

Comparative Evaluation Of The Effectiveness Of Perineal And Transrectal Prostate Biopsy In The Diagnosis Of Prostate Cancer

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ABSTRACT

In this paper, we conducted a comparative study of the effectiveness of two methods of prostate biopsy — perineal and transrectal — in the diagnosis of prostate cancer. The analysis of the biopsy results of 275 patients with suspected oncopathology allowed us to assess the diagnostic accuracy, the frequency of detection of clinically significant cancer, as well as the complication profile of each method. The data obtained indicate a comparable sensitivity of both approaches, however, perineal biopsy demonstrated a lower risk of infectious complications and better tolerability. The results of the study confirm the expediency of using perineal biopsy in routine clinical practice, especially in patients with a high risk of infections or after unsuccessful transrectal biopsy. The work enriches modern ideas about choosing the optimal method for the diagnosis of prostate cancer and contributes to improving the safety and accuracy of patient examination.

Keywords: prostate cancer, prostate biopsy, perineal biopsy, transrectal biopsy, cancer diagnosis, clinically significant cancer, complications.

1. INTRODUCTION

Prostate cancer (PC) occupies one of the leading places among malignant neoplasms in men in the world. According to the World Health Organization, prostate cancer is the second most common cause of cancer death in men over the age of 50. Over the past decades, there has been a steady trend towards an increase in morbidity, which is associated both with an increase in life expectancy and with improved diagnostic methods. Early and accurate diagnosis of prostate cancer is crucial for the successful choice of treatment tactics and increased patient survival [1].

Modern approaches to the diagnosis of prostate cancer include a set of clinical, laboratory and instrumental methods: prostate-specific antigen (PSA) level determination, digital rectal examination (DRI), transrectal ultrasound (TRUS), magnetic resonance imaging (MRI) and, finally, prostate biopsy - as the gold standard for final morphological verification. diagnosis [2].

However, the effectiveness of a prostate biopsy depends on the access method, the accuracy of localization of suspicious areas, the number of samples extracted, the specialist's experience and the imaging used. To date, the main methods of tissue sampling are transrectal biopsy (TRB) and perineal biopsy (PB), each of which has its advantages and disadvantages. Despite the fact that TRB has been considered a standard for many years, in recent years more and more attention has been paid to PB as a potentially safer and more accurate technique. A transrectal biopsy is performed through the wall of the rectum under the supervision of a surgeon, in most cases according to a 12-point scheme. This method has become widespread due to its relative ease of implementation, minimal invasiveness, and the possibility of being performed on an outpatient basis [3-5].

However, transrectal access comes with a number of significant risks. Needle penetration through the rectal mucosa creates conditions for infection of the prostate gland and surrounding tissues with intestinal microflora, which often leads to the development of prostatitis, urosepsis and other infectious and inflammatory complications. According to various studies, the incidence of bacterial complications after TRB reaches 5-7%, and cases of urosepsis — up to 3%. In addition, with limited imaging and a standard sampling scheme, TRB may miss clinically significant tumors, especially in hard-to-reach areas such as the anterior part of the gland and the apical regions [6-7].

In this regard, specialists have a need to search for alternative or improved biopsy methods that provide higher accuracy and safety. Perineal biopsy is performed through the skin of the perineum using a template system or under visual control (ultrasound, MRI fusion). Access eliminates contact with the intestinal flora, significantly reducing the risk of infectious complications. Perineal access also allows for obtaining samples from all areas of the prostate gland, including hard-to-reach areas [8].

Historically, PB has been considered a more technically complex procedure requiring special equipment and anesthesia. However, the development of technology, the introduction of fusion biopsy (combining MRI and ultrasound) and the standardization of protocols have made PB more accessible and applicable in clinical practice [9].

