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## **Modern Approaches to Prostate Cancer Diagnosis: From PSA to AI-Assisted Imaging**

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## **Abstract**

**Background.** Prostate cancer is one of the most common malignancies in men, and its early diagnosis remains challenging due to the lack of specific symptoms in the initial stages.

**Aim.** This review aimed to present current methods used in prostate cancer diagnosis, with emphasis on modern imaging, biomarkers, and artificial intelligence.

**Materials and methods.** A focused narrative review of the relevant literature was conducted, including studies on PSA testing, prostate biopsy, multiparametric MRI, MRI/TRUS fusion biopsy, PSMA PET, molecular biomarkers, and AI-based diagnostic tools.

**Summary.** Traditional methods remain important but have limited specificity. Modern imaging techniques improve lesion detection and biopsy targeting, while biomarkers such as PCA3, PHI, and 4Kscore support risk stratification. AI shows growing potential in imaging and histopathological analysis.

**Conclusions.** An integrated diagnostic approach may improve the detection of clinically significant prostate cancer while reducing unnecessary biopsies, overdiagnosis, and overtreatment.

**Key words:** Prostate cancer, Diagnosis, Multiparametric MRI, PSMA PET, Prostate-specific antigen, Fusion biopsy, Molecular biomarkers, PCA3, 4Kscore, Prostate Health Index , Artificial intelligence, Radiomics, Machine learning, Pathomics, Active surveillance

## **1. Introduction**

The prostate, an accessory reproductive organ in men, is located below the urinary bladder. Its primary role is to produce secretions essential for sperm motility in semen and for maintaining sperm viability. In adults, the prostate is divided into central, transitional, and peripheral zones. Over 95% of prostate cancer (PCa) cases are adenocarcinomas, the majority of which are acinar in origin, while only a small proportion originates from the ducts. Approximately 80% of prostate adenocarcinomas arise from epithelial cells in the peripheral zones, which make up more than 70% of the prostate's total volume. The incidence of PCa in men over the age of 65 is around 60%. Prostate cancer is more common in men of Caribbean African descent and African Americans compared to men of other races, although the reasons for this disparity remain unknown [1]. Prostate cancer is a major contributor to cancer-related morbidity and mortality [2]. According to the World Health Organization, in 2020, prostate cancer was the third most commonly diagnosed malignant tumor. With approximately 1,414,259 cases (7.3% of all cancers), it ranked third, just behind lung cancer with 2,206,771 cases (11.6%) and colorectal cancer with 1,148,515 cases (10%) [3]. In the early stages of prostate cancer, there are no specific clinical symptoms. The most common symptoms include frequent urination, urinary urgency, nocturia, and a weak urine stream, which can resemble the symptoms of benign prostatic hyperplasia. When more pronounced symptoms appear, the disease has usually already progressed to intermediate or advanced stages, which is associated with a higher mortality rate [4]. In many men, prostate cancer is diagnosed through biopsy, analysis of prostate-specific antigen (PSA) levels, digital rectal examination, magnetic resonance imaging (MRI), or screening tests. Risk factors for prostate cancer include family history, ethnicity, age,

obesity, and other environmental factors. Prostate cancer is a heterogeneous disease, both epidemiologically and genetically. Interactions between genetics, environmental factors, and social determinants result in race-dependent survival rates, which contribute to differences in the incidence of this disease across various countries [5]. Transrectal or transperineal prostate biopsy is currently the most commonly used method for diagnosing prostate cancer in many regions of the world. It is performed when the PSA level is elevated or when digital rectal examination results are abnormal. The established PSA-based screening method can significantly improve early diagnosis rates, enabling the detection of nearly 90% of prostate cancer cases at the time of diagnosis [6]. In this review, we present a holistic overview of modern diagnostic methods for prostate cancer.

