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# Standard 12-Core Transrectal Ultrasound-Guided Prostate Biopsy, a Useful Tool in Screening for Prostate Cancer: A Prospective Study in Uyo, Akwa Ibom State, Nigeria

Dr. Emmanuel Kunle Abudu[1*], Albert Effiong Ukpong[2], Elijah Asuquo Udoh[2], Okon Edet Akaiso[2], Unyime Aniekpon Fabian[3], Ikwo Jonathan Kudamnya[1], Cecilia Ndiuwem Okuku[3], Felix Uduma Uduma[4], Olugbemi Oluseyi Motilewa[5], Sunday Mkpouto Ekpedeme[4], Oluwasayo Omolara Abudu[6], Otobong Okpoho Peters[2], Oscar Asuquo Collins[4]

[1]Department of Pathology/Histopathology, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria
[2]Department of Surgery, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria
[3]Department of Chemical Pathology, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria
[4]Department of Radiology, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria
[5]Department of Community Medicine, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria
[6]Department of Nursing Services, University of Uyo Teaching Hospital, Uyo, Akwa Ibom State, Nigeria

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***Corresponding author:** Dr. Emmanuel Kunle Abudu
Department of Pathology/Histopathology, University of Uyo & Teaching Hospital, Uyo, Akwa Ibom State, Nigeria

## Abstract

***Introduction*:** Guided prostate biopsy is still relevant in confirming the diagnosis of suspected prostate cancer. Objective: This study evaluated the role of Transrectal Ultrasound (TRUS) guided biopsy along with histopathological evaluation in the detection of prostate cancer on the basis of abnormal digital rectal examination (DRE) findings and elevated prostate specific antigen levels (PSA). ***Participants and Methods*:** This prospective study was undertaken among consenting men aged 40 years and above screened for prostate cancer at the University of Uyo Teaching Hospital using targeted, stepwise protocol including DRE, PSA and standard 12-core transrectal ultrasound guided biopsy technique. Biopsy samples were sent for histopathological evaluation. Findings were documented, analyzed and presented in tables and figures. ***Results*:** Among 437 participants, abnormal DRE findings, elevated PSA level above 4.0 ng/ml and abnormal TRUS findings were 17.2%, 21.1%, and 17.3% respectively. Of 44 participants who had prostate biopsies with histopathologic assessment, benign prostatic diseases were 24 cases (54.5%), slightly outnumbering malignant prostatic diseases seen in 20 (45.5%).The prostate cancer detection and prevalence rates were 45.5% and 4.6% respectively. Prostatic adenocarcinoma (45.5%), nodular hyperplasia (45.5%), basal cell hyperplasia (6.8%) and high grade prostatic intraepithelial neoplasia (2.2%) were identified histologic subtypes. Nodular hyperplasia was commonly associated with chronic prostatitis (80.0%). A significant association between DRE findings, outline of prostate, and tumour subtype was ascertained. ***Conclusion*:** Targeted screening protocol encompassing TRUS guided 12- core biopsy is a final arbiter in the diagnosis of prostate cancer and has a fairly high prostate cancer detection rate of 45.5%.

**Keywords:** Biopsy Protocols, Detection rate, TRUS, Guided Prostate Biopsy, Prostate Cancer.



## INTRODUCTION

In the past, opportunistic or population screening programme encompassing prostate specific antigen (PSA) test was deployed solely for detection of localized prostate cancer stages that may progress to advanced disease as well as assessing response to treatment and recurrence of cancer [1-3]. However, diagnosis of prostate cancer relies on a tripod of digital rectal examination (DRE), prostate-specific antigen (PSA), and confirmatory transrectal ultrasound guided biopsy of the prostate [4, 5]. Prostate biopsy has been established as the gold standard confirmatory diagnostic tool for suspected prostate cancer [3, 4, 6-8]. Prostate biopsy is usually indicated in conditions such as elevated or rising total serum PSA, abnormal digital rectal examination (DRE), abnormal prostate ultrasound scan and metastatic bone deposit with elevated PSA [1, 2, 4, 5, 9-12]. Uncommon indications for prostatic biopsy include free PSA 0.75 ng $ml^{-1}$ per year (rate of

prostate specific antigen change), previous negative biopsies, but continuing high suspicion for prostate cancer and prior biopsies demonstrating atypical small acinar neoplasia [1, 5, 12]. The prostate cancer detection and prevalence rates vary from region to region and depend on many variables including racial difference, timing of presentation, abnormal DRE findings, elevated or rising PSA, number of core biopsy, expertise of healthcare personnel [9-11, 13-20]. Many studies have advocated targeted to systematic, stepwise prostate cancer screening protocol for men aged 40 years and above detailing DRE, PSA, TRUS, TRUS-guided prostate biopsy, contrast enhanced transrectal ultrasound (CE- TRUS), real-time sonoelastography (RTE) and MRI-TRUS fusion techniques [1, 5, 21]. The protocol for effective, result-targeted prostate biopsy has been described in many studies with emphasis on 'number of biopsy cores ranging from 8- 22' and 'biopsy reporting [1, 3-5, 8, 9, 11, 13, 18, 21-23]. This study is designed to evaluate the role of Transrectal Ultrasound (TRUS) guided biopsy along with histopathological evaluation in the detection of prostate cancer on the basis of abnormal DRE findings and elevated prostate-specific antigen levels (PSA).