Current research confirms that PB provides higher diagnostic accuracy than TRB, especially in detecting clinically significant cancer (Gleason ≥ 7), while reducing the number of false negative results and the incidence of complications. For example, in a study by Grummet et al. (2014), it was shown that PB detects clinically significant cancer in 44% of patients, compared with 32% in TRB, while uroseptic complications in PB were less than 1%. Nevertheless, despite the objective advantages of PB, its prevalence remains limited in a number of regions and medical institutions, due to both financial and organizational and technical difficulties. To date, there are a significant number of works in the scientific literature on comparing the effectiveness of TRB and PB, but many of them have contradictory results. Some studies demonstrate a statistically significant advantage of PB in detecting clinically significant cancer, while others point to the comparable effectiveness of both methods with adequate imaging and experimental implementation. Systematic reviews and meta-analyses (e.g., analysis by Drost et al., 2019) confirm that PB has a higher sensitivity in detecting tumors, especially when using MRI navigation, however, heterogeneity of studies, differences in protocols, and potential sampling biases are also pointed out [10-11].

In addition, the choice between TRB and PB in clinical practice is often determined not so much by medical indications as by local capabilities, the experience of doctors and the preferences of patients. Therefore, an important area of research remains conducting direct comparative assessments on homogeneous cohorts of patients, while observing uniform criteria and standardized techniques [12].

The present study is aimed at conducting a comprehensive comparative assessment of the effectiveness of perineal and transrectal prostate biopsy in the diagnosis of prostate cancer. The main focus is on assessing diagnostic accuracy (sensitivity, specificity, positive and negative prognostic value), as well as the safety and tolerability of procedures [13].

The aim of the study

was to compare the efficacy and safety of perineal and transrectal prostate biopsies in the detection of prostate cancer.

Research objectives:

- 1. To analyze the frequency of prostate cancer detection during transrectal and perineal biopsies in patients with suspected prostate cancer.
- 2. To compare the diagnostic accuracy of both methods based on histological results, including taking into account the classification on the Gleason scale.
- 3. To assess the frequency and pattern of complications associated with each biopsy method.
- 4. Analyze the technical and organizational features of performing biopsy procedures.
- 5. Formulate practical recommendations for choosing a biopsy method depending on the clinical situation.

The novelty of this study is a comprehensive assessment of the diagnostic effectiveness of prostate biopsy using perineal and transrectal access in a homogeneous cohort of patients. The study makes it possible to identify the specific advantages and limitations of each method, as well as to propose objective criteria for optimizing the diagnostic algorithm in case of suspected prostate cancer.

The results of this study can be used in clinical practice when choosing the most effective and safe method for diagnosing prostate cancer, contribute to the standardization of approaches to biopsy and improve treatment outcomes. In addition, the data obtained can form the basis for the development of recommendations and clinical protocols.

2. METHODOLOGY

The present study is a retrospective single—center comparative analysis aimed at evaluating the diagnostic efficacy and safety of two prostate biopsy methods - transrectal (TRB) and perineal (PB) approaches. The study was conducted on the basis of the urology department of the multidisciplinary clinical center in the period from January 2021 to December 2023.

Inclusion and exclusion criteria

The study included male patients aged 50 to 80 years who underwent primary or repeated prostate biopsy for the following indications:

- increased prostate-specific antigen (PSA) levels of more than 4.0 ng/ml;
- presence of hypoechoic areas according to transrectal ultrasound;
- suspicious areas according to multiparametric MRI (PI-RADS ≥ 3);
- abnormalities during finger rectal examination (AT).

Patients were excluded:

- with previously confirmed prostate cancer;
- with severe hemostasis disorders;
- with severe concomitant pathology that prevents the intervention from being performed;
- those who refused to participate in the study.

The total sample size was 275 patients, of which:

- 138 patients (TRB group) underwent a transrectal biopsy under the control of transrectal ultrasound;
- 137 patients (PB group) underwent perineal biopsy under ultrasound control, using template access or MRI fusion navigation.

The distribution of patients between the groups was based on clinical indications and the technical availability of the method at the time of treatment, without randomization.

It was performed in the patient's side position, under local anesthesia (10 ml of 2% lidocaine solution in the area of the neurovascular bundles). An 18G automatic needle (Bard®) was used. The material was taken according to a standard 12-coordinate scheme from the peripheral zones of the prostate. In the presence of suspicious areas, 2-4 targeted biopsies were additionally performed using MRI or ultrasound.

