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THE EVOLUTION OF PROSTATE CANCER DIAGNOSIS: FROM PALPATION TO ARTIFICIAL INTELLIGENCE

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Abstract

Being one of the most common types of cancer, prostate cancer requires a specific diagnostic approach, using modern, highly sensitive, and specific diagnostic methods. An analysis of existing methods will allow us to determine the most effective strategies for early detection and control of the disease.

The purpose of this study. To summarize existing data on the diagnostic algorithm for prostate cancer, identify the strengths and weaknesses of each of the procedures used, and evaluate the impact and effectiveness of modern diagnostic methods.

Methods and materials. Information was searched and analyzed in Google Scholar, PubMed, Elsevier, Web of Science, and Medline databases. The review includes data from meta-analyses, randomized controlled trials, systematic reviews, and clinical trials. Duplicate articles have been deleted, information verified, and irrelevant works excluded. As a result, 75 full-text documents and abstracts were selected, providing a comprehensive analysis of the problem under consideration.

Conclusion. Combined approaches increase the accuracy of pancreatic cancer diagnosis. PSMA-PET improves the detection of metastases, but remains expensive and difficult to access in developing countries. A liquid biopsy has potential, but requires improved sensitivity. Transrectal ultrasound examination remains an important tool, but its diagnostic value is limited. A magnetic resonance imaging-targeted biopsy reveals more clinically significant prostate cancer than a systematic biopsy. Artificial intelligence in diagnostics requires development, but its use should be regulated.

Keywords: *prostate cancer diagnosis, prostate cancer screening, prostate cancer biomarkers, digital rectal examination, early detection of prostate cancer.*

Introduction

Prostate cancer (hereinafter – PCa) is one of the most common cancers in the world, ranking as the second most common among men worldwide, with approximately 1,467,854 new cases in 2022, accounting for 7.3 % of all new cancer cases. In 2022, PCa caused about 397,430 deaths, making it a significant factor in cancer mortality among men [1]. PCa affects middle-aged men aged 45 to 60 years and is the leading cause of cancer mortality in Western countries [2]. Obesity, malnutrition, tobacco and alcohol use, family history, racial differences, and age are potential risk factors associated with PCa [3]. Uneven access to early diagnosis and treatment in low-income countries remains a serious problem, leading to worse disease outcomes [4]. Early diagnosis allows for a wider range of less invasive treatments and increases the likelihood of effective management. When detected at an early stage, the 5-year survival rate is nearly 100 %, and the 10-year survival rate is 99 % [5]. This indicator decreases significantly as the disease progresses to the late stages, where it can drop to 47.7 %, depending on the presence of metastasis and other factors. [6; 7]. PCa varies from indolent to aggressive forms. After diagnosis, staging is crucial for prognosis, treatment, and follow-up. Despite advancements, PSA testing and rectal examination remain key for screening, while multiparametric magnetic resonance imaging (mpMRI) plays a central role in local diagnosis,

particularly for targeted biopsy, though indications remain debated. Nuclear medicine and new radiopharmaceuticals (choline, 68Ga) have enhanced metastasis, lymph node, and relapse detection [8].

The review examines various methods of PCa diagnosis, including traditional approaches such as PSA, digital rectal examination (hereinafter – DRE), mpMRI, and prostate biopsy (hereinafter – PB), as well as new technologies like artificial intelligence (hereinafter – AI), genomic markers, and improved imaging techniques to enhance the accuracy of diagnosis and risk stratification.

The purpose of this study. To summarize existing data on the diagnostic algorithm for PCa, identify the strengths and weaknesses of each of the procedures used, and evaluate the impact and effectiveness of modern diagnostic methods.

Novelty. This study presents an original review and critical analysis of modern methods for diagnosing PCa from the radiologist's perspective. The work emphasizes the role of mpMRI in combination with new approaches, including machine learning, automated PI-RADS assessment, and the integration of positron emission tomography (hereinafter – PET). This enables well-founded recommendations for individualizing diagnostic strategies.

Methods and Materials

A comprehensive search for information was conducted in the databases Google Scholar, PubMed, Elsevier, Web of Science, and Medline for this literature review. Articles published between 2014 and 2024 were selected and reviewed; earlier studies were included due to their relevance.

The search was conducted using the following keywords: prostate cancer diagnosis, prostate cancer screening, prostate cancer biomarkers, digital rectal examination, early detection of prostate cancer, prostate-specific antigen, PB techniques, artificial intelligence in prostate cancer, and PSMA PET in prostate cancer. The following meta-analyses, reviews, randomized controlled trials, systematic reviews, and clinical trials were selected for analysis. Duplicate articles were deleted, data was checked, and irrelevant works were excluded, after which 75 full-text documents and abstracts were selected to provide complete information on the problem.