## PARTICIPANTS AND METHODS

This prospective, observational, multidisciplinary study was carried out in the Departments of Surgery, Radiology, Chemical Pathology and Histopathology of the University of Uyo Teaching Hospital, Uyo, Akwa Ibom State between November 2021 and May 2022. All male patients aged 40 years and above were invited for the study via a variety of methods, including online interactive systems such as whatsApp and Facebook, postal mail, and telephone advertising, invitations and health campaign talks. They were registered at the Surgical Outpatient Unit of the Surgery Department after explanation regarding inclusion and exclusion criteria as well as details of the screening methods were made known to them. Informed written consents were also obtained from all the participants for inclusion in the study. Inclusion criteria entailed the presence of one or the combination of abstinence from sexual intercourse two weeks prior to taking of blood samples for PSA, absence of lower urinary tract symptoms (LUTS), persistently elevated PSA, abnormal DRE findings and abnormal findings on transrectal ultrasound scan of the prostate including visible nodule. Exclusion criteria comprised participants who declined consent or had symptomatic urinary tract infections or that were already on treatment for prostate cancer or a history of previous prostate surgery or history of mental disorders or prostatitis or uncorrectable bleeding diathesis (abnormal coagulation indices) or uncooperative participants. Participants were enrolled into the study on a consecutive basis on the fulfillment of inclusion criteria and documented consent. Patients on antiplatelet drugs such as aspirin and clopidogrel were asked to discontinue the drug for a minimum of 10 days before the biopsy. In patients with normal DRE findings and PSA elevation, repeat PSA testing was done. If both PSA levels were above 4 ng/ml, the patient was subjected to transrectal ultrasound scanning (TRUS). Participants were further evaluated by TRUS-guided biopsy for diagnosing prostate cancer. Each participant was prepared for the prostate biopsy using intravenous antibiotic, Dulcolax suppository and enema. Also, 1g Ceftriazone was commenced 48 hours and 1 hour before the biopsy respectively. The suppository was administered in the evening preceding the examination day and a proctoclysis enema was given in the morning on the day of biopsy. On arrival, the procedure was explained again to the participants and then an intravenous access was secured before all procedures. In the interval following administration of the intravenous antibiotic, TRUS assessment of the prostate was repeated. In addition, local anaesthesia was given by per rectal instillation of 2 % Lignocaine gel, 5 to 10 minutes before the TRUS biopsy procedure. Neither systemic sedatives nor analgesic agents were administered. All procedures were done as day cases. The TRUS imaging of the prostate was done with the patient in the left lateral decubitus (Sims) position using a GE Logiq P7 ultrasound machine (GE Ultrasound Ltd Korea, Gyeonggi-do 462-120, Republic of Korea 2020). The TRUS probe - a high frequency 8.0 - 10.0 MHz Bi-plane Endocavitary transducer, (GE Logiq P7, Korea) with a condom worn on it and a needle guide attached to it was lubricated with sonogel and was then gently inserted into the rectum while the participant bears down. The imaging was done simultaneously in the longitudinal and transverse planes. Any abnormality in echogenicity of the prostate was noted, the dimensions of the prostate was taken and the volume was calculated using a - reset prolate ellipsoid formula (L x W x H x 0.524). The Pro-Mag Ultra automatic biopsy instrument (Angiotech Pharmaceuticals Inc., North Bend, WA, USA) with an 18-G, 20-cm needle was used for the prostate biopsy. A systematic 12- core biopsy was done including the abnormal areas in the biopsy region. The sites of the 12 cores were as follows: right periphery, 3 (1 base, 1 mid, 1 apex); right paramedian, 2 (1 mid, 1 apex); left periphery, 3 (1 base, 1 mid, 1 apex); left paramedian, 2 (1 mid, 1 apex) and base of each lateral lobe. Tissue bits collected in the core biopsy procedures were placed directly into a universal bottle filled with 10% buffered formalin. After the biopsy, the participant was cleaned, the protective rubber sheath disposed and the probe properly cleaned. Each client's core biopsy was sent in a separate bottle to the Histopathology Department for histopathological examination. Patients were advised to take oral antibiotics (Levofloxacin 250 mg + Ornidazole 500 mg twice daily) and analgesics (combination of Tramadol 50 mg + Paracetamol 500 mg twice daily) for 3 days starting from the day of biopsy. Each participant was re-informed about possibility of a transient blood-stained stool and also

