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Evaluation cut-off point of Prostate-Specific Antigen (PSA) and Prostate-Specific Antigen (PSA)-density in prostate cancer suspected patients at Dr. Wahidin Sudirohusodo Hospital, Makassar, Indonesia



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ABSTRACT

Background: PSA is a test performed to detect prostate cancer. There is currently no rational standard for its cut-off point, resulting in the increasing number of patients with prostate biopsy complications. This study aims to determine the estimated cut-off point of PSA and PSAD among patients with suspected prostate cancer (PCa) in Makassar.

Methods: A single-center retrospective analysis using a cross-sectional design was applied in this research. The sample was obtained through medical record data from benign prostate enlargement (BPE) and PCa patients in three affiliate hospitals from January 2014 to December 2019. Mann-Whitney U, Chi-Square, Fisher's Exact, and ROC tests were performed in the statistical analysis (considered significant if $p < 0.05$). Data were analyzed using SPSS version 22 for Windows.

Results: Among 470 subjects, 88.3% were BPE patients, and 11.7% were PCa. Lower urinary tract symptoms (LUTS) were found in 70.6% of patients, and those with hematuria remained at 10.6%. The average prostate volume was 53.8 ± 25.72 ml. The prostate consistency examination with the digital rectal examination (DRE) made up 84.3% Solid Chewy in the BPE sample and 96.4% hard solid in the PCa sample. The average PSA value in BPE was 14.82 ± 20.1 ng/ml, and the PCa was 48.10 ± 42.58 ng/ml, while the average PSAD BPE value was 0.287 ± 0.40 ng/ml, and PCa was 1.19 ± 1.32 ng/ml. PSA cut-off point was 18.62 ng/ml. PSAD cut-off point was 0.533.

Conclusion: PSA and PSAD cut-off points in this study 18.62 ng/ml and 0.533. The cut-off point obtained is far higher than the value agreed upon in advance.

Keywords: Benign Prostate Enlargement, Prostate Cancer, PSA, PSAD

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INTRODUCTION

Prostate cancer (PCa) is the second most common urinary tract malignancy after bladder malignancy and the second leading cause of death by cancer in men.¹ On the other hand, a protein-specific antigen (PSA) is one of the tests performed to detect prostate cancer. However, its value interpretation is still controversial. There are patients with prostate carcinoma without an increase in PSA, while many BPE patients have high PSA density.²

Generally, the incidence of PCa in Asia is low. Therefore, the higher cut off point for PSA and PSAD becomes a reference for biopsy. Research from 2000 to 2013 stated that 2606 Chinese people had an initial 4.5 ng/ml PSA cut-off point and 0.12 ng/ml PSAD.³ Furthermore, PSAD above 0.12 ng/ml is known as a significant predictor for prostate cancer.

A study conducted in the Hasan Sadikin hospital in Bandung from 2010 – 2014, with a total of 502 patients undergoing a prostate biopsy due to the

suspicion of PCa and reveals the value of the cut-off point of PSA at 14.6 ng/ml and PSAD at 0.23 as the parameter of the patients for the prostate biopsy.² Due to different characteristic of demographic, further study needs to evaluate the appropriate cut-off point of PSA in assessing the patient with suspected prostate cancer (PCa) at Dr. Wahidin Sudirohusodo Hospital, Makassar, Indonesia

According to those mentioned above, this study aims to determine the estimated cut-off point of PSA and PSAD in patients with suspected prostate cancer (PCa) at Dr. Wahidin Sudirohusodo Hospital, Makassar, Indonesia

METHODS

A single-center retrospective study with a cross-sectional design was employed. The samples were obtained based on the secondary data from medical records of BPE and PCa patients under treatment at The General Hospital of Dr. Wahidin Sudirohusodo, Hasanuddin University Hospital,

and Akademis Jaury Hospital from January 2014 to December 2018. The patients were divided into BPE and PCa groups. The diagnosis of BPE and PCa was established according to the prostate histopathological examination. Afterward, we evaluated other characteristics that support diagnostics such as age, clinical symptoms, e.g., LUTS, hematuria, urinary retention, prostate consistency from DRE, prostate volume using transabdominal ultrasound examination, PSA, and PSAD levels.