Results

History of prostate cancer diagnosis

PCa detection has evolved from basic to advanced methods. Until the 1970s, DRE was the primary tool, but its low sensitivity and specificity often led to late-stage detection [9]. In the 1990s, PSA testing became key in early PCa detection, but, like DRE, it lacks strict specificity. In the 1980s, a 4.0 ng/mL threshold was adopted without validation, thereby excluding biopsies at lower levels and fostering a mistaken belief in low PCa risk. This approach was later revised [10]. Transrectal ultrasound examination (hereinafter – TRUS) and a systematic biopsy have become the gold standard for PCa diagnosis. In the early 1990s, a systematic approach to PB, proposed by Hodge et al, became widespread [11]. The evolution of magnetic resonance imaging (hereinafter – MRI) since the 1980s has significantly enhanced PCa detection, providing detailed images to identify and characterize tumors. Recent developments include the use of biomarkers in urine and blood to enhance diagnostic accuracy and reduce the number of unnecessary biopsies. AI models, particularly Deep Learning, are continually evolving to aid in diagnosis, prediction, and support clinical decisions [9; 11; 12]. Research on the use of AI in the diagnosis of PCa is developing rapidly. AI can improve all stages of the standard diagnostic process, including histological image analysis, Gleason staging, mpMRI interpretation, and disease course prediction [9].

Prostate-specific antigen

PSA is a biomarker secreted by prostate epithelial cells, a normal component of ejaculate, and a precursor to adenocarcinoma. It is widely used for screening asymptomatic patients and detecting PCa [13]. Despite the debate about screening, in many countries, PSA and DRE tests are part of routine medical examinations for men, especially those over 50 or at higher risk [14]. The purpose of screening is to identify the disease at the stage of its natural development when treatment can be carried out to prevent death or negative consequences [13]. As a rule, PSA levels above 4.0 ng/mL are considered elevated and may lead to a recommendation for PB. The PSA test exhibits particularly high sensitivity at values exceeding 20 ng/mL. The use of free-to-total PSA (hereinafter – f/t PSA) indices, the ratio of PSA to prostate volume (hereinafter – PSAD), and the rate of increase in PSA (hereinafter – PSA V) increases its accuracy [15]. Since PSA levels increase with age, some doctors establish a higher threshold (e.g., 5 ng/mL) for older men and a lower threshold (e.g., 2.5 ng/mL) for younger men.

Oesterling et al. proposed taking age reference values into account to improve cancer detection rates in young men. They recommended the following thresholds: 2.5 ng/mL for men aged 40 years, 3.5 ng/mL for men aged 50 years, 4.5 ng/mL for men aged 60 years, and 6.5 ng/mL for men aged 70 years and older.

After establishing PCa, PSA levels are monitored to assess the effectiveness of treatment and detect any recurrence [16]. The PSA test helps diagnose prostate conditions like benign prostatic hyperplasia and prostatitis in men with urinary symptoms. Its widespread use in the USA and Europe remains controversial due to overdiagnosis, leading to mixed results in preventive screening programs [17,18], which led to an increase in the number of unnecessary biopsies, often revealed asymptomatic or clinically insignificant forms of cancer, which adversely affected the mental health of patients, causing anxiety and depression [19]. PSA has a relatively low specificity, as confirmed by recent research findings. In a research paper by Ehiremhen Ozah et al., the specificity index was 12.1%. A more effective result is obtained with a combination of DRE and PSA. Numerous studies have demonstrated that the combination of DRE and PSA has a higher diagnostic value for PCa. In this study, the sensitivity in combination was 91.7 %, and the specificity was 91.4 % [20]. These figures are confirmed by A.A. Abdrabo et al., who reported 100 % and 92 %, respectively [21]. Thus, when combined, these methods significantly exceed the results of individual methods.

The low accuracy of PSA led to the use of another indicator, PSA density, as a more reliable predictor of PCa. Calculated as PSA level divided by prostate volume, PSAD > 0.15 ng/mL² increases cancer risk and improves detection accuracy over PSA alone [22]. Seo Yeon Youn et al. found high consistency between ultrasound and MRI in measuring prostate volume. Both methods aligned well with the gold standard, though MRI tended to overestimate volume, while ultrasound underestimated it [23]. The prostate volume calculated from MRI data allows using PSAD as an effective parameter for assessing the risk of PCa before biopsy, especially in patients with negative or ambiguous MRI results. The likelihood of clinically significant PCa (csPCa) in the study by Shu Wang et al. It was low, at 4 % in patients with a negative MRI before biopsy and 6 % in patients with foci rated at 3 points on the PI-RADS scale (Likert scale). A biopsy may be less justified at PSAD below 0.10 ng/mL [24].

