

Diagnostic Accuracy of Prostate Cancer in TRUS-Guided Prostatic Biopsy in Patients with PSA Levels of 4–10 ng/mL

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ABSTRACT

Background: Prostate carcinoma (CoP) remains a major health concern worldwide, with high incidence and mortality rates, particularly in developed countries, and early detection is critical to improving patient outcomes. The purpose of the study is to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. **Methods & Materials:** This prospective observational study at the Department of Urology, Bangladesh Medical University (BMU), Dhaka, Bangladesh (April 2024–March 2025) included 120 men with PSA 4–10 ng/mL. All underwent DRE and systematic TRUS-guided prostate biopsy, with histopathology classified by ISUP Grade Group and TRUS findings correlated to assess diagnostic accuracy. Mean PSA was compared between cancer and benign groups ($p < 0.05$). **Results:** Among 120 men with PSA 4–10 ng/mL, the mean age was 64.5 ± 6.8 years, and mean PSA was 6.8 ± 1.7 ng/mL. Prostate cancer was detected in 58 patients (48.3%), including clinically significant disease in 38 (31.7%), while 62 (51.7%) had benign pathology. Suspicious TRUS findings correctly identified cancer in 45 cases, with 10 false positives and 13 false negatives, giving a sensitivity of 77.6%, specificity of 83.9%, PPV of 81.8%, NPV of 80.0%, and overall accuracy of 80.8%. Mean PSA was significantly higher in cancer patients than in those with benign disease (7.6 ± 1.9 vs. 6.3 ± 1.4 ng/mL; $p < 0.0001$). **Conclusion:** TRUS-guided prostatic biopsy is an effective and reliable method for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL.

Keywords: Prostate Cancer, TRUS-Guided Biopsy, PSA Gray-Zone.

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INTRODUCTION

Prostate carcinoma (CoP) is recognized as a significant health concern among men. In Europe, its annual incidence reaches 214 cases per 1000 men, making it the most common solid tumor in the male population [1]. The prevalence of CoP varies worldwide, with higher rates observed in developed countries. In the United States, it ranks as the second leading cause of cancer-related mortality in men and is the sixth most common cause of cancer-related deaths globally [2,3]. While CoP generally progresses slowly, certain tumors can exhibit aggressive behavior. Many patients remain symptom-free in the early stages, whereas others may present with symptoms that typically reflect advanced disease. Early detection, especially at a localized stage, is critical to achieving a successful cure. Globally, prostate cancer is the second most frequently diagnosed malignancy and the fifth leading cause of cancer-related deaths among men.

Traditionally, a “normal” prostate-specific antigen (PSA) level has been considered ≤ 4 ng/mL; however, no PSA threshold

guarantees the absence of prostate cancer [4]. Clinical guidelines from the European Association of Urology (EAU) recommend that the decision to perform a prostate biopsy should consider both PSA levels and digital rectal examination (DRE) findings [5]. Differentiating between prostate adenocarcinoma and benign prostatic hyperplasia (BPH) is particularly challenging in patients whose PSA falls within the “gray-zone” range of 4–10 ng/mL [6]. The presence of an elevated PSA or an abnormal DRE is associated with a higher likelihood of detecting prostate cancer.

For early diagnosis and monitoring, DRE in combination with PSA testing is widely employed. When PSA is elevated or DRE reveals abnormalities, transrectal ultrasound-guided (TRUS-guided) prostate biopsy is generally performed [7]. This technique has become routine in urology and can be safely carried out on an outpatient basis without anesthesia. The use of Trucut needles with spring-loaded biopsy guns ensures the procedure is straightforward and well-tolerated. Despite its widespread use, TRUS detection of

prostate malignancy remains challenging due to the variable ultrasonographic appearance of tumors. This has led to the development of the sextant TRUS-guided biopsy technique, initially described by Hodge et al. [8]. In cases where ultrasound images show suspicious lesions, targeted biopsies are often performed alongside the sextant approach [9]. However, even with these improvements, the overall sensitivity and specificity of detecting prostate cancer remain suboptimal, with false-negative rates reported between 30% and 45% for a single biopsy session [10,11]. Consequently, modifications in biopsy protocols, including taking more than six systematic cores, have been suggested to improve coverage of the prostate and enhance detection rates [12,13].