advised to report any haematuria. The result of the biopsy was studied. Ethical approval to conduct the study was obtained from the University of Uyo Teaching Hospital, Uyo Institutional Health Research Ethical Committee (IHREC). Written informed consents were obtained from all participants before embarking on the study. Brief education on the purpose and nature of the study was given to all respondents. All participants were assigned a unique code to ensure confidentiality. Only the lead researcher had access to the information linking the identity of the study participants to the study codes to ensure anonymity. This allowed for easy identification and prevention of risk of stigmatization. Participants were reliably informed that information provided shall be strictly kept secret and he is at liberty to withdraw from the study at any time they wished without any negative consequences to them. The study was fully supported by TETFund Institutional Research based funds. Data were collated and analyzed using Statistical Packages for the Social Sciences (SPSS Inc., Chicago, IL, USA) statistical software for Windows, version 20 (IBM). Descriptive analyses with calculated measures of central tendency and variation were computed. Categorical data were presented as actual numbers, percentages, tables and figures. Inferential statistics [Chi square, Student t-test, Fischer's exact test and Pearson's r test) were used to explore association between two or more variables. Confidence interval of 95% was used while $p \leq 0.05$ was considered statistically significant.

## RESULTS

Results of TRUS-guided prostate biopsy in men suspected of having prostate cancer on the basis of the outcome of DRE or PSA measurement or TRUS of prostate were analyzed. The age range of participants was 40 to 89 years with a mean age of 55.7 ± 10.1 years. The peak age for men with prostate cancer and nodular hyperplasia were in the 6th decade of life. The peak age range was 40–59 years and accounted for 65.2% of the entire study population. The majority of participants were married (91.8 %) with 83.5 % having more than secondary level of education. Participants of Ibibio extraction constituted 62.2 % of the entire study population (Table 1).

**Table 1: Socio - demographic characteristics of the participants**

| Variables | Frequency (N = 437) | Percentage (%) |
|---|---|---|
| **Age (years)** | | |
| 40 - 49 | 143 | 32.7 |
| 50 - 59 | 142 | 32.5 |
| 60 - 69 | 115 | 26.3 |
| 70 - 79 | 32 | 7.3 |
| 80 - 89 | 5 | 1.2 |
| Mean (SD) =55.7 (10.1) | | |
| **Marital Status** | | |
| Single | 26 | 6.0 |
| Married | 401 | 91.8 |
| Previously married | 10 | 2.2 |
| **Level of education** | | |
| Primary | 17 | 3.9 |
| Secondary | 55 | 12.6 |
| Tertiary | 178 | 40.7 |
| Postgraduate | 187 | 42.8 |
| **Tribe** | | |
| Annang | 85 | 19.5 |
| Ibibio | 272 | 62.2 |
| Oro | 27 | 6.2 |
| Others | 53 | 12.1 |

Of the 347 apparently healthy participants screened, seventy five (17.2%) had abnormal DRE findings (Figure 1). Ninety- two participants had elevated PSA level above 4.0 ng/ml (21.1%). Prostate specific antigen (PSA) values ranged from 0.1 to105.0 ng/ml, with a mean of 5.0 ng/ml and serum PSA levels ≤ 4 ng/ml occurring in the majority of the participants (n = 345, 78.9%). The mean (range) serum PSA levels in those diagnosed of benign prostatic disease after prostate biopsy was 14.1 (0.1–89.0) ng/ml whereas those diagnosed with prostate adenocarcinoma histologically was 27.0 (5.2–105.0) ng/ml. (Tables 2 & 3).