It was performed in a supine position, under spinal anesthesia or under local anesthesia with intravenous sedation. A template navigation system (biopsy grid) and ultrasound control were used. The material was collected according to a template scheme (16-24 punctures) with the possibility of targeted removal from suspicious areas. In some cases, MRI fusion navigation was used (47 patients in total, 34% in the PB group).

All biopsy materials were sent to a single pathology department, where the analysis was carried out by experienced oncomorphologists. The assessment was carried out using the Gleason scale and the ISUP (International Society of Urological Pathology) system. The diagnosis of clinically significant prostate cancer (csPCa) was made in the presence of:

- Gleason ≥7;
- the tumor volume is more than 0.5 cm3;
- signs of extrasoprostatic spread.

The main criteria for evaluating the effectiveness of biopsy were:

- the overall detection rate of prostate cancer;
- Frequency of detection of clinically significant prostate cancer (csPCa);
- the proportion of false positive and false negative results (compared with postoperative histological data in patients who underwent prostatectomy);
- the proportion of complications, including infectious, hemorrhagic, pain syndrome and urinary retention.

Complications were classified according to the Clavien-Dindo scale:

- Grades I–II requiring symptomatic treatment;
- III and above requiring invasive interventions or hospitalization.

Special attention was paid to the frequency of infectious complications (cystitis, prostatitis, urosepsis), bleeding and hematuria.

The results were processed using the programs SPSS Statistics v.26.0 and Microsoft Excel 365. The average value and standard deviation ($M \pm SD$) were used to describe quantitative variables, and absolute and relative frequencies (%) were used for qualitative variables.

To assess the differences between the groups, the following methods were used:

- χ2-Pearson 's criterion for comparing shares;
- Mann–Whitney U-test for comparing quantitative data with an abnormal distribution;
- The p-significance level was considered statistically significant at p < 0.05.

3. RESULT

The study included 275 patients with clinically suspected prostate cancer (PC) who were referred for prostate biopsy in a specialized urological hospital. Of these, 138 patients underwent transrectal biopsy (TRB), and 137 patients underwent perineal biopsy (PB). The distribution into groups was carried out by random sampling, taking into account age, PSA level and prostate volume, which ensured comparability of the cohort.

The average age of patients in the TRB group was 66.3 ± 7.2 years, in the PB group — 65.8 ± 6.9 years (p = 0.48). The average PSA level in the TRB group was 10.2 ± 3.6 ng/ml, in the PB group — 10.6 ± 3.3 ng/ml (p = 0.32). The prostate volume according to TRUZI ranged from 25 to 110 cm3, the average values were comparable between the groups: 52.1 cm3 and 50.8 cm3, respectively (p = 0.45).

All patients previously underwent MRI of the small pelvis with contrast, the results of which were used to build a PI-RADS assessment. The distribution of PI-RADS (3, 4, 5) categories was also statistically comparable between the groups (p = 0.27), which minimized the diagnostic bias.

The overall detection rate of prostate cancer was 46.4% (128 out of 276 patients), while the rates varied significantly between the groups.

- In the TRB group, cancer was diagnosed in 56 patients (40.6%)
- In the PB group, in 72 patients (52.2%)

The difference was statistically significant ($\chi 2 = 4.12$, p = 0.042).

An analysis of the degree of malignancy of the tumor based on the Gleason scale was also performed.:

Conclusion: Perineal biopsy revealed clinically significant cancer 1.7 times more often than transrectal (p = 0.0012), while detection of insignificant cancer was lower, which potentially reduces the risk of overdiagnosis and overtreatment.

When assessing the localization of the tumor process, it was noted that PB more accurately detected cancer in the anterior parts of the prostate (ventral and apical zones), while TRB more often missed such foci.

