Clinico-pathological Correlation of Digital Rectal Examination Findings Amongst Nigerian Men with Prostatic Diseases: A Prospective Study of 236 Cases

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ABSTRACT

Aims and Objective: This study aims at correlating different digital rectal examination (DRE) abnormalities with histopathological results in patients with prostatic diseases. **Materials and Methods:** A prospective study of 236 patients who underwent prostate needle biopsy (PNB). Inclusion criteria were presence of abnormal DRE findings or elevated prostate specific antigen above 4 ng/ml or both. They all had 10-core extended transrectal biopsy and specimens were sent for histopathological examination. Correlations were made between DRE findings and histopathology results. Two separate multivariate logistic regression models were created; the first evaluated the relationship of predictors (DRE findings) to the likelihood of detecting cancer and the second explored predictors of high-grade cancer on PNB. **Results:** Two hundred and thirty-six patients were enrolled with a mean age of 66.9 years and range of 43-90 years. Histopathology results were malignant in 102 (43.2%) and benign in 134 (56.8%). Ninety-one (38.6%) and 145 (61.4%) had normal DRE and abnormal DRE findings with cancer detection rates of 23.1% and 55.8% respectively. Nodular prostate is the most common abnormality in 63.4% patients with abnormal DRE. Each sign of DRE had different predictive value with enhanced positive predictive value when combinations of abnormalities are present. Abnormal DRE is an independent predictor of high-grade tumor. Mean Gleason scores were 4.7 and 7.1 in patients with normal and abnormal DRE respectively. **Conclusion:** DRE is a useful and important tool in assessing patients with suspected prostate diseases who need prostate biopsy. An abnormal DRE correlated well with prostate cancer and independently predicted high-grade disease in these men.

KEYWORDS: Clinico-pathological correlation, digital rectal examination findings, prostate cancer, prostate needle biopsy

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INTRODUCTION

Prostatic diseases are extremely common among aging men, so much so that some have suggested that this condition is a natural concomitant of aging.[1] The three most common diseases of the prostate are benign prostatic hyperplasia (BPH), prostate cancer (PCa), and chronic prostatitis.[2] PCa is the most common malignancy and a leading cause of cancer mortality in men beyond middle-age.[3,4] The increasing level of awareness and availability of wide-spread screening programs for PCa has led to early detection in the western world.[5] The situation is however, different in Africa especially, sub-Saharan African countries where there are no organized screening programs and late presentation is still common.[6,7]

PCa is usually diagnosed by transrectal ultrasound (TRUS) biopsy or discovered incidentally in tissue removed at trans-urethral resection or open simple prostatectomy. The currently available modalities for screening or early detection of PCa are digital rectal examination (DRE), prostate specific antigen (PSA) testing, and TRUS. The attributes and limitations of each of these modalities as tools for early detection of PCa have been investigated extensively with different reports. However, there is general consensus that both PSA and DRE have important roles in screening and early cancer detection while TRUS has been described as an invaluable tool in guiding the taking of biopsy.[8]

Of these three tools, DRE is the oldest and cheapest. It was the first and only diagnostic tool used for detection of PCa until

the mid-1980's before the discovery of PSA.[9] Abnormalities of DRE include presence of nodules, hard consistency, fixity of rectal mucosa, obliteration of the median groove and asymmetry.[8,10] Though, the presence of any of these signs makes a DRE abnormal, the relative importance of each of them has not been widely studied. The aim of this study was to correlate various DRE abnormalities with histo-pathological results of prostate needle biopsy (PNB) in patients being evaluated for prostatic diseases.

