Original Article

The Diagnostic Accuracy of Prostate-Specific Antigen and Digital Rectal Examination in the Diagnosis of Prostate Cancer at the University of Benin Teaching Hospital

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Abstract

Objectives: To assess and compare the diagnostic accuracy of prostate-specific antigen (PSA) and digital rectal examination (DRE) in the diagnosis of prostate cancer. **Materials and Methods:** It was a prospective, comparative study carried out over a period of 14 months at the University of Benin Teaching Hospital, Benin City. It involved male patients ≥50 years who presented at the urology clinic with lower urinary tract symptoms (due to prostatic disease), PSA > 4 ng/mL and or abnormal DRE findings. They had serum total PSA determined. Patients were recruited for prostate biopsy and samples sent for histopathological assessment. Histopathology was determined by a histopathologist dedicated to the study. Using a researcher-administered, structured proforma, data were collected, collated and subjected to statistical analysis for assessment and comparative analysis of the diagnostic accuracy of PSA and DRE. **Results:** The study involved 94 patients; they were all Nigerians. The age range of the study population was 50–85 years, with a mean age of 70.4 ± 8.6 years. Most (89.4%) of the patients were exposed to formal education. PSA of the study population ranged between 2.5 and 840 ng/mL. For patients with carcinoma of the prostate (CaP), median PSA value was 79.2 ng/mL, whereas patients with benign prostatic disease had a median PSA value of 16.0 ng/mL. The difference in median PSA value between the two groups was statistically significant ($P < 0.001$). In this study, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy of PSA was 97.2%, 12.1%, 40.7%, 87.5% and 44.7%, respectively. However, a sensitivity, specificity, PPV, NPV and diagnostic accuracy of DRE was 88.9%, 70.7%, 65.3%, 91.1% and 77.7%, respectively. Combination of PSA and DRE had sensitivity, specificity, PPV, NPV and diagnostic accuracy of 91.7%, 91.4%, 86.8%, 94.6% and 91.5%, respectively. In this study, 36 (38.3%) patients had CaP whereas 57 (60.6%) patients had benign prostatic disease and 1 (1.1%) patient had high-grade prostatic intraepithelial neoplasia. **Conclusion:** The study revealed a low specificity, high sensitivity and low diagnostic accuracy of PSA in diagnosis of CaP. However, sensitivity, specificity, and diagnostic accuracy of DRE were high but not sufficient in diagnosis of CaP. A combination of PSA and DRE had a higher sensitivity, specificity and diagnostic accuracy in diagnosis of prostate cancer.

Keywords: *Digital rectal examination, positive and negative predictive values, prostate cancer, prostate-specific antigen, sensitivity, specificity*

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Introduction

The male organ most often affected by malignant neoplasms is the prostate gland.[1] In males over 50 years, prostate cancer is a high prevalent condition.[2-4] Across all continents, prostate cancer is prevalent.[5,6] It has been reported as the most common male genital cancer in American men.[7] It is a condition that is becoming more and more important globally, and in the United States of America, where it has also been called a public health crisis among African Americans, it is one of the main causes of cancer mortality.[5,8] Prostatic carcinoma occurs more commonly in blacks than Caucasians, and the mortality rate is also higher among blacks.[7] Data from several clinical investigations conducted in Nigeria provide a hint that the prevalence of prostate cancer may have been incorrectly underestimated.[9] To this end, early detection and treatment are important.

