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Feasibility and Diagnostic Yield of Blind Transrectal Digital Core Biopsy for Prostate Cancer in a Resource-Limited Setting: A Cross-Sectional Study.

Faisabilité et rendement diagnostique de la biopsie prostatique transrectale digitale à l'aveugle en milieu à ressources limitées : étude transversale .

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Abstact

Introduction: Prostate cancer imposes a significant burden in resource-limited settings where advanced imaging like transrectal ultrasound or MRI is unavailable, necessitating evaluation of simpler biopsy techniques. This study aimed to assess the feasibility, diagnostic yield, safety profile, and prognostic utility of serum PSA in blind transrectal digital-guided core prostate biopsy performed at a low resource setting. The primary research question was whether this technique provides clinically meaningful histopathological confirmation and risk stratification in high-prevalence, late-presentation populations.

Methods: This prospective cross-sectional study included 46 consecutive men (mean age 71 years) who underwent blind digital transrectal core biopsy at HEAL Africa Hospital (April 2023–September 2025). Histopathology categorized specimens as benign or malignant. Continuous variables were summarized as mean ± standard deviation, categorical variables as frequencies and percentages. Because PSA values were non-normally distributed, non-parametric analyses were applied, including Spearman's correlation and receiver operating characteristic (ROC) curve analysis to assess PSA discrimination (AUC, optimal cutoff via Youden index). Statistical significance was set at $p < 0,05$.

Results: Adenocarcinoma was confirmed in 69.6% (32/46), with high-grade tumors (Gleason ≥8) in 46.8%. PSA strongly associated with cancer diagnosis (r_s =0.782, p<0.001) and Gleason score (r_s =0.423, p=0.016). ROC analysis yielded AUC 0.953 (95% CI 0.895-1.000), optimal cutoff 49.8 ng/mL (sensitivity 75%, specificity 100%). Complications were low (6.5%, mild hematuria/rectal bleeding); repeat biopsy was needed in 4.3%.

Conclusion: Blind digital transrectal prostate biopsy demonstrates feasibility and safety in resource-limited environments. When combined with prostate-specific antigen (PSA) testing, this approach provides robust diagnostic and prognostic utility. These findings highlight a pragmatic pathway toward equitable access to prostate cancer diagnosis in settings where imaging modalities are unavailable.

Keys-words: Prostate cancer, blind digital-guided biopsy, transrectal biopsy, resource-limited setting,

Résumé

Introduction : Le cancer de la prostate représente une charge importante en milieu à ressources limitées, où les techniques d'imagerie avancées telles que l'échographie transrectale ou l'IRM ne sont pas disponibles, rendant nécessaire l'évaluation de méthodes de biopsie plus simples. Cette étude visait à évaluer la faisabilité, le rendement diagnostique, le profil de sécurité et l'utilité pronostique du dosage sérique du PSA dans la biopsie prostatique transrectale digitale à l'aveugle réalisée en contexte de faible disponibilité de ressources. La question principale de recherche était de déterminer si cette technique permet une confirmation histopathologique cliniquement pertinente et une stratification du risque dans des populations à forte prévalence et à présentation tardive.

Matériels et méthode : Il s'agit d'une étude prospective transversale incluant 46 hommes consécutifs (âge moyen : 71 ans) ayant bénéficié d'une biopsie prostatique transrectale digitale à l'aveugle à l'hôpital HEAL Africa (avril 2023 – septembre 2025). L'histopathologie a classé les prélèvements en bénins ou malins. Les variables continues ont été résumées par la moyenne ± écart-type, les variables catégorielles par fréquences et pourcentages. Étant donné la distribution non normale des valeurs de PSA, des analyses non paramétriques ont été appliquées, incluant la corrélation de Spearman et l'analyse de courbe ROC pour évaluer la discrimination du PSA (AUC, seuil optimal via l'indice de Youden). Le seuil de significativité statistique a été fixé à $p < 0,05$.