## **2. Materials and methods**

A focused narrative review of the relevant literature was conducted to examine current approaches to prostate cancer diagnosis. The review aimed to evaluate the available evidence regarding traditional diagnostic methods, modern imaging techniques, molecular biomarkers, and the emerging role of artificial intelligence in improving diagnostic accuracy. The literature search was based on publications addressing both established clinical tools, such as PSA testing and prostate biopsy, and newer diagnostic strategies, including multiparametric magnetic resonance imaging (mpMRI), MRI/TRUS fusion biopsy, PSMA PET, and biomarker-based assays. Particular attention was given to studies assessing the detection of clinically significant prostate cancer, reduction of unnecessary biopsies, risk stratification, and the potential contribution of AI to image and histopathological analysis. Clinical studies, randomized trials, systematic reviews, meta-analyses, and narrative reviews were considered in order to provide a broad and critical overview of the topic.

## **3. Research results**

### **3.1 Traditional diagnostic methods**

#### **3.1.1 Measurement of PSA levels**

PSA is a protease secreted by the prostate gland, widely used in the diagnosis of prostate cancer since the late 1980s. It is useful not only for diagnosis but also for risk stratification, and after treatment, it serves as a marker of recurrence [7,8]. The PSA test is typically performed in two situations: to evaluate a patient presenting to a general practitioner or specialist with lower

urinary tract symptoms (LUTS), or as a screening test in asymptomatic individuals concerned about their risk of prostate cancer [7,9]. Nevertheless, prostate cancer screening has been a subject of controversy for many years, and primary care physicians often question whether they should offer PSA testing to asymptomatic men. Major concerns include the possibility of missing cancer in men with elevated PSA levels due to benign conditions, the risk of infection associated with transrectal biopsy, overdiagnosis of indolent cancers, and side effects of treatment such as erectile dysfunction and urinary incontinence [10]. Patients with elevated PSA levels are typically referred to a urologist who may order further diagnostic tests, including magnetic resonance imaging (MRI) or a prostate biopsy [11]. Consequently, international guidelines emphasize assessing individual risk and making shared decisions with patients, including a discussion of the risks and benefits. The goal is to ensure that patients are aware of the potential for false-positive results and the risks of overtesting and overtreatment before undergoing PSA testing [8].

### 3.1.2 Prostate biopsy

Transrectal ultrasound (TRUS) guided prostate biopsy is used to obtain a histopathological diagnosis of prostate cancer and has been a cornerstone of urological practice for nearly thirty years. The TRUS biopsy is performed as a day procedure. The patient is given 500 mg of oral ciprofloxacin one hour prior to the procedure. The urologist stands on the patient's right side while the patient lies on their back. The patient is then positioned on their left side to begin the procedure. The probe is inserted into the rectum and directed toward the anterior wall, allowing visualization of the prostate [12]. The standard biopsy procedure involves collecting samples from both sides along the midline, as well as from the lateral, apical, mid, and basal regions typically a total of 12 cores, with additional samples taken from any suspicious areas [13]. However, the procedure may be associated with complications such as infections, sepsis, and bleeding, which can lead to prolonged hospitalization and increased healthcare costs [14].

### 3.1.3 Fusion biopsy

Fusion biopsy is a modern technique that combines the lesion-detection capabilities of mpMRI with the real-time approach used in ultrasound (US). It enables biopsy procedures to be performed in an office setting rather than on an MRI table, without losing the detection advantages offered by MRI. This method can be particularly useful in high-volume centers where time is limited and a dedicated MRI unit for biopsies is unavailable. In this technique,

T2-weighted images obtained during a prior mpMRI are fused with real-time TRUS images. The biopsy is performed under ultrasound guidance, and the technique can be used with either the transrectal or transperineal approach, depending on the capabilities of the system in use. Ultrasound allows for real-time visualization of the lesion, and once it is located, the software merges the US and mpMRI image [15]. MRI/TRUS fusion biopsy also plays a role in detecting clinically significant PCa in patients with previously negative biopsy results, and it shows an increased likelihood of diagnosing clinically significant prostate cancer (Cs PCa) with rising PI-RADS scores. Although further studies are needed, MRI/TRUS fusion biopsy is becoming an important diagnostic tool [14].