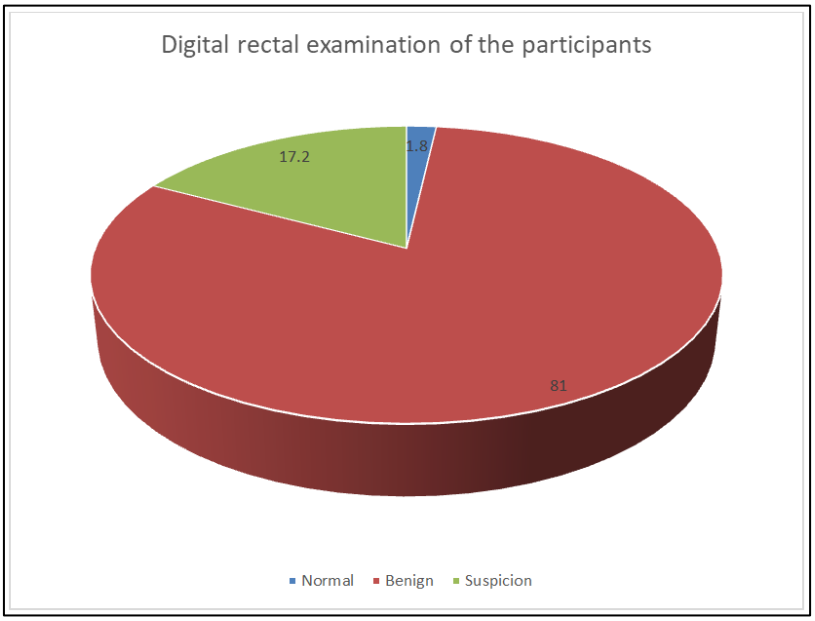


**Figure 1: A Pie chart showing the digital rectal examination (DRE) findings among the participants**

**Table 2: Ultrasound findings and the outcomes of DRE among the participants**

| Ultrasound scan findings | DRE n (%) | | Statistical indices |
|---|---|---|---|
| | Benign (n=362) | Suspicion (n=75) | |
| **Prostate Outline** | | | Df = 1 |
| Lobulated | 43 (46.7) | 49 (55.4) | $X^2 = 33.5671$ |
| Regular | 319 (92.5) | 26 (7.5) | p value<0.0001 |
| **Prostate Volume** | | | Z = 6.2481 |
| Median (Min -Max) | 28.5 (0.6-150.7) | 37.2 (13.8-152.9) | p value=0.012 |
| **Echogenecity Pattern** | | | |
| Homogenous | 189 (89.6) | 22 (10.4) | Df = 4 |
| Heterogenous | 124 (73.4) | 45 (26.6) | $X^2 = 33.5671$ |
| Hyperechoic | 39 (92.9) | 3 (7.1) | p value = 0.001 |
| Hypoechoic | 10 (66.7) | 5 (33.3) | |
| **Post-micturition volume** | | | |
| Median (Min -Max) | 28.4 (0.3-436) | 44.3 (2-376.2) | Z=8.009 |
| | | | p value = 0.005 |

**Table 3: Serum PSA range among participants.**

| Serum PSA Level (ng/ml) | Number (n) | Percentage (%) |
|---|---|---|
| 0.1- 4.0 | 345 | 78.9 |
| 4.1 – 10.0 | 35 | 8.0 |
| 10.1 – 20.0 | 31 | 7.1 |
| 20.1 and above | 26 | 6.0 |
| **Total** | **437** | **100.0** |

Among participants who had TRUS of the prostate, only 60 participants had abnormal findings suspicious of prostate cancer (13.7%). The TRUS prostate volume range of all the participants was between 0.61 mls and 152.9mls with a mean prostate volume of 35± 19 mls. The mean (range) prostate volume in those histologically diagnosed of benign prostatic disease was 46.5 (15.5–150.7) mls whereas those diagnosed with prostate adenocarcinoma histologically was 44.8 (22.8-152.9) mls.

Furthermore, radiological examination revealed that majority of prostate gland had regular outline in 345 (78.9%) outnumbering those with lobulated outline, 92 (21.1%). In both benign and malignant prostate diseases, lobulated sonographic outline of prostate glands predominated and distributed as 51.3% and 48.7% respectively. Most of the participants had homogenous echotexture of the prostate gland in 211 (48.3%) whereas heterogenous echogenecity was seen among 169 participants (38.7%). Hyperechoic and hypoechoic echogenecity were found in 42 (9.6%) and 15 (3.4%) participants respectively (Table 2).

**Table 4: The prostate biopsy and ultrasound scan findings among the participants**

| Ultrasound scan findings | Prostate biopsy n(%) | | Statistical indices |
|---|---|---|---|
| | Benign (n=24) | Malignant (n=20) | |
| **Echogenecity Pattern** | | | |
| Homogenous | 1 (33.3) | 2 (66.7) | Df = 4 |
| Heterogenous | 22 (59.5) | 15 (40.5) | p value = 0.087 |
| Hyperechoic | 1 (100.0) | 0 (0.0) | |
| Hypoechoic | 0 (0.0) | 3 (100.0) | |
| **Prostate Outline** | | | |
| Lobulated | 19 (51.3) | 18 (48.7) | Df = 1 |
| Regular | 5 (71.4) | 2 (28.6) | p value = 0.428* |
| **Prostate Volume** | | | |
| Median (range) | 46.5 (15.5-150.7) | 44.8 (22.8-152.9) | Z = 0.000 |
| | | | p value = 1.000 |
| **Post-micturition volume** | | | |
| Median (range) | 39.6 (17-273) | 54.5 (376.2-2.0) | Z= 0.3667 |
| | | | p value = 0.525 |

