Evaluation Of The Diagnostic Utility Of Prostate-Specific Antigen (PSA) In Differentiating Prostate Cancer From Benign Prostatic Hyperplasia: A Study From White Nile State, Sudan

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Abstract

Background: Serum PSA is the main prostate cancer (PCa) screening test, and accurate reference levels are needed. This study examined the diagnostic utility of prostate-specific antigen (PSA) in separating BPH from prostate cancer using prostatic needle biopsy samples.
Method: 200 prostate needle biopsy specimens obtained between 2023 and 2024 were used in this case-control research. Every patient who had complete data for age, histological diagnosis, and PSA levels was chosen for the research. This sample was split up into 100 prostatic adenocarcinoma cases and 100 BPH controls.
Results: Statistical analysis confirmed no sizeable difference in mean age between PAC and BPH. At a price of 0.908, PAC patients had a little better mean age (67.2 ± 7.7 years) than BPH patients (65.8 ± 7.5 years). The most general age institution for both illnesses turned into 60–70, with fifty-two percent of PAC instances and 55% of BPH controls. The corporations' while had been no longer notably unique (p=0.618). Serum PSA ranges had been relatively higher inside the PAC institution (20 ± 10.2 ng/mL) as compared to the BPH group (18.4 ± 10.2 ng/mL), but now they are not considerably distinct amongst the looked-at populations. PSA readings within the maximum danger organization (>10 ng/mL) were seen within the majority of PAC patients (eighty%) and BPH sufferers (75%). High sensitivity of 99% and coffee specificity of seven% indicate insufficient diagnostic capability of overall PSA (tPSA). With an AUC of 0.53 (95% CI: 0.54–0.61; p < 0.001) from the ROC curve, it could be concluded that even as PSA is powerful in detecting most cancer cases, it is not a dependable approach to distinguish between benign and malignant conditions. Poor analysis accuracy is evidenced by means of the AUC of 0.53.
Conclusion In order to decrease overdiagnosis and increase specificity, the study suggests integrating PSA with other indicators.

Keywords: Prostate Cancer; Prostate Adenocarcinoma; Benign Prostatic Hyperplasia; Sudan

Introduction

Cancer is still a substantial international fitness burden, contributing considerably to morbidity and mortality across the globe (1). The most familiar disorder recognized in guys globally is prostate cancer, which is deadly. It is the second most common motive of cancer-related mortality in guys, after lung cancer (2, 3). By 2030, 499,000 deaths and 1.7 million new instances are predicted, indicating a boom in its prevalence. A rising range of specialists has discovered that populations of African descent have a notably better incidence and mortality rate of most prostate cancers compared to other ethnic agencies. Genetic susceptibility, especially in connection to racial heritage and the circle of relatives' history, may be liable for the high occurrence of PCa in African populations. It is extra common in older men, with an average prognosis age of 66. About 60% of the time, it arises in guys 65

years of age or older, and it's far unusual in the ones underneath 40. The hazard starts to climb appreciably approximately at age 40 (4).

Men 65 years of age or older account for approximately 60% of instances, while adult males beneath 40 are not often affected (5). After age 40, the threat starts to rise sharply. The most ordinary type of cancer among Sudanese men is prostate cancer (PCa), which makes up 51% of all male cancer instances. The disorder has a big impact, with an incidence rate of 4.9% (1,404 sufferers) and a death rate of 3.9% (716 humans). It is the fourth most common universal cancer in Sudan for both genders (6). It affects participants of several ethnic agencies and is the most customary cancer among guys in Sudan. With an average age of 72.2 years, most Sudanese adult males are recognized at an overdue level (three or beyond), making early detection and treatment extremely tough (7). BPH is a non-cancerous prostate situation that particularly affects middle-aged and older men. This condition, which normally appears after the age of 40, is often linked to male incontinence. The prognosis calls for a digital rectal exam, scientific assessment, clinical history, and exclusion of different capability reasons. It is delivered on with the aid of the increase of cells within the transitional area of the prostate (8).

