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DIAGNOSTIC VALUES OF DIGITAL RECTAL EXAMINATION, PROSTATE SPECIFIC ANTIGEN AND TRANS-RECTAL ULTRASOUND IN MEN WITH PROSTATISM
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DIAGNOSTIC VALUES OF DIGITAL RECTAL EXAMINATION, PROSTATE SPECIFIC ANTIGEN AND TRANS-RECTAL ULTRASOUND IN MEN WITH PROSTATISM

J. P. MANYAHI, P. MUSAU and A.K. MTETA

ABSTRACT

Objective: **To determine the diagnostic values of digital rectal examination (DRE), prostate specific antigen (PSA) and trans-rectal ultrasound (TRUS) individually and in combinations in men aged 50 years and above presenting with prostatism.**
***Design*: A prospective, descriptive, cross-sectional, hospital-based study.**
Setting: **The urology ward of Kilimanjaro Christian Medical Centre (KCMC), a 500 bed tertiary hospital in the Kilimanjaro region, Tanzania.**
Subjects: **Ninety four consecutive admissions of men aged 50 years and above admitted with urinary symptoms suggestive of prostatism.**
Main outcome measures: **Primary outcome measures included race and age of patient; Positive predictive values, sensitivities and specificities for DRE, PSA and TRUS individually and in combinations and histology of the prostate specimens submitted after Tru-cut, TURP or open prostatectomy. The secondary outcome measures were mean PSA and PSA density.**
Results: **There was a prostate adenocarcinoma incidence of 25.5%; all found among patients with PSA levels greater than 10ng/ml. The positive predictive value (PPV), sensitivity and specificity of DRE for prostate cancer were 0.67%, 66.7% and 88.6% with an accuracy of 82.8%; while for TRUS, the respective values were 0.58%, 58.3% and 85.7% with an accuracy of 78.7%. PSA alone had a positive predictive value of 0.16. A combination of abnormal DRE and PSA (more than 4.0ng/ml) had a positive predictive value (PPV) of 0.75 while when DRE, TRUS and PSA were all abnormal, the PPV rose to 0.80.**
Conclusion: **A combination of DRE and PSA yields 75% diagnostic sensitivity for prostate cancer and is reliable enough to exempt TRUS where not available since it only adds 5% to this strong diagnostic combination.**

INTRODUCTION

The World Health Organisation (WHO) recommends standard diagnostic tests in patients presenting with lower urinary tract symptoms (LUTS) suggestive of prostatism. Besides the International Prostate Symptoms Score (IPSS) and urodynamic evaluations, these include adequate medical history, focused physical including digital rectal examination and serum prostate specific antigen (PSA) with trans-rectal ultrasound (TRUS) as an optional complimentary study. In resource limited settings as in Africa, one would be interested in ascertaining the reliability of the means available for dependable diagnosis. Regional differences also call for local data that is to date missing in the East African region.

Race, age and size of the prostate influence significantly the prostate specific antigen (PSA) value (2,3) yet PSA rise among men with either normal or abnormal digital rectal examination (DRE) findings suggests likely malignancy and adds important information to that of DRE regarding the risk of cancer presence. Histology remains the gold standard in reaching a conclusive diagnosis in patients presenting with prostatism.

The combined value of DRE, PSA and TRUS for detection of prostate cancer has been demonstrated

in the developed world but local data is sorely missing. This study was an attempt at addressing the local deficit with reference to published data in the diagnosis of patients with prostatism and will hopefully inform the approach to patients with prostatism in our region.

MATERIALS AND METHODS

A total of 94 consecutive men aged 50 years and above admitted with prostatism to the Urology ward of the Kilimanjaro Christian Medical Centre (KCMC), Moshi, were recruited into the study upon consenting.

Detailed presentation and medical history were taken, followed by a thorough physical (including digital rectal) examination and a focused neurological examination aimed at assessing the anal sphincteric tone, bulbocarvenous reflex and sensori-motor function of the lower extremeties. During DRE, the shape, size and consistency of the prostate gland were determined and recorded. DRE was considered abnormal when the gland exhibited an induration, nodules, asymmetry, irregularity or fixity of overlying rectal mucosa.

Two millilitres of whole blood were taken for PSA assays. Serum was separated within 24 hours, and stored at -80°C as per the recommendations of the kit in use.

Serum total PSA value of each sample was determined by PATHOZYME Prostate Specific Antigen Ref 00 327, Omega Diagnostic (UK). PSA values below 4ng/ml were considered normal while those in excess of this were adjudged abnormal on the basis of the PATHOZYME kit specifications. Samples were coded and analysed within a week of collection.

All recruited men were subjected to TRUS using Aloka SSD 650 Echo Camera equipped with a 7.5 MHz transducer probe; with the patient in the left lateral decubitus position and full flexion of both hip and knee joints. A well lubricated probe covered with a condom was introduced rectally, scanning the prostate gland in axial and sagital planes. The prostate contours were mapped and the prostate volume, including intra-vesicle extensions, was recorded. Special attention was focused on presence of hypo-echoic lesions within the prostate, breach of the overlying capsule and any changes involving the seminal vesicle. Presence of these features qualified as abnormal TRUS findings.