Although 60 participants had abnormal TRUS findings (13.7%), only 44 were available for TRUS - guided prostate biopsy. Of these, benign prostatic diseases were 24 cases (54.5%), slightly outnumbering malignant prostatic diseases seen in 20 (45.5%). Details of histopathologic assessment showed prostatic adenocarcinoma and nodular hyperplasia accounting for 20 (45.5%) each while basal cell hyperplasia and high grade prostatic intraepithelial neoplasia were seen among 3 (6.8%) and 1 (2.3%) participants respectively. The prostate cancer detection and prevalence rates were 20 out of 44 (45.5%) and 20 out of 437(4.6%) respectively. All the 24 prostatic adenocarcinomas had significant Gleason score 7 or more on the final grading assessment with Gleason score of 9, WHO/ISUP Grade group 5 accounting for 14 out of 24 cases (58.3%).

It was observed that the outline of the prostate during TRUS assessment differs significantly; those with histologically diagnosed prostatic adenocarcinoma

have a higher proportion for lobulated sonographic outline while benign prostatic diseases have a higher proportion for regular sonographic outline (p value < 0.0001).

The outline of the prostate differs significantly; those participants with suspicious DRE findings have a significantly higher proportion of lobular sonographic outline (53.3 %) when compared with those with benign DRE findings (46.7%) whereas those with benign DRE findings have a significantly higher proportion of regular sonographic outline (92.5%) compared to those with suspicious DRE findings (7.5%), p value < 0.0001.

It was observed that there is an insignificant difference in the sonographic echogenecity pattern of the prostate glands between histologically diagnosed benign prostate diseases and prostate adenocarcinoma (p value < 0.087).

