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Are Prostate Biopsies with Inadequate Cores Truly Benign?: A Clinicopathological Evaluation

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Research Article

Keywords: Prostate core biopsy, inadequate cores, specimen adequacy, body mass index, prostate apex, PI-RADS, PSA velocity, clinical follow-up

Posted Date: June 22nd, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9746462/v1

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Additional Declarations: No competing interests reported.

Abstract

Background: Prostate needle biopsy is the gold standard for prostate cancer diagnosis; however, “inadequate cores” lacking sufficient tissue may compromise diagnostic accuracy. This study investigated clinical factors associated with inadequate cores and evaluated their clinicopathological outcomes.

Methods: Patients with benign prostate core biopsies reported between June 2020 and June 2025 were retrospectively screened. Cases with at least two inadequate cores and a minimum one-year follow-up were included. Clinical, radiological, and pathological data were analyzed statistically.

Results:A total of 117 patients were included. The mean age was 63.7 ± 7.2 years. Inadequacy in two cores was most common (55%, n=65), and the apex was the most frequent localization (68%, n=80). Inadequacy involving four and more cores was significantly higher in apex and midline locations ($p<0.01$). Increased body mass index correlated with higher Prostate Imaging Reporting & Data System scores ($p=0.01$) and more inadequate cores ($p<0.01$). The patients with diabetes mellitus exhibited a higher prevalence of benign magnetic resonance imaging (MRI) lesions ($p=0.03$), whereas patients with hypertension showed higher initial prostate specific antigen levels ($p=0.04$). Among patients undergoing repeat biopsy or surgery during follow-up, histopathology revealed benign findings in 91% (n=39), malignancy in 7% (n=3), and atypical small acinar proliferation in 2% (n=1).

Conclusions: Inadequate cores are predominantly associated with anatomically challenging regions, particularly the apex. While the clinical course remains overwhelmingly benign during follow-up, patients with suspicious MRI findings or elevated PSA kinetics require close monitoring. Standardized adequacy criteria may improve pathological assessment and clinical management.

Background

Prostate cancer is one of the most common malignancies in men, and prostate biopsy remains the gold standard for its diagnosis (1). In clinical practice, elevated prostate-specific antigen (PSA) levels, PSA density, accelerated PSA velocity, and suspicious findings on multiparametric magnetic resonance imaging (mpMRI) constitute the primary determinants for biopsy decisions (2). Nevertheless, technical constraints or patient-specific characteristics often result in the reporting of "inadequate cores" that lack sufficient tissue for definitive pathological evaluation. Currently, standardized consensus criteria for assessing the adequacy of prostate core biopsy specimens remain unestablished.

Characterized by the absence of prostatic tissue, marked fragmentation, or insufficient core length, inadequate cores compromise diagnostic accuracy, potentially leading to missed malignancies or the underestimation of clinically significant prostate cancer (3). Evidence suggests that inadequate cores stem from a complex, multifactorial interplay of technical, anatomical, and pathological factors, rather than being solely attributable to operator error (4).

When a pathology report indicates inadequate cores, current management guidelines recommend a collaborative re-evaluation of biopsy quality with the pathologist. This should be followed by mpMRI assessment, if not previously performed, to detect any overlooked suspicious lesions. If indicated, MRI-guided fusion re-biopsy is preferred over repeat systematic biopsy due to its superior diagnostic yield (5,6).

To date, the underlying factors and clinicopathological implications of inadequate cores have not been adequately emphasized in the literature. More importantly, there is an absolute lack of data investigating the clinical courses and long-term outcomes of patients whose biopsies contain inadequate cores but are reported as overall benign. Therefore, we aimed to investigate the clinical factors associated with sampling inadequacy within this specific benign cohort, to explore the definition of core adequacy, and to thoroughly evaluate the subsequent clinical outcomes it leads to.

Methods

The study protocol and informed consent form were approved by the Ethics Committee of the University of Health Sciences, Basaksehir Cam and Sakura City Hospital (Approval date/no: May 12, 2026/275). Written informed consent was obtained from all participants. Additionally, patients provided permission for the utilization of their clinical data retrieved from the hospital's electronic health record system.

