ORIGINAL ARTICLE

Factors Related to Prostate Cancer Detection after Initial TRUS Biopsy in Lerdsin Hospital

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Objective: The primary objective was to identify clinical factors associated with prostate cancer detection following an initial transrectal ultrasound-guided (TRUS) biopsy. The secondary objective was to evaluate the diagnostic accuracy of prostate-specific antigen (PSA) and PSA density (PSAD).

Materials and Methods: A retrospective study was conducted on patients who underwent their first TRUS prostate biopsy at Lerdsin Hospital between 2018 and 2022. Clinical data collected included age, body mass index (BMI), PSA level, prostate volume, digital rectal examination (DRE) findings, and PSAD. Univariate and multivariate logistic regression analyses were performed to identify independent factors associated with prostate cancer detection. Receiver operating characteristic (ROC) curve analysis was used to assess the diagnostic performance of PSA and PSAD, including their sensitivity, specificity, and optimal cut-off values. A p-value of less than 0.05 was considered statistically significant.

Results: Of 267 patients, 200 were analyzed, and prostate cancer was detected in 32%. Multivariate analysis identified prostate nodule (adjusted OR 5.34), PSA (adjusted OR 1.02), prostate volume (adjusted OR 0.97), and PSAD (adjusted OR 4.67) as significant predictors ($p<0.05$). ROC analysis demonstrated higher diagnostic accuracy for PSAD with an AUC of 0.883 and a cut-off of 0.225 ng/mL^2 compared with PSA with an AUC of 0.798 and a cut-off of 13 ng/mL.

Conclusion: PSA, prostate nodule, prostate volume, and PSAD were independent predictors of prostate cancer detection after initial TRUS biopsy. Among these, PSAD showed the highest diagnostic performance and may serve as a useful parameter for guiding biopsy decisions.

Keywords: Prostate cancer; Factors related prostate cancer; TRUS biopsy; PSA; Prostate nodule; Prostate volume; TRUS predictive model; PSAD

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Prostate cancer (PCa) is the most common malignancy among men worldwide and the second leading cause of cancer-related death in males in the United States[1]. In Thailand, the incidence is rising rapidly, ranking PCa as the fourth most common cancer among men[2].

Prostate-specific antigen (PSA) remains the most widely used biomarker for PCa screening since its introduction into clinical practice in the 1980s[3,4]. Although PSA testing has improved cancer detection rates, it lacks specificity and contributes to overdiagnosis. According to the National Comprehensive Cancer Network (NCCN) Guidelines, the probability of detecting PCa increases with PSA levels, at 10% for PSA 3 to 4 ng/mL, 33% for 4 to 10 ng/mL, and 67% for more than 10 ng/mL[5]. To improve diagnostic accuracy, additional tools such as PSA density (PSAD), PSA velocity, PCA3, and the Prostate Health Index (PHI) have been developed. However, their use remains limited due to variable accuracy, high cost, and lack of availability in many regions.

Prostate biopsy remains the gold standard for diagnosis, but it carries procedural risks such as hematuria, hemospermia, urinary tract infection, sepsis, and, in severe cases, septic shock. Magnetic resonance imaging (MRI) with the Prostate Imaging-Reporting and Data System (PI-RADS) has improved pre-biopsy risk stratification[6], yet its accessibility in Thailand remains limited.

Studies[7-10] have developed nomograms incorporating parameters such as age, total PSA, prostate volume, free-to-total PSA ratio, and PSAD to predict PCa risk. However, the predictive value of these factors varies across populations due to

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differences in genetic background and healthcare accessibility. Moreover, the complexity of these models limits their practical application in routine clinical settings. In Thailand, these nomograms are not widely utilized, and PSA testing remains the primary screening tool for PCa detection.

The present study aimed to identify factors associated with PCa detection following an initial transrectal ultrasound-guided (TRUS) biopsy in patients with PSA levels greater than 4 ng/mL and to evaluate the diagnostic performance of PSA and PSAD by determining their sensitivity and specificity for PCa detection.

