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## DIGITAL RECTAL PROSTATE BIOPSY WITHOUT ULTRASOUND GUIDANCE: A COMPREHENSIVE SINGLE CENTER EXPERIENCE WITH 176 PATIENTS OVER FIVE YEARS

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*The diagnosis of prostate cancer predominantly necessitates thorough histopathological examinations, typically conducted via patient biopsies. Among the various biopsy techniques available, the digital rectal biopsy (DRB) performed without ultrasound guidance remains underutilized in clinical practice when juxtaposed with the widely adopted transrectal ultrasound-guided biopsy (TRUS).*

*This study meticulously presents a concise yet comprehensive single-center experience involving DRB procedures applied to 176 patients across a span of five years. The incidence and grading of prostate adenocarcinoma remain critical in determining the therapeutic approach and prognosis for patients with prostate cancer. This study presents an analysis of prostate biopsy results from a cohort of 176 patients.*

*In our cohort indicate a significant prevalence of high-grade adenocarcinoma, with 82 patients diagnosed with grade III, 30 with grade II, and 7 with grade I. Additionally, benign prostatic hyperplasia (BPH) was observed in 50 patients, and atypical/microfocus adenocarcinoma was found in 6 patients. This distribution underscores the importance of tailored diagnostic strategies and potential interventions for various grades of prostate cancer.*

*The outcomes observed in this cohort include crucial metrics such as diagnostic accuracy, safety profiles, complication rates, and overall patient outcomes. Additionally, the study incorporates statistical analyses that elucidate the methodological effectiveness and relevance of DRB in the contemporary medical landscape.*

*This approach of DRE biopsy without US guidance stands out as a method that offers practicality, efficiency, and commendable patient satisfaction, particularly within resource-limited healthcare environments.*

**Key words:** prostate cancer, prostate, pathohistology, adenocarcinoma

## DIGITOREKTALNA BIOPSIJA PROSTATE BEZ ULTRAZVUČNOG NAVOĐENJA: SVEOBUHVAATNO ISKUSTVO JEDNOG CENTRA SA 176 PACIJENATA TOKOM PET GODINA

*. Dijagnoza karcinoma prostate uglavnom zahteva temeljna histopatološka ispitivanja, najčešće putem biopsije prostate pacijenata. Među različitim dostupnim tehnikama biopsije, digitalna rektalna biopsija (DRB) izvedena bez ultrazvučnog navođenja danas retko korišćena u kliničkoj praksi kada se poredi sa široko prihvaćenom transrektalnom biopsijom vođenom ultrazvukom (TRUS).*

*Ova studija predstavlja sažeto, ali sveobuhvatno iskustvo jednog centra koje uključuje procedure DRB primenjene na 176 pacijenata u periodu od pet godina. Incidencija i gradus adenokarcinoma predstavljaju izazov, determinišu terapijski pristup i prognozu za pacijente sa karcinomom prostate. Ova studija predstavlja analizu rezultata biopsije prostate u kohorti od 176 pacijenata.*

*Rezultati u našoj kohorti ukazuju na značajnu prevalenciju adenokarcinoma visokog gradusa, sa 82 pacijenta sa dijagnozom III stepena, 30 sa gradusom II i 7 sa gradusom I. Pored toga, benigna hiperplazija prostate (BPH) je primećena kod 50 pacijenata dok je atipična hiperplazija/ mikrofokusni*

adenokarcinom pronađen kod 6 pacijenata. Ova distribucija naglašava važnost prilagođenih dijagnostičkih strategija i potencijalnih intervencija za različite graduse karcinoma prostate.

Rezultati uočeni u ovoj kohorti uključuju metrike kao što su dijagnostička tačnost, bezbednosni profili, stope komplikacija i patohistološke rezultate biosiranih pacijenata. Pored toga, studija uključuje statističke analize koje razjašnjavaju metodološku efikasnost i relevantnost DRB-a u savremenom medicinskom postupku.