Patients with prostate needle biopsy specimens reported as benign between June 2020 and June 2025 at the Department of Pathology, University of Health Sciences, Basaksehir Cam and Sakura City Hospital, were retrospectively screened using the hospital database. Biopsies from patients with a prior diagnosis of acinar adenocarcinoma or those containing malignant/suspicious foci in other cores were excluded. Only patients with a minimum of one year of clinical follow-up were included in the study. Cases previously defined in the literature as "inadequate cores" (7)—specifically those lacking glandular tissue, containing only rectal mucosa, periprostatic adipose tissue, or fibromuscular tissue, as well as highly fragmented or dried samples—were documented. Examples of inadequate biopsy specimens consisting of fibromuscular tissue and rectal mucosa are shown in Fig. 1. Cases presenting with only a single inadequate core were excluded to minimize the confounding effect of isolated technical artifacts and to focus on clinically meaningful inadequacy patterns.

Initial screening identified 152 cases with two or more inadequate biopsy cores. Patients lacking clinical follow-up data or those lost to follow-up were subsequently excluded. Consequently, a total of 117 prostate needle biopsy cases were included in the final analysis.

The sample size was determined based on the total number of eligible patients identified during the study period. This study was reported in accordance with the STrengthening the Reporting of OBservational Studies in Epidemiology (STROBE) guidelines (8). Data regarding age, follow-up duration (months), initial and final PSA levels (ng/L), PSA velocity (PSA difference/year), prostate volume (mL), PSA density (PSA/prostate volume), and body mass index (BMI; kg/m²) were retrospectively retrieved from hospital records. Additionally, clinical variables including comorbidities, the presence or absence of

MRI findings along with corresponding Prostate Imaging Reporting & Data System (PI-RADS) scores, history of medical treatments, and subsequent interventional procedures were documented. Comorbidities were classified according to the presence or absence of diabetes mellitus (DM), hypertension (HT), and coronary artery disease (CAD). Medical treatments were categorized as no treatment, alpha-blocker monotherapy, or combination therapy consisting of an alpha-blocker and a 5-alpha reductase inhibitor. Interventional procedures were classified as no surgical intervention, repeat prostate needle biopsy, or transurethral resection of the prostate (TURP)/Holmium laser enucleation of the prostate (HoLEP). Inadequate biopsy cores identified in pathology reports were re-evaluated and confirmed by reviewing hematoxylin and eosin (H&E)-stained slides.Furthermore, histological diagnoses obtained from repeat biopsies during follow-up were reassessed and categorized as benign, malignant, or atypical small acinar proliferation (ASAP).

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation or median (minimum–maximum) based on data distribution, whereas categorical variables were presented as frequencies and percentages. The normality of continuous variables was evaluated using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Intergroup comparisons were performed using the independent samples t-test or the Mann–Whitney U test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables, as appropriate. A p value of < 0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA).

Results

The mean age of the study cohort was 63.7 ± 7.2 years (range, 49–81 years), with a mean follow-up duration of 26.5 ± 16.8 months (range, 12–72 months). Detailed clinical characteristics, including baseline and final PSA levels, PSA velocity, prostate volume, and PSA density, are presented in Table 1.

Table 1
Distribution of prostate-specific antigen (PSA) parameters and prostate volume in the study population.

Mean	**Initial PSA**	**Final PSA**	**PSA velocity**	**Prostate volume**	**PSA density**
	10,2	**6,7**	**-2**	**82,3**	**0,1**
Median	7	5,6	-0,32	75	0,1
Standart Deviation	17,2	5,9	5,3	46,3	0,2
Minimum	2	0	-27	20	0
Maximum	176	44	6	300	3

The mean BMI of the patients was 28.3 ± 1.7 kg/m² (range, 24–33). Regarding comorbidities, DM was present in 38% (n = 45) of the patients, HT in 57% (n = 67), and CAD in 31% (n = 36).