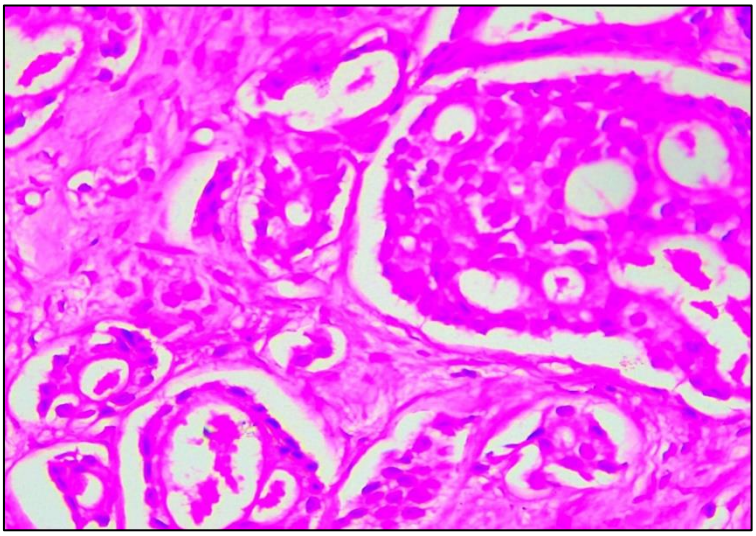

**Figure 2: Photomicrograph of prostate carcinoma, Gleason score of 7 at 40x magnification**

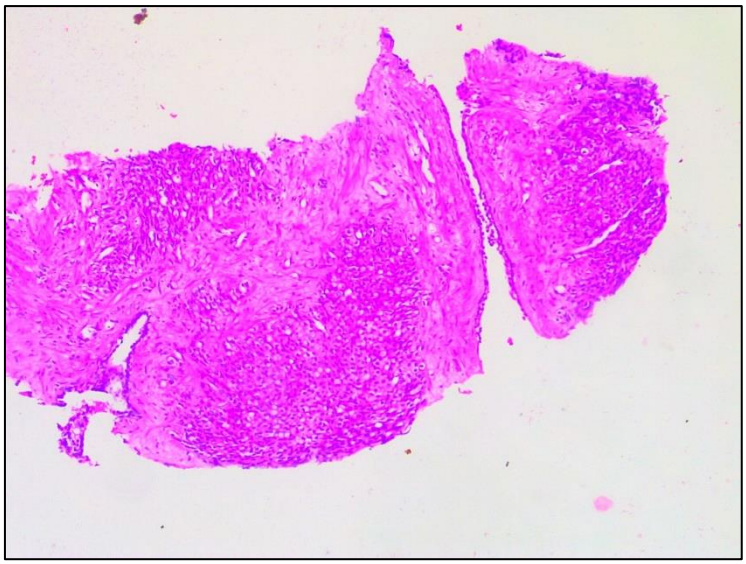

**Figure 3: Photomicrograph of prostate carcinoma, Gleason score of 9 at 4x magnification**

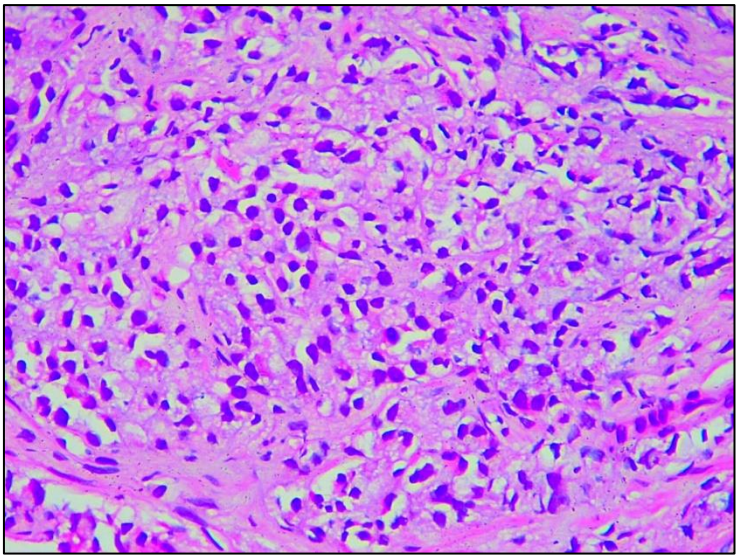

**Figure 4: Photomicrograph of prostate carcinoma, Gleason score of 10 at 10x magnification.**

## DISCUSSION

Prostate specific antigen (PSA) assay was used as a sole diagnostic tool in opportunistic or population screening programme in the past [1-3]. However, a paradigm shift from a sole screening modality to a tripod of digital rectal examination (DRE), prostate-specific antigen (PSA), and confirmatory transrectal ultrasound guided biopsy of the prostate have been reported [4, 5]. Consequently, histopathological assessment of prostate biopsy still remains the gold standard for diagnosis of prostate cancer [4, 6-8]. Common indications for prostatic biopsy have been reported to be elevated or rising total serum PSA (>4ng/ml), abnormal digital rectal examination (DRE), abnormal prostate ultrasound scan and metastatic bone deposit with elevated PSA in a descending order [1, 2, 4, 5, 9-12]. In addition, free PSA 0.75 ng ml−1 per year (rate of prostate specific antigen change), previous negative biopsies, but continuing high suspicion for prostate cancer and prior biopsies demonstrating atypical small acinar neoplasia were uncommon, current indications for prostate biopsy [1, 5, 12]. In our study, overall prostate cancer detection and prevalence rates by the standard 12-core biopsy technique was 45.5 % and 4.6 % respectively. Ogbetere *et al.,* in South-southern Nigeria recorded outstandingly higher prostate cancer detection rate of 65.0 % which is significantly above rates ranging from 13.3% to 48.8% recorded within and outside Nigeria [9, 11, 13-18]. In addition, our prostate cancer prevalence rate of 4.6 % is however lower than 13.3 %, 15.0 % and 24.0 % recorded in Lagos, South West Nigeria, Antalya and Ankara in Turkey respectively [10, 19, 20]. The prostate cancer detection and prevalence rates vary from region to region. These variations may be adduced to racial difference, late presentation, number of core biopsy and expertise of healthcare personnel. Furthermore, it has been shown that cancer detection rate is higher in participants with increasing PSA, abnormal DRE and increasing core biopsy from 10- to 16-core biopsies [17, 18]. This finding underpins a need to screen adult males from age of 40 years using targeted to systematic, stepwise screening protocol encompassing DRE, PSA, TRUS, TRUS-guided prostate biopsy, contrast-enhanced transrectal ultrasound (CE-TRUS), real-time sonoelastography (RTE) and MRI-TRUS fusion techniques [1, 5, 24]. Although advance imaging techniques such as contrast-enhanced transrectal ultrasound (CE- TRUS), real-time sonoelastography (RTE) and MRI-TRUS fusion techniques provide more favorable template for targeted biopsies and improved detection of prostate cancer [1, 5], these imaging equipment are however not available in our center. Nevertheless, tripod of DRE, PSA and TRUS-guided prostatic biopsy is still relevant for successful screening in low resource settings like ours, though with few drawbacks. Abnormal DRE findings were observed in 17.2 % of participants. This compares but lowers than values of 43.3 % and 60.0 % reported by Shanbhag *et al.,* in India and Jehle *et al.,* in South-Africa respectively [2, 8]. Although, digital rectal examination (DRE) is a vital component of the clinical examination of the prostate gland, DRE findings in men being screened for prostate cancer vary from region to region probably due to low sensitivity and positive predictive value as well as high false positive rate of DRE related to a degree of inter-examiner variability with DRE [2]. In spite of these limitations, DRE is still recommended as a vital component of screening technique protocol for prostate cancer such as PSA estimation, free PSA estimation, TRUS, and if required, a prostate biopsy [2]. Overall mean serum PSA value amongst our participants was 5.0 mg/ml, though lower than 14.1 ng/ml and 27.0 ng/ml observed in histologically confirmed benign and malignant prostate diseases respectively in our study. Equivocally, Shanbhag *et al.,* in India reported much lower rates of 6.8 and 7.4 ng/ml in benign and malignant diseases [2]. These values are