Prostate cancer screening programmes are more widely recognised and accessible in the western world, which has resulted in early detection.[10] In contrast, Sub-

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Saharan African nations do not have organised screening programmes, and late presentations are nevertheless prevalent.[11,12] Prostatic-specific antigen (PSA) tests, trans-rectal ultrasound scans (TRUS) and digital rectal examinations (DRE) are the methods that are now accessible to detect prostate cancer.[13] However, there is broad agreement that both PSA and DRE play significant roles in the screening and early diagnosis of prostate cancer; therefore, it is necessary to underline their significance for diagnostic accuracy.[13,14] Of these tools, DRE is the oldest, cheapest and least invasive modality, and the abnormalities of DRE include presence of nodules, hard consistency, fixity of rectal mucosa and asymmetry.[14,15] For the detection and treatment of prostate cancer, PSA is thought to be the most helpful tumour marker currently available.[16]

The health burden of carcinoma of the prostate (CaP), its prevalence and associated mortality especially in black men have brought to fore the importance for diagnostic accuracy. To achieve this goal of diagnostic accuracy of prostate cancer in patients presenting with lower urinary tract symptoms, the determination and comparison of sensitivity, specificity and positive predictive value (PPV) of elevated PSA and abnormal DRE as tools in detecting prostate cancer come handy, and thus may reduce the percentage of misdiagnosis or needless prostatic biopsies. To this end, this study is, therefore, aimed to demonstrate the sensitivity, specificity, and PPV of PSA and DRE separately, and in combination, in the diagnosis of prostate cancer in patients who presented to the University of Benin Teaching Hospital (UBTH), over a 14-month period.

Materials and Methods

This study was a prospective comparative study that was carried out in the Urology Unit of the University of Benin Teaching Hospital (UBTH), Benin City, Edo State, Nigeria, over a period of 14 months (May 2015 and June 2016).

The study population was patients referred to the urology outpatient clinic on account of lower urinary tract symptoms due to prostatic disease. Detailed history and examination were done. Digital rectal examination was considered abnormal when the gland exhibited nodules, asymmetry, irregularity, or fixity of overlying rectal mucosa. An automated multiparametric immunoassay system employing an enzyme-linked fluorescence test was used to assess the PSA levels. A PSA level of more than 4 ng/mL was regarded as high. All patients with abnormal DRE and/or high PSA had digitally guided prostate biopsies.

The histopathology department received the biopsies in bottles containing 10% formalin for processing and reporting. All patients attended a follow-up clinic after the biopsy procedure on day 7 to assess complications and on day 21 to discuss the histopathology results.

The data obtained were analyzed using the IBM SPSS statistics (version 20) produced by the International Business Machines Corporation, Armonk, New York. The approval of the ethics and research committee of UBTH was obtained before the commencement of the study. Informed consent was obtained from all patients included in the study. A limitation of this study is the absence of facilities for transrectal ultrasound scan (TRUS), which prevented the use of TRUS-guided prostate biopsy. This would have permitted the use of extended core biopsies as it is more sensitive than digitally guided biopsy for diagnosing early stages of cancer of the prostate.

Results

A total of 106 patients who met the inclusion criteria were recruited for this study. Only 94 (88.7%) patients presented for prostate biopsy, after clinical evaluation.

All patients in this study were Nigerians with age range between 50 and 85 years. The mean age of the study population was 70.4 ± 8.6 years. About a third of the study population (35 patients), were between 60-69 years followed by the 70-79year age range accounting for 31.9% of the study population. Of the study population 36 (38.3%) were diagnosed of adenocarcinoma of the prostate. Most of the patients who formed the study population had exposure to formal education (89.3%). As shown in Table 1.

Fifty-six (59.6%) patients had both obstructive and irritative symptoms, whereas 30 (31.9%) patients had only obstructive symptoms and 8 (8.5%) patients had only irritative symptoms. Forty-three (45.7%) patients had abnormal DRE findings whereas others had normal DRE findings. Hard consistency and palpable nodules of the prostate were common abnormal DRE findings as shown in Table 2.

