



## A COMPARATIVE STUDY OF THE RELEVANCE OF DRE, TRUS, AND PSA IN THE DIAGNOSTIC EVALUATION OF PATIENTS WITH CARCINOMA OF THE PROSTATE.

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### ABSTRACT

Carcinoma of the prostate (CaP) is currently the most frequently diagnosed cancer among males<sup>1</sup>.

Although it was initially thought to be uncommon in Africans, recent studies have shown that the incidence and prevalence rates are higher in Africans than in age-matched African-Americans. The clinical outcome is also known to be relatively poor among blacks who typically present for treatment at advanced stages of the disease and at relatively younger ages<sup>2</sup>. Before the advent of sophisticated diagnostic techniques, the diagnosis of carcinoma of prostate was mainly done with digital rectal examination (DRE) with the attendant limitations as it was only useful in detecting advanced diseases. Previous studies have also shown that the findings and conclusions reached at DRE were subjective and observer dependent<sup>3</sup>. The subsequent introduction of the transrectal ultrasound (TRUS), which was greeted with much expectation with the hope that it would assist in detecting cancer nodules eluding detection by DRE turned out to be a disappointment<sup>4</sup>. Nevertheless, the introduction of the serum prostate-specific antigen (PSA) test brought about a revolution in the diagnosis of CaP since it allowed the detection of the disease in its early stages. This resulted in a significant reduction in the number of cases of CaP diagnosed at advanced stages. Since then, researchers have concentrated on the merits and demerits of the PSA in the early detection of CaP<sup>5</sup>. In recent times, however, controversies have trailed the use of the PSA in the screening and early diagnosis of CaP since it is becoming apparent that serum PSA estimation has some significant drawbacks in the evaluation of patients with prostatic disorders<sup>6</sup>. Although a larger percentage of cases of carcinoma of prostate are still being diagnosed at advanced stages in most African nations, only extremely very few studies have examined the role of serum PSA in the management of such cases<sup>7</sup>. Thus, the aim of this study was to compare the diagnostic yield of DRE, TRUS scan and PSA in the diagnostic evaluation of advanced carcinoma.

**KEYWORDS :** Prostate, digital rectal examination, PSA, screening,

### MATERIALS AND METHODS

This study was aimed at calculating and comparing the sensitivity and specificity of DRE, TRUS and PSA and to give recommendation(s) as to their continuous use in the evaluation of advanced CaP. This study was conducted over a 2-year period (November 2017 to October 2019) in department of general surgery ANMMCH, Gaya, Bihar.

**INCLUSION CRITERIA** - All patients who presented with symptoms and signs of prostatic disease during the study period.

**EXCLUSION CRITERIA** - Patients with incomplete clinical records and those who have had some form of treatment for benign prostatic Hyperplasia (BPH) or carcinoma of prostate.

The age of the patients and their mode of presentation, including DRE findings were documented at first clinical contact. Blood was taken for serum PSA, which was done using ELISA method in the hospital's chemical pathology laboratory. TRUS was done in each case. A prostatic biopsy was performed on all patients with a serum PSA above 4 ng/ml and/or with features suggestive of malignant disease on DRE and TRUS. All patients diagnosed with benign disease had prostatectomy (transvesical prostatectomy), and the specimens were sent to the histopathology laboratory for histological evaluation. The histology reports of the biopsy and post-prostatectomy specimens were documented.

### RESULTS

One hundred and eight patients were seen during the study period. The age distribution of the patients is as shown in Table 1.

Age (in years)	Frequency	Percentage
50-59	16	14.8
60-69	31	28.7
70-79	47	43.5
80-89	10	09.3
90-99	04	03.7

This shows that the highest incidences of prostatic diseases were seen in the 8th and 7th decades. Histo-pathological evaluation showed that 52 (48.1%) cases were CaP while 56 (51.9%) cases were BPH. The occurrence of BPH and CaP among different age groups with BPH occurring more commonly than CaP in the 6th and 7th decades although CaP becomes more common from the 8th decade. All the patients presented with lower urinary tract symptoms of varying severity, and none was diagnosed at screening. Forty-three (82.3%) patients diagnosed with CaP presented with urinary retention (acute or chronic) and needed catheterization while 36 (69.2%) had significant urinary tract infection at presentation and 32 (61.5%) had features of distant metastasis at presentation.

Diagnostic outcome of DRE findings was compared with the final histological diagnosis with DRE with a sensitivity of 73.1% and a specificity of 84.62% in the diagnosis of CaP. Diagnostic outcomes of TRUS findings with the final histological diagnosis, with TRUS had a sensitivity of 78.6% and a specificity of 67.5%. Comparison of the diagnostic outcomes of serum PSA and the final histological diagnosis shows a linear relationship between the PSA value and the occurrence of CaP. Surprisingly, 2 cases (3.9%) of advanced CaP had PSA values <4 ng/ml while 19 (33.9%) patients with benign prostatic hyperplasia had serum PSA values above 20 ng/ml. The sensitivity and specificity of serum PSA at the cut-off levels of 4, 10, 20, and 50 ng/ml were calculated and compared with those of DRE and TRUS. At 4ng/ml, PSA has the highest sensitivity and lowest specificity. Increasing cut-off values of serum PSA were associated with a corresponding reduction in its sensitivity and a corresponding increase in its specificity.