Résultats : Un adénocarcinome a été confirmé chez 69,6 % (32/46), avec des tumeurs de haut grade (Gleason ≥8) dans 46,8 %. Le PSA était fortement associé au diagnostic de cancer ($r_s = 0,782$, $p < 0,001$) et au score de Gleason ($r_s = 0,423$, $p = 0,016$). L'analyse ROC a montré une AUC de 0,953 (IC 95 % : 0,895–1,000), avec un seuil optimal de 49,8 ng/mL (sensibilité 75 %, spécificité 100 %). Les complications étaient faibles (6,5 %, hématurie ou saignement rectal légers) ; une reprise de la biopsie a été nécessaire dans 4,3 %.

Conclusion : La biopsie prostatique transrectale digitale à l'aveugle démontre sa faisabilité et sa sécurité en milieu à ressources limitées. Associée au dosage du PSA, cette approche offre une utilité diagnostique et pronostique robuste. Ces résultats mettent en évidence une voie pragmatique vers un accès équitable au diagnostic du cancer de la prostate dans les contextes où les modalités d'imagerie sont indisponibles.

Mots-clés : Cancer de la prostate, biopsie digitale guidée à l'aveugle, biopsie transrectale, milieu à ressources limitées.

Introduction

Prostate cancer remains one of the most frequently diagnosed malignancies among men worldwide and represents a major contributor to cancer-related morbidity and mortality [1,2]. Histopathological confirmation obtained through prostate biopsy remains the gold standard for establishing the diagnosis of prostate cancer and serves as the foundation for subsequent therapeutic decision-making [3,4]. When appropriately utilized, tissue-based biomarkers derived from prostate cancer specimens can substantially enhance prognostic assessment, facilitate risk stratification, and inform treatment selection.[5]. Image-guided techniques, particularly transrectal ultrasonography (TRUS), magnetic resonance imaging (MRI), and fusion biopsy, which integrates multiparametric MRI (mpMRI) findings with real-time TRUS, represent highly effective modalities for sampling suspicious prostatic lesions [4,6,7]. However, access to these advanced imaging technologies remains markedly uneven worldwide. In many low-resource settings, particularly within sub-Saharan Africa, such

modalities are not readily available, thereby limiting the integration of imaging guidance into routine clinical practice [8,9].

Blind digital core biopsy has historically been criticized for potential sampling limitations and reduced systematic coverage of the prostate [10]. Nevertheless, in contexts where no alternative exists, it provides critical histological confirmation and directly influences patient management [8,11]. In regions where patients often present with advanced disease and markedly elevated prostate-specific antigen (PSA) levels, the clinical performance of such simplified techniques warrants careful evaluation rather than dismissal [11].

Beyond procedural feasibility, understanding the relationship between serum PSA levels, biopsy-confirmed cancer, and tumor aggressiveness is particularly important in resource-constrained settings [12,13]. PSA testing is often more accessible than advanced imaging, and its diagnostic and predictive value may play an even more central role in guiding biopsy decisions where technology is limited [12,14].

Against this background, the present study aimed to evaluate the clinical performance, safety profile, and histopathological outcomes of blind transrectal digital core prostate biopsy in a low-resource facility. By documenting our experience, we aim to contribute pragmatic evidence from a real-world, resource-limited context and to inform discussions on equitable prostate cancer diagnosis in settings where advanced technologies remain inaccessible.

Materials ans method

Study Design and Setting

This was a prospective observational study conducted at a low-resource healthcare facility, HEAL Africa Hospital located in the eastern Democratic Republic of the Congo. The study included consecutive patients who underwent blind transrectal digital core prostate biopsy between 1 April 2023 and 30 September 2025 (30 months).

Study Population

All adult male patients who underwent transrectal digital-guided prostate biopsy during the study period were eligible.