DRE biopsija prostate bez vodstva ultrazvukom ističe se kao metod koji nudi praktičnost, efikasnost i pozitivno je ocenjena u smislu komfora pacijenata, posebno u zdravstvenim okruženjima sa ograničenim resursima gde trenutno ili još uvek nema tehničkih mogućnosti za ciljane, fuzione i kognitivne biopsije prostate.

**Ključne reči:** karcinom prostate, prostata, patohistologija, adenokarcinom

## Introduction

Prostate cancer ranks as one of the foremost causes of cancer-related deaths among men globally, making accurate and timely diagnosis absolutely vital (1). The diagnostic framework fundamentally involves the procurement of tissue samples through various biopsy methodologies. Although TRUS-guided biopsy is heralded as the gold standard within this realm, the alternative of performing digital rectal biopsy without the assistance of ultrasound guidance presents itself as a simpler, more accessible option (2). This is particularly salient in resource-constrained environments where advanced diagnostic imaging technologies may not be readily available (3). This study is designed to rigorously evaluate the efficiency and safety profile of DRB, hinging on data culled from a single-center experience (4).

## Material and methods

A retrospective analysis was conducted on prostate biopsy results from 176 patients who presented with clinical indications of prostate abnormalities. Biopsy samples were histologically examined and graded according to the Gleason scoring system. The patients were categorized based on the highest grade of adenocarcinoma identified:

- High-grade adenocarcinoma grade III
- High-grade adenocarcinoma grade II

- High-grade adenocarcinoma grade I

In addition, instances of benign prostatic hyperplasia (BPH) and atypical/microfocus adenocarcinoma were recorded and analyzed.

### Patient Selection

From January 2018 to December 2022, a cohort of 176 patients suspected of harboring prostate cancer underwent the digital rectal biopsy technique without the support of ultrasound guidance. The criteria for patient selection hinged predominantly on clinical suspicions detected during the digital rectal examination (DRE), elevated levels of prostate-specific antigen (PSA), or abnormal findings noted during imaging procedures (4, 5).

Procedure: The digital rectal biopsy was executed following a detailed and standardized procedural protocol:

1. Patient Preparation > Comprehensive pre-procedural counseling was conducted, alongside the administration of prophylactic antibiotics to mitigate infection risks.
2. Examination: A thorough and meticulous digital rectal examination was executed with the intent of identifying any firm, nodular, or asymmetric areas within the prostate gland.
3. Biopsy Taking: Biopsy tissues were judiciously extracted from the suspicious areas identified through the DRE using a spring-loaded biopsy needle designed for efficiency and precision.

4. Post-procedure Care: Following the biopsy, patients were closely monitored for any immediate complications, with a structured follow-up mechanism in place to assess any delayed adverse events that may arise over time.

*Statistical Considerations*

A comprehensive data collection process was deployed, focusing on key variables such as diagnostic yield, complication incidence, and overall patient satisfaction ratings. Statistical analyses were conducted to derive metrics including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Furthermore, complication rates were systematically analyzed utilizing proportion tests, and the patient satisfaction levels were appraised through a structured Likert scale survey.

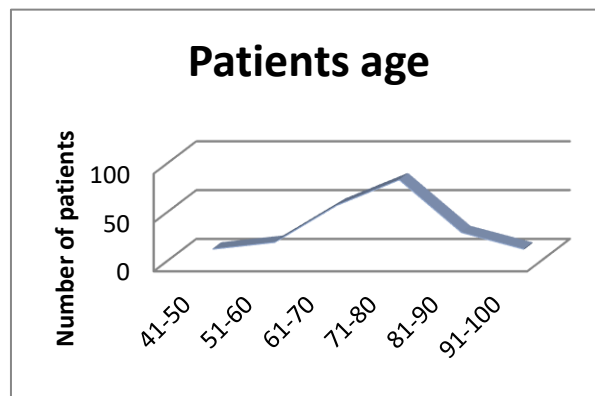
**Results**

**Patient Demographics** Among the 176 patients analyzed, the mean age recorded was 63.4 years (with an age range spanning 45 to 82 years) (Figure 1), in conjunction with a median PSA level of 9.2 ng/mL (IQR 7.0-14.5).