All of the data were analyzed using SPSS version 22 for Windows. Statistical analysis was performed using descriptive statistical calculations and

frequency distribution, the Mann-Whitney U test, Chi-Square, Fisher's Exact, and Receiver operator characteristic (ROC) curves. The test result is significant if the p-value less than 0.05.

RESULTS

Table 1 shows that the most BPE and PSAd patients were within the age 60-69 years at 176 (37.4%) samples, followed by the 70-79 years age group with a total sample of 157 (33.4%). A total of 332 samples or sufferers (70.6%) reported the symptoms of Lower Urinary Tract Symptoms (LUTS). In contrast, those with urinary retention stood at 138 samples (29.4%), with only a small proportion of subjects with hematuria (10.6%) (Table 1).

On the rectal touche examination, based on its consistency, it is clear that most of the samples (74.9%) had prostate consistency at springy level, but the rest were hard solid. This study sample's prostate volume ranged from 30-50 ml (47.7%) at most. The other consisted of 142 samples (30.2%) with prostate volume ranging from 51-80 ml, 54 samples (11.5%) with prostate volume >80ml and 50 samples (10.6%) with prostate volume <30 ml (Table 1). The PSA examination results were fairly evenly distributed in our study sample, but the highest PSA levels were in the range of 4 - 10 ng/ml, such as 135 samples (28.7%). In addition, 124 samples had PSA levels <4 ng/ml (26.4%), 109 samples with PSA levels > 20 ng / ml, and the rest (102 samples) had PSA levels ranging from 10 - 20 ng/ml (21.7%) (Table 1). Most of the samples (53.2%) had PSAd scores ≥ 0.15 ng/ml² and the others were below 0.15 ng/ml². Our study subjects were also dominated by patients with a diagnosis of Benign Prostate Enlargement (88.3%) and the rest was Prostate Cancer (11.7%), which was identified based on the results of the Anatomic Pathology examination (Table 1). Most patients were treated using the TUR-P procedure (96.6%) and only 16 were treated using the open prostatectomy procedure (3.4%). 94% of the sample did not have a risk factor for type II diabetes mellitus, and 67.4% of the sample did not have a risk factor for hypertension.

Table 2 shows patients' characteristics based on anatomic pathology examination, Benign Prostate Enlargement (BPE) and Prostate Cancer (PCa). The average age of BPE patients was 67.62. 67.62 ± 9.20 years, while the average age of PSAD patients was 69.31 ± 10.63 . Based on the results of statistical tests, it is found that there was no relationship between the age of the patient and the anatomic pathology results ($p > 0.05$) (Table 2). The same finding was also found in the ultrasound examination results, which showed no significant relationship ($p > 0.05$) with pathology anatomy. Besides, the average

Table 1. Baseline characteristic of respondents

Variables	Respondents (n = 470)	Percentage (%)
Age group		
40-49	8	1.7
50-59	83	17.7
60-69	176	37.4
70-79	157	33.4
≥ 80	46	9.8
LUTS Symptom		
Yes	332	70.6
No	138	29.4
Hematuria		
Yes	50	10.6
No	420	89.4
Urinary Retention		
Yes	138	29.4
No	332	70.6
Consistency		
Solid Chewy	352	74.9
Solid Hard	118	25.1
Ultrasound volume		
<30 ml	50	10.6
30-50 ml	224	47.7
51-80 ml	142	30.2
> 80 ml	54	11.5
PSA		
<4 ng / ml	124	26.4
4-10 ng / ml	135	28.7
10-20 ng / ml	102	21.7
> 20 ng / ml	109	23.2
PSAD		
<0.15 ng / ml ²	220	46.8
≥ 0.15 ng / ml ²	250	53.2
PA		
BPE	415	88.3
PCa	55	11.7
Operation		
TUR-P	454	96.6
Open prostatectomy	16	3.4
DM		
Yes	28	6
Not	442	94
Hypertension		
Yes	153	32.6
Not	317	67.4