Inclusion criteria: Patients presenting with one or more of the following: elevated serum prostate-specific antigen (PSA) levels, and/or abnormal findings on digital rectal examination (DRE), and/or clinical suspicion of prostate cancer. These three parameters traditionally constitute the principal indications for proceeding with prostate biopsy [15]

Exclusion criteria: Incomplete clinical or laboratory records, missing histopathological results and Prior confirmed diagnosis of prostate cancer. A total of 46 patients met the inclusion criteria and were included in the final analysis.

Clinical Evaluation

All patients underwent: Detailed clinical history documentation, physical examination including DRE and Serum PSA measurement prior to biopsy. PSA levels were recorded as continuous variables and further categorized for descriptive analysis (<10, 10–20, 20–100, and >100 ng/mL). DRE findings were categorized according to prostate volume, surface characteristics, and tenderness.

Biopsy Procedure

All biopsies were performed using a blind transrectal digital-guided core biopsy technique due to the absence of transrectal ultrasound (TRUS) guidance at the study center. All procedures were performed under standard aseptic precautions, with analgesia administered as needed. Patients received intravenous ceftriaxone as antibiotic prophylaxis within 60 minutes prior to the procedure. Biopsy sampling followed a sextant template whereby six cores were obtained per patient—one core from each of the right and left apex, mid-gland, and base—using a spring-loaded biopsy gun; however, all cores from each procedure were pooled into a single, labeled container, fixed in 10% neutral buffered formalin, and submitted as a single specimen for histopathological processing. Histological assessment was performed by a board-certified pathologist who provided a case-level diagnosis and assigned Gleason grading where applicable, but the pathology reports did not enumerate the number of positive versus negative cores or provide core-level localization. Consequently, per-core positivity rates and sextant mapping could not be determined. In instances where rectal mucosa was inadvertently sampled in the absence of prostatic tissue, a repeat biopsy was conducted. Immediate post-procedural complications were closely monitored and systematically documented.

Histopathological Assessment

Diagnoses were classified into the following categories: benign prostatic hyperplasia (BPH), BPH with prostatitis, and prostate adenocarcinoma; these were further grouped as benign prostatic disease or prostate adenocarcinoma. For malignant cases, Gleason grading was performed in accordance with the International Society of Urological Pathology (ISUP) system [16,17]. High-grade tumors were defined as Gleason score ≥8.

Outcome Measures

The primary outcome was biopsy-confirmed prostate adenocarcinoma. Secondary outcomes included, association between PSA level and prostate cancer diagnosis, correlation between PSA level and Gleason score, diagnostic accuracy of PSA using receiver operating characteristic (ROC) curve analysis and procedural complication rate.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics (version 26, IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Given the non-normal distribution of PSA values, non-parametric tests were used. Spearman's rank correlation coefficient (r_s) was calculated to assess: The association between PSA levels and biopsy-confirmed prostate cancer and the correlation between PSA levels and Gleason score among cancer patients, Receiver operating characteristic (ROC) curve analysis was performed to evaluate the discriminatory ability of PSA for predicting prostate cancer. The area under the curve (AUC) with 95% confidence intervals (CI) was calculated. The optimal PSA cut-off value was determined using the Youden index. Sensitivity and specificity were reported. A two-tailed p-value < 0.05 was considered statistically significant.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki. Institutional approval was obtained prior to data collection. Patient confidentiality was maintained through anonymization of data.

Results

Patient characteristics

A total of 46 patients underwent blind transrectal digital core prostate biopsy at our low-resource facility between 1st April 2023 and 30 September 2025. Mean age was 71 years (range, 54–91 years; standard deviation 7.599). The most common presenting complaint was lower urinary tract symptoms (LUTS) (63%), while 6 patients (13%) underwent biopsy following screening evaluation. Regarding past medical history, 32 patients (69.6%) had no reported chronic medical conditions and 2 (4.3%) had previous transvesical prostatectomy. On DRE, 23 patients (50%) had an enlarged prostate with smooth surface and no tenderness. Nearly half of the patients (47.8%) had PSA levels >100 ng/mL. Only 11 patients (23.9%) had PSA <10 ng/mL (see table I).