Materials and Methods

Study design and patient population

The present study was a retrospective study conducted at Lerdsin Hospital between January 2017 and December 2022. Eligible participants were men with a PSA level greater than 4.0 ng/mL who underwent their first TRUS prostate biopsy during this period. Exclusion criteria included elevated PSA levels following recent sexual intercourse, acute prostatitis, any urological procedure performed within the previous month, a history of other malignancies, and a prior TRUS biopsy. Prostate volume was measured using TRUS or prostate MRI. TRUS biopsies were performed with a General Electric (BK Medical) ultrasound system using a 6-MHz transrectal probe. Each biopsy included 10 to 16 cores per patient, depending on the physician's discretion, following sextant or extended biopsy protocols. Collected clinical variables included age, body mass index (BMI), PSA, presence of lower urinary tract symptoms (LUTS), history of acute urinary retention (AUR), findings from digital rectal examination (DRE), presence of prostate nodules, prostate volume from TRUS or MRI, and PSAD, calculated as PSA divided by prostate volume (mL^3).

Statistical analysis

The sample size was calculated using the formula: N = 50 + 8m where m represents the number of predictors, as recommended for studies involving multiple factors associated with PCa[11]. Statistical analyses were performed using Stata Statistical Software, version 18 (StataCorp LLC, College Station, TX, USA). Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate. Categorical variables were summarized as frequencies and percentages. Group comparisons were performed using the independent t-test or Mann-Whitney U test for continuous data and the chi-square or Fisher's exact test for categorical data. A p-value of less than 0.05 was considered statistically significant. Receiver operating characteristic (ROC) curve analysis was used to determine optimal cut-off values for PSA and PSAD, based on the Liu, Youden, and nearest-to-(0,1) index methods.

Ethics approval

The present study was approved by Ethics Committee of Lerdsin Hospital, LH651043.

Results

Two hundred sixty-seven patients underwent TRUS biopsy between January 2018 and December 2022. Of these, 200 were included in the analysis. Sixty-two were excluded due to a history of prior biopsy and five due to other malignancies. Some variables contained missing data owing to the retrospective nature of the study; however, the available data was sufficient to identify significant factors. The mean age of the patients was 70 years (SD 7.1), and the mean BMI was 24.3 kg/m^2 (SD 4.3). The median serum PSA level was 12.1 ng/mL, mean prostate volume 55.60 mL, and median PSAD of 0.229 ng/mL^2. Among all participants, 39.3% had PSA levels between 4 and 10 ng/mL, 34.2% between 10.1 and 20 ng/mL, and 26.5% greater than 20 ng/mL. The overall PCa detection rate from the initial TRUS biopsy was 32% (64 out of 200 cases). Clinical findings showed that 21.9% of patients had abnormal DRE results and 14.0% had a palpable prostate nodule. LUTS were reported in 30.4% of patients, and a history of AUR was present in 8.5% (Table 1). Univariate analysis identified age younger than 75 years, abnormal DRE findings, presence of a prostate nodule, PSA level, PSAD, and prostate volume as factors significantly associated with PCa detection ($p<0.05$) (Table 2). In multivariate analysis, only PSA level, prostate volume, and PSAD remained statistically significant ($p<0.05$) (Table 3). Because of the strong correlation between PSA, prostate volume, and PSAD, these variables were analyzed separately in the multivariate model.

ROC curve analysis demonstrated that the area under the curve (AUC) for PSA was 0.798 (Figure 1) and for PSAD was 0.883 (Table 4). The optimal cut-off values were 13 ng/mL for PSA, with a sensitivity of 75%, a specificity of 69%, and an AUC of 0.73, based on the nearest-to-(0,1) index method, and 0.225 ng/mL^2 for PSAD with a sensitivity of 96%, a