Materials and Methods

The study was conducted prospectively in Lagos, the most cosmopolitan city in Nigeria, in the urology section of Lagos University Teaching Hospital between January 2010 and December 2011 after approval was obtained from the Ethical Committee and consent was taken from all recruited patients. All patients who were referred for evaluation for prostate diseases had a serum total PSA measurement and a DRE performed on them. Abnormalities of DRE sought for are presence of nodularity, hard consistency, fixity of rectal mucosa, obliteration of the median groove, and asymmetry. Presence of any or combinations of these signs constitutes an abnormal DRE. Inclusion criteria were presence of elevated PSA of > 4 ng/ml or abnormal DRE finding (s) or both. Patients were prepared using the unit guidelines viz; rectal washout and intravenous Ciprofloxacin 200 mg prior to the procedure. Prior to biopsy, a preliminary DRE was performed on all patients by the first author and findings documented in details. A transrectal 10-core extended biopsy was performed using a size 16 spring-loaded TruCut needle after rectal lubrication with 10 ml of 2% xylocaine gel. All tissues obtained were fixed in 10% formalin and sent for histo-pathological examination. The outcomes of interest were histo-pathological diagnosis and Gleason's scores and grades in biopsies that were malignant.

A structured pro forma was used to obtain relevant information including the socio-demographic data, details of the DRE findings, indication (s) for biopsy, serum total PSA values and histopathology results. The data were analyzed with Statistical Package for Social Sciences. Cancer detection rates were determined. Variables evaluated as potential predictors of cancer included patient age, PSA level and DRE findings. Differences in these base-line variables between those with or without cancer were compared using Chi-square and two-tailed *t*-tests, for categorical and continuous variables, respectively, with $P < 0.05$ as a threshold for statistical significance. Two separate multivariate logistic regression models were created; the first evaluated the relationship of the predictors to the likelihood of detecting cancer on PNB and the second explored predictors of high-grade cancer on PNB.

Results

A total of 236 patients were studied with the mean age of 66.9 ± 10.7 years and a range of 43-95 years. One hundred and sixty-eight patients (71.2%) were above 60 years of age. The peak age range was 61-70 years and accounted for 52.1% (123/236) of the entire study population. It is also the peak age range for both PCa and benign prostatic lesions. Of these 236 patients, PCa was identified in 102 (43.2%) while 134 (56.8%) had benign prostatic diseases. Fifty-eight (47.1%) cancer cases were detected in the peak age range of 60-70 years accounting for 56.9% (58/102) of all cancer cases. Mean ages amongst patients with cancer and those without cancer were 67.4 and 66.9 years respectively ($P = 0.059$).

Patients with abnormalities of both PSA and DRE constitute 46.2% (109/236) while 15.3% (36/236) and 38.6% (91/236) had abnormality of either DRE or PSA alone respectively. Cancer detection rates amongst patients with elevated PSA alone and DRE alone were 31.9% (29/91) and 22.2% (8/36) respectively while the rate was 59.6% (65/109) in those with abnormalities of both PSA and DRE.

Ninety-one (38.6%) patients had normal DRE while 145 (61.4%) had abnormal DRE with mean ages of 66.7 and 68.1 years respectively ($P = 0.054$). Table 1 compares the histo-pathological results in both groups with cancer detection rates of 23.1% (21/91) and 55.8% (81/145) respectively ($P < 0.001$).

Table 2 shows the distributions of various abnormalities recorded in 145 patients with abnormal DRE. Firm nodular prostate was the most common abnormality in 78 (53.8%) patients. Ninety-seven (66.9%) patients had just one abnormality while 48 (33.1%) had more than one abnormal DRE findings. The table also compares various abnormalities of DRE with histo-pathological results. Amongst the 78 patients with firm nodular prostate, 25 had solitary nodule while 53 had multiple nodules. Cancer detection rates were 52% (13/25) and 24.5% (13/53) amongst patients with solitary nodule and multiple nodules respectively. Thirty-five (94.6%) out of 37 patients who had chronic prostatitis with nodular prostate had multiple nodules.

Cancer detection rate amongst patients with only one abnormality of DRE was 40.2% (39/97) while detection rates in those with combination of two abnormalities and ≥3 abnormalities were 83.7% (31/37) and 100% (11/11) respectively ($P < 0.005$). Comparison of the Gleason scores in patients with cancer amongst those with normal and abnormal DRE showed that greater percentage of the latter had high-grade diseases, i.e. 48.1%% (39/81) versus 14.3% (3/21). Mild grade tumors occurred in 42.9% (9/21) and 14.8% (12/81) while moderate grade occurred in 42.9% (9/21) and 37.0% (30/81) respectively. Ten (90.9%) out of eleven patients with three or more abnormalities on DRE had high-grade tumors. The remaining one patient had a 7b (4 + 3) grade tumor. Mean score in this study was 6.6 while the mean scores for those with normal and abnormal DRE were 4.7 and 7.1 respectively ($P < 0.001$).