Table I. Patient characteristics

Variable		n	%
Complaints	LUTS	29	63
	Screening	6	13
	LUTS and Urinary retention	11	23.9
Past medical and surgical history	Hypertension	10	21.7
	Hypertension and diabetes	2	4.3
	No	32	69.6
	Transvesical prostatectomy	2	4.3
DRE	Increased volume, nodularity, non-tender	15	32.6
	Increased volume, nodularity, tender	1	2.2
	Increased volume, smooth surface, non-tender	23	50
	Increased volume, smooth surface, tender	7	15.2
PSA	<10	11	23.9
	>100	22	47.8
	10-20	3	6.5
	20-100	10	21.7
Post operative complication	Hematuria	1	2.2
	Mild rectal bleeding and hematuria	2	4.3
	No	43	93.5

*LUTS: Low Urinary Tract Symptoms, PSA: Prostate specific antigen

*DRE: Digital rectal exam

Procedural Outcomes and Complications

Post-biopsy complications occurred in 3 patients (6.5%): isolated hematuria in 1 (2.2%) and mild rectal hemorrhage with hematuria in 2 (4.3%). Two patients (4.3%) required repeat biopsy due to initial rectal mucosa sampling without prostatic tissue.

Histopathological Findings

Prostate adenocarcinoma was confirmed in 32 patients (69.6%), with benign pathology (benign prostatic hyperplasia alone or with prostatitis) in 14 (30.4%).

Among the 32 patients diagnosed with adenocarcinoma, high-grade tumors (Gleason score ≥8) predominated (46.8%) (see table II).

Associations with Prostate Cancer

Spearman's rank correlation demonstrated a moderate, statistically significant positive association between serum PSA levels and Gleason score among patients with

prostate cancer (r_s = 0.423, p = 0.016), suggesting that increasing PSA levels correlate with greater tumor aggressiveness. PSA also demonstrated a strong and statistically significant association with prostate cancer diagnosis (r_s = 0.782, p < 0.001), suggesting that increasing PSA values markedly increased the likelihood of malignancy (See table III).

Table II. Histological findings

Variables		n	%
Biopsy result	BPH	12	26.1
	BPH + Prostitis	2	4.3
	Adenocarcinoma	32	69.6
Gleason score	<6	11	23.9
	3+4	5	10.9
	4+3	1	2.2
	8	7	15.2
	9 and 10	8	17.4

BPH: Benign Prostate Hypertrophy.

Table III. PSA association with Gleason score and prostate cancer

Variables	n	Spearman's rho (r_s)	p-value
PSA vs Gleason Score	32	0.423	0.016*
PSA vs Biopsy-confirmed Cancer	32	0.782	<0.001*

*: Statistically significant, PSA: Prostate specific antigen

Receiver operating characteristic (ROC)