### **3.2 Modern imaging techniques**

#### **3.2.1 Magnetic Resonance Imaging (MRI)**

In recent decades, magnetic resonance imaging (MRI) technology has gained significant advantage in the diagnosis of prostate cancer compared to traditional methods such as digital rectal examination (DRE) or PSA level measurement. MRI demonstrates higher sensitivity in detecting primary prostate lesions, which has enabled it to play a key role not only in assessing disease stage but also in early detection. As a result, diagnostic priorities have shifted from standard TRUS-guided biopsy toward targeted or MRI-guided biopsy (MRI-Tb). The use of MRI in targeted biopsy is particularly justified by its high negative predictive value of 89% in diagnosing clinically significant prostate cancer (csPCa) [16]

##### **3.2.1.1 Multiparametric MRI (mpMRI)**

In recent years, mpMRI has gained importance as a diagnostic tool, particularly in the context of preoperative local staging of prostate cancer (T stage). Thanks to its ability to precisely differentiate soft tissues surrounding the prostate, mpMRI enables the detection of cancerous lesions that may have been missed during standard biopsy. Moreover, in cases where a repeat biopsy is being considered, mpMRI offers significant advantages. The use of this technology to identify patients requiring rebiopsy not only increases the detection rate of both general and csPCa, but also allows for a substantial reduction in the number of biopsies performed by approximately 73% [17]. The foundation of mpMRI is the PI-RADS system, which assesses prostate cancer risk based on images acquired using T2-weighted imaging (T2WI), diffusion-weighted imaging (DWI), and dynamic contrast-enhanced imaging (DCE), with results classified on a scale from 1 to 5. Targeted biopsy, performed in cases with PI-RADS scores of

3–5, significantly improves the detection of clinically significant prostate cancer compared to traditional TRUS biopsy, while also reducing the number of cores collected [18].

### 3.2.2 PSMA Positron Emission Tomography (PET PSMA)

PSMA (prostate-specific membrane antigen) is an antigenic receptor found in prostate tissue and prostate-related tumors. It is a type II transmembrane protein that functions as a glutamate carboxypeptidase, composed of 750 amino acids. To utilize PSMA in diagnostics, antibodies targeting its extracellular domain have been developed, including the humanized monoclonal IgG antibody “J591” and ligands such as DKFZ-PSMA-617 and DOTAGA-(I-y)fk (Sub-KuE), which have been radiolabeled. When interpreting PET-CT scans, it is important to consider the natural expression of PSMA in tissues such as the prostate, salivary and lacrimal glands, nasal cavity, larynx, liver, spleen, intestines, kidneys, and sympathetic ganglia. Moreover, PSMA is also expressed in various types of cancers, including gliomas, thyroid, breast, lung, colorectal, and kidney cancers. Uptake is also observed in benign tumors such as hemangiomas, thyroid adenomas, schwannomas, desmoid tumors, and in inflammatory conditions, including Paget’s disease. PSMA is overexpressed in nearly all cases of prostate cancer, with expression levels reaching 100 to 1000 times higher than in healthy tissues, although the exact mechanisms behind this phenomenon are not yet fully understood [19]. PSMA PET imaging also has the ability to detect clinically significant prostate cancer in about half of patients with a strong clinical suspicion of the disease, but with negative or inconclusive mpMRI findings or negative biopsy results. Therefore, PSMA PET may serve as an alternative to image-guided biopsy in selected cases with a high suspicion of prostate cancer. Furthermore, the need for an alternative to MRI-based targeted biopsy is particularly relevant for patients who cannot undergo MRI due to claustrophobia, magnetic implants, or other electronic devices [20].

## 3.3 Molecular and genetic imaging

### 3.3.1 Genotyping and biomarkers

In recent years, research on biomarkers has gained importance, serving as complementary tools to support clinical decision-making. Molecular analysis of prostate cancer biomarkers in solid tumors has become an integral part of guidelines such as those developed by the National Comprehensive Cancer Network (NCCN) in the context of risk assessment and staging of localized disease. Currently, numerous molecular tests are available that provide valuable information at various stages of the prostate cancer care process, including diagnosis, initial

treatment, and supportive therapies [21]. To aid in predicting the aggressive course of prostate cancer following biopsy or repeat biopsy, several molecular tests based on the analysis of biological fluids have been developed. The most notable biomarkers include PHI, ProgenSA, 4Kscore, MyProstateScore, Select mdx, ExoDX Prostate, Apifyny, and Proclarix [22].