Post-biopsy multiparametric MRI (mpMRI) evaluation was available for 88% (n = 103) of the patients. According to the imaging findings, the most common PI-RADS category was PI-RADS 2 (40%, n = 47), followed by PI-RADS 3 (28%, n = 3). When stratified into clinical risk groups, the benign category (PI-RADS 1–2) was the most frequently observed, accounting for 57% (n = 67) of the cases, followed by the suspicious (PI-RADS 3) (37%, n = 43) and highly suspicious (PI-RADS 4–5) (6%, n = 7) categories.

Regarding post-biopsy management, alpha-blocker monotherapy was the most commonly administered medical treatment (47%, n = 55). In terms of subsequent interventional procedures, the majority of patients required no further intervention (63%, n = 74). A repeat prostate biopsy was performed in 15% (n = 18) of the cohort, whereas 21% (n = 25) underwent TURP or HoLEP due to persistent lower urinary tract symptoms (LUTS) or enlarged prostate volume.

When the cases were evaluated in terms of inadequate cores, the number and localization of inadequate cores are presented in the Table 2. Accordingly, inadequacy in two cores was the most common finding (55%, n = 65), while the apex was the most frequent location for inadequate samples (68%, n = 80). Inadequacy involving four or more cores was found to be statistically significantly more frequent in the midline location ($p < 0.01$). The cases with inadequacy in five or more cores were statistically significantly more frequently observed in the apex location ($p < 0.01$) (Table 2).

Table 2
Distribution of Inadequate Core Counts Across Different Anatomical Localizations in Prostate Needle Biopsies.

Anatomical Localization	Number of Inadequate Cores	Absent n (%)	Present n (%)	p-value[1]
Apex (n = 117)	2	28 (23%)	37 (32%)	**< 0.01***
	3	6 (5%)	26 (22%)	
	4	3 (2%)	7 (6%)	
	> 5	0 (0%)	10 (8%)	
Midline (n = 117)	2	43 (37%)	22 (19%)	**< 0.01***
	3	14 (12%)	18 (15%)	
	4	2 (2%)	8 (7%)	
	> 5	1 (1%)	9 (7%)	
Base (n = 117)	2	32 (27%)	33 (28%)	0.05
	3	13 (11%)	19 (16%)	
	4	1 (1%)	9 (7%)	
	> 5	2 (2%)	8 (7%)	

*[1] Chi-square test * Statistically significant (p < 0.05)*

The quantification, anatomical localization, and statistical associations of inadequate biopsy cores are summarized in Table 2. Inadequacy involving exactly two cores was the most prevalent finding (55%, n = 65), with the apex being the most frequent site for inadequate sampling (68%, n = 80). Inadequacy involving three and more cores was significantly higher in apex and base locations ($p < 0.01$ and $p = 0.04$, respectively). Severe inadequacy involving five or more inadequate cores were significantly associated with the apex location ($p < 0.01$).

Among the 43 patients who underwent repeat biopsy or surgical intervention following a report of inadequate cores, subsequent histopathological evaluations revealed benign findings in 91% (n = 39), malignancy in 7% (n = 3), and atypical small acinar proliferation (ASAP) in 2% (n = 1). No significant associations were found between the number of inadequate cores and the type of subsequent interventional procedure or medical treatment received ($p > 0.05$).

In patients with elevated PSA levels and increased PSA velocity, the rates of proceeding to interventional procedures and not using medical treatment were statistically significantly higher ($p < 0.01$). As prostate volume increased, the rate of performing interventional procedures statistically significantly increased ($p < 0.01$).

Higher BMI values significantly correlated with elevated PI-RADS scores ($p = 0.01$) and a greater number of inadequate cores ($p < 0.01$). When stratified by chronic comorbidities, patients with DM exhibited a significantly higher prevalence of benign lesions on MRI compared to suspicious or malignant lesions ($p = 0.03$). Regarding patients with HT, higher initial PSA levels ($p = 0.04$) and significantly larger prostate volumes ($p = 0.02$) were observed. Finally, among cases with benign histopathological outcomes following an intervention, prostate volume was found to be significantly higher ($p = 0.01$).