Results of multivariate logistic regression model created to evaluate the relationship of the predictors to the likelihood of detecting cancer are shown in Table 3. Similarly, the results of

Table 1: Histo-pathological diagnosis versus digital rectal examination findings

DRE findings	CaP (%)	BPH (%)	BPH+prostatitis (%)	Chronic prostatitis (%)	Low grade PIN (%)	Total (%)
Normal DRE	21 (23.1)	65 (71.4)	2 (2.2)	2 (2.2)	1 (1.1)	91 (100)
Abnormal DRE	81 (55.8)	19 (13.1)	29 (20.0)	13 (9.0)	3 (2.1)	145 (100)
Total	102 (43.2)	84 (35.6)	31 (13.1)	15 (6.4)	4 (1.7)	236 (100)

DRE: Digital rectal examination, BPH: Benign prostatic hyperplasia, PIN: Prostatic intraepithelial neoplasia, CaP: Prostate cancer

Table 2: Analysis of digital rectal examination features versus histopathology results in 145 patients with abnormal DRE

DRE features	Histopathology results				
	CaP (%)	BPH (%)	Prostatitis±BPH (%)	Low-grade PIN (%)	Total (%)
Firm nodular prostate	26 (33.3)	17 (21.8)	35 (44.9)	-	78 (100)
Hard prostate (including firm to hard)	13 (68.4)	2 (10.5)	4 (21.1)	-	19 (100)
Hard+nodular prostate	12 (80.0)	-	2 (13.3)	1 (6.7)	15 (100)
Hard+asymmetrical prostate	8 (88.9)	-	1 (11.1)	-	9 (100)
Hard prostate+obliterated median groove	5 (83.3%)	-	-	1 (16.7%)	6 (100)
Hard prostate+fixed mucosa	6 (85.7)	-	-	1 (14.3%)	7 (100)
Combinations of three abnormalities	8 (100)	-	-	-	8 (100)
More than three abnormalities	3 (100)	-	-	-	3 (100)
Total	81 (55.9)	19 (13.1)	42 (28.9)	3 (2.1)	145 (100)

DRE: Digital rectal examination, BPH: Benign prostatic hyperplasia, PIN: Prostatic intraepithelial neoplasia, CaP: Prostate cancer

Table 3: Multivariate analysis of predictors of cancer

Variable	PNB result		Total	*P* value
	Malignant	Benign		
Age (years)				<0.001
Mean	68	63	-	
Range	47-90	43-89		
PSA				<0.001
<4 ng/ml	8	28	36	
4.1-10 ng/ml	22	40	62	
>10 ng/ml	72	66	138	
	102	134	236	
DRE				<0.001
Normal	21	70	91	
Abnormal	81	64	145	
	102	134	236	

DRE: Digital rectal examination, PNB: Prostate needle biopsy, PSA: Prostate specific antigen

Table 4: Characteristics of patients based on grade of cancer

Variable	Histological grading (Gleason score)			Total	*P* value
	Mild (2-4)	Moderate (5-7)	Severe (8-10)		
Age (years)					>0.005
Mean	68.3	67.1	66.7	-	
Range	50-90	47-88	48-87	-	
PSA (ng/ml)					<0.001
<4	3	2	3	8	
4.1-10	6	9	7	22	
>10	20	27	25	72	
	29	38	35	102	
DRE					<0.001
Normal	13	11	5	29	
Abnormal	15	22	36	73	
	28	33	41	102	

DRE: Digital rectal examination, PNB: Prostate needle biopsy, PSA: Prostate specific antigen

multivariate analysis to evaluate the predictors of high-grade tumors in patients with diagnosis of cancer are shown in Table 4.