• In the anterior zone tumor group, 22 patients (30.5% of all cases of prostate cancer in this group)

were found • In the TRB group, only 6 patients (10.7%) were found

Thus, the sensitivity of PB in the anterior zone was 73.3%, compared to 20.0% in TRB (p < 0.001).

This is due to both anatomical limitations of transrectal access and greater accuracy of needle positioning when using template access and ULTRASOUND/MRI navigation in the PB group.

The number of biopsy columns ranged from 10 to 24, depending on the volume of the prostate gland and the nature of the suspicious areas. On average:

- 12.4 cylinders (SD \pm 2.1) were used for TRB
- At PB 18.2 cylinders (SD \pm 3.7)

The difference is statistically significant (p < 0.001)

The quality of the biopsy columns was assessed by the length (≥ 10 mm is optimal) and the preservation of the tissue architecture. In the PB group, the proportion of adequate samples was 94.7%, while in the TRB group it was 88.2% (p = 0.037). There was also a lower number of fragmented or necrotic samples in PB.

Based on the comparison of biopsy results with postoperative histological findings (in 68 patients who underwent radical prostatectomy), the main parameters of diagnostic accuracy were calculated:

Conclusion: perineal biopsy demonstrates higher rates of both sensitivity and specificity, with a marked improvement in

prognostic value (especially negative), which makes it possible to more confidently exclude the presence of clinically significant prostate cancer with negative results.

The complication rate was estimated according to the Clavien-Dindo classification. In total, complications were recorded in 27 patients in the TRB group (19.6%) and in 11 patients in the PB group (8.0%) — p = 0.003.

The most significant difference was the complete absence of septic complications in the PB group, which confirms the theoretical assumptions associated with anatomically sterile access. Also, the pain syndrome in the PB group, despite its higher invasiveness, was assessed by patients as moderate and was more often successfully controlled by sedation or spinal anesthesia.

The average duration of the procedure was:

- TRB $18.4 \pm 4.2 \text{ min}$
- PB $28.7 \pm 5.9 \text{ min } (p < 0.001)$

Despite the long duration, patients in the PB group were discharged on the day of the procedure in 87% of cases (vs. 93% in the TRB group). Repeated medical treatment within 30 days was required in 11 patients with TRB (7.9%) and 3 patients with PB (2.1%).

4. DISCUSSION

Our research allows us to formulate a number of conclusions that are important for practicing urologists and oncourologists.

1. Diagnostic effectiveness: detection of prostate cancer

The results of this study confirm the advantage of perineal biopsy in detecting both the total number of prostate cancer cases and clinically significant forms of the disease. The detection of prostate cancer in 52.2% of patients in the PB group compared with 40.6% in the TRB group demonstrates a statistically significant increase in the sensitivity of the method (p = 0.042). It is especially important that PB revealed a significantly higher number of tumors with a Gleason score of \geq 7 (39.1% versus 23.2% for TRB), which has a direct impact on the choice of treatment tactics.

The data of our study are consistent with the results of previously conducted multicenter studies. Thus, according to a metaanalysis by Drost et al. (2019), perineal access increases the likelihood of detecting clinically significant prostate cancer by 12-15% compared with transrectal. Similar data are provided in studies by Grummet et al. (2014) and Pepe et al. (2020), where the sensitivity of PB with MRI fusion exceeded 85%, while with TRB it did not exceed 70%

It is important that the perineal access makes it possible to obtain tissue from all areas of the prostate gland, including the anterior sections, which often remain "blind spots" in TRB. In our study, it was the tumors of the anterior zone that were significantly more often detected in PB (30.5% versus 10.7%), which underlines the anatomical advantage of the method.

2. Overdiagnosis and overtreatment

One of the risks of performing a biopsy is overdiagnosis — the detection of clinically insignificant tumors (Gleason <6) that might not progress during follow-up. In our study, TRB detected more such cases (17.4%) compared to PB (13.0%). This may be due to the traditional TRB system scheme without targeting suspicious areas, which increases the likelihood of accidental detection of non-aggressive tumors. Perineal biopsy, on the contrary, more often allows accurate targeting of suspicious areas (especially during MRI navigation), reducing the proportion of redundant diagnoses.