Puncture of the prostate gland

Initially, PB was performed using a biopsy needle when abnormalities were detected. While transrectal access remains common, transperineal biopsy is gaining popularity due to improved accuracy [25]. Systematic biopsy protocols, such as the sextant method, involve taking three samples from each prostate side and were effective for detecting TRUS-detected lesions [26]. However, the sextant protocol has a high false-negative rate, especially for apical and lateral lesions [27]. Transrectal extended biopsy (10-12 samples) increases sensitivity and is now the diagnostic standard, supplementing sextant biopsy with lateral zone samples. Transrectal saturated biopsy (20-30 samples) is used in cases of high cancer suspicion after negative biopsies, detecting 34 % of cases with two prior negative results. Transperineal template biopsy (50-70 samples) under anesthesia reduces missed diagnoses to 5 % compared to 30-40 % with transrectal biopsy, improving the detection of small lesions [28]. To optimize sampling, new biopsy schemes were developed, such as the Ginsberg's scheme for prostate biopsy (Figure 1) [29], which divides the prostate into three sectors per side, taking 24-32 samples for larger prostates, ensuring high detection rates. Biopsy analysis remains a key diagnostic method, as tissue samples are examined microscopically for the presence and spread of cancer. Results may be negative (no cancer), positive (cancer detected), or suspicious (abnormal but uncertain cells) [30].

Liquid biopsy (hereinafter – LB)

LB is an alternative to traditional biopsy, an innovative tool in the field of personalized medicine, for the minimally invasive diagnosis of clinically significant abnormalities in various types of cancer in real-time. LB allows isolating the circulating tumor DNA (hereinafter – ctDNA), circulating tumor cells (hereinafter – CTCs), and free circulating DNA (hereinafter – cfDNA) from blood samples and other biological fluids [31; 32]. The discovery of CTCs has drawn attention to liquid biopsy as a potential diagnostic tool for PCa. CTCs serve as both prognostic and predictive biomarkers, enabling the early detection of metastases and facilitating the monitoring of treatment. Recent studies have found 613 CTCs per 1.7 mL in PCa

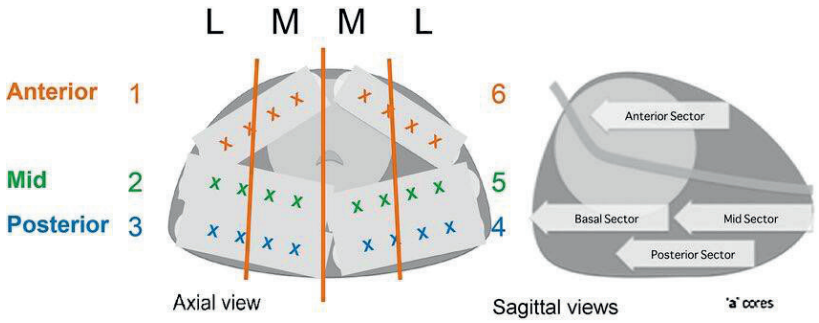

Figure 1. Ginsberg's scheme for prostate biopsy [29]

patients, compared to 6 CTCs per mL in healthy donors. The number of CTCs in seminal biopsies correlated with PSA levels, particularly in patients with metastatic castration-resistant PCa (hereinafter – mCRPC) [32]. LB shows promise but is limited by its low tumor content, specificity, and challenges in isolating biomarkers. However, it offers a potential minimally invasive alternative to tissue biopsy for real-time patient monitoring [31].

Biparametric and Multiparametric MRI

MRI is a valuable tool in the diagnosis and treatment of PCa. In diagnostics, it is preferable to use devices with a magnetic field strength of 3.0 T; 1.5 T is the minimum acceptable value. The study showed that the sensitivity of mpMRI ranged from 42 % to 100 %, and the specificity from 12 % to 100 % [33]. Another study found an mpMRI sensitivity of 86 % and a specificity of 99 % for detecting clinically significant PCa [34]. The PICTURE study showed that mmMRI helps to avoid repeat biopsies with high sensitivity to significant cancer. However, the choice of the assessment threshold affects the risk of missing aggressive tumors and overdiagnosis [35]. The PROMIS trial (2017) showed that mmMRI reduces unnecessary biopsies by 27 % and improves diagnostic accuracy. A quarter of men could have avoided a biopsy, and a negative mpMRI result indicates a low risk of clinically significant cancer. The method reduces the overdiagnosis of minor tumors and improves the detection of aggressive forms. However, in case of suspicious findings, a biopsy remains necessary [36]. Biparametric MRI (hereinafter – bpMRI) is a promising alternative to mpMRI for PCa diagnosis. Studies show that bpMRI is not inferior to mpMRI in detecting csPCa and provides comparable diagnostic accuracy. Among the advantages of bpMRI are reduced examination time and lower cost, as there is no need for dynamic contrast enhancement (hereinafter – DCE), which makes the method more accessible for clinical practice. However, the absence of DCE may reduce sensitivity in detecting small or less aggressive tumors. Additional studies are needed to confirm the effectiveness of bpMRI in various clinical patient groups. Thus, bpMRI is an economically and practically advantageous method that can be used in routine clinical practice without compromising diagnostic accuracy [37-39].