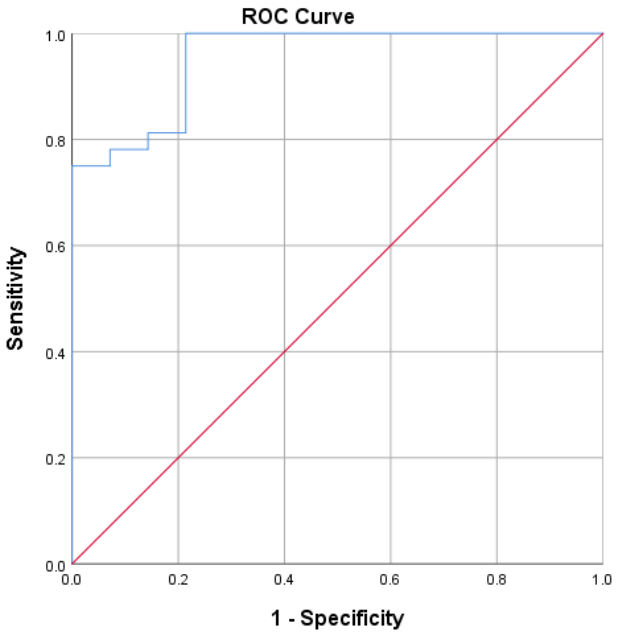

Figure 1. Receiver operating characteristic (ROC) curve demonstrating the diagnostic performance of serum Prostate specific antigen for predicting biopsy-confirmed prostate cancer.

Receiver operating characteristic (ROC) curve analysis demonstrated outstanding discriminatory ability of serum PSA for predicting biopsy-confirmed prostate cancer, The area under the curve was 0.953 (95% CI 0.895–1.000), p < 0.001). The optimal PSA cut-off value was ≥49.8 ng/dL, yielding a sensitivity of 75.0% and a specificity of 100%. These findings indicate excellent diagnostic performance of PSA in this population.

Discussion

This study evaluated the feasibility and clinical performance of blind transrectal digital-guided core prostate biopsy in a resource-constrained setting. Three key findings emerged. First, the technique achieved a high cancer detection rate (69.6%) with a low complication profile. Second, a substantial proportion of detected tumors were high grade, reflecting advanced presentation in our population. Third, serum prostate-specific antigen (PSA) demonstrated excellent discriminatory ability for biopsy-confirmed prostate cancer (AUC 0.953) and correlated significantly with Gleason score.

Collectively, these findings highlight that, even in the absence of imaging guidance, clinically meaningful prostate cancer diagnosis is achievable; more broadly, they underscore the importance of context-adapted strategies in global urologic care [11,13].

In high-income countries, transrectal ultrasound (TRUS)-guided systematic biopsy and, increasingly, multiparametric MRI-targeted biopsy are considered standards of care [18]. These approaches improve lesion targeting and reduce unnecessary sampling [19]. However, they depend on imaging infrastructure, trained personnel, and financial resources that remain inaccessible in many regions [8,20].

The cancer detection rate observed in our study (69.6%) is higher than that typically reported in TRUS biopsy, where detection rates range from 25% to 56% [21]. This likely reflects patient selection rather than procedural superiority. Nearly half of our patients had PSA levels exceeding 100 ng/mL, and most presented with symptoms rather than being identified through screening. In such high-prevalence contexts, even limited sampling may yield substantial diagnostic returns [13].

Historically, digitally directed biopsies were widely performed before the adoption of systematic TRUS-guided protocols [10]. Although later criticized for limited sampling distribution, data demonstrated reasonable performance in patients with abnormal digital rectal examination findings or markedly elevated PSA levels [8,11]. Our findings suggest that in high-risk clinical scenarios, blind digital biopsy remains capable of

confirming malignancy and guiding management decisions where alternatives are unavailable.

A notable feature of our cohort was the predominance of high-grade tumors (Gleason ≥8 in nearly half of cancer cases). This pattern contrasts with trends in high-resource settings, where PSA-based early detection has contributed to stage migration toward earlier, lower-grade disease [3,22]

In many low- and middle-income countries, however, delayed presentation remains common due to limited awareness, financial barriers, geographic inaccessibility, and constrained diagnostic capacity [2,22]. Global disparities in prostate cancer outcomes are well documented, with higher mortality-to-incidence ratios in resource-limited regions [23].

Our findings therefore reflect not only diagnostic realities but broader structural inequities. The predominance of advanced disease suggests that improving early detection pathways may ultimately have greater impact than procedural refinements alone [9]. Expanding access to PSA testing, strengthening referral systems, and building diagnostic capacity are central components of equitable urologic care [22,24].