Patients with suspicious or abnormal nodules on DRE were subjected to trans-rectal digitally guided lesion biopsy using a standard 18 gauge needle loaded in a spring driven gun without any form of anaesthesia. Systematic sector biopsies were taken to a total six core biopsies. All patients got Ciprofloxacin 500mg orally twice a day and Metronidazole 400mg orally thrice a day for five days, and Diclofenac 50mg orally thrice daily or Paracetamol 1 gm orally thrice a day for three days after the procedure.

The tru-cut biopsies, prostate chips recovered during trans-urethral resection of prostate (TURP) and glands enucleated during retro-pubic prostatectomy of recruited patients were submitted for histological analysis. This was the gold standard test.

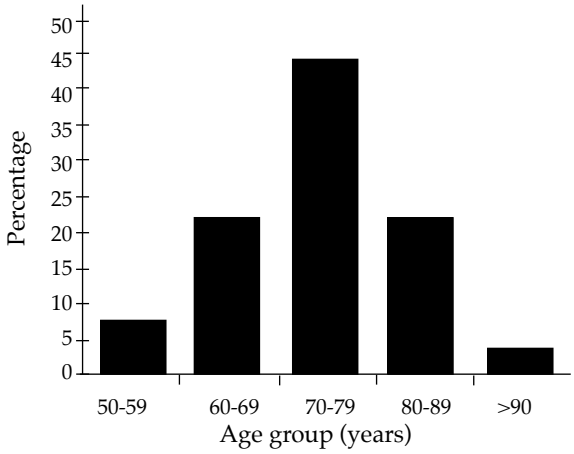
A structured questionnaire was used to collect information including the patients' age, symptoms, digital rectal examination findings, prostate size and trans-rectal ultrasound (TRUS) findings, prostate specific antigen values and histology results.

Statistical analysis using Statistical Package for Social Sciences (SPSS) version 11.5 software included correlations, determination of positive predictive value, sensitivity and specificity. Tests were considered significant if less than 0.05.

RESULTS

All the 94 patients were blacks. Their age range was 50-93 years; a mean of 73 years. The majority (44.2%) were in the 70-79 years age group (Figure 1).

Figure 1
Age distribution of patients with prostatism



Twenty four patients (25.5%) were found to have prostate cancer on histology; the rest had benign prostate hyperplasia (BPH). Twenty four were found to have abnormal DRE findings. Out of these, 16 had prostate cancer, giving a positive predictive value of 0.67. Seventy patients were considered to have normal DRE results but eight of these had prostate cancer. The sensitivity and specificity for DRE were 66.7% and 88.6% respectively. An abnormal digital rectal examination, therefore, had a diagnostic value of 67%.

None of the patients diagnosed to have cancer of the prostate had PSA levels less than 10ng/ml. These patients had a significantly higher mean PSA and prostate specific antigen density (PSAD) than of patients with benign prostate disease (p values of 0.036 and 0.035 respectively). The youngest of them was 53 years old. An isolated abnormal prostate specific antigen with the rest of the findings normal had a diagnostic value of 16%.

A total of 24 patients showed abnormal TRUS findings out of which 14 were found to have prostate cancer. The positive predictive value was 0.58. Out of the 70 patients adjudged to have normal TRUS results, 10 had prostate cancer. The sensitivity and specificity of TRUS was 58.3% and 85.7% respectively. The individual diagnostic value of trans-rectal ultrasound was 58%.