In comparison to the 51.1 million cases recorded in 2000, the incidence of BPH rose dramatically to 94 million cases in 2019. About 80% of men in their 80s, 50% of men in their 60s, and 8% of men in their 40s are affected by BPH, according to research. BPH is one of the three most prevalent urological conditions in low- and middle-income nations. It resulted in 1.86 million disability-adjusted life years (DALYs) worldwide in 2019; the age-standardized rate was 48.9 DALYs per 100,000 (9). PSA testing along with digital rectal examination (DRE) can be used to assess BPH and PCa. These techniques are frequently used as instruments in PCa screening programs and help urologists identify suitable treatment choices (8, 10).

As an economical and effective way to detect asymptomatic prostatic diseases, PSA testing was initially approved in 1986 (10). PSA screening has been linked to lower PCa-specific death rates and has been shown to be a more accurate diagnostic method for detecting prostate cancers (11). This prostate-derived glycoprotein, also known as kallikrein-3, promotes cervical mucus liquefaction and sperm motility. PSA enters the circulation when prostatic epithelial cells are disrupted by tumors. Age-specific reference ranges were created since men's PSA levels normally increase with age. For instance, males in their 40s and 50s often have levels between 0.6 and 0.7 ng/mL, but men 60 years of age and beyond usually have levels between 1.0 and 1.5 ng/mL (3). Currently, 0–4 ng/ml is the generally recognized normal PSA range (5). The "gray zone" is the range of serum PSA values between 4 and 10 ng/mL. There is a chance of overtreating clinically minor PCa in this range, and TRUS-guided prostate biopsies might not be required (12). Due to more stringent regulations, PSA testing originally caused a significant rise in PCa cases before declining. A PSA level between 4 and 10 ng/mL is linked to a 25% risk of cancer, which more than doubles to nearly 50% for levels over 10 ng/mL, even though concentrations of PSA usually increase alongside aging. PSA screening for early diagnosis has increased survival rates by facilitating prompt treatment. Depending on risk factors, screening is advised at various ages. Following a positive test, a biopsy is often performed under the guidance of imaging methods, and the Gleason Score is used to determine the severity of the malignancy (8, 10). Based on the results of a prostatic needle biopsy, the current investigation assesses the diagnostic significance of PSA in differentiating between PAC and BPH.

Method

A retrospective case-control study was set up to analyze the diagnostic performance of the prostate-specific antigen (PSA) check in Sudanese men affected with prostate cancers. A total of two hundred paraffin-embedded tissue samples had been included inside the take a look at: one hundred cases of prostate adenocarcinoma (PAC) with varied histological grades and a hundred controls recognized with benign prostatic hyperplasia (BPH). The investigation was performed within the Histopathology Laboratory Department in Al-Duwaym City, White Nile State, Sudan. Data were collected from sufferers who underwent a prostate biopsy between Jan. 2023 and Dec. 2024.

Patients had been eligible for inclusion if their furnished records contained entire statistics on PSA tiers, age, and histopathological effects. Cases with lacking or incomplete statistics have been excluded. Patient statistics, along with age, general PSA (tPSA), and histopathological consequences, were accumulated from scientific information.

Statistical analysis

Data had been analyzed on the usage of IBM SPSS software v. 23. Continuous records were suggested as mean ± standard deviation (SD), and express variables were summarized as frequencies and changes. Associations between categorical variables have been investigated using the chi-squared test. The diagnostic overall performance of PSA was tested using the usage of receiver working characteristic (ROC) curve evaluation, and the vicinity underneath the curve (AUC) turned into determined to determine sensitivity and specificity. A p-cost of much less than 0.05 was judged statistically sizeable.

Ethical approval was received from the Research Committee of the Faculty of Medical Laboratory Sciences, University of Bakhtalruda. Owing to the retroactive nature of the research, the necessity for person-informed consent was waived.

