

Complications of Trans rectal Ultrasound-Guided Extended 12-Core Prostate Biopsy

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ABSTRACT

Background: In Nigeria, Prostate cancer is the most diagnosed cancer in males from middle age. The only definitive way to confirm prostate cancer is through prostate biopsy. Trans-rectal Ultrasound (TRUS) guided core needle biopsy of the prostate has become the procedure of choice for obtaining high quality tissue cores for histopathologic assessment in patients with suspected prostate cancer. Despite being considered generally a safe technique, TRUS-guided prostate biopsy is an invasive process with potential risks. We assessed the complications arising from 12-core prostate biopsy performed under TRUS guidance in this prospective study. **Objectives:** The aim of this study was to report the common complications and incidence rate after 12-core extended biopsy protocol using TRUS guided needle biopsy amongst patients being evaluated for prostate cancer in Lagos University Teaching Hospital, Lagos. **Methodology:** This study was a prospective hospital-based study involving patients evaluated for prostate cancer. All study participants, mean age 68.1years received antibiotic prophylaxis five minutes to the procedure and a laxative was administered a day prior to the procedure. Also, all patients had thorough clinical evaluation including digital rectal examination (DRE), serum assay for prostate specific antigen (PSA), radiologic imaging of the prostate with Trans-Rectal Ultrasound (TRUS) and TRUS guided Extended 12-core needle biopsy of the prostate (including 6-Sextant and 6-lateral core biopsies). **Results:** Result of 134 prostate biopsies performed in selected patients were reported. 134 men (aged 37-89years) were enrolled in this study and had Extended 12-Core TRUS guided prostate needle biopsy. 78 men (58.2%) were positive for cancer, 52 men (38.8%) had BPH and 4 men (3%) had prostatitis. Complications occurred in 60.4% (81) of patients but most of these complications were minor bleeding complications. The most common complication of the biopsy was rectal bleeding which occurred in 59.7% of patients, followed by Hematuria/ bleeding per urethra in 23.9% of patients. Urinary tract infection after biopsy was most common in patients with prostatitis ($p=0.020$). Majority of patients (84.3%) found the procedure tolerable with only mild discomfort and 67.9% felt no pain. Study results were generally consistent with other reports on complication rates. **Conclusion:** The study showed that the TRUS guided 12-core extended biopsy procedure can be safely performed as it is well tolerated with no significant pain or morbidity and without significant increase in complication rate.

Keywords: Prostate cancer, Trans-rectal Ultrasound (TRUS), prostate needle biopsy, Prostate core biopsy protocol.

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INTRODUCTION

Prostate cancer represents a major burden on Urological services at Lagos University Teaching Hospital and is among the most common causes of hospital admission in elderly men. It is also the leading cause of cancer-related mortality in men over 50 years of age in our setting. The incidence of prostate cancer is rising worldwide and may be caused mainly by demographic factors particularly the increasing elderly population and more importantly the increasing number of cases identified from prostate specific antigen (PSA) testing.

Histological confirmation via prostate biopsy remains the definitive method for diagnosing prostate cancer¹. The procedure requires taking a biopsy through the rectal, during which an inoculum of bacteria from the rectum can be introduced into the prostate parenchyma.

Over the past three decades, rapid technological advances have facilitated the widespread integration of prostatic imaging into clinical practice. Modalities such as multiparametric ultrasound, multiparametric magnetic resonance imaging (mpMRI), and nuclear imaging with positron emission tomography (PET) are now routinely employed for prostate cancer detection and localisation, staging, active surveillance, treatment planning—including whole-gland and focal therapies and monitoring for disease recurrence.

Transrectal ultrasound (TRUS)-guided prostate biopsy is the standard technique for obtaining tissue cores for histopathological assessment in men with suspected prostate cancer. The procedure is generally safe, well tolerated, and can be performed on an outpatient basis without the need for narcotic analgesia or intravenous sedation.

Random systematic sextant biopsy was shown to be superior to lesion-directed biopsy for cancer detection and subsequently became the reference standard technique, involving bilateral parasagittal sampling from the base, mid-gland, and apex of the

prostate^{2,1}. However, increasing evidence suggests that sextant biopsy under-samples the prostate and may fail to detect a significant proportion of clinically relevant tumours. This has generated ongoing debate regarding the optimal number and anatomical distribution of biopsy cores, as well as the need to balance improved cancer detection against the risk of increased biopsy-related morbidity.

Complications associated with Transrectal Ultrasound-Guided Prostate Biopsy are well documented^{3,4,5} and may be broadly categorised into infectious and non-infectious events. Infective complications range from asymptomatic bacteriuria, reported in approximately 10–20% of cases, to symptomatic urinary tract infection in 2–6% of patients. Febrile urinary tract infection or acute prostatitis occurs in 1–3%, while sepsis has been reported in 0.5–2% of cases. Hospital admission following post-biopsy infectious complications is required in approximately 1–3% of patients.