One of the most compelling findings of this study is the excellent performance of PSA in predicting biopsy-confirmed prostate cancer (AUC 0.953). However, PSA is organ-specific rather than cancer-specific, which explains the considerable overlap in PSA concentrations between malignant disease and benign conditions such as benign prostatic hyperplasia (BPH) and prostatitis [14]. Consequently, PSA's discriminative ability to distinguish prostate cancer from benign prostatic disease is limited, although multiple studies report that progressively higher PSA values tend to be more specific for prostate cancer and therefore increase the likelihood that an elevated result reflects malignancy [3,13,25]. The high AUC observed here likely reflects the elevated pre-test probability of malignancy in symptomatic patients with markedly elevated PSA levels.

Importantly, PSA levels correlated significantly with Gleason score, supporting its association with tumor aggressiveness. Previous studies have demonstrated that very high PSA values often correspond to increased tumor burden and advanced pathological stage [12,26]. In our context, where advanced imaging and molecular biomarkers are unavailable, PSA assumes an even more central role in risk stratification.

The optimal PSA threshold identified in this study demonstrated high specificity. While such cut-offs should not be generalized beyond similar high-prevalence populations, they may help refine biopsy decision-making where procedural capacity is limited. In resource-constrained environments, optimizing existing tools can meaningfully enhance efficiency and reduce unnecessary interventions [7].

The overall complication rate in this cohort was low (6.5%), consisting of mild hematuria or limited rectal bleeding, with no infectious events observed. Numerous complications have been documented in the literature, with bleeding—presenting mainly as hematuria, rectal bleeding, and hemospermia—being the most common and infectious complications representing the greatest clinical concern [6,11,27,28]. Although our cohort is relatively small, the absence of serious adverse events in this series indicates that blind digital prostate biopsy, when performed with rigorous aseptic technique, can be carried out safely.

The need for repeat biopsy in two cases due to rectal mucosa sampling highlights a technical limitation inherent to the blind approach. Nevertheless, procedural feasibility remained high overall, supporting its pragmatic role where imaging guidance is unavailable [8,11].

Technological standards developed in high-income countries are not always directly transferable to resource-limited settings; instead, interventions should be scalable, context-sensitive, and adapted to local infrastructure, workforce capacity, and health-system constraints to ensure feasibility, sustainability, and equitable impact [29,30]. While MRI-targeted biopsy represents an important advancement, its global accessibility remains limited [9,22].

Our findings contribute to an emerging body of evidence emphasizing pragmatic adaptation rather than technological dependency. Blind digital core biopsy should not be viewed solely as obsolete, but rather as a context-dependent diagnostic tool within a broader continuum of system development. Strengthening local capacity, while advocating for long-term investment in imaging and pathology infrastructure, represents a balanced approach.

Moreover, the predominance of advanced disease in this study reinforces the need to prioritize early detection strategies and health system strengthening over exclusive focus on procedural sophistication [31].

Limitations and Future Directions

This study has several limitations. Its retrospective design introduces potential selection bias, and the sample size is modest. The high cancer prevalence limits generalizability to screening populations. Direct comparison with TRUS- or MRI-guided biopsy was not possible.

Future prospective studies with larger cohorts are needed to validate these findings and refine PSA-based risk

stratification strategies adapted to high-prevalence settings. Comparative effectiveness research, when imaging becomes available, would further clarify relative diagnostic performance. Most importantly, efforts should focus on strengthening early detection and expanding diagnostic infrastructure to reduce late-stage presentation.

Conclusion

In this low-resource setting, blind transrectal digital-guided core prostate biopsy demonstrated good feasibility, high cancer detection, and a low complication rate. Serum PSA showed excellent diagnostic accuracy and correlated significantly with tumor aggressiveness. Although image-guided biopsy remains the standard of care, blind digital biopsy represents a pragmatic and clinically valuable alternative where advanced technologies are unavailable. Future prospective, larger-scale studies are needed to validate these findings and to further optimize diagnostic strategies for prostate cancer in resource-constrained environments.

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