significantly higher than results of 1.46 ng/ml, 1.84 ng/ml, 2.21 ng/ml and 2.9 ng/ml reported by Aisuodionoe-Shadrach *et al.,* Ikuerowo *et al.,* Eboreime *et al.,* and Amadi *et al.,* respectively [25-28]. Only 21.0% of the participants had their PSA values equal or greater than 4.0 ng/mL in our center; this is however higher than 8.0 % and 9.4 % reported by Aisuodionoe-Shadrach *et al.,* and Ikuerowo *et al.,* respectively [25, 26]. These findings are further supported by a study in Lagos, South Western Nigeria confirming that 91.2 % of the patients had PSA level of > 4ng/ml [9]. The important role of PSA in screening for prostate cancer has been highlighted and offers prostate cancer detection sensitivity at a bench-mark of 4.0 ng/ml of 2.0 % and 51.0 % for any prostate cancer and high-grade cancer respectively [2]. Furthermore, it has been documented that a higher PSA level tend to be associated with a higher risk of malignancy, high-grade cancer, a higher tumour stage, or even metastases [2]. In addition, effectiveness and high diagnostic rates of TRUS guided sextant core biopsy in diagnosing of prostate cancer have been related to PSA levels of >50 ng/ml and gland volume between 30-50 cc [29]. Corroboratively, Reddy *et al.,* demonstrated a strong correlation between PSA level and tumour diagnosis [26]. Agreeably, prostate specific antigen (PSA) test is not specific to prostate cancer, but the value may increase to an extent such as value greater than 20ng/ml which is useful in predicting prostate cancer [30]. In addition, Shanbhag *et al.,* suggested that the use of Percentage fPSA as complementary diagnostic test in patients with a PSA range between 4.0 – 10.0 ng/ml. PSA, is proffered for avoidance of unnecessary biopsies in patients [2].

TRUS is the most commonly used modality for guiding and visualizing systematic prostate biopsy for diagnosis of suspected cancer of prostate as well as providing accurate assessment of size and anatomy of prostate [1, 3, 5]. In the index study, an overall mean prostate volume of 35 ± 1.9 mls and abnormal TRUS findings with 13.7% were recorded. The mean prostate volumes of 46.5 mls and 44.8 mls were recorded in histologically confirmed benign and malignant prostatic diseases respectively. In both benign and malignant prostate diseases, lobulated outline of prostate glands predominated and distributed as 51.3 % and 48.7% respectively. This compares with result of the average prostate volume of 36 mls reported by Omer *et al.,* in Turkey [20]. Another study in India showed that mean prostate volumes of 69.2 mls and 47.8 mls were recorded for benign and malignant prostatic diseases respectively [2]. Prostate volumes of the cancer patients were significantly lower than the non-cancer lesions similar to the index study [14]. This is however in contrast to the findings of Ogbetere *et al.,* who reported that the mean prostate volume of men with carcinoma of the prostate was significantly higher than those with benign prostatic hyperplasia (BPH) [4]. A prostate cancer with a Gleason score of 7 or greater, and a prostate volume greater than 0.5 $cm^3$ has been described as a clinically significant cancer, thus, further highlighting the important role of TRUS in clearly delineating prostate zonal anatomy necessary for diagnosis of prostate neoplastic diseases [5]. Although 60 participants had abnormal TRUS findings, only 44 participants were available for TRUS guided prostate biopsy (73.3 %). Of these, benign prostatic diseases were 54.5 %, slightly outnumbering malignant prostatic diseases seen in 45.5%. Adenocarcinoma and nodular hyperplasia of prostate were the predominant histologic subtypes and accounting for 45.5 % each. This is not totally different from other studies reporting predominance of adenocarcinoma [4, 29, 30]. These studies gave credence to the reports of increasing incidence of prostate cancer in sub - Sahara Africa including Nigeria and globally. In the index study, all the participants diagnosed of prostatic adenocarcinoma had high Gleason score of ≥7 with a peak score of 7. This compares well with the findings of 32.6%, 39.7%, 41.9%, and 62.8% in centers in Nigeria, India, and China respectively [4, 9, 17, 18, 31]. The probable reason for the high Gleason score and resultant poor prognosis at presentation may be adduced to absence of regular screening program and ineffective health insurance scheme in sub-Saharan Africa as well as the fact that the majority of our patients present when they develop complications or in the advanced stage of the disease [4]. In addition, lack of awareness of prostate cancer may be responsible for the late presentation related to the high prevalence of high Gleason score with dismal prognosis [4, 9]. It is pertinent to emphasize the role of effective, result-orientated protocol for Trucut biopsy. In the index study, transrectal ultrasound-guided standard 12-core biopsy was deployed and yielding at least 12 cores of prostate tissue; this compares with other studies [1, 3-5, 8, 9, 11, 13, 18, 21, 22]. These findings are further corroborated by a report of Harvey *et al.,* in UK who asserted 10 -12 cores biopsy as the minimum standard for diagnosis of prostate cancer in variance with conclusion of Joshi *et al.,* in Nepal who claimed that 10-12 cores biopsies are not an established ideal number of biopsies [1, 21, 23, 32]. Corroboratively, they suggested an extended (saturation) 22 core biopsies which have been found to improve the concordance of Gleason scores between prostatic biopsies and prostatectomy [1, 23]. This finding concurs with a report of Ogbetere *et al.,* in Auchi, Southern South Nigeria which has demonstrated an increase in cancer detection and decreases the probability of repeat biopsy when compared to the sextant protocol if an extended biopsy protocol encompassing 8 to 26 tissue cores is employed [4]. Initially, there were controversy with regard to increasing the number of biopsies in detection of prostate cancer in such a way that saturation biopsy is considered as a minimum of 20 cores tissue sampling with a more accuracy, though associated with increased