To assess the risk of clinically significant PCa, the Prostate Imaging Reporting and Data System (PI-RADS) standardizes the interpretation of mpMRI results. The system helps detect clinically significant PCa (Gleason ≥7, volume ≥0.5 mL, invasion). In the PI-RADS system, the assessment of the MR structure of the prostate gland is based on the classical classification of the zonal structure of the prostate, as described by J. E. McNeal [40]. The PI-RADS system standardized interpretation, allowing risk stratification and prediction of aggressiveness prior to biopsy. Clinical trials and national guidelines have confirmed its effectiveness. mmMRI also aids in staging and planning treatment, influencing the therapeutic tactics [41]. The current version of PI-RADS v2.1 has the following advantages: updated assessment criteria reduce the number of false-positive and false-negative cases, there is a clear gradation of foci and separation of prostate zones, as well as improved stratification of patients [42]. A study by Ö. Önder et al. We evaluated the long-term follow-up results of 1,359 patients after mp-MRI of the prostate gland and the prognostic value of PI-RADS. The greatest risk of csPCa was found with PI-RADS 5 (HR = 29.52) and PI-RADS 4 (HR = 14.46), as well as with high mPSAD (HR = 3.12), elderly age, and the absence of previous biopsies.

Survival without csPCa decreased with the growth of PIRADS: PI-RADS 1-2: 99.1 % (1 year), 96.5 % (3 years), 93.8 % (5 years). PIRADS 3: 94.9 %, 90.9 %, 89.1 %. PIRADS 4: 56.6 % at

all stages. PIRADS 5: 24.2 %. With PI-RADS 3, low mPSAD (< 0.15 ng/mL2) was associated with a lower risk of csPCa, whereas with PI-RADS 4-5, the probability of csPCa was high, requiring histological confirmation [43]. The ASIST study showed that MRI before biopsy reduces the failure rate of active surveillance (hereinafter – AS failure) by 50 % and slows down the progression of PCa. The prospective multicenter study involved 273 patients with GG1, divided into two groups: one underwent systematic biopsy, the other underwent MRI with systematic and targeted biopsy. After 2 years, AS failure was 35% in the group without MRI and 19 % in the group with MRI (p = 0.017), and clinically significant cancer (Grade Group ≥ 2) was detected in 23 % without MRI and 9.9 % with MRI (p = 0.048). Differences in AS failure among medical centers were noted only in the MRI group (p = 0.019). Thus, an MRI scan before a biopsy reduces the likelihood of failure to actively monitor and progress the disease; however, the effectiveness of this method may depend on the specific medical center. The study confirms the value of MRI in the strategy of active surveillance of patients with PCa [44]. The introduction of new techniques will expand the possibilities of MRI, reduce the need for invasive procedures, and accelerate the choice of treatment tactics [40]. A significant disadvantage of mmMRI is the variability of results due to the complexity of interpretation, the lack of uniform criteria, and the varying levels of qualification among radiologists [44].

Transrectal ultrasound examination

TRUS is widely used for the diagnosis and biopsy of PCa, but its sensitivity (~40-50 %) and specificity are limited, which often leads to the missed detection of tumors. TRUS is the gold standard for PCa biopsy [45]. The procedure lasts approximately 10 minutes, is performed under local anesthesia, and does not require expensive equipment, making it an affordable and cost-effective option. The ease of use and absence of radiation make it one of the most common methods of diagnosing PCa. [46] Modern methods, such as contrast-enhanced ultrasound (CEUS) and elastography, enhance diagnostic accuracy, with sensitivities of up to 90 % when using shear wave elastography [47; 48]. CEUS is an ultrasound method that involves the intravenous injection of gas–filled microbubbles to assess microvascular perfusion. Microbubbles (1-10 microns) penetrate capillaries, providing better visualization of microcirculation compared to spectral Doppler ultrasound, which captures only vessels larger than 1 mm. CEUS evaluates blood flow exclusively, without penetrating the surrounding tissues [49]. The MRI-TRUSE fusion biopsy combines the advantages of MRI accuracy and ultrasound accessibility, achieving a sensitivity of ~88 %. Increased efficiency is achieved by combining ultrasound with modern methods, such as CEUS and elastography, as elastography enhances cancer detection by 15 %. Currently, minimally invasive techniques are becoming increasingly important among the possible treatment options for localized PCa, one of which is high-intensity focused ultrasound ablation of the prostate (HIFU - High Intensity Focused Ultrasound) [31]. In HIFU, high-intensity ultrasonic energy is focused on a fixed target. Exposure of a large amount of energy to a focused area leads to cell destruction and coagulation necrosis by two mechanisms: heat exposure and cavitation [28]. These treatments show promising results, but their role requires further research, especially in comparison with mpMRI [47; 48].