Despite the widespread use of PSA testing, DRE, and TRUS-guided biopsy, there remains considerable variability in prostate cancer detection rates, particularly in patients with PSA levels in the gray-zone of 4–10 ng/mL. Previous studies have reported differing sensitivities and false-negative rates, and there is limited data from Bangladesh and similar populations

regarding the diagnostic performance of TRUS-guided biopsies in this PSA range. Furthermore, questions remain about the optimal biopsy strategy and the correlation between TRUS findings and histopathology in these patients. Addressing these gaps is essential to improve early detection and guide clinical decision-making. The purpose of the study is to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. The aim of the study to evaluate the diagnostic accuracy of TRUS-guided prostatic biopsy for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL.

METHODS & MATERIALS

This prospective observational study was conducted at the Department of Urology, Bangladesh Medical University (BMU), Dhaka, Bangladesh, from April 2024 to March 2025. A total of 120 male patients with serum PSA levels of 4–10 ng/mL were enrolled based on predefined inclusion and exclusion criteria. Data were collected on demographic characteristics, digital rectal examination (DRE) findings, and TRUS-guided prostate biopsy results to evaluate the diagnostic accuracy of TRUS in detecting prostate cancer.

Inclusion Criteria:

- Male patients aged ≥50 years.
- Serum PSA level between 4 and 10 ng/mL.

- Patients referred for TRUS-guided prostate biopsy.
- Provided informed consent for participation.

Exclusion Criteria:

- History of prostate cancer or prior prostate surgery.
- Active urinary tract infection or prostatitis at the time of biopsy.
- Use of 5-alpha-reductase inhibitors or other medications affecting PSA levels.
- Incomplete clinical or histopathological data.

Demographic data, including age, were recorded for all participants. DRE was performed by experienced urologists to identify abnormal or suspicious findings. Serum PSA levels were measured within one month prior to biopsy. All patients underwent systematic TRUS-guided prostate biopsy, with suspicious lesions such as hypoechoic nodules or asymmetry specifically targeted. A minimum of 12 cores were obtained from each patient to ensure adequate sampling. Biopsy specimens were examined by experienced pathologists and classified according to the International Society of Urological Pathology (ISUP) Grade Group system, distinguishing clinically significant cancer (ISUP Grade Group ≥2) from clinically insignificant cancer (ISUP Grade Group 1). Benign tissue, prostatitis, high-grade prostatic intraepithelial neoplasia

(PIN), and atypical lesions were also recorded. TRUS findings were correlated with histopathology to determine true positive, false positive, true negative, and false negative results. Diagnostic performance was calculated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy. Mean PSA levels were compared between patients with prostate cancer and those with benign pathology using appropriate statistical tests, with p < 0.05 considered statistically significant. Written informed consent was obtained from all participants prior to inclusion in the study.

RESULTS

Table I shows the mean age of the study participants was 64.5 ± 6.8 years (range: 50–82 years). Most patients were aged 60–69 years (64 patients, 53.3%), followed by those aged 50–59 years (28 patients, 23.3%) and those aged ≥70 years (28 patients, 23.3%). The mean PSA level was 6.8 ± 1.7 ng/mL. Regarding PSA categories, 45 patients (37.5%) had PSA 4.0–6.0 ng/mL, 43 patients (35.8%) had PSA 6.1–8.0 ng/mL, and 32 patients (26.7%) had PSA 8.1–10.0 ng/mL. On digital rectal examination (DRE), 89 patients (74.2%) were normal, whereas 31 patients (25.8%) had abnormal or suspicious findings.

Table I
Demographic and Clinical Characteristics of the Study Population (n = 120).

Variable	Frequency (n)	Percentage (%)	
Age group (years)	50–59	28	23.3
	60–69	64	53.3
	≥70	28	23.3
	Mean ± SD		64.5 ± 6.8
	Range		50–82
PSA level (ng/mL)	Mean ± SD		6.8 ± 1.7
PSA category (ng/mL)	4.0–6.0	45	37.5
	6.1–8.0	43	35.8
	8.1–10.0	32	26.7
Digital Rectal Examination (DRE)	Normal	89	74.2
	Abnormal/Suspicious	31	25.8

Table II presents TRUS-guided biopsy detected prostate cancer in 58 patients (48.3%), with clinically significant cancer (ISUP Grade Group ≥2) in 38 patients

(31.7%) and clinically insignificant cancer (ISUP Grade Group 1) in 20 patients (16.7%). Benign pathology was observed in 62 patients (51.7%), including 55 cases

of benign prostatic tissue (45.8%), 5 cases of prostatitis (4.2%), and 2 cases of high-grade PIN or atypical lesions (1.7%).