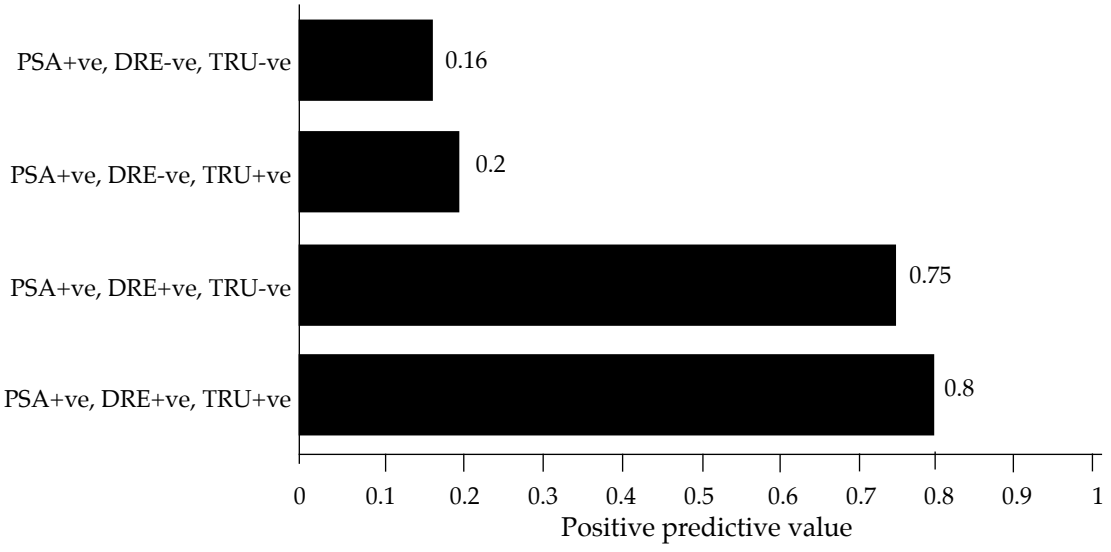
The three means of diagnosis were analysed in combinations to ascertain their combined diagnostic values. Patients who had normal PSA (<4ng/ml) but subjectively thought to have abnormality in both DRE and TRUS had no significant correlation with prostate cancer. A PSA in excess of 4ng/ml but less than 10ng/ml with normal DRE and TRUS findings showed a positive predictive value of 0.16 for prostate cancer. A combination of abnormal PSA and DRE had a positive predictive value of 0.75. When all the variables (PSA, DRE and TRUS) were abnormal, the positive predictive value rose to 0.8 (Figure 2).

DISCUSSION

Twenty five point five per cent of the patients evaluated had adenocarcinoma of the prostate. This rate is lower than that previously found by Nassanga (4) with a rate of 32.5% but compares well with findings by Men *et al* (5) in Turkish men with a rate of 23.1%. The difference in the detection rate might be due to use of different methods of biopsy collection. In the Nassanga series, all patients were subjected to systematic six core biopsies regardless of DRE findings, with digitally directed needle biopsies in patients with palpable nodules. In contrast, in this study, the majority of the biopsies (78 specimens) were prostate chips obtained after trans-urethral resection of prostate (TURP) with enucleated glands after retro-pubic prostatectomy and digitally directed needle biopsies in those with grossly discern able pathology accounting for the remaining 16 samples. During TURP, the peripheral zone which harbours about 70% of prostate cancer may not be adequately sampled and this may account for the differences in the detected numbers of prostate cancer.

Digital rectal examination had a positive predictive value of 0.67 and specificity of 88.6%. In a European study by de Reijke *et al* (6) on patients with prostatism, the positive predictive value was 0.48, suggesting geographical differences on the predictive value of DRE in evaluation of men with prostatism.

Figure 2
The positive predictive values of diagnostic modes in combination



+ve means abnormal; –ve means normal

The PSA values found in this study group are relatively high with none of the cancer cases having PSA levels less than 10 ng / ml; unlike in the developed countries where cancer of the prostate has been found in patients with PSA values as low as 1.1 ng / ml (7) and debate is on to push down the cut off point to values below 4.0ng / ml with respect to, particularly, age and race of the patient (8,9); the size of the prostate as well as non-neoplastic causes of PSA elevation like inflammation and recent instrumentation require the prostate specific antigen (PSA) density and the PSA velocity respectively to ascertain malignancy. Studies done elsewhere have highlighted the PSA difference among races with Africans having higher levels than Arabs whose PSA levels are in turn higher than for Caucasians (6, 10) mainly because of the racial differences in prostate sizes and levels of testosterone produced.

The positive predictive value and overall accuracy of TRUS were both lower than for DRE. Generally, TRUS use in the diagnosis of prostate cancer has such limitations as interpretation difficulties of suspicious hypo-echoic lesions that is user dependent. In this study, the tru-cut prostate biopsies were not TRUS guided and this may have contributed further to the limited value for TRUS in the diagnosis.

Digital rectal examination (DRE) and trans-rectal ultrasound (TRUS) rely on subjective analysis that depends on experience. Prostate specific antigen (PSA) estimation is more objective than both DRE and TRUS. With delays in presentation as occurs in our setting, the DRE predictive value becomes better than in localities where patients present earlier. Seen in totality, the best combination of these means of diagnosing prostate cancer are DRE and PSA. The addition of TRUS to this combination has a limited advantage that in resource deficient countries can be dispensed with without significant compromise on the diagnostic process. This finding of our study is in line with the World Health Organisation (WHO) suggestion that DRE and PSA be used as complementary tests and TRUS be considered optional in the primary evaluation of men with prostatism (1). These two assessment modes should be an integral part in the evaluation of patients presenting with prostatism in our local setting of East Africa given that they give a predictive value of 0.75 in this study and abnormal TRUS adds only 0.05 to this predictive value.

In conclusion, the PSA levels in the local African population are strikingly higher than in the European studies and the cases histologically confirmed to be prostate cancer were all beyond 10ng / ml.

A combination of DRE and PSA yields 75% diagnostic sensitivity for this malignancy and are reliable enough to exempt TRUS where not available since it only adds 5% to this strong diagnostic combination.

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