Table 2. Patient characteristics are based on anatomic pathology test results

Variables	Groups (Mean±SD) (N=470)		p
	BPE(n=415)	PCa (n=55)	
Age	67.62 ± 9.20	69.31 ± 10.63	0.314
USG	53.86± 25.72	51.04 ± 23.63	0.495
PSA	14.82 ± 20.1	48.10 ± 42.58	<0.001
PSAd	0.287 ± 0.40	1.19 ± 1.32	<0.001

*Mann-Whitney U Test was considered statistically significant if p-value less than 0.05

Table 3. Patient characteristics based on anatomic pathology test results by categorical variables

Variables	Groups (N=470)		P-value
	BPE(n=415)	PCa (n=55)	
Symptoms, n (%)			
LUTS	325 (78.3)	7 (12.7)	<0.000
Urinary Retention	90 (21.7)	48 (87.3)	
Hematuria, n (%)			
Yes	32 (7.7)	18 (32.7)	<0.001
No	383 (92.3)	37 (67.3)	
Consistency, n (%)			
Solid Chewy	350 (84.3)	2 (3.6)	<0.001
Solid Hard	65 (15.7)	53 (96.4)	
Type II Diabetes Mellitus, n (%)			
Yes	26 (6.3)	2 (3.6)	0.760
No	389 (93.7)	53 (96.4)	
Hypertension, n (%)			
Yes	140 (33.7)	13 (23.6)	0.168
No	275 (66.3)	42 (76.4)	

Chi-Square and Fisher's Exact Test statistically significant if p-value less than 0.05

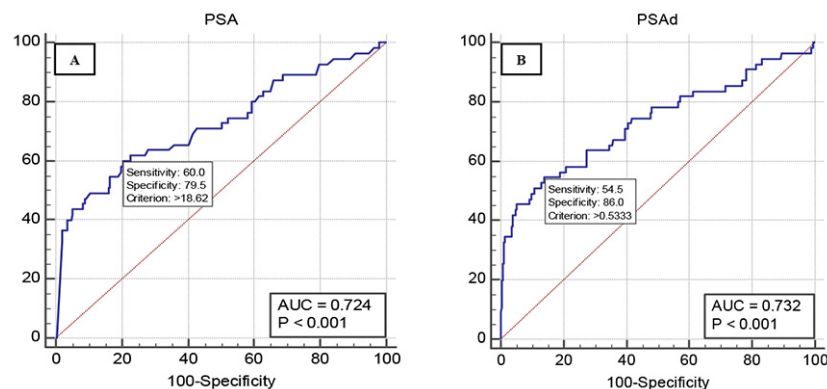


Figure 1. ROC curves on (A) PSA scores and (B) PSAd scores

Table 4. ROC test regarding the prognostic PSA and PSAd accuracy, and Area Under Curve (AUC)

Variables	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC	p
PSA						
> 18.62	60.00	79.52	28.0	93.8	0.724	<0.001*
PSAd						
> 0.533	54.55	86.02	34.1	93.5	0.732	<0.001*

*ROC Test statistically significant if p-value less than 0.05.

prostate volume of BPE patients was 53.86 ± 25.72 ml, and those with PSAd were 51.04 ± 23.63 ml (Table 2).

These numbers seem to be different from the PSA and PSAd levels that had a significant relationship (p <0.001) with the pathology examination results of the patients' anatomy. The average BPE patient had a PSA level of 14.82 ± 20.1 ng/ml and a PSAd level of 0.287 ± 0.40 ng/ml². The average PSAd patient had a PSA level of 48.10 ± 42.58 ng/ml² and a PSAd level of 1.19 ± 1.32 ng/ml² (Table 2).

Based on Table 3, it is known that most BPE patients (78.3%) experienced LUTS symptoms, with only a small portion of PSAd patients (12.7%). However, hematuria symptoms were only complained by 7.7% of BPE patients, with 32.7% coming from PSAd patients. Most BPE patients (65.1%) did not experience urinary retention, but a majority of PSAd patients (18.2%) experienced a different trend (Table 3).