Table II
Histopathological Diagnosis on TRUS-Guided Prostatic Biopsy (n = 120).

Histopathological Finding	Number (n)	Percentage (%)
Any Prostate Cancer	58	48.3
- Clinically Significant (ISUP Grade Group ≥2)	38	31.7
- Clinically Insignificant (ISUP Grade Group 1)	20	16.7
Benign Pathology	62	51.7
- Benign Prostatic Tissue	55	45.8
- Prostatitis	5	4.2
- High-grade PIN / Atypical	2	1.7
Total	120	100.0

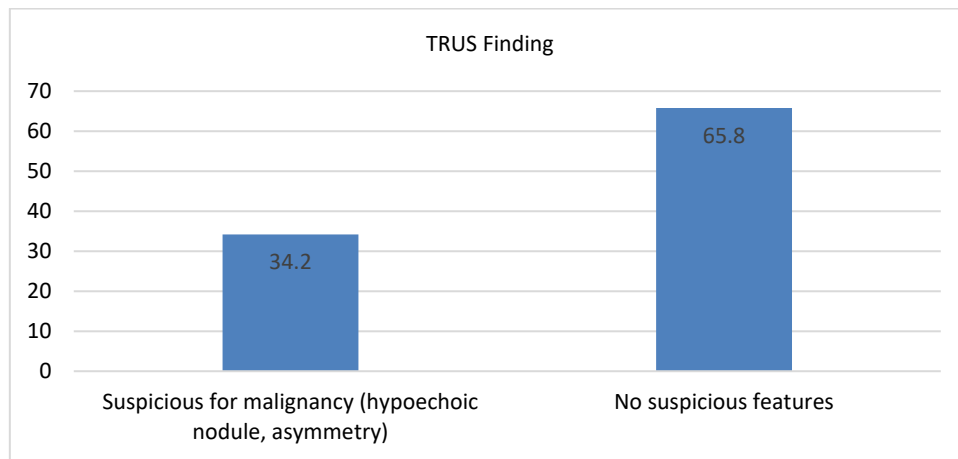


Figure 1 TRUS Findings in the Study Population (n = 120).

Figure 1 presents Suspicious findings on TRUS, including hypoechoic nodules and asymmetry, were identified in 41 patients (34.2%). The remaining 79 patients (65.8%) had no suspicious features on TRUS examination.

Table III shows Among the 55 patients with suspicious TRUS findings, 45 (81.8%) were confirmed to have prostate cancer (true positives), while 10 (18.2%) had benign histology (false positives). Of the 65 patients with non-suspicious TRUS

findings, 52 (80.0%) had benign histology (true negatives), whereas 13 (20.0%) were diagnosed with prostate cancer (false negatives).

Table III
Correlation of TRUS Findings with Histopathology (n = 120).

TRUS Finding	Prostate Cancer Present (n)	Prostate Cancer Absent (n)	Total (n)
Suspicious on TRUS	45 (TP)	10 (FP)	55
Not Suspicious on TRUS	13 (FN)	52 (TN)	65
Total	58	62	120

Table IV presents the diagnostic performance of TRUS-guided biopsy in this study showed a sensitivity of 77.6%,

specificity of 83.9%, positive predictive value (PPV) of 81.8%, negative predictive

value (NPV) of 80.0%, and an overall diagnostic accuracy of 80.8%.

Table IV
Diagnostic Performance of Suspicious TRUS Findings (n = 120).

Diagnostic Parameter	Value (%)
Sensitivity	77.6
Specificity	83.9
Positive Predictive Value (PPV)	81.8
Negative Predictive Value (NPV)	80.0
Overall Diagnostic Accuracy	80.8

Table V shows the mean PSA level was significantly higher in patients diagnosed

with prostate cancer (7.6 ± 1.9 ng/mL) compared to those with benign pathology

(6.3 ± 1.4 ng/mL) ($p < 0.0001$).