The PSA range (median) for cancer of prostate and benign prostatic hyperplasia was 3.8-840ng/ml (79.2ng/ml) and 2.5-53.3ng/ml (16.0ng/ml) respectively. The difference in

Table 1: Patient's characteristics

Variable	Frequency (n = 94)	Percentage
Age group (years)*		
50–59	10	10.6
60–69	35	37.2
70–79	30	31.9
≥80	19	20.2
Level of education		
None	10	10.6
Primary	16	17.0
Secondary	32	34.1
Tertiary	36	38.3

*Mean ± SD = 70.4 ± 8.6 years

Age range for benign prostatic disease = 54–83 years. Mean age for benign prostatic disease = 71.2 ± 8.1. Age range for CaP = 50–85 years. Mean age for CaP = 69.3 ± 9.3, P = 0.315

median PSA was statistically significant ($P < 0.001$). The interquartile range for PSA total was 14.00–59.23, and the median PSA total was 22.24. The interquartile range for prostate volume on ultrasound was 55.85–126.50, and the median prostate volume on ultrasound was 86.20.

The mean PSA for patients with abnormal DRE exclusively, patients who had prostate biopsy solely on account of elevated PSA, and patients who had biopsy on the account of abnormal DRE and elevated PSA are as shown in Table 3.

The sensitivity, specificity, PPV, negative predictive value (NPV) and diagnostic accuracy of PSA exclusively, DRE exclusively and both in diagnosis of CaP are as shown in Table 4.

Discussion

Digital rectal examination and assessment of PSA level are critical steps aimed at diagnosing carcinoma of the prostate.[17] There was a statistically significant difference between the serum total PSA of patients with prostate cancer and benign prostatic disease in this study, which is in consonance with the study by Udeh *et al.*,[18] who reported a statistically significantly higher PSA value in patients with CaP (49.86 ng/mL) compared with those with BPH (13.71 ng/mL), $P = 0.002$. The statistically significant higher PSA value in CaP patients is supported by the fact that prostate cancer tissue contributed more to an increased PSA value than benign prostatic disease.[19] However, there may be a significant overlap in values between CaP and benign prostatic disease.[20]

The importance of PSA in the diagnosis of carcinoma of the prostate cannot be underestimated. Elevated PSA above 4 ng/mL in this study has revealed a low specificity, positive predictive value, and diagnostic accuracy. The high sensitivity but rather low specificity of PSA in the diagnosis of CaP is well documented in the literature.[21] Prostate-specific antigen is organ-specific and not disease-specific, consequently, the presence of other prostatic diseases such as BPH and prostatitis may influence its effectiveness for cancer detection.[22]

The finding in this study was similar to the findings by Song *et al.*[23] in their study among Korean men, in which overall sensitivity and specificity for PSA cutoff level of >4 ng/mL were 91.2% and 35.9%, respectively, revealing, a low specificity for detection of CaP. Tijani *et al.*[24] in Lagos demonstrated a low positive predictive value (PPV) for an elevated PSA with normal DRE findings, whereas they noted an increase in PPV for an elevated PSA irrespective of DRE findings. Similarly, Abdrabo *et al.*[25] in their study revealed sensitivity, specificity, and PPV of PSA was 91.6%, 24%, and 34.7%, respectively. Ojewola *et al.*[26] in their study showed that elevated PSA irrespective of DRE findings has a high sensitivity, low specificity, and low PPV, hence low diagnostic accuracy, which was in consonance with findings in this study. The result of this study further confirmed the low specificity and positive predictive value of PSA in the diagnosis of prostate cancer.

In contrast, Mistry *et al.*[27] in a meta-analysis demonstrated a high specificity at PSA >4 ng/mL of 93.2% in the diagnosis of CaP, this variation could be explained by the fact that

Table 2: Digital rectal examination findings of study population

Findings	Frequency ($n = 94$)*	Percentage (%)
Normal DRE findings		
Yes	51	54.2
No	43	45.7
Abnormal DRE findings ($n = 43$)		
Hard prostate	42	47.7
Nodules	41	46.6
Asymmetry	39	44.3
Fixity	6	6.8

*Multiple response

Table 3: Indications for biopsy and mean total PSA of study population

Reasons for biopsy	PSA total (mean ± SD)	*P*-value
Elevated PSA only	23.70 ± 21.34	0.016+
Abnormal DRE only	3.95 ± 0.21	
Both	80.17 ± 131.84	

