



# Outcomes of Transrectal Ultrasound-Guided Prostate Biopsy by the 12-Core Method at Can Tho University Hospital

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Received 2023 January 02; Revised 2023 May 26; Accepted 2023 July 05.

## Abstract

**Background:** Prostate cancer (PCa) is a common disease in men, possessing the second-highest incidence rate and the fifth-highest mortality rate worldwide. Diagnosis of PCa depends on factors such as rectal examination, total serum PSA level, and the result of prostate biopsy. Our study aimed to evaluate the results of rectal prostate biopsies taken through the 12-core method under the direction of ultrasound.

**Objectives:** To assess the results of transrectal ultrasound-guided prostate biopsy by the 12-core method.

**Methods:** This cross-sectional research was conducted on 60 patients with prostate tumors who had indications for biopsy from 5/2021 to 5/2022 at the Can Tho University of Medicine and Pharmacy Hospital. Our patients were required to score 2 points on the international prostate syndrome score (IPSS) and quality of life (QoL) index. We used descriptive statistics to present the data. Indications for undergoing prostate biopsy were abnormal digital-rectal examination findings and/or an elevated total prostate-specific antigen (PSA) serum level (greater than 10 ng/mL). The participants received prophylactic intravenous baclofen (1000 mg) and oral metronidazole (500 mg) before the procedure, which was continued for about 3 days. A Fleet enema was self-administered the night before the procedure for rectal cleansing.

**Results:** The average age of the patients was 68.72 years, and the most common reason for hospitalization was dysuria (80%). The average IPSS score was  $26.21 \pm 4.49$ , and the average QoL index was  $3.38 \pm 0.67$ . The mean serum total PSA was 26.11 ng/mL. The PCa detection rate after the biopsy was 40% (24/60), and Gleason's score for 45.83% (11/24) of these patients was 8 or above. There were two cases of strong rectal bleeding (3.33%) and one case of strong hematuria (1.67%).

**Conclusions:** Transrectal ultrasound-guided prostate biopsy is a valuable and feasible procedure for the diagnosis of PCa at our hospital.

**Keywords:** Prostate Biopsy, Prostate Cancer, Transrectal Ultrasound

## 1. Background

Prostate cancer (PCa) is a fairly common disease in men, claiming the second highest incidence rate and the fifth leading cause of mortality among men worldwide (1). The diagnosis of PCa is established based on the results of procedures and tests such as rectal examination, total prostate-specific antigen (PSA) in serum, and prostate biopsy (2). According to the EAU, ultrasound-guided transrectal prostate biopsy is considered the gold standard for prostate histopathology examination (3). The Can Tho University of Medicine and Pharmacy Hospital performs transrectal prostate biopsies under ultrasound guidance since 2020. Our study aimed to evaluate the

outcomes of rectal prostate biopsies conducted through the ultrasound-guided 12-core method.

## 2. Objectives

To assess the outcomes of transrectal ultrasound-guided prostate biopsy conducted via the 12-core method.

## 3. Methods

Our research was approved by the Science Council and Medical Ethics Council of Can Tho University of Medicine

and Pharmacy. This non-controlled clinical intervention included all patients presenting with the symptoms of lower urinary tract disorders admitted to the urology clinic and treated at the Urology Center-HIFU of Can Tho University of Medicine and Pharmacy Hospital from 5/2021 to 5/2022.

Biopsy taking was considered in patients with a solid or nodular mass in the rectal examination of the prostate (i.e., clinical presentation), serum PSA levels above 10 ng/mL (i.e., subclinical presentation), or suspicious ultrasound, CT, or MRI images (muffler drive, unbalanced prostate, breakage of the prostate capsule, etc.). The procedure was conducted when there were no contraindications (blood clotting disorders, immunodeficiencies, acute prostatitis, unstable clinical condition, complicated prostatic hyperplasia (e.g., bladder stones, urinary tract infections, and kidney failure), and anorectal diseases (hemorrhoids, anal infections, perineum, anal stenosis), or when the patient refused to undergo prostate biopsy.