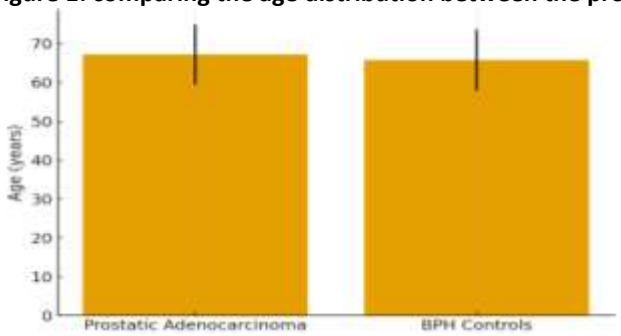
Results

Our results, as shown in table 1, found the age profile of the studied populace proved that individuals identified with prostatic adenocarcinoma had been typically older than people with benign prostatic hyperplasia. Patients with malignancy exhibited a median age of 67.2 ± 7.7 years, with a long time ranging from 50 to 81 years. In assessment, the managed organization tormented by benign prostatic hyperplasia showed a barely decreased mean age of 65.8 ± 7.9 years, ranging between 50 and 79 years. Although each shared a comparable decrease in age restriction, the most cancers cohort found out a tendency closer to older age, reflecting the age-based nature of malignant prostatic pathology.

Table 1: Age Distribution of Prostatic Adenocarcinoma Cases and BPH Controls

Study Group	Sample Size (n)	Mean Age (years)	Standard Deviation (SD)	Age Range (years)
Prostatic Adenocarcinoma (Cases)	100	67.2	7.7	50–81
Benign Prostatic Hyperplasia (Controls)	100	65.8	7.9	50–79

Figure 1: comparing the age distribution between the prostatic adenocarcinoma and BPH control groups

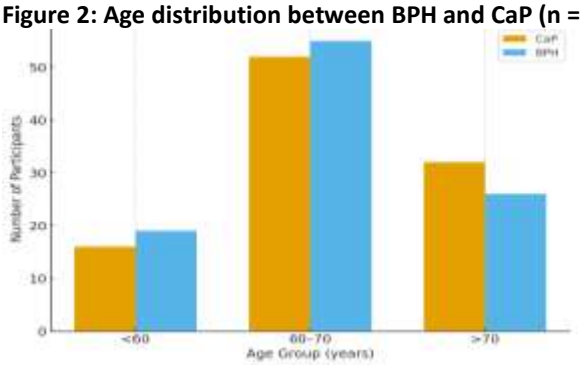


The contrast of age-institution distribution between patients with prostate adenocarcinoma and those with benign prostatic hyperplasia confirmed no statistically enormous differences. Individuals more youthful than 60 years represented 16% of the most cancerous institutions and 19% of the managed organizations, while the bulk of individuals in both groups had been dispensed inside the 60–70-yr class (fifty-two percent of CaP and fifty-five percent of BPH). Participants older than 70 years accounted for 32% of CaP cases compared with 26% of the BPH organization. A chi-square takes a look at confirmed that these versions were no longer statistically significant ($\chi^2 = 0.962$, df = 2, p = 0.618), indicating that age organization was similarly disbursed throughout each take a look at population and did no longer fluctuate when it comes to disorder fame. (Table and figure 2).

Table 2: Age distribution between BPH and CaP (n = 200)

Age Group (years)	CaP (n)	BPH (n)	Total (n)	P-value
< 60 years	16	19	35	
60–70 years	52	55	107	0.618
> 70 years	32	26	58	
Total	100	100	200	

Figure 2: Age distribution between BPH and CaP (n = 200)



The total serum PSA in prostate carcinoma patients ranged between 2 and 45 ng/ml, with a mean tPSA result of (20 ± 10.2) ng/ml, while the control group ranged from 2 to 50 years, with a mean tPSA result of (18.4 ± 10.2) ng/ml. There was a statistical insignificance in the mean tPSA results between prostatic cancer and BPH patients (p = .908) (Table 3).

Table 3: The mean and standard deviation (STD) of serum tPSA in the study population.