Positron emission tomography CT and MRI

Despite various diagnostic methods, results remain uncertain in some patients. NCCN recommends 18F-flucyclovine PET-CT for biochemical recurrence after prostatectomy, while EAU prefers PSMA PET-CT, which is the most accurate for relapse, staging, and treatment planning. New tracers, including GRP-targeting agents and 18F-FDHT, show promise for castration-resistant PCa. A study conducted in 2022, which included 30 patients with suspected prostate cancer with PSA levels in the «gray zone» of 2-10 ng/mL and Pi-RADS 3 according to mpMRI, and were examined on PET CT with PSMA, showed a high sensitivity (86 %), specificity (100 %), diagnostic accuracy (86 %) and positive prognostic significance (100 %) of the method. The negative prognostic significance was 27 % [49; 50]. A prospective single-center study (UCLA, USA) compared PSMA PET-CT and 18F-flucyclovin PET-CT to detect biochemical recurrence of PCa with PSA levels <2.0 ng/mL in 50 patients. Recurrence rate: PSMA 56 % (28/50), 18F-flucyclovin 26 % (13/50), p=0.0026. In the pelvic lymph nodes: PSMA 30 % (15/50), 18F-flucyclovin 8 % (4/50), p=0.0034. Outside the pelvis: PSMA 16 % (8/50) vs 18F-flucyclovin 0 % (0/50), p=0.0078 [51-54]. The

criteria for recurrence of PCa after local therapy are determined by an increase in PSA >0.2 ng/mL after radical prostatectomy (RP) and >2 ng/mL above nadir after radiation therapy [55]. The introduction of PSMA-PET has significantly enhanced the detection of PCa recurrence. PSMA-PET is more sensitive at low PSA levels compared to PET with 11C-choline and CT. Additionally, MRI and biopsy are important follow-up procedures after radiation therapy.

mpMRI, which combines morphological and functional sequences (T1, T2, DWI, DCE), has become widely used over the past decade to detect clinically significant cancers and currently plays a key role in conducting targeted biopsies [56]. A systematic review and meta-analysis by Laura Evangelista et al. involving a total of 50 studies and 2,104 patients has shown that PET MRI is highly sensitive in detecting primary PCa. The cumulative sensitivity in the analysis of patients was 94.9 %, and the detection of relapses reached 80.9 %, especially when using radiolabeled PSMA ligands [57].

In a study by B. Grubmüller et al., PSMA PET MRI correctly detected PCa in 119 out of 122 patients (97.5 %). Eighty-one patients were treated with radical prostatectomy and pelvic lymphadenectomy. The stage T accuracy was 82.5 % (confidence interval [CI] 73-90; $P < 0.001$), for stage T2 – 85 % (95 % CI, 71-94; $P < 0.001$), for T3a – 79 % (95 % CI, 43-85; $P < 0.001$), for T3b – 94 % (95 % CI, 73-100; $P < 0.001$), and for stage N1 – 93 % (95 % CI, 84-98; $P < 0.001$). PSMA-PET/MRI altered treatment strategies in 28.7% of patients, resulting in the initiation of systemic therapy or radiation therapy (n = 16) or the selection of an active surveillance approach (n = 19) [58]. The MRI component of PET/MRI with 68Ga-PSMA-11 is particularly effective for detecting local relapses, especially at PSA levels below 1.69 ng/mL [59]. PET-MRI assesses local and regional spread, while PET-CT is superior for detecting distant bone and visceral metastases [59]. Despite the high cost, lengthy scans, and the need for qualified specialists, PET/MRI accurately detects tumors and metastases, facilitating personalized treatment. The development of technologies and the integration of AI can accelerate the implementation of the method and increase its effectiveness [60].

Biomarker-based diagnostics

The US National Cancer Institute defines biomarkers as molecules in blood, tissues, or fluids that indicate normal or pathological processes. They are classified as diagnostic, prognostic, or predictive, forming the basis of precision medicine [61]. PSA screening risks overdiagnosis and overtreatment, prompting the development of new biomarkers. TMPRSS2-ERG, PCA3, and kallikrein (FI, 4K) improve PSA accuracy and reduce unnecessary biopsies. Guidelines recommend them in conjunction with standard methods, with risk calculators aiding in personalized cancer assessment [62].