morbidity and adverse effects, especially infection [11]. However, Ghafoori and other researchers concluded that the optimum number of obtained prostate biopsies to reach acceptable diagnostic power with least infection rate is 12-core biopsy [1, 3-5, 8, 11, 13, 18, 21, 22]. Nevertheless, many new biopsy protocols have been proposed with respect to their main features 'number of biopsy cores' and 'biopsy reporting [1]. Although, transrectal scan guided prostate biopsy is routinely used for diagnosis of prostate cancer in our environment and other centers in Nigeria [4, 9]. Available literature have reported a paradigm shift from transrectal scan guided prostate biopsy to advance imaging techniques in developed countries such as contrast- enhanced transrectal ultrasound (CE-TRUS)-, real-time sonoelastography (RTE)- and MRI- TRUS fusion techniques- guided prostate biopsy for targeted biopsies and improved detection of prostate cancer [1, 5]. From the foregoing, it is obvious that biopsy protocol including number of biopsy cores and biopsy reporting play a crucial role in accurate diagnosis of prostate cancer from region to region, thus, training and retraining of healthcare workers on patient's preprocedure preparations, biopsy sampling, processing and reporting techniques are paramount for decision making in the screening and treatment of prostate cancer among the populace.

## CONCLUSION

Targeted to systematic, stepwise screening protocol encompassing TRUS guided 12- core biopsy is a final arbiter in the diagnosis of prostate cancer. We found the overall prostate cancer detection and prevalence rates at our center to be 38.8% and 4.6% respectively, which are comparable to other studies. The results of our study corroborate other studies advocating DRE, serum PSA and TRUS as efficient tools in directing surgeons whether to proceed for prostatic biopsy. There is a need for a targeted prostate cancer awareness campaign in sub-Saharan Africa including Nigeria to enhance the early detection of prostate cancer and pre-cancerous lesions for possible treatment.

### Limitations

1) In our study, direct digital examination (DRE) was performed on all participants by at least 5 Consultant Surgeons with tendency for a degree of inter-examiner variability related to false positive rate of DRE.
2) Blood samples for serum PSA level were collected at different time, and stored in refrigerator before analysis.
3) Inability to carry out Percentage fPSA as complementary diagnostic test in participants with a PSA range between 4.0 – 10.0 ng/ml aimed at avoiding unnecessary biopsies.
4) It is a short-term study spanning for 6 months which did not encompass long term follow-up of those participants with elevated serum PSA and suspicious TRUS findings.
5) Guided prostate biopsy does have some limitations including mild to moderate complications such as fever, haematuria which were followed-up.

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### Authors' Contributions

1. EKA and UAF conceptualized the study;
2. IJK, OOA and EKA, collated the data and carried out the formal analysis;
3. EAU, AEU, OEA, OOP, FUU, SME, UAF, IJK and EKA, CNO and OAC carried out the investigations and developed the methodology;
4. EKA, UAF, EAU, OOM and FUU supervised the study,
5. EKA., OOM and OOA validated the data;
6. EKA, IJK and OOA were responsible for data visualization;
7. Roles/writing original draft was by EKA and OOA; and
8. Writing-review and editing were carried out by EAU, AEU, OEA, OOP, FUU, SME and EKA.

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