Bleeding-related complications are more frequently observed but are typically self-limiting. Haematuria occurs in 30–60% of patients, rectal bleeding in 10–30%, and haematospermia in 40–80%. Less commonly reported adverse events include acute urinary retention (0.2–1.7%), vasovagal reactions (1–5%), and transient erectile dysfunction. Overall, while most complications are minor and resolve without intervention, infectious complications remain the most clinically significant due to their potential for systemic morbidity and need for hospitalisation.

In this prospective study, we evaluated the complication rate of Transrectal Ultrasound guided 12-core extended biopsy protocol in patients undergoing prostate biopsy as part of evaluation for prostate cancer in our hospital.

METHODOLOGY

This prospective study was carried out amongst 138 men who were being investigated for prostate cancer at our centre. Approval for the study was

obtained from the Human Research and Ethics Committee of the Lagos University Teaching Hospital administration building. The HREC assigned number is ADM/DCST/HREC/APP/2631 and approval was obtained on the 20th of February 2019 spanning a 1 year. An informed written consent was obtained from all the patients. Inclusion criteria were the presence of one or any combination of elevated total serum prostate specific antigen (PSA >4ng/ml), abnormal digital rectal examination findings of the prostate and abnormal findings on imaging studies (TRUS/MRI). Additionally, patients with painful perianal pathology, those who declined the procedure, individuals deemed medically unfit to undergo the procedure, and those with symptomatic or laboratory evidence of urinary tract infection were excluded from the study. Patients were recruited on a consecutive basis on the fulfilment of criteria and documented consent. Patients on antiplatelet medications (clopidogrel) or anticoagulants (warfarin, dabigatran) were requested to discontinue for 7-10days prior to the procedure and INR (international Normalized ratio) needed to be normalized before we proceeded. According to Unit's protocol, all patients had single preoperative day of rectal suppository (Bisacodyl 10mg nocte) the night prior to the procedure to reduce faecal loading and enhance visualization for TRUS. Single doses of broad spectrum antibiotics (i.e Intravenous levofloxacin 500mg stat and metronidazole 400mg stat) administered five minutes (5mins) prior to commencing the biopsy and the oral preparations of same antibiotics were continued for 5 days post procedure. No systematic sedatives or analgesic agents were administered. All procedures were done as day case.

Patients were usually placed in the left lateral decubitus position with knees and hips flexed at 90° for biopsies. An arm board attached parallel to the table and a pillow between the knees allowed patients to maintain this position. The buttocks were flushed with the edge of the procedure table to allow easy installation of anaesthetic and manipulation of the probe without obstruction. Preliminary DRE was carried out by researcher and findings documented

and then, 10mls of 2% xylocaine hydrochloride jelly introduced intrarectally for topical anaesthesia and lubrication 15minutes before the procedure is commenced.

The TRUS probe (Mindray product DP2200 model with a 7.5MHz transducer, China) with a condom worn over it and a needle guide attached to it was lubricated with a sonogel and was inserted gently into the rectum. TRUS evaluation of the prostate was carried out and documented. Each patient then received local anaesthesia via peri-prostatic blockade using 5mls of plain 1% lidocaine injection applied to the prostate- seminal vesicle junction on each side of the basolateral region of the prostate using a 22G spinal needle introduced through the needle guide and a waiting period of 5mins to allow the anaesthetic work. After ensuring correct placement of rectal probe into individual zones of the prostate, biopsies were obtained using 18G core biopsy needle mounted on a spring-loaded automatic biopsy gun through and end fire needle guide attached to the rectal probe, six core biopsies were obtained from the apex, middle and base of each lateral lobe para-sagittal representing the sextant group. Additional six core biopsies, (three cores from each lateral lobe) was obtained in all patients to make extended 12-core biopsies from the far lateral portion of the prostate (apex, middle and base). Suspicious nodules were targeted in all groups as well as part of the biopsy protocol and included to the most approximate region in the protocol. Biopsy cores taken from the sextant, and lateral peripheral zone (PZ) were all individually and appropriately labelled and submitted separately in formalin filled containers to the department of Pathology for histopathologic analysis. The rectum was then temporarily packed with gauze. The result of the biopsy histopathology was documented as Malignant, Benign, and Prostatitis. The histological type and Gleason grade/score of biopsies that turn out to be malignant were also requested.