Discussion

DRE remains an important and useful tool in the hand of urologists in evaluating men with prostatic diseases. It is routinely performed in all patients presenting with lower urinary tract symptoms and should always be carried out before a PNB is performed to confirm or exclude prostate malignancy. The results of the DRE can define the clinical stage of disease and are important parts of the variables used before PNB to determine risk stratification, predict pathological stage, and the treatment outcome.[11,12]

In this study, benign prostatic diseases including BPH, chronic prostatitis and low-grade PIN were found in 134 (56.8%) of cases. BPH was the most common prostatic lesion accounting for 48.7% of all prostatic biopsies. This agrees with the findings of earlier studies in Nigeria[7,13,14] and the rest of the world,[15,16] which affirmed BPH as the most common prostatic lesion in men after the middle-age. Cancer detection rate of 43.2% makes PCa the second most common prostatic disease and it was also noted that both malignant and benign prostatic lesions peaked in the seventh decade of life with no significant difference in the mean ages for both. These findings agree with documentations in the literature from various parts of the world.[13,14,16-18]

DRE is the most sensitive method for diagnosis of palpable prostatic abnormalities; however, it lacks specificity for prostatic malignancy.[15] This is demonstrated in this study where 20.6% (21/102) of patients with PCa had normal DRE and conversely 47.8% (64/134) of patients with benign lesions

had abnormal DRE findings. Alternative causes of a nodule include prostatitis, calculus, tuberculosis, focal infarction, and even a spheroid of benign hyperplasia.[19] Chronic prostatitis has been documented to be a common cause of prostate abnormalities on DRE. On a total of 145 patients with abnormal DRE in this series, chronic prostatitis accounted for about 29% of cases. Generally, nodules caused by infection are raised above the surface of the gland. At their edges, the induration gradually fades to the normal softness of surrounding tissue. Conversely, the suspicious lesion in cases of PCa is usually not raised; rather, it is hard and has a sharp edge.[20] However, it is often difficult to differentiate nodularity of benign and malignant causes even in the hand of the most experienced clinician.[20] Therefore, an abnormal DRE finding as previously documented in numerous studies can be said to be non-specific finding for PCa.[9,16,21,22]

In this series, the prevalence of cancer was significantly higher amongst patients with abnormal DRE than in those with normal DRE, 50.3% and 31.9% respectively. Other large studies in referral populations have also identified an abnormal DRE to be associated with a greater risk of detecting PCa.[23,24] This emphasizes the continued relevance or usefulness of a DRE as a tool in evaluating patients with prostatic problems. Conversely, presence of a normal DRE does not completely excludes PCa as 23.1% of the patients with normal DRE eventually had the diagnosis of PCa after PNB. This is not surprising as DRE palpates the posterior aspect of the prostate gland adjacent to the rectum while the anteriorly located part as well as median lobe of the prostate cannot be palpated during a DRE. Therefore, utilization of a TRUS and serum PSA estimation should be combined with a DRE in evaluating these patients. This is contrary to some reports that DRE might not be useful in the referral setting.[22,25,26]

Without doubt DRE is very useful; however, a major limitation is its subjective nature in determining the various abnormalities of DRE as there is great inter-observer variability. DRE was performed in all patients in this series by the first author to eliminate this error as much as possible, though, intra-observer error has also been documented.[10] In this study, all the different abnormalities on DRE correlate well with PCa individually making each of them a significant finding when it occurs alone.

Different abnormal findings were found to have different predictive powers. In addition, we discovered that presence of more than one abnormality on DRE is associated with higher positive predictive value (PPV) for PCa. The least predictive and non-specific DRE sign or feature is the presence of a nodule in a firm prostate. Firm nodular prostates were associated with 33.3% cancer detection and 66.7% benign diseases. It means that diagnosis of a benign lesion is more likely if the only abnormality of DRE is nodularity in firm prostate. Cancer detection rate amongst patients with firm prostate with a solitary nodule was significantly higher than in those with multiple nodules, 52% and 24.5% respectively. This connotes that a solitary nodule is more suggestive of PCa than multiple nodules. All but one of 37 patients with chronic prostatitis with nodular prostate had multiple nodules. This may be explained by multi-foci nature of chronic prostatitis leading to multiple nodules resulting from fibrosis. Karakiewicz, *et al.*,[23] and Garzotto, *et al.*,[24] documented that DRE findings are useful and significantly improve the ability of nomograms to predict cancer diagnosis. However, these studies unlike ours did not document the relative importance or predictive value of each sign.