Table 1. Decriptive data of TRUS biopsy and patients variable

Variables	Total	TRUS biopsy n (%)		Adjusted OR	95% CI		p-value
		Negative	Positive		Lower	Upper	
BMI (kg/m^2)	173	117	56	0.945	0.871	1.025	0.174*
Mean±SD	24.319±4.270	24.626±4.193	23.678±4.396				
Age (years)	200	136	64	1.073	1.026	1.122	0.002*
Mean±SD	70.855±7.080	69.772±6.413	73.156±7.893				
LUTS	191	130	61				
No		36 (64.3)	20 (35.7)	Ref.			
Yes		94 (69.6)	41 (30.4)	0.785	0.406	1.516	0.471
DRE	151	110	41				
Normal		93 (78.2)	26 (21.8)	Ref.			
Abnormal		17 (53.1)	15 (46.9)	3.156	1.391	7.160	0.006*
Prostate nodule	150	109	41				
No		102 (77.3)	30 (22.7)	Ref.			
Yes		7 (38.9)	11 (61.1)	5.343	1.905	14.986	0.001*
PSA (ng/mL)	193	134	59	1.016	1.005	1.027	0.004*
Median (IQR$_{25}$, IQR$_{75}$)	12.1 (8.3, 21.41)	9.875 (7.83, 14.78)	26.99 (13, 61)				
PSAD (ng/mL^2)	169	115	54	4.667	2.036	10.700	<0.001*
Median (IQR$_{25}$, IQR$_{75}$)	0.223 (0.157, 0.468)	0.174 (0.136, 0.264)	0.708 (0.294, 1.558)				
Prostate volume (mL)	171	116	55	0.969	0.953	0.985	<0.001*
Mean±SD	55.600±26.752	61.045±27.047	44.116±22.297				

TRUS=transrectal ultrasound; OR=odds ratio; CI=confidence interval; BMI=body mass index; LUTS=lower urinary tract symptoms; DRE=digital rectal examination; PSA=prostate specific antigen; PSAD=PSA density; SD=standard deviation; IQR=interquartile range

* Significant, p<0.05

Table 2. Multivariate logistic regression analysis of TRUS biopsy†

Variables	Adjusted OR	95% CI		p-value
		Lower	Upper	
Age (years)	1.063	0.981	1.152	0.136
DRE				
Normal	Ref.			
Abnormal	0.807	0.144	4.525	0.807
Nodule				
No	Ref.			
Yes	5.355	0.685	41.836	0.110
PSA (ng/mL)	1.078	1.038	1.119	<0.001*
Prostate volume (mL)	0.942	0.912	0.973	<0.001*

Variable	Adjusted OR	95% CI		p-value
		Lower	Upper	
Age (year)	1.043	0.965	1.128	0.290
DRE				
Normal	Ref.			
Abnormal	1.042	0.152	7.163	0.967
Nodule				
No	Ref.			
Yes	3.338	0.400	27.842	0.265
PSAD (ng/mL^2)	75.936	8.878	649.498	<0.001*

OR=odds ratio; CI=confidence interval; DRE=digital rectal examination; PSA=prostate specific antigen; PSAD=PSA density

† Because of the strong correlation between PSA, prostate volume, and PSAD, the multivariate analysis was performed separately for these variables

* Significant, p<0.05

specificity of 70%, and an AUC of 0.83, determined using the Liu method.

Discussion

PSA has long been used for PCa screening. However, it has low specificity for detecting the disease. A recent meta-analysis[12] reported that the sensitivity of PSA was 0.93 (95% CI 0.88 to 0.96), while its specificity was only 0.20 (95% CI 0.12 to 0.33). The area under the hierarchical summary receiver operating characteristic (HSROC) curve was 0.72 (95% CI 0.68 to 0.76). Due to this low specificity, PSA screening has led to a high number of unnecessary biopsies over time. Random or MRI-fusion biopsies are invasive procedures with potential complications, some of which can be severe or even life-threatening.

