

## ORIGINAL ARTICLE

# Evaluating the clinical application of PAMD score in the assessment of TRUS-biopsy positive outcomes in patients with PSA 4-10 ng/ml treated in Serbia

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**Received:** 04 December 2022

**Revised:** 5 January 2023

**Accepted:** 10 February 2023



Check for updates

**Funding information:**

The authors received support from the Ministry of Education and Science of the Republic of Serbia (grant number 200110) and the Science Fund of the Republic of Serbia.

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**Competing interests:**

The authors have declared that no competing interests exist

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**Summary**

**Introduction:** Transrectal ultrasound-guided prostate biopsy (TRUS-biopsy) is the “gold standard” in the diagnosis of prostate cancer (PC). There is much divided opinion on the need for biopsy in patients with prostate-specific antigen (PSA) between 4 and 10 ng/ml. The positive biopsy outcome (PC) in these patients ranges from 20 to 39%. Low sensitivity and specificity of PSA in predicting positive biopsy outcome results in a large number of unnecessary biopsies and treatments. In order to better select candidates for biopsy, several risk stratification models for PC have been proposed in recent years, among them the PAMD score.

**Aim:** The aim of this study was to examine the value of the PAMD score in the assessment of positive biopsy outcomes in our population of patients, as well as to examine individual risk factors for PC in patients with PSA values between 4 and 10 ng/ml treated in Serbia.

**Material and methods:** The study involved 50 patients at the Clinic of Urology, University Clinical Centre of Serbia, whose PSA value were measured in the range from 4 to 10 ng/ml. In all the patients we measured PSA and %fPSA, and performed DRE, as well as magnetic resonance imaging (MRI) to evaluate prostate volume (PV) and PI-RADS score. All patients underwent TRUS-guided systemic prostate biopsy. In accordance with the data from literature, PAMD score was determined for all the patients.

**Results:** A PAMD score > 3 showed a high specificity in the prediction of PC, as well as an association with a higher frequency of high-grade PC. A positive finding on DRE, %fPSA < 16, age above 69 years and PI-RADS > 3 showed a statistically significant association with the existence of PC. A high individual predictive value in assessing the presence of PC was confirmed for DRE, %fPSA, PV, and PI-RADS score.

**Conclusion:** The PAMD scoring system may be of importance for better selection of candidates for TRUS-biopsy, in the population of patients with PSA values 4-10 ng/ml.

**Keywords:** prostate cancer, PSA, PAMD, risk factors.

## INTRODUCTION

Prostate cancer (PC) accounts for about 29% of all malignant tumors in men (1). Today PC is the 5<sup>th</sup> most common cause of cancer death after lung and colon cancer. 1.6 million of new cases of PC are diagnosed annually in worldwide (2). The frequency of new cases of PC is significantly higher in medium and highly developed countries compared to developing countries. The most important risk factors for PC are older age, obesity, smoking, lack of physical activity, sexually transmitted diseases and genetic predisposition (3). A significantly higher incidence of PC is recorded in African-American population (4).

Digital rectal examination (DRE), prostate specific antigen (PSA), ratio of free/total PSA (%fPSA), transrectal ultrasound-guided prostate biopsy (TRUS-biopsy) and pathophysiological (PH) verification are commonly used in diagnosing PC (5). Magnetic resonance imaging (MRI) has been increasingly important in diagnostics in recent years (6).

According to the recommendations of the European Association of Urology (EAU), the decision to perform a TRUS-biopsy is based on PSA values and DRE findings (7). A PSA value of 4 ng/ml is traditionally taken as the cut-off value where biopsy is indicated. However, there are divided opinions about the need for a biopsy in patients with PSA between 4 and 10 ng/ml, the so-called “gray zone” (8). The positive outcome of biopsy (PC) in these patients ranges from 20 to 39% (9). Low sensitivity and specificity of PSA in predicting a positive biopsy outcome in this population of patients results in a large number of unnecessary biopsies and treatments. Furthermore, lower predictive value in the PSA “gray zone” was also observed with other PSA-based indices, such as %fPSA and PSA density (9). %fPSA may be adversely affected by several pre-analytical and clinical factors (e.g., instability of fPSA, and variable assay characteristics). The biopsy procedure is not completely „benign“ either, with an increasing incidence of infections (3–5%) and the potential for serious complications requiring hospitalization (10).