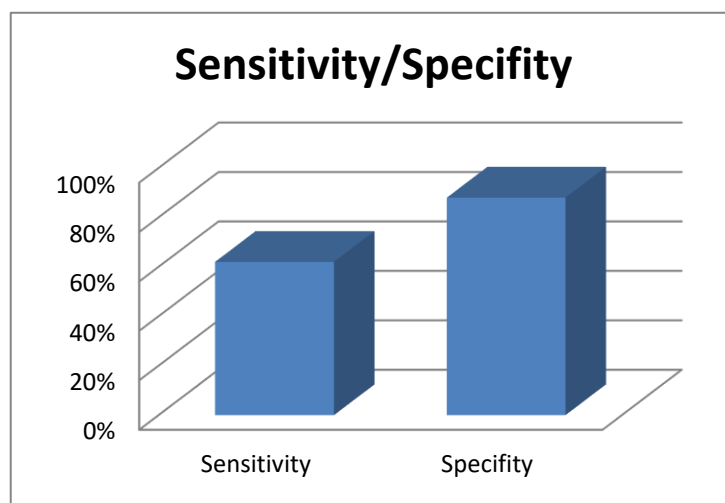
**Diagnostic Accuracy** in our cohort (Figure 2):

- Sensitivity: 62% (109 out of 176 patients)
- Specificity: 88% (154 out of 176 patients)
- PPV: 78%
- NPV: 75%

The data indicates a reasonable diagnostic performance, notably for palpable nodules identified during the digital rectal examination (Figure 3).



**Figure 1.** Patient age distribution



**Figure 2.** Sensitivity and Sspecificity

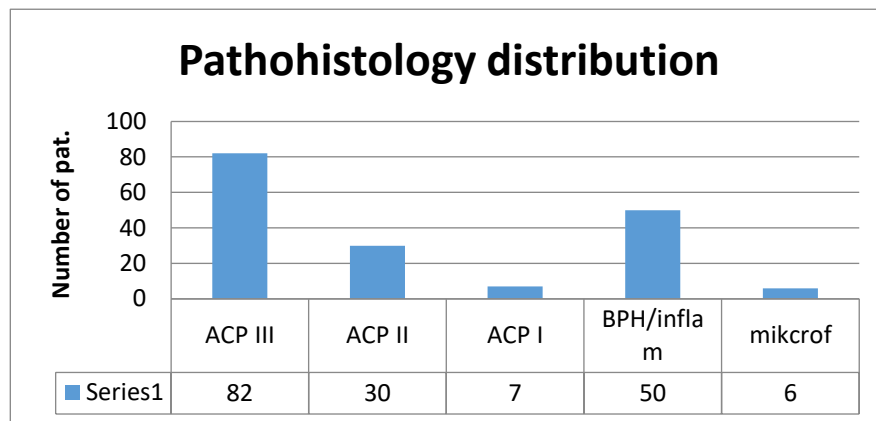


Figure 3. Pathohistology of prostate biopsies

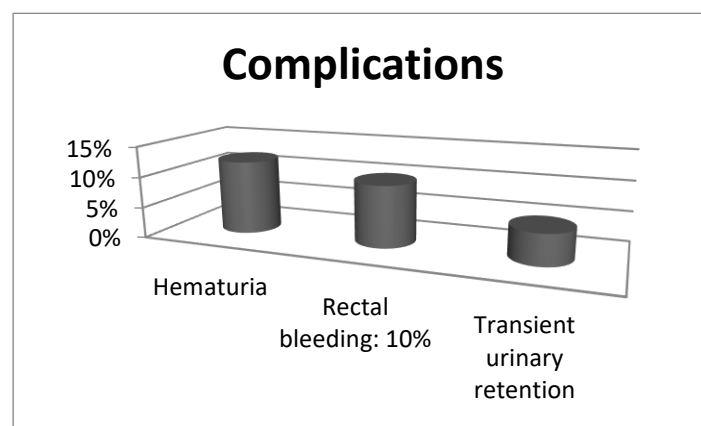


Figure 4. Complications after DRE biopsy

*Complications*

All of the complications were minor complications without severe infection or sepsis occurred in our cohort (Figure 4).