### 3.1. Selection of Patients Eligible for Prostate Biopsy

All patients were surveyed using a questionnaire to conduct history taking, recording presenting complaints, and past medical and surgical history. The patients also underwent clinical examination and the tests required to identify patients meeting pre-specified eligibility criteria.

All the data were recorded in a questionnaire and presented using descriptive statistics (mean  $\pm$  standard deviation for continuous variables and rates and percentages for categorical variables). The data were analyzed using Statistical Package for the Social Sciences version 20.0 (SPSS Inc).

The data included the patient's medical history, administrative information, reason for admission, history of other diseases, clinical examination findings, and the international prostate syndrome score (IPSS) and quality of life (QoL) indices.

### 3.2. Rectal Examination

A rectal examination was performed after obtaining a blood sample from the patient. The patient was lying in the obstetrical position (lying on the back, bending and spreading out legs to the sides). The doctor stood to the right of the patient. If the patient was lying on the left side, the lower leg was extended; the upper leg was bent, and the doctor stood behind the patient's back in an inferior position to the patient's buttocks.

The urologist wore gloves and applied the lubricant before inserting his index finger slowly and gently into the anus. The finger must be rotated so that the entire circumference of the rectal ball can be examined. The superior surface of the rectum was touched to determine the groove between the prostate and the 2 lateral lobes and to assess the surface and density of the prostate.

### 3.3. Paraclinical Testing

The patient's blood sample was taken to measure the total PSA serum level before rectal examination. Abdominal ultrasound was conducted when the patient was urinating to estimate prostate size and other features. Then the patient underwent an ultrasound of the bladder to determine the residual urine volume. Based on the results of these tests, the patients indicated for prostate biopsy were identified.

### 3.4. Research Materials

Research tools included a data collection checklist, Siemens ultrasound system, hematology and biochemistry auto-analyzers, and a prostate biopsy system [including a color ultrasound system with 7.5 MHz rectal transducers and a synchronous integrated biopsy canal, a biopsy gun compatible with the biopsy needle (18 G, length: 200 mm, cores length: 22 mm)].

### 3.5. Procedures

The transrectal biopsy of the prostate gland was performed under ultrasound guidance. Patient preparation steps before biopsy included antibiotic treatment (bicefzidim 1 g daily by slow intravenous injections twice a day, each time one vial, metronidazole 0.25 g, orally two times per day, two tablets each time). The patients were instructed to eat soft easy-to-digest food and remain completely fasted before the procedure. For colon preparation, fleet enema (2 tubes of anal pump 3 - 4 hours before biopsy) was administered. The patients were explained about the biopsy procedure and its possible peri- and post-complications to help the patient prepare psychologically and cooperate well with the physician. The patient's vital signs were recorded before biopsy taking. The patient would lay on the left side; the thigh was perpendicular to the body, and the leg was perpendicular to the thigh. The tools required were disinfectants, the ultrasound device and probes, a biopsy gun, a biopsy needle, lidocaine 2%, and sample vials containing a fixative for biopsy specimens (formalin) numbered in order from 1 to 12.

Treatment steps included disinfection of the perineum, anus, and rectum via sterile towels, inserting the ultrasound probe into the rectum, moving the probe to observe and evaluate the prostate, injecting anesthetics around the prostate, targeting the biopsy site, inserting the biopsy gun into the biopsy canal, obtaining needle biopsy samples, place specimens into labeled fixative-containing vials, proceeding toward next positions.

The biopsy was performed at 12 cores, 6 cores per lobe (left, right), according to prostate location (top, center, base of prostate). After completing the procedure, vital signs were checked, and if they were stable, the patient

was released and returned to rest in the ward. The samples (12 biopsies) were sent for pathological examination at the Pathology Department of Can Tho University of Medicine and Pharmacy Hospital. The patients in the ward were followed up for post-biopsy complications, including pain, anal bleeding, urinary status, infections, etc.