Discussion

Although prostate core biopsy remains the definitive gold standard for diagnosing prostate cancer, technical challenges and patient-specific anatomical or clinical factors frequently result in "inadequate cores"—specimens that lack sufficient cellular architecture or tissue volume for a definitive pathological evaluation. Despite the clinical significance of this issue, there are currently no universally established or standardized criteria to evaluate specimen adequacy in prostate core biopsies. Consequently, our study offers a novel and valuable contribution to the literature by comprehensively investigating the underlying clinical factors and long-term outcomes associated with this diagnostic entity.

According to the existing literature, studies examining 12-core systematic biopsies indicate that a significant proportion of specimens may lack glandular tissue or exhibit insufficient core length (9,10). Indeed, a traditional six-core "sextant" biopsy is now widely considered inadequate compared to modern 10-to-12 core sampling techniques (11). The absence of prostatic glandular elements was most frequently detected at the apical location in a previous study by Dogan et al. (10), which corroborates our findings. The prostatic apex is notoriously challenging to sample adequately. If the biopsy needle is suboptimally angled through the rectal wall, apical tissue can easily be missed, or the needle may fail to reach the necessary glandular depth (12). Conversely, the midline region is prone to undersampling, particularly if the biopsy focus is directed too heavily toward the far lateral zones, thereby leaving the transition zone and central areas poorly represented (13). Consistent with these reports, a key finding of our study is that inadequate cores occurred most frequently in the apex, followed by the midline location. Notably, the apex remained the most significantly affected site when five or more cores were inadequate. Together, these results strongly suggest that inadequate sampling is primarily driven by complex anatomical and technical factors inherent to these specific regions rather than being solely attributable to operator error.

To date, no specific data exist in the literature regarding the optimal clinical management strategies based on the exact number of inadequate cores. Although previous studies have generally recommended close clinical surveillance using biochemical parameters and advanced imaging techniques following such biopsies, the term "inadequate" itself remains poorly defined (6). Notably, our study demonstrated that an increase in the number of inadequate cores did not significantly influence the type of subsequent interventional procedures or medical therapies administered. This finding implies that merely reporting the quantity of inadequate cores does not directly alter active patient management. Furthermore, it underscores the critical paradigm that a histopathological report should not be

interpreted in isolation, but rather serves as a diagnostic tool that must be carefully integrated with clinical and radiological findings to guide clinical decision-making effectively.

Elevated PSA levels (> 4.0 ng/mL) and high PSA velocity (> 0.35–0.5 ng/mL/year) are widely recognized clinical indicators prompting a repeat biopsy (14). Particularly in cases exhibiting rapid PSA velocity following an initial negative biopsy, many experts currently advocate for immediate re-biopsy to minimize the risk of missed neoplastic lesions (15). Furthermore, a larger prostate volume (> 30–50 cc) is significantly associated with an increased likelihood of false-negative outcomes on standard initial 12-core biopsies (16). Corroborating these literature insights, our findings similarly demonstrate that high initial PSA levels, accelerated PSA velocity, and larger prostate volumes remain the primary clinical drivers for proceeding to subsequent interventional procedures.

Body Mass Index (BMI) exhibits a complex, often paradoxical relationship with prostate cancer screening paradigms and histopathological outcomes (17,18). Although obesity can technically compromise the biopsy procedure and frequently correlates with suppressed baseline PSA levels, it remains paradoxically linked to an elevated risk of detecting high-grade prostate malignancies (17,18). Crucially, our data highlights a clear association between elevated BMI and suboptimal specimen quality. Consistent with the literature, we observed a statistically significant correlation between increased BMI and a higher burden of inadequate cores. Furthermore, patients with a higher BMI tended to present with more elevated PI-RADS scores. Conversely, pathologically confirmed malignancy rates did not reach statistical significance within this specific cohort. Taken together, these findings strongly suggest that obesity not only poses intraoperative technical challenges but may also concurrently contribute to both physical sampling difficulties and radiologically suspicious phenotypes.