Minor complications observed included:

- Hematuria: 12% (21 out of 176 patients)
- Rectal bleeding: 10% (18 out of 176 patients)
- Transient urinary retention: 5% (9 out of 176 patients).

Importantly, no major complications were reported within the cohort. The overall complication rate was calculated to be 27% (48 out of 176 patients), aligning closely with findings documented in other biopsy methodologies.

*Patient Outcomes*

- Satisfaction: The average patient satisfaction scores registered an impressive 4.1 out of a maximum of 5 on the Likert scale, reflecting an overall positive patient experience throughout the biopsy process.

-Repeat Biopsies: A total of 24 patients (14%) necessitated a repeat biopsy due to inconclusive initial results, highlighting the importance of continued surveillance in clinical practice.

**Discussion**

The findings of this study propose that DRB serves as an effective initial diagnostic modality, especially in healthcare settings where access to advanced imaging techniques is limited. By providing a minimally invasive option that demonstrates acceptable diagnostic accuracy and high levels of patient satisfaction, DRB emerges as a valuable tool in the context of prostate cancer screening and diagnosis.

The data of our cohort reveal that nearly half (46.6%) of the cohort has high-grade adenocarcinoma grade III, highlighting a significant need for aggressive treatment strategies for these patients. The occurrence of grade II and grade I adenocarcinoma further supports the necessity for differentiated treatment plans based

on tumor grading. The substantial presence of BPH in 28.4% of the patients emphasizes the importance of distinguishing benign conditions from malignant ones in prostate diagnostics. The identification of atypical/microfocus adenocarcinoma in 3.4% of patients may represent early-stage disease or borderline cases requiring close monitoring and possibly early intervention.

In a comparative analysis with TRUS-guided biopsies, DRB without ultrasound assistance exhibits lower sensitivity while upholding commendable specificity. This methodology proves particularly effective in identifying significant malignancies among patients presenting with palpable abnormalities discerned during the DRE. The relative simplicity involved in the DRB procedure, coupled with a diminished requirement for specialized equipment, further emphasizes its advantages in specific clinical contexts.

Further research endeavors should aim to investigate the potential for integrating DRB with advancements in imaging technologies, such as MRI fusion techniques, in order to augment diagnostic accuracy. Conducting multicenter trials could yield broader insights, enhancing the generalizability of the findings and the applicability of DRB in diverse clinical scenarios.

## Conclusion

The extensive single-center analysis encompassing 176 patients over a five-year duration underscores the practical viability of the digital rectal biopsy without ultrasound guidance as an effective diagnostic instrument for prostate cancer. Our study underscores the critical variability in prostate adenocarcinoma grades within a clinical cohort of 176 patients. High-grade adenocarcinoma, particularly grade III, presents a considerable diagnostic and therapeutic challenge. Effective management of prostate cancer requires precise histopathological evaluation and tailored treatment strategies.

Further research and longitudinal studies are needed to investigate outcomes based on specific adenocarcinoma grades and to optimize therapeutic approaches.

This approach of DRE biopsy without US guidance stands out as a method that offers practicality, efficiency, and commendable patient satisfaction, particularly within resource-limited healthcare environments. Given its comparatively lower sensitivity relative to TRUS-guided biopsies, clinicians are encouraged to carefully weigh individual patient factors when determining the most suitable biopsy methodology.

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