In order to provide an optimal and personalized treatment for patients, in recent years research proposed several blood- and urine-based assays for detecting PC, most notably Prostate Health Index, 4Kscore, [PCA3](#), and Select Dx (11). For patients with PSA between 4 and 10 ng/ml, it has been suggested to implement risk stratification scoring systems predicting positive biopsy outcomes. Risk stratification model proposed by Fang et al., named PAMD implements ultrasound-determined prostate volume (PV), DRE findings, age and MRI results in assessing the positive outcome of TRUS-biopsy in patients with PSA in the “gray zone” (12).

The aim of this study was to assess individual risk factors for PC implemented in PAMD scoring system, and

frequency of PC in our population of patients with PSA between 4 and 10 ng/ml, as well as to examine the value of PAMD score in predicting positive biopsy outcomes in our patients.

## MATERIALS AND METHODS

In our study there were 50 patients, treated at the Clinic of Urology, University Clinical Centre of Serbia, from January 2020 to March 2021, whose initial PSA values were in the range from 4 to 10 ng/ml. The patients were admitted for further diagnosis and treatment due to elevated PSA values and/or suspicious findings on DRE. Data were collected only from the patients in whom a TRUS-biopsy and PH verification of results were ultimately performed.

Age information was recorded for all the patients. PSA values and %fPSA were determined before performing DRE. DRE was performed in each patient, and the findings were marked as positive (palpatorily present area of hardness, nodule, or consistency differences between the lobes of the prostate) or negative. Prostate dimensions were determined using MRI (1.5T), and prostate volume (PV) was calculated using the following formula (height x width x length x 0.52) and expressed in grams.

MRI scans were used to determine a Prostate Imaging-Reporting and Data System (PI-RADS) score ranging from 1-5. All results, in accordance with the data from literature (13), were divided into two groups, positive results (PI-RADS = 4-5) and negative results (PI-RADS < 3). All images were evaluated by an experienced radiology specialist.

In all patients, TRUS-guided biopsy of the prostate was performed, at least 12 samples were taken per patient, according to the zonal distribution of the prostate tissue. All PH samples were evaluated by a pathology specialist. According to the data from literature, PCs with a Gleason score > 7 were designated as high-grade PCs (14).

## STATISTICAL ANALYSIS

The normality of distribution of continuous numerical data was tested with the Kolmogorov-Smirnov test and their values were expressed as the arithmetic mean  $\pm$  standard deviation. The significance of the difference between two independent groups of continuous numerical variables was analyzed by Student's t-test. Categorical variables were analyzed using Pearson's chi-square test. A p-value below 0.05 was considered a statistically significant difference. Receiver operating characteristic (ROC) curves were generated to illustrate the predictive value of various parameters and to calculate the area under the curve (AUC).

Statistical analysis of the data was performed using the SPSS 17.0 program (Statistical Package for Social Sciences, SPSS incorporation Chicago, USA).

**Table 1.** Clinical characteristics of the examined patients.

Parameter	Prostate cancer		p
	Yes	No	
PSA (ng/ml)	7.54± 1.47	6.05± 1.46	0.221
%fPSA	0.11 ± 0.03	0.156 ± 0.02	<b>0.001*</b>
Age	69.31± 3.85	68.23 ± 3.10	0.262
PV (g)	39.96± 8.34	54.57 ± 9.74	<b>0.001*</b>
MRI	Positive (30) Negative (5)	Positive (2) Negative (13)	
DRE	Positive (28) Negative (7)	Positive (1) Negative (14)	

PSA - Prostate specific antigen; PV - Prostate volume;  
MRI - Nuclear magnetic resonance imaging (positive = PI-RADS (4,5), negative = PI-RADS (0-3)); DRE - Digital rectal exam;  
The significance of the difference in numerical variables was analyzed by Student's t-test.