### 3.3.1.1 New molecular markers in prostate cancer diagnosis

#### PCA3

The PCA3 gene, which is specific to prostate cancer, shows strong overexpression in cancerous cells. The FDA-approved ProgenSA PCA3 test is used to detect this biomarker and may be considered to reduce the need for repeat biopsies in men with previously negative biopsy results. The PCA3 score is calculated by determining the ratio of PCA3 mRNA to PSA mRNA in urine, expressed as  $PCA3/PSA \times 1000$ . A study conducted by Merola and colleagues on a group of 407 men with prior negative biopsies demonstrated the superiority of the PCA3 test over total PSA and free PSA testing in the diagnosis of prostate cancer. Additionally, higher PCA3 scores were associated with greater tumor aggressiveness [21,23]

#### PTEN

Alterations in the PTEN gene are more frequently observed than other mutations in advanced, localized, or metastatic prostate cancer and have a significant impact on prognosis. The variability of this gene is well documented in the context of prostate cancer. PTEN is a tumor suppressor gene located on chromosome 10, and its mutations are known to be involved in the PI3K/AKT signaling pathway. PTEN deletions have been identified in 10–70% of prostate cancer cases following radical prostatectomy. PTEN is one of the most commonly altered tumor suppressor genes, and the heterogeneity in deletion frequency is likely related to the risk group, with higher-risk disease correlating with a greater frequency of PTEN deletions [22].

#### 4K Score

The 4K Score test includes the assessment of total PSA, free PSA, intact PSA (a form of free PSA), and human kallikrein 2 (hK2) [24, 25]. The algorithm combines these biomarker levels with the patient's age, DRE findings, and results of previous biopsies to estimate the probability of high-grade prostate cancer. Multiple studies have shown that, similar to the PHI test, the 4K

Score is more accurate in diagnosing prostate cancer particularly high-grade tumors compared to total PSA or percent free PSA [25].

## PHI

The Prostate Health Index (PHI) is an FDA-approved test that combines three blood-based PSA isoforms: [-2]proPSA (p2PSA), free PSA (fPSA), and total PSA (tPSA), to create a composite score that predicts the likelihood of prostate cancer based on biopsy results. This test is included in the NCCN guidelines. It is important that blood samples are centrifuged within 1–3 hours of collection, as the level of p2PSA increases significantly when blood is kept at room temperature after being drawn [25]. Recent studies indicate that the use of the PHI test can reduce the number of unnecessary prostate biopsies by up to 40%, and it also supports disease monitoring during active surveillance of prostate cancer [26].

### **3.4 Application of artificial intelligence in prostate cancer diagnosis**

#### 3.4.1 AI in image analysis

##### 3.4.1.1 AI in MRI image analysis

Artificial intelligence (AI) models are being used to assist clinical experts in the analysis of medical images across various fields, including the diagnosis of prostate and breast cancer. The application of AI in image interpretation can help meet the growing global demand for medical imaging services. However, the limited amount of scientific evidence supporting the effectiveness of these systems remains a barrier to their widespread implementation in prostate cancer diagnostics [27]. AI may play a key role in overcoming some of the limitations associated with the use of magnetic resonance imaging (MRI) in active surveillance (AS), for example by improving the evaluation process of follow-up MRI scans, reducing interobserver variability, and supporting image interpretation by individuals without specialized experience. Current studies are exploring AI techniques such as machine learning and deep learning to enhance AS. Machine learning classifiers primarily utilize clinical data and radiomic features from MRI scans taken at different time points. Radiomics refers to the extraction of quantitative texture measurements and patterns from MRI images that are not visible to the human eye. Deep learning methods enable automated learning to perform various diagnostic tasks using large, annotated datasets of medical images. Both radiomics and deep learning models have demonstrated high performance in the detection and evaluation of prostate cancer [28].

### 3.4.1.2 AI in ultrasound image analysis

The detection of prostate cancer in ultrasound images using artificial intelligence (AI) models remains limited, and the literature on the application of AI in grayscale ultrasonography is scarce. The development of AI-based approaches for prostate cancer diagnosis using ultrasound presents a significant research opportunity. Further studies are also needed to evaluate the generalizability of these methods, as most have been assessed on small patient cohorts using retrospective data from single institutions [29].