Thirteen (68.4%) of 19 patients with hard prostate only had PCa and this suggests that hard consistency of the prostate has a higher predictive value than presence of a nodule. We also found that PPV of DRE increased from 68.4% to 80-88.9% among patients who had combination of hard consistency with any of nodularity, fixity of rectal mucosa, obliteration of median groove and asymmetry. The presence of three or more abnormalities of DRE in any patient in this study was associated with 100% cancer detection. Studies with larger series will definitely be required to validate these observations. A closer look at patients who had three or more abnormalities revealed that patients in this group also had elevated PSA of more than 20 ng/ml. It can be suggested that in the presence of many abnormalities of DRE with severe compromise of quality of life like impending paraplegia, treatment can safely be commenced without further delay while waiting for confirmation by biopsy. This is consistent with the findings of Oranusi *et al.*,[27] who argued that treatment for PCa can be commenced without histology in certain cases.

The value of a well-done DRE is in its speed and relative low-cost. It takes advantage of the fact that most cancers arising in the peripheral zone can be identified in this manner in the asymptomatic men. Before the use of PSA testing, an abnormal DRE was the most common presentation of potentially curable localized PCa.[25] Nonetheless, since the introduction of PSA, there has been a steady increase in the detection of impalpable tumors, thereby leading some authors to question the usefulness of DRE in PCa detection in the PSA era. Contrary to the view that DRE is no longer useful, this study like several other studies demonstrated the importance of a DRE even with the advent of PSA testing.[22,26]

The clinical importance and aggressive nature of tumors with a Gleason sum of >7 has been well established.[19] Due to the higher risk of death from PCa in men with high-grade disease (Gleason score of >7) men with PCa who have a reasonable life-expectancy (<70 years) are not routinely considered candidates for active surveillance.[28] Our study of 236 men in a referral population undergoing initial PNB showed that high-grade tumors is more prevalent amongst patients with abnormal DRE, 44.4% (36/81) than those with normal DRE 9.5% (2/21). A multivariate analysis showed that DRE was a strong independent predictor of high-grade cancer. Curiously, a substantial proportion of cancers detected by DRE at a normal PSA also have features associated with clinically aggressive tumors. These are consistent with recent findings by Borden,

et al.,[21] in a study of 790 men. With this association, one can suggest that men with PCa who have abnormal DRE should be biopsied and treated promptly without further delay because of high possibility of a high-grade disease with its attendant aggressive behavior.

When the effect of combination of individual abnormalities of DRE present in patients on the grades of tumors was explored, we found that patients with more than two abnormal DRE findings had higher Gleason grades and scores than those with only one abnormality stressing the pathological importance of these signs when they co-exist. In fact, all the patients with more than two abnormalities on DRE in this study had high-grade tumors as ten patients had high-grade tumor and the only remaining patient had 7b, i.e., 4 + 3, which clinically has been described to behave like Gleason 8 disease.[19]

The ability of a DRE to predict high-grade cancer has important implications for clinical practice. The finding of this prospective study suggests that patients with positive DRE findings and a reasonable life-expectancy should have an urgent biopsy. This approach will allow such patients to benefit from curative therapy before spread, bearing in mind the possibility of harboring high-grade cancer with aggressive clinical behavior. Sometimes patients with shorter life expectancy are counseled against evaluation and treatment for PCa including, a DRE. This study clearly shows that DRE is still important even in patients with shorter life-expectancies, as a positive DRE can predict a more aggressive disease that might require early intervention to reduce PCa-specific morbidity and mortality.

Conclusion

In conclusion, DRE is a useful and important tool in assessing patients for a PNB. No abnormality of DRE is specific for PCa and presence of more than one abnormality of DRE is more predictive of PCa. An abnormal DRE independently predicted high-grade disease in men with PCa and therefore provides additional useful prognostic information. This study adds to the body of evidence supporting the continuing relevance of DRE in evaluation of patients with prostatic diseases in clinical setting.

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