#### 4. Results

According to our research on 60 patients who agreed to undergo prostate biopsy, the average age was 68.72 years old, the highest age being 95 years and the lowest 53 years old. The age group of 60 - 69-year-old accounted for 50% of the patients (Table 1). This was similar to the results of Philip et al., who performed prostate biopsies on 445 patients with a mean age of 64.5 years (4). Shim et al. obtained prostate biopsies from 516 patients with a mean age of  $64.1 \pm 7.8$  years in Korea (5). Regarding age, our findings were consistent with that of most previous studies.

Table 1. Distribution by Age Group

| Age Groups | No. (%)    |
|------------|------------|
| 50 - 59    | 8 (13.33)  |
| 60 - 69    | 30 (50)    |
| 70 - 79    | 13 (21.67) |
| ≥ 80       | 9 (15)     |
| Total      | 60 (100)   |

##### 4.1. Reason for Hospitalization

There were 5 main reasons causing patients to be hospitalized: Dysuria, hematuria, nocturia, intermittent urination, and urinary retention. The symptoms of early PCa are similar to those of benign prostatic hyperplasia; however, symptoms of metastasis (spinal pain, pelvic pain, etc.) may appear in the late stages of PCa. In our research, most patients were admitted to the hospital due to having lower urinary tract disorders (86.67%), followed by dysuria (80%). Eight patients (13.33%) were admitted to the hospital because of urinary retention, requiring urethral catheterization. There were no cases of hospitalization with metastatic symptoms (Table 2). Compared with the research of Le on 73 patients undergoing prostate biopsy, 12 (43.8%) patients complained of lower urinary tract disorders (6).

##### 4.2. International Prostate Syndrome Score and Quality of Life Scores at Admission

The average IPSS score was  $26.21 \pm 4.49$  (the range of 8 - 33), and the mean QoL score was  $3.38 \pm 0.67$  (the range of 3 - 4), indicating that most of the patients admitted to

Table 2. Reason for Hospitalization

| Reason for Hospitalization | No. (%)   |
|----------------------------|-----------|
| Dysuria                    | 48 (80)   |
| Hematuria                  | 1 (1.67)  |
| Nocturia                   | 1 (1.67)  |
| Intermittent urination     | 2 (3.33)  |
| Urinary retention          | 8 (13.33) |
| Total                      | 60 (100)  |

the hospital were in an acceptable condition with mild symptoms.

##### 4.3. Clinical Presentation

Prostate rectal examination is particularly important for establishing the correct diagnosis and starting timely treatment. In this research, we found that 5/60 patients (8.33%) had signs of suspected cancer (hardcore, loose boundaries, surrounding organization), while others (91.67%) had no suspicious findings (Table 3). According to the research of Vu (7), during prostate rectal examination, 27/120 (22.5%) patients had suspicious signs.

Table 3. Clinical Examination

| Rectal Examinations            | No. (%)    |
|--------------------------------|------------|
| Suspected prostate cancer      | 5 (8.33)   |
| Do not suspect prostate cancer | 55 (91.67) |
| Total                          | 60 (100)   |

##### 4.4. Total Prostate-Specific Antigen Concentration in Blood

Prostate-specific antigen level in blood is an invaluable marker for the early diagnosis of PCa. When total PSA is generally  $< 4$  ng/mL, the risk of PCa is 11%. At a PSA level between 4 and 10 ng/mL, the risk of PCa has been reported as 79% (2). In our research, a prostate biopsy was performed for patients with a total PSA concentration  $> 10$  ng/mL or if there were suspicious signs on rectal examination or imaging studies in patients with very high levels of total PSA, with an average level of 26.11 ng/mL (10.1-232.4 ng/mL).