The evaluation of chronic comorbidities yields essential insights into the clinical and radiological phenotypes of these patients. Hypertension has been widely documented as a potential risk factor for prostate cancer development, with accumulating evidence suggesting that this association may be driven by metabolic changes and androgen-mediated pathways that can simultaneously drive prostate growth and elevate baseline PSA kinetics (19). Corroborating these literature perspectives, our study demonstrated that both higher initial PSA levels and significantly larger prostate volumes were more prevalent in the hypertensive subgroup. Conversely, diabetes mellitus (DM) frequently correlates with a reduced overall risk of prostate malignancy and lower systemic androgen concentrations, which often shifts the clinical presentation toward less aggressive or non-suspicious findings (20). Consistently, we found that patients with DM exhibited a significantly higher prevalence of benign lesions on multiparametric MRI compared to suspicious or malignant lesions. Taken together, these distinct patterns reinforce the premise that chronic metabolic conditions can substantially skew biochemical and radiological parameters, thereby complicating the diagnostic risk-stratification pathway.

Subsequent interventions—specifically repeat biopsy or surgical resection—performed due to the presence of baseline inadequate cores or prompted by persistent clinical and radiological suspicion yielded predominantly benign diagnoses. Importantly, while malignancy and ASAP were detected in a

minimal subset of these cases, these low diagnostic conversion rates offer a substantial clinical reassurance. These findings strongly suggest that the likelihood of uncovering occult malignancy during longitudinal follow-up remains low, confirming that when clinical, biochemical, and radiological parameters do not indicate active progression, this patient cohort can be safely managed without immediate aggressive intervention.

Several limitations of this study warrant consideration. While its retrospective, single-center design may limit the generalizability of the findings, the lack of routine follow-up MRI evaluations and a relatively short follow-up period further restrict long-term assessments. Additionally, due to the predominantly benign nature of our cohort—with only a marginal subset demonstrating malignant outcomes during subsequent interventions—definitive subgroup analyses for clinically significant prostate cancer could not be performed. Lastly, potential interobserver variability represents a notable constraint, as both the biopsy procedures and the pathological evaluations were performed by multiple operators, which may introduce variations in sampling quality and subsequent clinical decision-making.

Conclusions

In conclusion, inadequate cores in prostate core biopsies are predominantly associated with anatomically challenging target regions, particularly the apex, rather than representing random technical failures alone. Although the overall rate of malignancy detection during follow-up was relatively low, patients exhibiting elevated PSA kinetics or highly suspicious multiparametric MRI findings require stringent surveillance and may derive substantial diagnostic benefit from targeted fusion re-biopsy. Furthermore, systemic patient factors, such as an increased BMI, can significantly complicate the retrieval of adequate samples. Importantly, the structural burden (absolute number) of inadequate cores does not appear to artificially drive aggressive clinical intervention, confirming that post-biopsy management remains appropriately guided by holistic risk factors rather than sampling artifacts alone. Establishing standardized, universally accepted criteria for defining "inadequate" prostate biopsy cores is essential to optimize interdisciplinary communication between pathologists and clinicians, ultimately contributing to more objective, risk-stratified patient management strategies.

Abbreviations

PSA: Prostate-specific antigen

mpMRI: Multiparametric magnetic resonance imaging

STROBE: STrengthening the Reporting of OBservational Studies in Epidemiology

BMI: Body mass index

PI-RADS: Prostate Imaging Reporting & Data System

DM: Diabetes mellitus

HT: Hypertension

CAD: Coronary artery disease

TURP: Transurethral resection of the prostate

LUTS: Lower urinary tract symptoms

ASAP: Atypical small acinar proliferation

Declarations

Ethics approval and consent to participate:

The study protocol and informed consent form were approved by the Ethics Committee of the University of Health Sciences, Basaksehir Cam and Sakura City Hospital (Approval date/no: May 12, 2026/275).

Consent for publication:

Written informed consent was obtained from all participants. Additionally, patients provided permission for the utilization of their clinical data retrieved from the hospital's electronic health record system.

Funding:

The authors received no specific funding for this work.

Authors' contributions: BCG and MM designed the study and drafted the manuscript. BCG evaluated pathological specimens. MM evaluated clinical data. BCG performed statistical analyses. All authors read and approved the final manuscript.

Author Contribution

BCG and MM designed the study and drafted the manuscript. BCG evaluated pathological specimens. MM evaluated clinical data. BCG performed statistical analyses. All authors read and approved the final manuscript.