It was ensured that patients not on urethral catheter voided urine before discharge to detect any haematuria or urinary retention. Subsequently all patients were discharged home after 2 hours of

observation if no complications warranting admission for further care were noticed. Patients were counselled to note the onset and duration of any concerns arising from the procedure. The importance of completing prescribed antibiotics was also emphasized. Patients were followed up on their mobile phones in between the time of the procedure and first clinic visit after the procedure (usually 5 days for any complications). The second clinic visit after the procedure was approximately 3 weeks and was dedicated to the review of their investigation results and complications. All complications noted and documented. We examined bleeding complications (haematuria/per urethral bleeding, rectal bleeding and haematuria), temperature elevation above 38.0°C, signs of inflammation (Systemic inflammatory response) or infection (UTI), pain during biopsy, acute urine retention, and hospital admission amongst others.

RESULT

A total of 138 men were recruited into the study but 134 patients were eligible for evaluation. The ages of the participants ranged from 37 to 89 years, with a mean age of 68.1 ± 9.5 years. The most represented age group was 61–70 years, accounting for 42% of the study population. Histopathological analysis revealed malignant prostate disease in 78 patients (58.2%), benign histology in 52 patients (38.8%), and prostatitis coexisting with benign histology in 4 patients (3.0%).

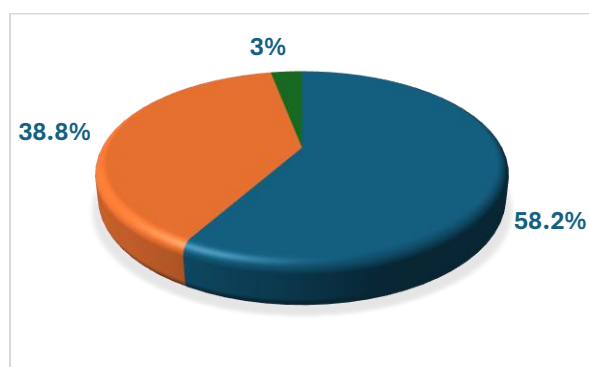


Figure 1: Distribution of Final Histopathological diagnosis

Procedure-related complications were observed in 81 patients (60.4%). The most frequently reported complication was rectal bleeding, occurring in 80 patients (59.7%), followed by haematuria or bleeding per urethra in 32 patients (23.9%). All bleeding episodes were self-limiting lasting between 24–72 hours from patient's self-report and required no further intervention.

Post-biopsy urinary tract infection occurred in 9 patients (6.7%). The incidence of infection was significantly higher among patients with histological evidence of prostatitis compared with those with benign or malignant findings ($p = 0.020$) and the commonest organism was *Escherichia coli* in 60% of cases, although other organisms like *klebsiella*, *proteus* and *pseudomonas* were cultured. No cases of severe sepsis requiring intensive care admission were recorded. Also, one patient developed post biopsy epididymitis and we had two cases of intraoperative vasovagal episodes in the study population.

Overall complication rates did not differ significantly across histopathological diagnostic categories ($p = 0.897$). Similarly, there were no statistically significant differences in rates of rectal bleeding ($p = 0.620$) or haematuria ($p = 0.861$) between patients with prostate cancer, benign prostatic hyperplasia, and prostatitis (Table 1).

Patient tolerance of the procedure was high. The majority of participants (113; 84.3%) described the procedure as very comfortable, while only 3 patients (2.2%) reported discomfort. With respect to pain perception, 91 patients (67.9%) reported no pain, 35 (26.1%) reported mild pain, and only 8 patients (6.0%) experienced moderate pain. Pain scores and patient satisfaction did not differ significantly across diagnostic groups.

Table 1: Complications in participant

	Overall (n=134)	Prostate Cancer (n=78)	BPH (n=52)	Prostatitis (n=4)	p-value
Presence of complication					
Yes	81(60.4)	48(61.5)	31(59.6)	2(50.0)	0.897
No	53(39.6)	30(38.5)	21(40.4)	2(50.0)	
Complications					
Urosepsis					
Yes	9(6.7)	5(6.4)	2(3.8)	2(50.0)	0.020*
No	125(93.3)	73(93.6)	50(96.2)	2(50.0)	
Rectal bleeding					
Yes	80(59.7)	49(62.8)	29(55.8)	2(50.0)	0.620
No	54(40.3)	29(37.2)	23(44.2)	2(50.0)	
Haematuria					
Yes	32(23.9)	20(25.6)	11(21.2)	1(25.0)	0.861
No	102(76.1)	58(74.4)	41(78.8)	3(75.0)	
Patient satisfaction					
Uncomfortable	3(2.2)	2(2.6)	1(1.9)	0(0.0)	0.253
Fairly comfortable	18(13.4)	11(14.1)	5(9.6)	2(50.0)	
Very comfortable	113(84.3)	65(83.3)	46(88.5)	2(50.0)	
Pain level					
None	91(67.9)	52(66.7)	38(73.1)	1(25.0)	0.117
Mild	35(26.1)	20(25.6)	13(25.0)	2(50.0)	
Moderate	8(6.0)	6(7.7)	1(1.9)	1(25.0)	