##### 4.5. MRI/MSCT/Transabdominal Ultrasound Findings

Help detected that 5% (3/60) of the patients had suspected prostate cancer signs such as muffler drive, capsule breakage, invasion of seminal vesicles, and ureter-caused hydronephrosis. The mean prostatic mass detected in ultrasound was 44.83 grams (the range of 28 to 126 grams).

#### 4.6. Procedural Complications

Rectal bleeding (10%) and hematuria (6.67%) were the most common complications. Most of these patients had mild bleeding; there were two cases of severe rectal bleeding and one case of developed severe hematuria, all of which were resolved spontaneously within 1 - 2 days upon medical treatment. Urinary retention was observed in 5% of the patients after catheter removal (Table 4). Efesoy et al. evaluated complications in 2049 patients undergoing prostate biopsies and reported that hematuria, rectal bleeding, and genital tract infections accounted for 66.3%, 28.4%, and 6.1% of complications (8). According to a study by Le, gross hematuria accounted for 16.4% of complications, pain for 28.8%, and there were no cases of urinary tract infections (6). Thereby, transrectal prostate biopsy seems to be a safe procedure if the patient is appropriately prepared for the procedure in advance.

**Table 4.** Biopsy Accidents

| Complications             | No. (%)    |
|---------------------------|------------|
| No complications recorded | 47 (78.33) |
| <b>Complications</b>      |            |
| Anal-rectal bleeding      | 6 (10)     |
| Hematuria                 | 4 (6.67)   |
| Urinary retention         | 3 (5)      |
| <b>Total</b>              | 60 (100)   |

#### 4.7. Prostate Biopsy Results

Out of 60 patients assessed in this research, the PCa detection rate was 40% (24 patients), and 60% of them had benign prostatic hyperplasia (Table 5). According to Vu Le et al., based on biopsies taken from 87 patients, 11.5% had PCa (9), and this rate was reported as 26% by Le (6), 27.4% by Vu as cited in Nguyen et al. (10), and 27.8% by Shim et al. (5). In another study, Vu obtained biopsies from 120 patients, and PCa was detected in 33.33% (7). Thereby, the rate of PCa detection rate was much higher in our study. The difference was statistically significant with  $P < 0.05$  (10).

**Table 5.** Prostate Biopsy Results

| Result                       | No. (%)  |
|------------------------------|----------|
| Prostate cancer              | 24 (40)  |
| Benign prostatic hyperplasia | 36 (60)  |
| <b>Total</b>                 | 60 (100) |

#### 4.8. Cancer Staging according to the Gleason's Scale

In this study, the degree of differentiation according to Gleason's scale ranged from 3 to 9, and 45.83% of the patients had Gleason's scores over 8 (Table 6). According to Epstein, a Gleason score  $> 6$  indicates the risk of advanced PCa (11), suggesting that most of our patients were detected at a late stage. Biopsies obtained based on 12 cores offer a high positive diagnostic rate, and Gleason's scale presents a prognostic value and helps choose appropriate treatments.

**Table 6.** Classification of Cancer Cells According to Gleason's Scale

| Score Gleason | No. (%) |
|---------------|---------|
| $\leq 6$      | 6 (25)  |

Thus, biopsies of 12 cores have a high positive diagnosis rate, and at the same time, the Gleason's scale also allowed the prognosis and gave the appropriate treatment direction

### 5. Discussion

Transrectal ultrasound-guided prostate biopsy by the 12-core method provided us with a cancer detection rate of 40%, and 45.83% of the biopsies examined revealed a Gleason score above 8. Bleeding episodes, including hematuria, hematospermia, and rectal bleeding, took the lead among the most common complications of TRUS-guided prostate biopsy. Bleeding events can be regarded in a wide spectrum, ranging from minor bleeding to life-threatening disseminated intravascular coagulopathy.