Table V
PSA Levels According to Histopathological Diagnosis ($n = 120$).

Diagnosis	Frequency (n)	Mean PSA (ng/mL) \pm SD	p-value
Prostate Cancer	58	7.6 \pm 1.9	< 0.0001
Benign Pathology	62	6.3 \pm 1.4	

DISCUSSION

Prostate cancer is a significant urological malignancy that poses a considerable health burden among men, particularly when detected late. Serum prostate-specific antigen (PSA) levels and digital rectal examination (DRE) serve as initial screening tools, but their diagnostic accuracy is limited, especially in patients with PSA levels in the gray-zone of 4–10 ng/mL. The findings of this study demonstrate that TRUS-guided prostate biopsy provides a reliable method for detecting prostate cancer in this population, with appreciable sensitivity, specificity, and overall diagnostic accuracy. These results highlight the clinical importance of employing TRUS-guided biopsy in patients with gray-zone PSA to improve early detection and facilitate timely management of clinically significant prostate cancer.

In the present study, the majority of patients were aged 60–69 years (53.3%), with a mean age of 64.5 ± 6.8 years, a finding that is consistent with previously reported biopsy cohorts. Similar age distributions have been described by Seo et al., who evaluated men aged ≥ 40 years and reported a predominance of patients in the sixth and seventh decades of life [14]. The mean PSA level in our cohort was 6.8 ± 1.7 ng/mL, with 37.5% of patients in the 4.0–6.0 ng/mL range, 35.8% in the 6.1–8.0 ng/mL range, and 26.7% in the 8.1–10.0 ng/mL range. This distribution closely reflects the PSA “gray zone” population analyzed by Seo et al., who reported a prostate cancer detection rate of 19.6% among men with PSA levels between 4.0 and 9.9 ng/mL [14]. In our study, abnormal or suspicious findings on digital rectal examination (DRE) were observed in 25.8% of patients, supporting earlier observations by Sheikh et al., who demonstrated that although DRE has limited sensitivity when used alone, it significantly improves cancer detection when combined with PSA testing, particularly in patients with lower or intermediate PSA values [15]. Taken together, these findings suggest that our study population is representative of a typical biopsy cohort within the intermediate PSA range, and they reaffirm the ongoing clinical relevance of DRE as an adjunctive diagnostic tool.

Histopathological examination of TRUS-guided prostate biopsies in the present study revealed prostate cancer in 58 patients (48.3%), of whom 38 patients

(31.7%) had clinically significant disease (ISUP Grade Group ≥ 2) and 20 patients (16.7%) had clinically insignificant cancer (ISUP Grade Group 1). Benign pathology was identified in 62 patients (51.7%), including benign prostatic tissue in 55 cases (45.8%), prostatitis in 5 cases (4.2%), and high-grade PIN or atypical lesions in 2 cases (1.7%). These findings are broadly consistent with those reported by Gupta et al., who identified prostate adenocarcinoma in 24% of men undergoing systematic TRUS-guided biopsy, with high-grade PIN and cellular atypia reported in 2.1% and 4.9% of cases, respectively, and benign tissue or prostatitis accounting for the majority of negative biopsies [16]. The higher proportion of prostate cancer and clinically significant disease observed in our cohort may be attributable to differences in patient selection and the restriction of our study population to individuals with PSA levels between 4 and 10 ng/mL. Overall, our results confirm that systematic TRUS-guided biopsy captures a wide spectrum of disease severity, while emphasizing that benign histology remains the most frequent outcome in patients presenting with intermediate PSA levels.

With respect to TRUS findings, suspicious sonographic features such as hypoechoic nodules and glandular asymmetry were identified in 41 patients (34.2%), while the remaining 79 patients (65.8%) showed no suspicious features on ultrasound. These findings are in agreement with previous studies underscoring the diagnostic value of hypoechoic lesions in prostate cancer detection. Noh et al. demonstrated that in a cohort of 970 men undergoing TRUS-guided biopsy, cancer detection was significantly higher in patients with hypoechoic lesions (43.9%) compared with those without visible abnormalities (21.4%) [17]. Similarly, Onur et al., in a large cohort of 3,912 patients, reported that hypoechoic areas were commonly observed during TRUS examinations, reinforcing their frequent occurrence in routine clinical practice [18]. Collectively, these studies support our observation that hypoechoic lesions on TRUS are meaningful indicators of potential malignancy, although a substantial proportion of cancers may still be missed due to the absence of visible sonographic abnormalities.