*Significant p value (<0.05)

DISCUSSION

Prostate cancer remains one of the most commonly diagnosed malignancies in men worldwide and a leading cause of cancer-related mortality⁶. Men of African descent are known to carry a disproportionately higher risk of both developing prostate cancer and experiencing adverse outcomes⁷. Current screening recommendations advocate annual prostate-specific antigen (PSA) testing and digital rectal examination (DRE) for men aged 50 years and above, with earlier screening advised for those with a positive family history^{8,9}. Although

prospective trials have yet to conclusively demonstrate a reduction in mortality attributable to routine screening, substantial advances in diagnostic modalities and therapeutic strategies have significantly transformed prostate cancer

management over recent decades. Histological confirmation via prostate biopsy remains the cornerstone of diagnosis.

Prostate biopsy techniques have evolved considerably, with image-guided approaches now central to optimising tissue yield and diagnostic accuracy. In high-resource settings, MRI-TRUS fusion biopsy has emerged as the preferred technique, while cognitive fusion TRUS-guided biopsy and the trans-perineal approach are also widely adopted. The Trans-perineal technique has gained popularity perhaps due to reduced incidence of post biopsy infective complication rate. However, in low- and middle-income settings, including our environment, routine use of multiparametric MRI is limited by cost and availability. In contrast, transrectal ultrasound (TRUS) is increasingly

accessible, underscoring the importance of evaluating extended TRUS-guided biopsy protocols within our population.

A theoretical concern associated with extended biopsy protocols is the potential for increased procedure-related morbidity due to a higher number of biopsy cores. In this study, the overall complication rate was 60.4%, a figure comparable to those reported in similar series^{10,11}, with all complications being minor. Bleeding-related complications were the most frequent, with transient rectal bleeding and haematuria observed in a substantial proportion of patients. Importantly, these events were self-limiting, resolving within minutes to days. No patient reported persistent bleeding episodes above three days and no patient required blood transfusion or further intervention.

Infective complications were infrequent and mild. Urine culture-confirmed urinary tract infection occurred in a small proportion of symptomatic patients and responded to oral antibiotic therapy without the need for hospital admission. The low rate of significant infection observed may be attributed to the routine use of antibiotic prophylaxis and pre-procedural rectal preparation. *Escherichia coli* was the most isolated pathogen, consistent with existing literature. A single case of epididymitis was successfully managed with prolonged antibiotic therapy. The two vasovagal episodes recorded resolved promptly with conservative measures.

Our findings are consistent with previously published studies^{11,12 13,4,5}, demonstrating a low incidence of major complications following TRUS-guided prostate biopsy. Prior reports have documented major complication rates of less than 2.5%, with minor complications predominating^{5,14,15,16}. In the present study, the rate of major complications was less than 1%, likely influenced by the relatively modest sample size. No demographic or clinical variables were significantly associated with the development of post-biopsy complications.

Patient tolerance of the procedure was high. The majority of participants reported minimal discomfort, with over 80% describing the procedure as very comfortable and only a small proportion experiencing moderate pain. While discomfort was more frequently reported among younger patients, the few individuals who described the procedure as uncomfortable were elderly and frail, suggesting that patient-specific factors rather than biopsy extent alone may influence procedural tolerance.

Overall, this study demonstrates that extended TRUS-guided prostate biopsy is a safe and well-tolerated procedure in our setting. Increasing the number of biopsy cores did not adversely affect patient comfort or satisfaction and did not result in a clinically significant increase in morbidity. These findings support the continued use of extended TRUS-guided biopsy protocols as a practical and effective diagnostic approach in environments where advanced imaging-guided biopsy techniques remain limited.

Limitation of the study

The transrectal ultrasound assessment used in this study focused on grayscale identification of prostatic nodules, with advanced imaging techniques like elastography and Doppler unavailable. This limitation may impact lesion characterization and targeted sampling, leading to increased reliance on systematic cores, potentially lowering cancer detection rates and raising complication risks due to higher instances of bleeding and infections associated with multiple core insertions.

CONCLUSION

This study demonstrates that extended 12-core transrectal ultrasound-guided prostate biopsy is a safe and well-tolerated diagnostic procedure, with a low incidence of clinically significant complications. The findings support the routine performance of prostate biopsy as an outpatient procedure without the need for substantial anaesthetic or additional analgesic interventions, provided that the benefits of histological diagnosis

are carefully balanced against potential procedural risks.

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