The Prostate Health Index (hereinafter – PHI) includes measurements of levels of -2propsa, percentage of free PSA (fPSA), and total PSA (tPSA). The values are combined using the formula (-2 proPSA/fPSA) × √tPSA [63]. The NCCN 2015 guidelines recommend using PHI for PCa early detection, but not as a primary test for all patients. PHI should be used before biopsy and when choosing treatment tactics [64]. A study conducted among 892 men without previously diagnosed PCa, with normal DRE results and PSA levels in the range of 2-10 ng/mL, showed that the PHI index with a value of 80 % provides 95 % sensitivity and significantly higher specificity (area under the curve (hereinafter – AUC) 0.703) compared with tPSA and %fPSA. This confirms that an increase in the PI index is associated with an increased risk of aggressive PCa and a positive biopsy [65].

The 4Kscore test is an enhanced blood test used to assess the risk of aggressive PCa. It combines four biomarkers (tPSA, fPSA, intact PSA (hereinafter – iPSA), and human kallikrein 2 (hereinafter – hK2)) within a patented algorithm, along with clinical factors such as treatment outcomes and patient age, to estimate risk from 0 % to 100 %. The test is designed to detect indolent tumors that do not require immediate intervention.

The primary validation of the 4Kscore test was conducted in 2008 on a cohort of 740 men from the Gothenburg segment of the European Randomized Study of Screening for Prostate Cancer (hereinafter – ERSPC). Men with a PSA level of 3 ng/mL or higher who had not previously undergone screening underwent a biopsy at six points. In combination with age, DRE results, and tPSA levels, the 4Kscore panel significantly improved the prognosis of high-grade PCa (Gleason score ≥7), increasing the AUC from 0.68 to 0.83, demonstrating its clinical usefulness. Further studies involving 740 people with similar PSA levels demonstrated

that incorporating a 4K panel into existing clinical factors increased the AUC for detecting high-grade PCa from 0.87 to 0.90, confirming the test's reliability under various conditions [65]. In a study of 531 men from Stockholm County with PSA levels between 3 and 15 ng/mL, 4Kscore and PHI tests were compared. 4Kscore and PHI showed similar accuracy in predicting PCa (AUC 69.0 and 71.8 for 4K, 70.4 and 71.1 for PHI). Both tests outperformed the model using PSA and age ($p < 0.0001$), but had no significant differences between them. With a 10 % risk threshold for high-grade cancer, biopsy was avoided in 29 % of cases, but diagnosis was delayed in 10 % of men with aggressive cancer. A limitation is the lack of data on rectal examination and biopsy decisions based solely on PSA [66].

PCA3 or DD3 is a prostate-specific mRNA biomarker that modifies the expression of the PCA3 gene in urine samples collected after DRE. Studies have shown that PCA3 levels are 10-100 times higher in 53 out of 56 prostate tissue samples compared to neighboring unchanged prostate tissue. PCA3 was absent in non-representative tissues, but was present in normal prostate tissue and benign prostatic hyperplasia (BPH) [64]. The Progensa PCA3 test, which detects PCA3 and PSA mRNA in urine samples, has predominant diagnostic potential. Combined data from 46 studies involving 12,295 individuals demonstrated encouraging sensitivity (0.65) and specificity (0.73) in detecting PCa, with an area under the curve of 0.75. Elevated PCA3 levels are associated with an increased risk of developing PCa and help identify patients who may require a biopsy [67; 68].

IsoPSA is a blood test that assesses PCa risk by detecting PSA structural isoforms using an aqueous two-phase system. A study by Eric A. Klein et al. (888 men, 2015-2020) across eight centers evaluated IsoPSA for diagnosing high-grade PCa (Gleason ≥7) and any PCa (Gleason ≥6) in men >50 years with PSA >4 ng/mL referred for biopsy. IsoPSA showed an AUC of 0.783 for high-grade PCa and 0.770 for any PCa, outperforming total and free PSA. It helped avoid 46 % of biopsies for high-grade cancer and 42 % for any PCa in low-risk patients. In another study (J.M. Scovell et al., 900 men with PSA > 4 ng/mL) [69], IsoPSA reduced biopsy recommendations by 55 % and MRI recommendations by 9 %, thereby lowering diagnostic invasiveness and patient stress [70]. Literature suggests that IsoPSA can be integrated into clinical practice considering insurance coverage, cost, MRI quality, and shared decision-making between doctors and patients [71].