The statistical test results showed that the two characteristics (risk factors of type II DM and hypertension) revealed a p-value at >0.05. Thus, it can be concluded that these two characteristics did not have a significant relationship with the pathology examination results of the patient's anatomy (Table 3). However, the remaining four characteristics (prostate consistency, LUTS symptoms, hematuria, and urinary retention) showed a significant correlation with p <0.05 (Table 3).

Cut-off point PSA and PSAd levels as a dividing boundary between groups with the results of a pathological test of BPE and PCa anatomy can be obtained through the Receiver Operator Curve (ROC) curve (Figures 1A and 1B). Also, sensitivity is depicted on Y ordinate while 1-specificity on X-axis. In contrast, the PSA prognostic accuracy and PSAd with ROC (sensitivity, specificity, positive and negative predictive value, and Area Under Curve (AUC)) are presented in Table 3.

Based on Table 4, it is clear that PSA cut value was 18.62 with 60.0% sensitivity, 79.52% specificity, 28% positive predictive value (PPV), 93.8% negative (NPV), and 0.724 Area Under Cover (AUC). Meanwhile, the PSAd cut value remained at 0.533 with 54.55% sensitivity, 86.02% specificity, 34.1% positive predictive value, 93.5% negative (NPV), and 0.732 area under the curve (AUC), respectively.

DISCUSSION

This study finds that from January 2014 until December 2019, only 11,7 % of patients with PCa from 470 patients. This finding is following research conducted by Siswandi et al. at Dr. H. Abdul Moeloek Hospital, which found more BPE (96.3%) than PCa (3.7%).⁴ Likewise, according to the research by Capogrosso et al. conducted among 1177 patients with prostate enlargement, 94% had BPE, and just 6% were PCa.⁵

The results of this study indicate that patients with Benign Prostate Enlargement (BPE) and Cancer (PCa) were mostly found within the age range of 60-79 years (70.8%). Only 1.7% suffer from BPE and PCa under the age of 50 years. The research supports this finding that about 50% of adult males aged 60-70 have an enlarged prostate (both BPE and PCa); the number increased to 90% in those aged over 70.^{6,7} Furthermore, it was found that age was not a significant factor in distinguishing BPE and PCa patients. Also, research by Siswandi A et al. found that BPE and PCa patients were similarly at the age of 60-79 years at BPE 54.4%, while PCa 68.2%.⁴

This research reveals that 70,6% of the patients experienced LUTS. When compared with the results of the PA, 78,3% of BPE patients experienced LUTS, and 12.7% of PCa patients had LUTS. We found that the presence of LUTS can predict the likelihood of patients' PA outcomes towards BPE. These findings are in accordance with the theory that patients who experience prostate enlargement accompanied by LUTS are most likely to suffer from BPE.⁸⁻¹⁰

Furthermore, this study also shows that only 10,6% of patients experienced hematuria. Compared with the anatomic pathology examination results, only a small proportion (7.7%) of BPE sufferers experience hematuria. We found 32.7% of patients with PCa undergoing hematuria. Our study found that hematuria symptoms can predict PA's outcome towards malignancy (PCa). This is in line with the theory in which prostate cancer-related hematuria occurs due to tumors that cause bleeding into the prostatic urethra or those that invade the bladder.^{10,11} Furthermore, when cancer develops, extracapsular neovascular anastomosis usually develops to the collateral vessels in the pelvis.^{10,11}

Another finding in this study is that only 29.4% of patients experienced urine retention. This finding is supported by the results of Rasul et al.'s survey, which found 34% of patients with enlarged prostate experienced urinary retention.⁷ According to the pathogenesis, urinary retention can occur due to increased prostate volume, causing urinary obstruction.^{12,13} When classified according to the results of the PA, 87.3% of PCa patients experience

urinary retention. Our study showed a tendency that urine retention could predict PA's outcome towards malignancy (PCa).

