performance of SelectMDx within a Romanian cohort, several limitations must be acknowledged. Firstly, the retrospective, single-center design introduces potential selection bias, as patient recruitment was limited to those meeting specific inclusion criteria at a tertiary care institution. Consequently, the generalizability of these findings might be limited, particularly when applied to broader populations or patients managed in diverse healthcare settings with varying baseline prostate cancer risk factors.

The study design intentionally excluded comparisons with mpMRI to exclusively focus on the independent performance of SelectMDx. Although this methodological choice clarifies the independent utility of the test, it limits the assessment of how SelectMDx integrates into existing imaging-based diagnostic pathways.

Finally, the limited sample size in certain subgroups - particularly patients with a positive family history of prostate cancer - may diminish the statistical precision of subgroup analyses.

Conclusions

This study highlights the clinical value of SelectMDx as a non-invasive tool for enhancing prostate cancer risk assessment, particularly among patients with biochemical suspicion of prostate cancer based on PSA and its derivatives. Its high sensitivity and strong negative predictive value support its role in reducing unnecessary biopsies while maintaining diagnostic accuracy. However, its moderate specificity and variable performance across subgroups necessitate further validation, particularly within underrepresented populations. Future research should focus on refining predictive models, integrating complementary diagnostic tools, and evaluating cost-effectiveness to facilitate broader implementation in urologic oncology practice.

Conflicts of Interest

The authors declare that they have no conflicts of interest regarding this study.

Ethical Statement

This study adhered to the ethical standards defined by institutional and national committees on human experimentation and conformed to the principles of the Declaration of Helsinki concerning human rights and ethical medical research. Ethical approval was obtained from the institutional ethics committee, and written informed consent was collected from all participants before their inclusion in the study.

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