The Mi-prostate score (hereinafter – MiPS) is a predictive algorithm that incorporates serum PSA levels and urine biomarkers, including PCA3 and TMPRSS2:ERG. MiPS has demonstrated the ability not only to detect the presence of PCa before biopsy, resulting in a 35-47% reduction in unnecessary biopsies, but also to predict high-severity PCa during biopsy, making it a valuable tool for assessing individual risk. MiPS has obvious disadvantages related to the availability of a high level of technical knowledge and platform capabilities for effective implementation. The algorithm highlights an important limitation related to the differences in the prevalence of the TMPRSS2: ERG gene fusion among various racial groups. Studies have shown significant differences: This fusion is present in 50 % of Caucasians, 31.3 % of African Americans, and 15.9 % of Japanese. The potential implications of this difference regarding the applicability of MiPS in patients from other countries remain uncertain and should be considered by healthcare providers [68; 72].

The Stockholm-3 (hereinafter – STHLM3) test combines PSA levels, protein biomarkers (tPSA, fPSA, iPSA, hK2, MIC1, MSMB), genetic markers, and clinical data to improve PCa risk assessment. It distinguishes aggressive from indolent forms and reduces unnecessary biopsies while maintaining accuracy. Initially validated in Sweden, its use is limited by high cost, complexity, and availability, which is currently restricted to Sweden. Integration into clinical guidelines is expected, especially for men with high PSA levels or genetic risk [73].

New biomarkers help reduce overdiagnosis, identify high-risk patients, and enable personalized treatment. However, ongoing clinical trials highlight the need for careful patient selection to ensure reliable data for their application [68].

Artificial intelligence

AI, particularly machine learning, plays a crucial role in overcoming the limitations of current PCa diagnostic methods. This technology enables the analysis of large amounts of data and the prediction of outcomes, facilitating more accurate and personalized diagnosis and treatment. Machine learning

is utilized to enhance diagnosis, prediction, and image analysis, such as MRI and CT scans, as well as to identify biomarkers, including lncRNA and miRNA, that aid in stratifying patients and determining treatment effectiveness. Algorithms have been developed that can analyze genetic data, assess the severity of the disease's aggressiveness, and predict its progression. The application of machine learning in clinical practice presents new opportunities for managing prostate cancer (PCa) data, thereby enhancing patient treatment [74]. Recent advances include AI models that detect cancerous tissue with greater accuracy than traditional methods. In the UCLA study, an AI tool detected PCa with an accuracy of 84 %, surpassing the doctors' accuracy of 67 % [75]. O. J. Pellicer-Valero et al. have presented a fully automated deep learning-based system for prostate mpMRI analysis, which utilizes the Retina U-Net algorithm to identify tumor foci, segment them, and predict the Gleason Scale group (hereinafter – GGG). Based on ProstateX and IVO test data, the system achieved an AUC of 0.96-0.95, a sensitivity of 1.00, and a specificity of 0.79-0.80 for GGG≥2, surpassing the IVO radiologist's PI-RADS accuracy. 4 (0,88/0,56) [76].

Discussion

Traditional PCa detection methods, including PSA testing and rectal examination, remain the primary methods in the early stages; however, their low specificity leads to overdiagnosis and unnecessary biopsies. TRUS is widely used, but its sensitivity is limited. A systematic biopsy is the «gold standard», but it has the risk of missing the tumor and false negative results. MRI-guided biopsy increases the detection of clinically significant PCa and reduces overdiagnosis, but requires high accuracy. mpMRI has improved tumor imaging, especially with PI-RADS; however, PI-RADS 3 remains diagnostically uncertain, requiring a combination with biomarkers (e.g., PSAD). PSMA-PET has become the new standard for the detection of relapses and metastases, surpassing PET with 11C-choline, especially at PSA <2 ng/mL, which calls into question the Phoenix criteria. LB, including CTCs and ctDNA analysis, is promising for noninvasive monitoring; however, it does not yet replace traditional biopsy. Modern 4Kscore, PHI, PCA3, and IsoPSA enhance risk stratification and reduce the number of unnecessary biopsies. AI is actively used for MRI analysis, histology, and forecasting, thereby increasing diagnostic accuracy, but it requires validation and standardization.

Conclusion

Combined approaches (mpMRI, biomarkers, AI, and PSMA-PET) enhance the accuracy of PCa diagnosis. PSMA-PET enhances metastasis detection but remains expensive and less accessible. LB is promising but requires improved sensitivity. TRUS retains diagnostic value but has limitations. MRI-targeted biopsy is more effective than systematic biopsy in detecting clinically significant PCa. AI in diagnostics needs further development and clear regulation. Despite advancements, high costs, a shortage of specialists, and limited accessibility remain barriers. The future of diagnostics lies in a personalized approach, AI integration, and improved availability of advanced technologies. Expanding patient access, especially for high-risk groups, and systematizing diagnostic strategies are crucial for more efficient early detection of PCa.