Study Group	N	Mean	SD	Minimum	Maximum	P-value
Prostatic Adenocarcinoma (Cases)	100	20.0	10.2	2	45	
Benign Prostatic Hyperplasia (Controls)	100	18.4	10.2	2	50	**0.908**

According to the total serum PSA, prostate carcinoma (cases) more ranged in the high-risk group level >10 (ng/ml) 80 (80%), and in the control group (BPH), the total serum PSA more ranged too in the high-risk group 75 (75%). There were no significant differences between CaP and BPH according to the tPSA test (Table 4). The diagnostic accuracy of PSA in discriminating between H&E-confirmed cancer and normal prostate tissues was tested using ROC curve analysis. One hundred (50%) of the 200 examples that were studied were H&E positive, whereas another hundred (50%) were H&E negative. With an AUC of 0.530, the PSA had very low discriminatory power. However, the divergence from the 0.5 reference value gained statistical significance (p = 0.0293). Nearly all malignant cases were effectively diagnosed by the marker's very high sensitivity (99%); however, this came at the expense of a relatively low specificity (7%), which frequently led to false-positive classifications. When combined, these findings suggest that while PSA is a relatively sensitive marker, its limited specificity greatly decreases its value as a stand-alone diagnostic tool for discriminating between benign and malignant prostate illness.

Table 4: PSA results between BPH and CaP (n = 200)

tPSA results	Prostate tumor		Total	P. value
	CaP	BPH		
Normal (< 4.0 ng/ml)	1	7	8	.096
Gray zone (4.0 – 10.0) ng/ml	19	18	37	
High risk (> 10.0 ng/ml)	80	75	155	
Total	100	100	200	

Discussion:

The most widely used technique for identifying PCa is still serum PSA testing, where values above 4 ng/mL are often regarded as abnormal. However, several studies conducted in the last few decades have shown that a sizable percentage of PCa cases occur in people whose PSA levels fall below this traditional cutoff. The limits of PSA testing and the existence of subclinical illness are further highlighted by postmortem investigations that have shown a significant frequency of occult PCa in men who passed away without a clinical diagnosis (13).

It is a frequently used test for PCa detection and has contributed to a decrease in the proportion of people with advanced diagnoses. However, because its levels can increase in non-cancerous illnesses, including prostatitis and BPH, it has weak diagnostic specificity and can result in overdiagnosis and overtreatment. Age-specific reference values are advised since the prostate's natural growth causes its levels to rise with age (3).

It is a commonly used, established serum biomarker for prostate cancer screening. It has a number of drawbacks, though, especially when it comes to distinguishing PCa from BPH. Interpreting results between 4.0 and 10.0 ng/ml can be particularly challenging, as this range is known as the diagnostic 'grey zone.' Furthermore, most studies only reported that PSA levels below 20 ng/ml were associated with prostate cancer diagnosis in 4% of patients, indicating considerable variation in PSA diagnostic accuracy at different concentration ranges (14). A person's age has a significant impact on the incidence of prostate cancer. As men age, PSA readings also increase with the gradual enlargement of the prostate gland. Hormonal activity, especially androgens, is the most important factor influencing development. Between the ages of 25 and 30, the prostate typically weighs approx. 20

grams. However, its tendency to expand after age 40 may contribute to higher PSA levels and make PSA more difficult to interpret as a clinical sign (4).

The mean age of the cases and controls did not differ considerably, according to the research. This outcome is consistent with Okidi et al.'s investigation (p value = 0.140) (15). The research by Islam et al., which found a significant age difference between patients with BPH (n = 155) and prostate cancer (n = 105), with a p-value of 0.00001 (13), is in contrast to this conclusion. The disparity in sample sizes across the groups might be the cause of this discrepancy. The findings also contradict those of Baruah et al. and Azizul Islam et al., who also noted notable age disparities across the research groups, most likely as a result of variations in sample composition and size (12, 16).

In line with what was found by Okidi et al., every participant in the present investigation was older than 50. 94.7% (93/97) of the population in their sample of men were over 50, with a median age of 71.2 years (range: 43–100 years) (12). The average age of the 85 male participants in Kaur's study was 68.98 years, with a standard deviation of 10.81, and they ranged in age from 40 to 86. Thirty patients, or 35.29 percent of the total, were between the ages of 61 and 70. The age pattern seen in our research (4) is consistent with these findings.