### 3.4.2 AI in biopsy result analysis

Pathomics is a field that utilizes artificial intelligence (AI) to analyze tissue samples, such as biopsy specimens, to identify prostate cancer at the molecular level. The Gleason score remains the strongest predictor of prognosis in prostate cancer. Machine learning (ML) systems offer the potential to reduce interobserver variability, improve diagnostic accuracy, and streamline the assessment process of prostate biopsies. Automated Gleason grading has the potential to provide more objective and consistent results, achieving performance comparable to that of pathologists, making it a reliable tool for screening or secondary verification. Clinically accurate AI systems can alleviate the workload of pathologists by screening benign biopsies and automating the measurement of tumor length in malignant ones. A significant concern regarding AI-based techniques is the potential risk of misclassification. Efforts to understand and reduce such errors are essential for improving AI algorithms [30].

## 4. Discussion

The diagnosis of prostate cancer is increasingly shifting from reliance on single conventional methods toward a multimodal approach that integrates laboratory testing, imaging, molecular biomarkers, and artificial intelligence. Although PSA remains a widely used and accessible tool, its limited specificity reduces its value as a standalone diagnostic marker, particularly because elevated levels may also occur in benign conditions and may contribute to overdiagnosis and overtreatment [7,10]. For this reason, current practice increasingly emphasizes individualized risk assessment and shared decision-making [8-10].

Among imaging techniques, mpMRI has become one of the most important advances in prostate cancer diagnostics. Its high negative predictive value and its ability to localize suspicious lesions have significantly improved the identification of clinically significant disease and reduced the number of unnecessary biopsies [16,17]. In parallel, MRI/TRUS fusion biopsy has improved sampling precision compared with systematic biopsy alone, especially in patients with previous negative biopsy results but persistent clinical suspicion of cancer [14,15]. PSMA PET also appears promising, particularly in selected cases with inconclusive MRI findings or contraindications to MRI, although its interpretation requires caution because PSMA uptake is not entirely specific to prostate cancer [19,20].

Molecular biomarkers such as PCA3, PHI, and 4Kscore further support risk stratification and may help reduce avoidable biopsy procedures, especially in diagnostically uncertain cases [21,23-26]. At the same time, artificial intelligence is emerging as a valuable supportive tool in MRI interpretation, ultrasound analysis, and histopathological assessment. AI may improve diagnostic consistency and reduce interobserver variability, but its broader implementation still requires validation in large and diverse clinical populations [27-30].

Overall, the evidence suggests that the greatest diagnostic benefit comes from combining conventional and modern tools rather than relying on any single method. Such an integrated approach may improve the detection of clinically significant prostate cancer while limiting unnecessary interventions and reducing the risk of overdiagnosis.

## **5. Conclusions**

Modern prostate cancer diagnosis increasingly relies on an integrated approach that combines traditional methods with advanced imaging, molecular biomarkers, and artificial intelligence. While PSA testing and biopsy remain essential, techniques such as mpMRI, MRI/TRUS fusion biopsy, and PSMA PET improve the detection of clinically significant disease and may reduce unnecessary procedures [7,8,14,16-20].

In parallel, biomarkers such as PCA3, PHI, and 4Kscore support risk stratification and clinical decision-making, especially in diagnostically uncertain cases [21-26]. AI-based tools also show growing potential in imaging and histopathological assessment, although further validation is needed before routine implementation [27-30].

Overall, combining conventional and modern diagnostic methods may improve diagnostic precision while reducing overdiagnosis and overtreatment. Further large-scale studies are needed to confirm the optimal role of these approaches in clinical practice.

## **Disclosure**

### **Author's contribution**

Conceptualization: P. Sosnowski ; methodology: K. Bakula ; software: I. M. Nowicka; check: P. R. Turek; formal analysis: E. Dybała; investigation: P. Sosnowski; resources: K. Bakula; data curation: P. R. Turek; writing-rough preparation: I. M. Nowicka; writing – review and editing: E. Dybała; visualization: P. Sosnowski; supervision: E. Dybała; project administration: K. Bakula

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The authors deny any conflict of interest.

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