### DISCUSSION

BPH and CaP remain common disorders of the prostate, especially in our environment. The highest incidences for both BPE and CaP in this study were in the 8th decades of life although BPH was relatively more common than CaP before

the 8th decade of life. This trend was reversed after the 8th decade. This finding is similar to reports from other parts of Nigeria and Africa at large<sup>7</sup>. "Late detection" has been the normal pattern of presentation of CaP in most African nations<sup>7,8</sup>. No early case of CaP was detected at screening; rather, various degrees and types of complications were observed at presentation. This may be partly due to the fact that CaP in Black Africans is typically associated with a rapid rate of progression as well as an initially high Gleason's score<sup>8</sup>. DRE is in most parts considered undesirable in the evaluation of CaP because it is predominantly useful in the diagnosis of advanced prostatic carcinoma even though a significant proportion of patients with DRE findings suggestive of malignancy turn out to be negative for malignancy after histological evaluation<sup>9</sup>. Despite these facts, DRE has remained an important modality in the diagnosis and staging of patients with CaP. In this study, although DRE had the lowest sensitivity, it had the highest specificity when compared to TRUS and PSA. Similar findings have been reported in other studies comparing the diagnostic relevance of DRE, TRUS, and PSA<sup>10</sup>. This seems to suggest that DRE still plays an important role in the diagnostic workup of patients with CaP. Indeed, quite a few studies have shown that DRE is very useful in the screening of patients with PSA values within the normal range. In a recent study, 23% of men with normal PSA (<4 ng/ml) were diagnosed with CaP based only on the findings at DRE<sup>11</sup>. In another study, about 18% CaP was detected by DRE alone irrespective of the PSA values<sup>12</sup>. The earlier introduction of TRUS as a screening tool for CaP was marked by its low sensitivity and specificity; therefore, it is no longer used as a screening modality for CaP. Our findings, however, show that TRUS has a sensitivity close to that of PSA but higher than that of DRE as well as a specificity close to that of DRE, but higher than that of PSA. Typical ultrasound findings were seen in our patients includes hypoechoic nodules, asymmetry of the prostate gland, heterogeneous echotexture, increased vascularity, and breach of the capsule. Although TRUS may no longer be relevant in the screening of early prostatic malignant disease, it may still be relevant in diagnosis of advanced CaP. In advanced disease, TRUS guidance will also lead to a reduction in the number of biopsies taken and improve the sensitivity of prostate cancer detection as biopsy specimens are then taken directly from the lesions seen<sup>13</sup>. Several controversies have trailed the continued use of PSA in the screening and diagnosis of CaP. Indeed, the normal reference values have been changed in some parts of the world from traditional 0-4 ng/ml to much lower values<sup>6,14</sup>. The ineffectiveness of serum PSA as it is currently being used in the evaluation of patients with prostatic disease has led to an increase in the number of biopsy specimens taken from the prostate from about 6 to 12 all in an attempt to increase the diagnostic yield of the procedure. Moreover, several studies have also shown that high-grade CaP can occur in men with a serum PSA as low as 0.6-1 ng/ml<sup>14</sup>. As expected, our findings show a linear relationship between the PSA value and the number of patients diagnosed with CaP. This is a significant finding, which further confounds the controversies surrounding the use of PSA in the evaluation of patients with enlarged prostates, as our study showed that patients with advanced CaP whose serum PSA was within the "normal reference value of 0-4 ng/ml" constituted 3.9% of all our patients with histologically confirmed CaP. This proportion raised to 17.6% for PSA values of 10 ng/ml. In one previous study, it was noted that setting the normal limit of serum PSA at 4ng/ml led to the inadvertent diagnostic exclusion of over 80% of cases of CaP in young men and 65% of cases in old men<sup>15</sup>. Although serum PSA was the most sensitive of the three modalities used in this study at 4 ng/ml, its specificity was the lowest. This will, therefore, result in high number of cases with false positive values as well as a large number of cases for which unnecessary prostatic biopsies are performed. On the other hand, however,

increasing the upper limit of the reference value will improve the specificity at the expense of the sensitivity, causing a high proportion of cases with false negative values. The reverse is the case for DRE, which has a high specificity and low sensitivity. Similar findings have been reported from other studies. Despite these shortcomings, however, the application of PSA density, PSA velocity, and age-specific PSA may improve the specificity of serum PSA, thereby reducing the percentage of false positives and preventing unnecessary prostate biopsies although these parameters may be unhelpful when the PSA values fall within normal limits. It is becoming clearer that serum PSA, as it is being used presently, has a lot of drawbacks, and no value of serum PSA can be considered safe to declare a patient CaP free. The use of a combination of these three diagnostic modalities in the evaluation of patients with the prostatic disease and, indeed CaP will remain the best practice until better diagnostic modalities are available, especially in resource-poor countries.

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