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ҚУЫҚ АСТЫ БЕЗІНІҢ ҚАТЕРЛІ ІСІГІН ДИАГНОСТИКАЛАУ ЭВОЛЮЦИЯСЫ: ПАЛЬПАЦИЯДАН ЖАСАНДЫ ИНТЕЛЛЕКТКЕ ДЕЙІН: ӘДЕБИ ШОЛУ

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Аңдатпа

Қатерлі ісіктің ең көп таралған түрлерінің бірі бола отырып, қуық асты безінің қатерлі ісігіуық асты безінің қатерлі ісігі заманауи, жоғары сезімтал және нақты диагностикалық әдістерді қолдана отырып, белгілі бір диагностикалық тәсілді қажет етеді. Қолданыстағы әдістерді талдау ауруды ерте анықтау мен бақылаудың ең тиімді стратегияларын анықтайды.

Зерттеудің мақсаты. Қуық асты безінің қатерлі ісігіндегі диагностикалық алгоритм туралы бар деректерді жалпылау, қолданылатын процедуралардың әрқайсысының күшті және әлсіз жақтарын анықтау, қазіргі диагностикалық әдістердің әсері мен тиімділігін бағалау.

Әдістер мен материалдар. Google Scholar, PubMed, Elsevier, Web of Science және Medline дерекқорларындағы ақпаратты іздеу және талдау. Шолуға Мета-анализдер, рандомизацияланған бақыланатын зерттеулер, жүйелі шолулар және клиникалық зерттеулер деректері кіреді. Қайталанатын мақалалар алынып тасталды, ақпарат тексерілді және маңызды емес жұмыстар алынып тасталды. Нәтижесінде қарастырылып отырған мәселе жан-жақты талдауды қамтамасыз ететін 75 толық мәтінді құжаттар мен дерексіз құжаттар таңдалды.

Зерттеу нәтижелері. Біріктірілген тәсілдер ұйқы безінің қатерлі ісігін диагностикалаудың дәлдігін арттырады. PSMA-pet метастаздарды анықтауды жақсартады, бірақ дамушы елдерде қымбат және қол жетімді емес. Сұйық биопсияның әлеуеті бар, бірақ сезімталдықты жақсартуды қажет етеді. Трансректальды ультрадыбыстық зерттеу маңызды құрал болып қала береді, бірақ оның диагностикалық мәні шектеулі. Магниттік-резонанстық мақсатты биопсия жүйелі биопсияға қарағанда клиникалық маңызды қатерлі ісікті анықтайды. Диагностикадағы жасанды интеллект дамуды қажет етеді, бірақ оны қолдану нақты реттелуі керек.

Түйін сөздер: *қуық асты безінің қатерлі ісігінің диагностикасы, қуық асты безінің қатерлі ісігінің скринингі, қуық асты безінің қатерлі ісігінің биомаркерлері, тік ішекті саусақпен тексеру, қуық асты безінің қатерлі ісігін ерте анықтау.*

ЭВОЛЮЦИЯ ДИАГНОСТИКИ РАКА ПРЕДСТАТЕЛЬНОЙ ЖЕЛЕЗЫ: ОТ ПАЛЬПАЦИИ ДО ИСКУССТВЕННОГО ИНТЕЛЛЕКТА

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Аннотация

Являясь одним из наиболее распространенных видов рака, рак предстательной железы требует к себе определенный диагностический подход, с применением современных, высокочувствительных и специфичных методов диагностики. Анализ существующих методов позволит определить наиболее эффективные стратегии для раннего выявления и контроля заболевания.

Цель исследования. Обобщение существующих данных о диагностическом алгоритме при раке предстательной железы, выявление сильных и слабых сторон каждой из применяемых процедур, оценить влияние и эффективность современных методов диагностики.

Методы и материалы. Проведен поиск и анализ информации в базах данных Google Scholar, PubMed, Elsevier, Web of Science и Medline. В обзор включены данные метаанализов, рандомизированных контролируемых исследований, систематических обзоров и клинических испытаний. Дубликаты статей были удалены, информация проверена, а нерелевантные работы исключены. В результате отобрано 75 полнотекстовых документов и абстрактов, обеспечивающих всесторонний анализ рассматриваемой проблемы.

Выводы. Комбинированные подходы повышают точность диагностики рака поджелудочной железы. PSMA-ПЭТ улучшает выявление метастазов, но остается дорогостоящим и труднодоступным в развивающихся странах. Жидкостная биопсия имеет потенциал, но требует улучшения чувствительности. Трансректальное ультразвуковое исследование остается важным инструментом, но его диагностическая ценность ограничена. Магнито-резонансная таргетная биопсия выявляет больше клинически значимого рака, чем систематическая биопсия. Искусственный интеллект в диагностике требует развития, но его применение должно быть четко регламентировано.

Ключевые слова: *диагностика рака предстательной железы, скрининг рака предстательной железы, биомаркеры рака предстательной железы, пальцевое ректальное исследование, раннее выявление рака предстательной железы.*

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