Studies[7-10] have therefore aimed to develop

Table 3. Subgroup analysis between PSA, prostate volume, and PSAD

Variables	TRUS biopsy		Adjusted OR	95% CI		p-value
	Negative	Positive		Lower	Upper	
PSA (ng/mL); n (%)	n=134	n=62				
4 to 10	68 (88.3)	9 (11.7)	Ref.			
10.1 to 20	50 (74.6)	17 (25.4)	2.569	1.058	6.235	0.037*
>20	16 (30.8)	36 (69.2)	17.000	6.835	42.280	<0.001*
Prostate volume (mL); n (%)	n=116	n=58				
<30	12 (41.4)	17 (58.6)	5.171	2.125	12.582	<0.001*
30 to 50	31 (59.6)	21 (40.4)	2.473	1.177	5.196	0.017*
>50	73 (78.5)	20 (21.5)	Ref.			
PSAD (ng/mL/cc); mean±SD	0.691±1.509		4.680	2.049	10.688	<0.001*

TRUS=transrectal ultrasound; OR=odds ratio; CI=confidence interval; PSA=prostate specific antigen; PSAD=PSA density; SD=standard deviation
* Significant, p<0.05

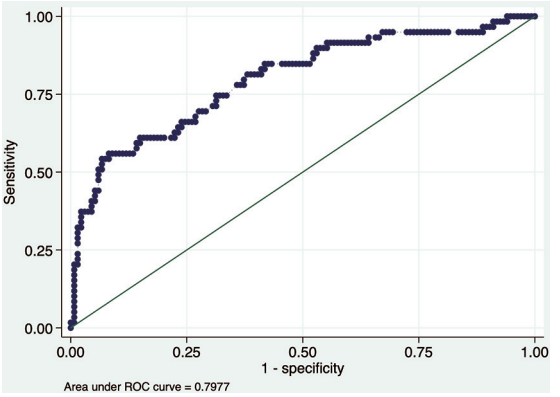

Figure 1. PSA with Area under ROC curve.

predictive nomograms to reduce unnecessary TRUS biopsies. In 2003, Garzotto et al.[13] developed a nomogram for patients with PSA of 10 ng/mL or less, using DRE, age, TRUS findings, and PSAD. This model achieved an AUC of 0.73 compared with 0.62 for PSA alone. However, its application was limited by complexity, reliance on TRUS interpretation, and restriction to a narrow patient group. In 2016, Lee et al.[9] proposed another model incorporating PSA, prostate volume, and DRE, yielding an AUC of 0.737 versus 0.642 for PSA alone. Despite its improved accuracy, its complexity and limited applicability hindered widespread adoption.

More recently, multiparametric MRI (mpMRI) has been used to assess PCa risk based on the PI-RADS scoring system. Systematic reviews and meta-analyses[14,15] have shown that mpMRI improves detection and risk stratification of clinically significant prostate cancer (csPCa). A meta-analysis of 19 studies including 3,879 patients reported a pooled sensitivity of approximately 0.84 (95% CI 0.79 to 0.88) and specificity of 0.76 (95% CI 0.65 to 0.84), with an AUC around 0.88. These findings confirm that mpMRI provides superior lesion localization compared with systematic TRUS biopsy, thereby reducing unnecessary procedures and improving diagnostic yield. However, widespread implementation is still limited by cost, availability, dependence on radiologist expertise, and inter-center variability[16].

Table 4. Comparison of the AUC between the TRUS predictive model and PSA-related parameter

Factor	TRUS biopsy positive	
	AUC	95% CI
PSA	0.798	0.726 to 0.869
PSAD	0.883	0.834 to 0.931

TRUS=transrectal ultrasound; AUC=area under the curve; CI=confidence interval; PSA=prostate specific antigen; PSAD=PSA density

The main objective of the present study was to identify factors associated with PCa detection after an initial TRUS biopsy at Lerdsin Hospital, considering potential differences in genetic background and clinical heterogeneity within the Thai population. Univariable analysis identified age, PSA, prostate volume, abnormal DRE findings, prostate nodules, and PSAD as significant factors, consistent with previous studies[2,3,7]. In the present study, prostate volume was measured by either TRUS or MRI, depending on physician preference. However, most measurements were obtained by TRUS during biopsy. Previous studies have shown that prostate volume measurements by TRUS differ only slightly from those obtained by MRI, with a mean difference of approximately 1.7 mL[17].