Rectal Touche (RT) tests showed the majority of BPE patients had prostate with solid Chewy consistency (85.3%), and the majority of PCa had a solid hard (96.4%). This is in accordance with the theory that prostate cancer patients experience changes in prostate consistency from solid to hard, accompanied by loss of median sulcus, difficulty in moving, and nodules appearance.¹⁴ The findings in our study are the same as those of Aminshari et al.¹⁵

Our study found that almost half of the sample (47.7%) had prostate volume (USG results) ranging from 30-50 ml. Furthermore, BPE patients in our study had an average prostate volume of 53.86 ml. In comparison, the average PCa patient in our study had a prostate volume of 51.04 ml. Our study found that prostate volume cannot predict anatomical pathology results (BPE and PCa). Our findings are quite different from the study of Khalil et al., which found that patients with small prostate volumes (less than 35 ml) on average had PCa biopsy results, whereas those with large (more than 70 ml) had BPE results. This may be due to ethnicity, as well as sample differences.¹⁶

According to the literature, diabetes mellitus is a risk factor for both, which is due to increased serum insulin, and fasting plasma glucose thought to increase the prostate size.^{6,17} However, this is quite different from this study in which only 6% are diabetic.

Theoretically, hypertension may not play a direct role as a risk factor. Still, a theory that suspects increasing the sympathetic activity in older men becomes a point of the pathophysiological relationship between prostate enlargement and hypertension. Therefore, it was found that 32.6% over 40 years had enlarged prostate and hypertension.

Several other risk factors, such as genetic, diet, alcohol, smoking, and lipid levels, are thought to increase BPE and PCa incidence.^{6,17-20} But they were not examined in this study. Therefore, it was found that those with hypertension and diabetes comorbidities could not determine anatomic pathology results.

Our research found that the average PSA level of BPE patients was 14.82 ± 20.1 ng/ml. Whereas in PCa patients, the average PSA level was higher at 48.10 ± 42.58 ng/ml. Our study found that PSA levels can predict patients' PA outcomes towards BPE or PCa. Mochtar et al. found PSA levels of BPE patients 21.9 ± 1.6 , while for PCa patients, the average PSA was higher at 371.3 ± 43.1 ng/ml.²¹ Similar findings were also found by Hsiao CJ et al. and Putra PCA et al., who obtained higher

PSA levels in PCa patients compared with BPE patients.²¹⁻²³

The cut-off point of effective PSA density in distinguishing BPE and PCa patients was at 18.62 ng/ml (Sensitivity 60%, specificity 79.52%, PPV 28%, NPV 93.8%, AUC 0.724). Research on Chinese men found that the optimal PSA cut point was at 4.5 ng/ml (Sensitivity 94.4%, specificity 14.1%, PPV 29.5%, NPV 86.9%)(3), which is lower than this study's findings.²³ In Indonesia, Mochtar et al found an optimal cut point at 42.7 ng/ml (sensitivity 74%, specificity 73%, PPV 85.2%, NPV 57.5%, AUC 0.81).²¹ It was also found that the average PSAD density of BPE patients was 0.28 ng/ml while that of PCa was higher at 1.19 ng/ml. Our study found that PSAD levels can predict patients' PA outcomes towards BPE or PCa.

The results indicate the cut-off point of PSAD density is at 0.533 ng/ml² (sensitivity 54.55%, specificity 86.02%, PPV 34.1%, NPV 93.5%, AUC 0.732). However, different results was presented by Aminisharifi who found the optimal cut point at 0.08 ng/ml² (sensitivity 98%, specificity 16%, PPV 26%, NPV 96%).¹⁴

CONCLUSION

Our study found that the PSA cut-off point was 18.62, and the PSAD cut-off point was 0.53. There is a significant difference higher than in other similar studies. This is significant due to the high rate of prostatitis infection in patients treated in our institution.

CONFLICT OF INTEREST

There is no competing interest regarding the manuscript.

ETHICS CONSIDERATION

Ethics approval has been obtained from the Ethics Committee, Faculty of Medicine, Universitas Hassanudin, Makassar, Indonesia, prior to the study being conducted.

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None.

AUTHORS CONTRIBUTION

All authors equally contribute to the study from the conceptual framework, data gathering, data analysis until reporting the results of study through publication.

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