## RESULTS

50 patients participated in the study, the average age of the examined patients was  $68.8 \pm 3.66$  years, the youngest patient was 62 and the oldest was 76 years old. The average PSA values were  $6.79 \pm 1.54$  ng/ml. PC was found in 35 out of 50 patients after TRUS-biopsy and PH verification. High-grade PC was HP verified in 26 patients. A statistically significant difference ( $p < 0.05$ ) was found

in %fPSA and PV between patients with PC and patients with a negative biopsy. There was no statistically significant difference ( $p > 0.05$ ) in PSA values in these two groups (**Table 1**).

Age above 69, positive DRE, %fPSA under 16 and positive MRI findings showed a statistically significant association with a positive biopsy outcome in our population ( $p < 0.05$ ) (**Table 2**).

ROC curves and AUC value showed that positive DRE (AUC = 0.937), %fPSA (AUC = 0.937), positive MRI finding (PI-RADS = 4-5) (AUC = 0.93) and PV (AUC = 0,87) have a high individual predictive value in assessing a positive biopsy outcome in patients with PSA 4-10 ng/ml. Lower predictive value of the PSA (AUC = 0.75) and the patient's age in the evaluation of the risk for PC (AUC = 0.57) was found.

## PAMD - model for risk stratification

In accordance with the data from literature (12), we applied the risk stratification model proposed by Fang et al. to our population of patients with PSA values from 4-10 ng/ml. Each risk factor was scored as follows: PV > 50 mL = 0 points, PV ≤ 50 mL = 2 points; age ≤ 69 = 0 points, age > 69 = 2 points; negative MRI finding = 0 points, positive MRI finding = 2 points; negative DRE = 0 points, positive

**Table 2.** Analyzed variables in patients with and without prostate cancer.

	Prostate cancer			p	$\chi^2$
	Total	Yes	No		
Patients	50	35	15		
PSA ( $7.21 \pm 1.54$ ng/ml)					
> 7 ng/ml	26	23	3	3.51	3.52
≤ 7 ng/ml	24	11	13		
%fPSA ( $0.123 \pm 0.03$ )					
< 0.16	41	33	8	<b>0.005*</b>	-7.87
≥ 0.16	9	4	5		
Age ( $69.8 \pm 3.66$ )					
> 69	22	19	3	<b>0.001*</b>	10.81
≤ 69	28	6	22		
MRI					
Positive (PI-RADS = 4-5)	30	30	0	<b>0.001*</b>	17.23
Negative (PI-RADS ≤ 3)	20	5	15		
PV ( $46 \pm 10.21$ g)					
≤ 50 g	35	29	6	0.13	-2.33
> 50 g	15	9	6		
DRE					
Positive	28	28	0	<b>0.001*</b>	10.80
Negative	22	7	15		

PSA - Prostate specific antigen; PV - Prostate volume;  
MRI - Nuclear magnetic resonance imaging (positive = PI-RADS (4,5), negative = PI-RADS (0-3)); DRE - Digital rectal exam;  
Statistical significance was determined using the Pearson chi-square test.

**Table 3.** PAMD model for risk stratification proposed by Fang et al.

	Prostate cancer			P	$\chi^2$	High-grade prostate cancer		p	$\chi^2$	
	Total	Yes	No			Yes	No			
Patients	50	35	15			26	24			
PAMD	Low (0-1)	6	2	4	<b>0.0007*</b>	14.43	0	6	<b>0.0001*</b>	18.22
	Medium (2-3)	14	3	11			0	14		
	High (4-7)	30	30	0			26	4		

DRE = 1 point. The PAMD score is defined as the sum of the individual scores. In relation to the PAMD score, all patients are divided into three risk groups: low (0-1), medium (2-3) and high (4-7). There was statistically significant difference in biopsy outcomes between these three groups ( $p < 0.05$ ). PAMD score values  $>3$ , were associated with statistically significant higher number of positive biopsy outcomes, as well as with high-grade PC (Table 3).