Availability of data and materials:

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Figures

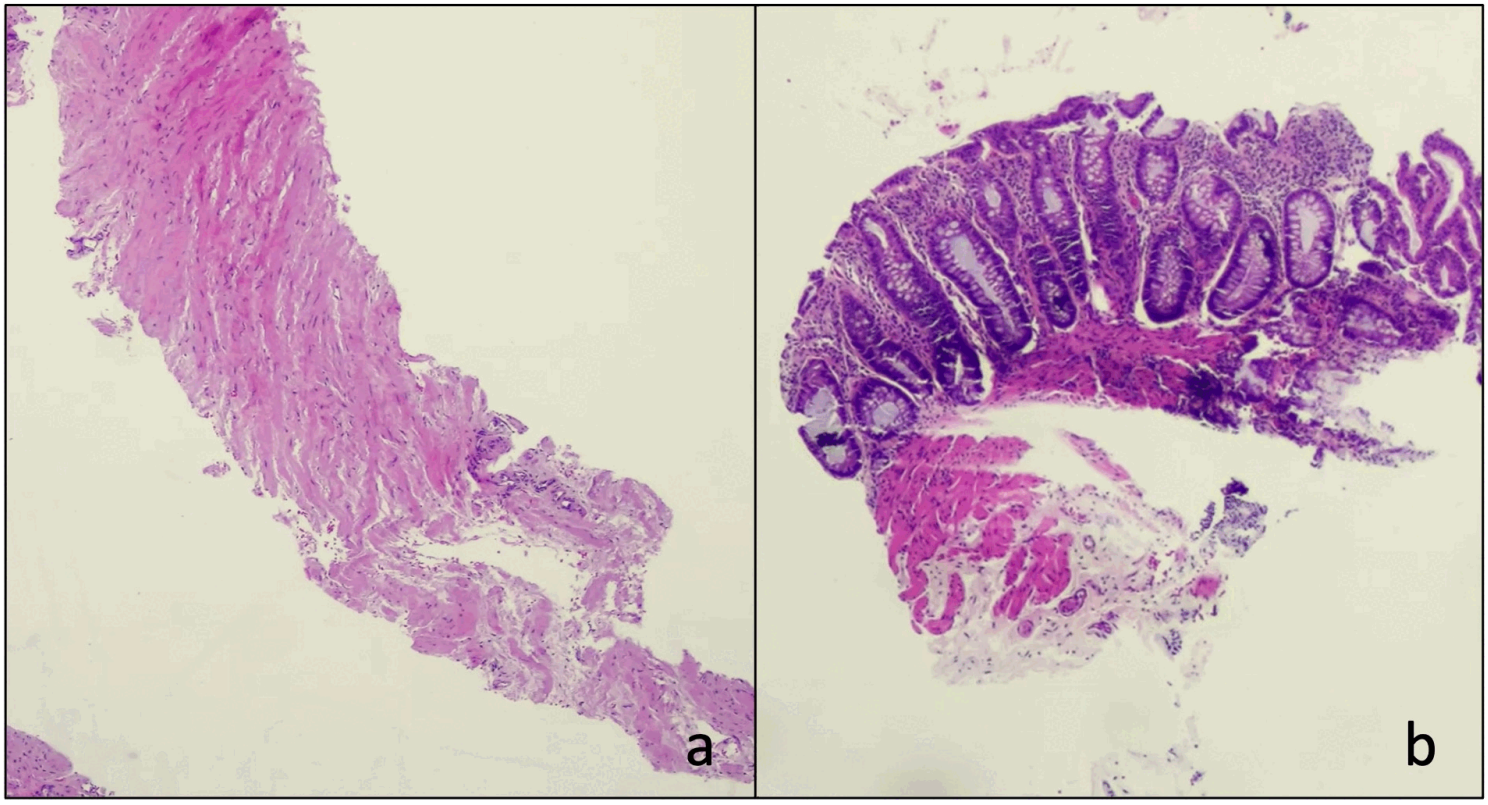


Figure 1

Hematoxylin and eosin-stained sections of inadequate core biopsy samples; (a) the biopsy specimen consists entirely of fibromuscular tissue (x4), and (b) the biopsy specimen contains rectal mucosa instead of prostatic glands (x4).