Correlation analysis between TRUS findings and histopathology demonstrated that among 55 patients with suspicious lesions on TRUS, 45 (81.8%) were

confirmed to have prostate cancer (true positives), while 10 (18.2%) had benign histology (false positives). Conversely, of the 65 patients with non-suspicious TRUS findings, 13 (20.0%) were diagnosed with prostate cancer (false negatives), and 52 (80.0%) were confirmed as true negatives. These results are comparable to those reported by Kuligowska et al., who found that gray-scale TRUS abnormalities were present in more than half of cancers among patients with PSA levels between 4 and 9.9 ng/mL and reported favorable predictive metrics, including specificity of approximately 89% and a positive predictive value of 76% [19]. Both studies highlight that although suspicious TRUS findings are strongly associated with malignancy, a notable proportion of cancers may remain undetected in the absence of ultrasound abnormalities, reinforcing the importance of systematic TRUS-guided biopsy in patients with intermediate PSA levels.

The diagnostic performance of suspicious TRUS findings in our study demonstrated a sensitivity of 77.6%, specificity of 83.9%, positive predictive value of 81.8%, negative predictive value of 80.0%, and an overall diagnostic accuracy of 80.8%. These results are broadly comparable to earlier reports. Maricic et al., in their long-term evaluation of TRUS-guided prostate biopsy before and after the implementation of PSA testing, reported similar PPV values (~80.5%) and slightly higher overall accuracy (~86.2%), as well as higher specificity and NPV [20]. Differences in patient characteristics, cancer prevalence, and diagnostic thresholds may account for these variations. Likewise, Tamsel et al. evaluated the performance of TRUS across different PSA strata and observed an overall diagnostic accuracy of approximately 80% in patients with PSA levels of 4–9.9 ng/mL, with specificity close to 89% and PPV near 76% [21]. Taken together, these findings confirm that TRUS provides reproducible and clinically useful diagnostic accuracy in patients with intermediate PSA levels, while underscoring the need for systematic biopsy to identify cancers that are not apparent on ultrasound imaging.

Finally, the present study demonstrated a statistically significant difference in mean PSA levels between patients diagnosed with prostate cancer (7.6 ± 1.9 ng/mL) and those with benign pathology (6.3 ± 1.4 ng/mL), with a p-value < 0.0001. This

observation is consistent with the findings of Zheng *et al.*, who reported that PSA levels and PSA-derived parameters differed significantly between malignant and benign groups among men with PSA values in the 4–10 ng/mL range, aiding in diagnostic discrimination [22]. Despite the significant difference, the overlap in PSA values between cancer and benign groups observed in both studies highlights the inherent limitation of relying on total PSA alone within this intermediate range. Nonetheless, our findings support the continued role of PSA as an important risk stratification tool when interpreted in conjunction with TRUS-guided biopsy and other clinical parameters to optimize prostate cancer detection and minimize unnecessary biopsies.

LIMITATIONS

The study had a few limitations:

- The study was conducted at a single center, which may limit the generalizability of the findings to other populations.
- The sample size was relatively small, which could affect the precision of diagnostic accuracy estimates.

CONCLUSION

Prostate cancer remains a significant health concern, and accurate early detection is essential for appropriate management. In this study, TRUS-guided prostatic biopsy proved to be a reliable diagnostic tool for detecting prostate cancer in patients with PSA levels of 4–10 ng/mL. Among the study population, nearly half were diagnosed with prostate cancer, with a substantial proportion exhibiting clinically significant disease, while the remainder had benign pathology. Suspicious TRUS findings demonstrated a strong correlation with histopathology, with good sensitivity, specificity, and overall diagnostic accuracy. Furthermore, patients with prostate cancer had significantly higher mean PSA levels compared to those with benign conditions. These findings highlight that TRUS-guided biopsy, combined with PSA assessment and careful evaluation of sonographic abnormalities, remains a valuable and effective approach for prostate cancer detection in patients within the intermediate PSA range.

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