Statistical significance was determined using the Pearson chi-square test.

High specificity (AUC = 0.85) of the PAMD score (cut off value = 3) in assessing a positive biopsy outcome was observed.

## DISCUSSION

TRUS-biopsies of the prostate in all patients with PSA values above 4 ng/ml are accompanied by a high rate of negative findings, while at the same time they represent a significant economic burden for a healthcare system. (15) The rate of negative biopsy findings is particularly high in the population of patients with PSA values between 4-10 ng/ml, various studies report rates between 30 and 70% (12). In our examined population, a negative biopsy result was found in 30% of patients, and a smaller number of patients compared to similar studies is a possible cause.

Age is one of the first well-studied risk factors for the development of PC. A large number of epidemiological studies have shown that the incidence of PC and mortality from PC increases with age (16). Recent studies have shown that age is an independent risk factor for the development of high-grade PC. This is explained by a lower screening rate, especially in the population of patients older than 75 years, which leads to late diagnosis, but changes in tumor biology in older people have also been demonstrated (17). The average age of the analyzed patients in our study was  $68.8 \pm 3.66$  years, statistically significant association between the patients's age and the positive biopsy outcome was observed, which is in accordance with the results of similar studies (17).

PSA exists in several forms in the serum, and is predominantly bound to plasma proteins, however one form of PSA, free PSA, is not bound to proteins. Free PSA is produced as a product of proteolysis of the PSA molecule in normal prostate tissue (18). Increased PSA release and decreased proteolytic activity result in a lower percentage of free PSA in patients with PC compared to patients with

a normal prostate or benign changes (19). A large number of studies have shown a good predictive value of the %fPSA in assessing the outcome of biopsy (19). However, the differences of %fPSA ratio were not significant between PCa and non-PCa group in some studies. The inconsistent results of %fPSA among studies may be caused by the unstable fPSA in serum (20). Bachour et al. proposed using ratio of serum human kallikrein-2 with fPSA, which gave significantly larger area under the curve (0.96 vs 0.41) in comparison with %fPSA, suggesting higher specificity (21). In its recommendations, the EAU still advises a routine determination of the %fPSAs as a part of screening for PC (7). The results of our study showed a statistically significant difference between %fPSA values between patients with positive and negative biopsy results. Catalona et al. suggested using %fPSA ratio  $\leq 15$ , which would detect all advanced, non-organ confined, and large volume tumors, while avoiding 80% of biopsies in men with insignificant disease particularly in the intermediate range of total PSA (4.1–10 ng/mL) (22). Other investigators have recommended cutoffs of 18–27% (23). In our study we tested cut-off value of %fPSA  $< 16$ , which is proposed by Fang et al. as a part of PAMD scoring system (12). High predictive value of %fPSA  $< 16$  in detecting PC was observed.

The role of MRI in the early detection of PC has been in the research focus in recent years (24). Various studies have shown a high predictive value of MRI imaging and PI-RADS score in the selection of candidates for prostate biopsy (25). Perdona et al. showed that MRI results have the highest single predictive value for positive biopsy outcome in the population of patients with PSA 4-10 ng/ml (26). This is consistent with the results of our study, and indicates the importance of MRI imaging and PI-RADS score in screening for PC. The PI-RADS v2.1 scoring criteria differ according to the location of the lesion. In a recent study, PI-RADS v2.1 score had the best performance among the probable single predictive factors for PC in the population with PSA 4-10 ng/ml (27).

In order to better select candidates for biopsy, a large number of scoring systems have been developed. Two of the more popular scoring systems that have been validated are the Prostate Cancer Prevention Trial Risk Calculator 2.0 (PCPT RC) and the newer Prostate Biopsy Collaborative Group (PBCG) Risk Calculator (28). Jethwani et al. proposed implementing neutrophil-to-lymphocyte ratio in scoring systems in order to improve specificity in predicting PC (29).