F-test (ANOVA)
+Significant

Table 4: Sensitivity, specificity and diagnostic accuracy of PSA, DRE and both (DRE and PSA)

Prostate parameters	Type of tumour		*P*-value	Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy
	Malignant	Benign						
Abnormal DRE only								
Yes	32 (88.9)	17 (29.3)	<0.001	88.9%	70.7%	65.3%	91.1%	77.7%
No	4 (11.1)	41 (70.7)						
Both (DRE and PSA)								
Yes	33 (91.7)	5 (8.6)	<0.001	91.7%	91.4%	86.8%	94.6%	91.5%
No	3 (8.3)	53 (91.4)						
PSA only								
Yes	35 (97.2)	51 (87.9)	0.791	97.2%	12.1%	40.7%	87.5%	44.7%
No	1 (2.8)	7 (12.1)						

the study by Mistry *et al.*[27] was a meta-analysis consisting of different races, which included screening population.

Digital rectal examination has been used in diagnosis and screening for carcinoma of the prostate for many decades, its importance is well documented,[28] and its limitations include the degree of interobserver variability.[29] However, in this study, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of DRE in the diagnosis of prostate cancer were 88.9%, 70.7%, 65.3%, 91.1%, and 77.7%, respectively. The specificity and positive predictive value of DRE in this study outperformed PSA in the diagnosis of prostate cancer. This could be attributed to the delay in presentations in our locality; late presentations improve the predictive value of DRE.[30] De *et al.*[31] recorded a high sensitivity, specificity, and positive predictive value of 60%, 92.5%, and 80%, respectively. Similarly, Manyahi *et al.*[32] in Tanzania recorded a high sensitivity, specificity, and PPV of 66.7%, 88.6%, and 67%, respectively. Tijani *et al*.[24] in their study also revealed higher positive predictive value of (88.9%) for DRE irrespective of the value of PSA. However, the study by Abdrado *et al.*[25] revealed that sensitivity and specificity of DRE in detecting prostate cancer were 68% and 63.3%, respectively, but recorded a much lower PPV of 47%, which was kept with findings by Galic *et al.*[33] who recorded a PPV of 49%. The variability could be as a result of racial difference in population being studied and time of presentation.

In this study, comparing a combination of PSA and DRE in the diagnosis of prostate cancer revealed a marked improvement in sensitivity, specificity, PPV, NPV, and diagnostic accuracy. In this study, 38 (40.4%) patients had both elevated PSA and abnormal DRE. There was a marked increase in specificity in the diagnosis of CaP from 12.1% and 70.7% for PSA and DRE, respectively, to 91.4% when both indications for biopsy are combined. The overall diagnostic accuracy also improved from 44.7% and 77.7% for PSA and DRE, respectively, to 91.5%. This alludes to the fact that combining both steps in the diagnosis of prostate cancer improves overall diagnostic accuracy. This is in keeping with findings of most studies. Abdrabo *et al*.[25] revealed that combining PSA and DRE, the sensitivity reaches 100% and that specificity increased to 92%.

Manyahi *et al.*[32] also reported that a combination of DRE and PSA yields a diagnostic accuracy of 75% for prostate cancer. Galic *et al.*[33] also reported that when PSA and DRE were combined, PPV was 80% as against 48.7% and 47% for abnormal DRE and PSA >4 ng/mL, respectively. Similarly, findings in this study corroborated studies by Tijani *et al.*[24] and Ojewola *et al.*[26] in Lagos; both demonstrated better specificity, positive predictive value, and diagnostic accuracy when both tools were combined in the diagnosis of prostate cancer.

Conclusion

In this study, prostate biopsies were requested for those with abnormal digital DRE and/or elevated PSA; however, the former is a better indicator of the likelihood of the presence of prostate cancer in the study population in comparison with the latter. A combination of DRE and PSA resulted in indices (sensitivity, specificity, positive predictive value, and negative predictive value) that are better indicators of the presence of prostate cancers in comparison with either elevated PSA or abnormal DRE.

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Conflicts of interest

There are no conflicts of interest.

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