In the multivariable analysis, only PSA, prostate volume, and PSAD remained significant predictors

of PCa detection. Subgroup analysis revealed that prostate volumes of less than 30 mL and 30 to 50 mL were significantly associated with higher cancer detection rates after initial TRUS biopsy, with adjusted odds ratios of 5.17 ($p<0.001$) and 2.47 ($p=0.017$), respectively. The inverse relationship between prostate size and PSA level may explain this finding. Evidence from studies in benign prostatic hyperplasia (BPH) suggests that men with prostate volumes of 30 mL or larger typically have PSA levels of 1.5 ng/mL or more[18]. Therefore, elevated PSA in patients with smaller prostate glands reflects tumor-related PSA production.

Regarding PSA levels, PCa detection rates were 11.7% for PSA 4 to 10 ng/mL, 25.4% for PSA 10.1 to 20 ng/mL, and 69.2% for PSA greater than 20 ng/mL. PSA levels of 10.1 to 20 ng/mL and greater than 20 ng/mL were significantly associated with PCa detection ($p=0.037$ and <0.001, respectively). Moreover, PSAD demonstrated a stronger association with PCa detection than PSA alone, aligning with findings from previous studies[19]. ROC analysis in the present study identified optimal cut-off values of 13 ng/mL for PSA with a sensitivity of 75%, a specificity of 69%, and an AUC of 0.73 and 0.225 ng/mL^2 for PSAD with a sensitivity of 96%, a specificity of 70%, and an AUC of 0.83, which are comparable to those reported in prior research[20].

The limitations of the present study include a small sample size, missing data inherent to its retrospective design, and reliance on manually recorded outpatient data. As this was a single-center study, the findings may not be generalizable to the broader Thai population and recall, or selection bias may have occurred. Additionally, the mean PSA level in the present study was high at 32.53 ng/mL, primarily due to the wide variability among patients with PSA levels greater than 20 ng/mL (range of 20 to 600). Therefore, the median value of PSA was 12.10 was used instead. However, subgroup analysis demonstrated a balanced distribution across PSA categories: 39.3% for 4 to 10 ng/mL, 34.2% for 10.1 to 20 ng/mL, and 24.6% for greater than 20 ng/mL. Despite these limitations, the present study provides preliminary data that may serve as a foundation for future Thai population-based research. The results indicate that PSAD is more strongly associated with PCa detection than PSA alone, with an AUC of 0.883 compared to 0.798 for PSA. These findings suggest that PSAD could be a valuable parameter for guiding biopsy decisions in clinical practice, particularly in resource-limited settings such as Thailand. Nevertheless, larger multicenter studies are warranted to validate these results and refine population-specific diagnostic thresholds.

Conclusion

PSA, prostate volume, and PSAD were identified as independent predictors of PCa detection after initial TRUS biopsy. Among these, PSAD showed the highest diagnostic accuracy with an AUC 0.883 and a cut-off of 0.225 ng/mL^2, outperforming PSA alone. PSAD may serve as a practical tool to improve biopsy decision-making, particularly in settings with limited access to MRI. These findings provide baseline data for developing PCa prediction models in the Thai population.

What is already known about this topic?

- PSA has long been the standard biomarker for PCa screening. However, its low specificity leads to unnecessary biopsies and overdiagnosis.
- PSAD, which adjusts PSA level for prostate volume, has been shown to improve diagnostic accuracy and reduce false positives, especially in men with borderline PSA levels.
- The mpMRI enhances PCa detection and localization, but its availability and cost limit its widespread use, particularly in resource-limited settings such as Thailand.

What does this study add?

1. This study identifies PSA, prostate volume, and PSAD as independent predictors of PCa detection after an initial TRUS biopsy in Thai patients.
2. Among these factors, PSAD demonstrated the highest diagnostic accuracy, with an AUC of 0.883 and an optimal cut-off value of 0.225 ng/mL^2, showing superior performance compared with PSA alone, with an AUC of 0.798.
3. The findings support the use of PSAD as a practical and cost-effective tool to improve PCa risk stratification and guide biopsy decisions, particularly in clinical settings where MRI is not routinely available.
4. This research provides baseline data for future population-specific predictive models and contributes to establishing localized diagnostic thresholds for PCa detection in Thailand.

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Conflicts of interest

The authors declare no conflict of interest.

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