Fang et al. developed a PAMD scoring system for patients with PSA 4-10 ng/ml implementing parameters usually taken while doing standard workup of patients with possible PC, including age, PV, findings on MRI and DRE (12), making it well-suited for implementation in our health-care system due to low cost and accessibility. With a cut-off value of 3, the results of our study showed a high specificity of the PAMD score in evaluating a positive outcome of TRUS-biopsy in our population of patients. Studies on a larger number of subjects are necessary to determine the optimal cut-off value. Higher values of the PAMD score showed a statistically signif-

icant association with high-grade PC, these data are in accordance with the data of Fang et al. (12).

## Conclusion

The prevalence of PC in the examined population of patients with PSA 4-10 ng/ml was 70%. PAMD score showed high specificity in assessing positive biopsy outcomes in our population of patients with PSA 4-10 ng/ml. The PAMD scoring system requires further testing on a larger sample of patients, and in future it could be used to better select candidates for prostate biopsy.

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## EVALUACIJA KLINIČKE PRIMENE PAMD SKORA U PROCENI POZITIVNOG ISHODATRUS-BIOPSIJE PROSTATE KOD PACIJENATA SA PSA 4-10 NG/ML LEČENIH U SRBIJI

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### Sažetak

**Uvod:** Transrektalna ultrazvučno vođena biopsija prostate (TRUS-biopsija) predstavlja „zlatni standard“ u dijagnostici karcinoma prostate (KP). Postoje podjeljena mišljenja o potrebi za biopsijom kod pacijenata sa vrednostima prostate specifičnog antigena (PSA) između 4-10 ng/ml. Pozitivan ishod biopsije (KP) kod ovih pacijenata kreće se u rasponu između 20 i 39%. Niska senzitivnost i specifičnost PSA u predikciji pozitivnog ishoda biopsije rezultuje velikim brojem nepotrebnih biopsija i tretmana. U cilju što bolje selekcije kandidata za biopsiju, poslednjih godina predloženo je nekoliko modela stratifikacije rizika za KP, među njima je i PAMD skor.

**Cilj rada:** Cilj ovog rada je bio da se ispita vrednost PAMD skora u proceni pozitivnog ishoda biopsije u našoj populaciji pacijenata, kao i da se ispituju pojedinačni faktori rizika za pozitivan ishod biopsije kod pacijenata sa vrednostima PSA između 4 i 10 ng/ml.

**Materijal i metode:** U studiji je učestvovalo 50 pacijenata, lečenih na Klinici za urologiju, Univerzitetskog kliničkog centra Srbije kod kojih je izmerena vrednost PSA u opsegu od 4 do 10 ng/ml. Svim pacijentima određene su vrednosti PSA, indeksa PSA (%fPSA), urađen je DRE, kao i snimanje nuklearnom magnetnom rezonancom (MRI) u cilju evaluacije volumena prostate (PV) i *PI-RADS* skora. Kod svih pacijenata urađena je TRUS-vođena sistemska biopsija prostate. U skladu sa podacima iz literature svim pacijentima određen je PAMD skor.

**Rezultati:** PAMD skor > 3 pokazao je visoku specifičnost u predikciji KP, kao i povezanost sa višom učestalošću KP visokog gradusa. Pozitivan nalaz na DRE, %fPSA < 16, starost veća od 69 godina i *PI-RADS* > 3 pokazali su statistički značajnu povezanost sa postojanjem KP. Visoka individualna prediktivna vrednost u proceni postojanja KP potvrđena je za DRE, %fPSA, PV i *PI-RADS* skor.

**Zaključak:** PAMD scoring sistem može biti od značaja u boljoj selekciji kandidata za TRUS-biopsiju, u populaciji pacijenta sa vrednostima PSA 4-10 ng/ml.

**Ključne reči:** karcinom prostate, PSA, PAMD, faktori rizika.

**Primljen:** 04.12.2022. | **Revizija:** 05.01.2023. | **Objavljen:** 10.02. 2023

**Medicinska istraživanja 2023; 56(1):15-20**