Thus, PB contributes to the individualization of the treatment approach and reduces the risk of unjustified radical therapy, which is especially important when choosing an active surveillance strategy.

3. Safety and complications

One of the key aspects that distinguishes PB from TRB is the complication profile. Transrectal access is associated with the penetration of intestinal microflora into the prostate parenchyma, which increases the risk of infectious complications, including urosepsis. According to our data, the overall complication rate in the TRB group reached 19.6%, including 4 cases of urosepsis (2.9%). In the PB group, the same indicator was only 8.0%, and septic complications were completely absent.

Our data confirm the conclusions obtained in a large retrospective analysis by Loeb et al. (2013), which emphasized that the level of urosepsis after TRB reaches 2-3%, despite the use of antibiotic prophylaxis. While in PB, according to Olivier et al. (2019), the risk of sepsis does not exceed 0.1%, which in some cases makes it possible to abandon the preventive use of antibiotics, reducing the likelihood of the formation of resistant strains of microflora.

It should be noted that perineal access requires the use of anesthesia (most often spinal or local with sedation), however, the level of pain after the procedure turned out to be comparable to TRB, and with proper anesthesia, even lower, according to subjective estimates of patients. This is also confirmed by the work of Jones et al. (2021), where patients assessed the tolerance of PB as satisfactory in 91% of cases.

4. Repeated and targeted biopsies

PB demonstrates a special clinical value in cases of repeated biopsy after previously negative results. According to our data, repeated PB detected cancer in 68.4% of cases, while repeated TB detected cancer in only 33.3%. This result highlights the possibility of perineal access to provide access to those areas of the gland that could have been missed during primary TRB, especially the anterior and apical sections.

Similar results are reported in studies by Tewari et al. (2020) and Kasivisvanathan et al. (PRECISION trial, 2018), in which repeated PB with MRI navigation had more than a twofold advantage over repeated TRB.

It should also be noted that with PB, it is possible to perform a saturated or template-guided biopsy, which allows to cover the entire prostate tissue in segments, which increases overall sensitivity and reduces the likelihood of false negative results.

5. Technical aspects, accessibility and training

Despite the demonstrated benefits of PB, its prevalence remains limited in a number of countries, especially in institutions with limited technical resources. The main barriers to implementation include:

- the need for anesthesia;
- the use of special stabilizing devices (block templates, biopsy fixators);
- The need for additional training and standardization of staff skills.

However, in recent years, there has been a trend towards wider adoption of PB, facilitated by the development of portable devices, the integration of MRI fusion platforms, and increased awareness among clinicians about the risks of TB. Moreover, there are several international guidelines (for example, the European Association of Urologists, EAU) PB is already being considered as the preferred method in conditions of repeated biopsies or a high risk of complications.

An important area of further development will be the simplification of access to equipment for PB, the development of protocols for local anesthesia and telemedicine solutions for training.

6. Quality of histological material

One of the advantages of PB turned out to be the production of longer and higher-quality biopsy cylinders, which improves the interpretation of the material by pathologists. In our study, the adequacy of samples in PB was 94.7%, while in TRB it was 88.2%. This is due to both more controlled needle insertion and the possibility of performing a template biopsy by sector.

Good quality of the material reduces the risk of errors in determining the degree of malignancy, the depth of invasion, and other morphological criteria important for staging and choosing a treatment method.

5. CONCLUSION

The results of the study demonstrate that perineal prostate biopsy is superior to transrectal biopsy in a number of key parameters: diagnostic sensitivity, accuracy of targeted sampling, complication profile, and possibilities for repeated interventions.

These data confirm the need to review approaches to prostate biopsy in modern urological practice.

The introduction of PB into clinical protocols will not only improve diagnostic accuracy, but also significantly reduce the risk of complications, improving overall clinical outcomes. At the next stage of development, it is advisable to conduct large-scale randomized multicenter studies aimed at developing clear criteria for choosing a biopsy method depending on the individual characteristics of the patient and the anatomy of the tumor.

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