In this investigation, there was a statistically insignificant difference in the age range amongst the patient groups with BPH and prostatic cancer (p=0.618). According to this finding, there was no discernible difference in age between the two groups in the current dataset. When it comes to distinguishing between PCa and BPH, age alone is not statistically significant. Therefore, although age is widely acknowledged as a risk factor, its diagnostic value as a discriminator between BPH and prostate cancer seems to rely on the features of the population being studied. Cases and controls had comparable mean total PSA levels (p = 0.908). These results are consistent with the absence of statistical significance (P = 0.109) reported by Bai et al. (17).

The statistical significance of age and tPSA level differences between PCa and BPH patients may have been impacted by sample size changes, which might account for the discrepancies between this study and others (Baruah et al., Okidi et al., and Maher et al.). (12), (15), (19) (p = 0.001). tPSA showed a 99% sensitivity and a 7% specificity in this research, suggesting that although PSA is very good at identifying the majority of PCa patients (high sensitivity), it is not very good at differentiating between malignant and non-cancerous situations (low specificity). These results are in line with those of Islam et al., who found that the sensitivity was 84% and the specificity was 48% (10).

The sensitivity and specificity of PSA for prostate cancer were estimated by Merriel et al. to be 0.93 (95% CI: 0.88–0.96) and 0.20 (95% CI: 0.12–0.33), respectively, based on pooled data from 14,489 individuals (18). The results of the research, however, are different from those of Daryanto et al., who established a PSA cutoff level of 19.71 ng/mL for suggesting prostate biopsy, with a significantly higher specificity of 72.5% and a sensitivity of 69.23%. Our results are in conflict with those of Daryanto et al., who employed a higher PSA threshold of 19.71 ng/mL, leading to a significantly greater specificity (72.5%) but a lower sensitivity (69.23%) (19). Poor diagnostic performance was shown by the ROC curve for tPSA based on histopathological data, which had an AUC of 0.53 (95% CI: 0.45–0.61; p = 0.452). This outcome differs from a number of earlier investigations. For example, a considerably higher AUC of 0.83 (95% CI: 0.77–0.89; p < 0.001) was found by Maher et al. in South Africa (10). Similarly, Islam et al. used a hierarchical summary receiver operating characteristic (HSROC) curve and determined that the AUC was 0.72 (95% CI: 0.68–0.76) (20).

Additionally, Daryanto et al. observed that PSA had the best sensitivity and specificity for identifying PCa, with an AUC ≤ 0.798 (18). Similarly, an AUC of 0.72 (95% CI: 0.68–0.76) was reported by Merriel et al. (19). Differences in patient selection, sample size, PSA cutoff levels, and study design may have contributed to the discrepancy between our findings and those of previous research. This suggests that depending just on tPSA levels may restrict its usefulness as a stand-alone diagnostic test by producing a high proportion of false positives and false negatives. Our study's lower AUC indicates that PSA's discriminatory power in our community may be restricted, underscoring the necessity for biomarkers or other diagnostic techniques to increase accuracy.

Although PSA is still a commonly used biomarker for PCa screening and surveillance, its low specificity limits its clinical value. Although increased PSA values are frequently associated with cancer, they can also indicate benign diseases such as damage to the prostate gland, BPH, prostatitis, and urine retention. Because of this, increased PSA does not always signify malignancy, and depending only on PSA might lead to diagnostic uncertainty (21).

Conclusion

Although PSA has a very high sensitivity (99%) for diagnosing prostate cancer, this study discovered that its relatively low specificity (7%) allows it to identify people who have PCa but fails to exclude those who do not (i.e., a large false-positive rate). This bolsters the data showing that although PSA is a useful screening tool for PCa, it is not specific enough to be a reliable diagnostic marker. With an AUC of 0.53, tPSA shows poor diagnostic accuracy when used alone and only marginally outperforms chance in terms of discriminatory capacity to distinguish PCa from benign situations. It is highly advised to combine tPSA measures with other biomarkers in order to improve the diagnostic tool of PSA screening for PCa's predictive accuracy, specificity, and danger of overdiagnosis.

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