Among these, hematuria was the most frequent complication following TRUS-guided prostate biopsy. As a minor complication, hematuria, which is frequently encountered after biopsy, generally lasts shortly and is spontaneously resolved without any need for additional treatment. In the presence of marked rectal bleeding, leading to hemodynamic impairment, intrarectal compression is applied on rectal bleeding sites by finger, ultrasound probe, or anoscope to achieve hemostasis. Also, the placement of an intrarectal tampon can achieve hemostatic control in most cases. If these methods fail, colonoscopic and endoscopic sclerotherapy might be required. Among the 60 patients undergoing a biopsy, 13 patients suffered post-operative complications. However, these complications were mild and resolved spontaneously after medical treatment.

In conclusion, TRUS-guided prostate biopsy is a tolerable procedure and can be easily applied on an ambulatory basis. Thanks to advances in pre-operative patient preparation methods and biopsy-taking techniques, serious and complex complications are

rarely encountered, but the rate of minor complications is still high. Since antibiotic prophylaxis has decreased infectious complications, short-term antibiotic therapy should be instituted for patients without any risk factors. However, high-risk patients should receive long-term antibiotic prophylaxis. Transrectal ultrasound-guided prostate biopsy based on the 12-core method appears to be a safe and effective method for the timely diagnosis of PCa.

#### Footnotes

**Authors' Contribution:** Hieu Trung Nguyen participated in designing the study, performing all statistical analyses, and helping in the drafting of the manuscript, and he is also the main author of the article. Kien Trung Nguyen played the main role in conducting the study, re-evaluating the clinical data, revising the manuscript, and performing parts of the statistical analysis. Cuong Quoc Tran and Duong Van Huynh collected the clinical data, interpreted them, and revised the manuscript. Binh Thanh Le re-analyzed the clinical and statistical data and revised the manuscript. All authors read and approved the final manuscript. Tu Minh Hoang and Yen Tieu Luong are the corresponding authors of this article.

**Conflict of Interests:** The authors declare no conflict of interest for this article, and none of the authors are members of the editorial board.

**Data Reproducibility:** The data presented in this study are uploaded during submission as a supplementary file and are openly available for readers upon request.

**Ethical Approval:** Our research was approved by the Science Council and Medical Ethics Council of Can Tho University of Medicine and Pharmacy. The ethical approval code is 511/PCT-HDDD based on decision No. 421/QD-DHYD on May 4th, 2020.

**Funding/Support:** There is no funding related to our article.

#### References

1. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Int J Cancer*. 2015;**136**(5):E359–86. [PubMed ID: 25220842]. <https://doi.org/10.1002/ijc.29210>.
2. Presti JC. Biopsy Strategies—How Many and Where? *Prostate Biopsy*. Springer; 2008. p. 165–78.
3. Mottet N, Bellmunt J, Bolla M, Briers E, Cumberbatch MG, De Santis M, et al. EAU-ESTRO-SIOG guidelines on prostate cancer. Part 1: screening, diagnosis, and local treatment with curative intent. *European urology*. 2017;**71**(4):618–29. <https://doi.org/10.1016/j.eururo.2016.08.003>.
4. Philip J, Ragavan N, Desouza J, Foster CS, Javle P. Effect of peripheral biopsies in maximising early prostate cancer detection in 8-, 10- or 12-core biopsy regimens. *BJU Int*. 2004;**93**(9):1218–20. [PubMed ID: 15180609]. <https://doi.org/10.1111/j.1464-410X.2004.04857.x>.
5. Shim HB, Park HK, Lee SE, Ku JH. Optimal site and number of biopsy cores according to prostate volume prostate cancer detection in Korea. *Urology*. 2007;**69**(5):902–6. [PubMed ID: 17482931]. <https://doi.org/10.1016/j.urology.2007.01.043>.
6. Le QT. *Evaluation of the results of the transrectal prostate biopsy of 12 cores in the diagnosis of prostate cancer*. Ho Chi Minh, Vietnam: University of Medicine and Pharmacy; 2012.
7. Vu TK. *Research on application of 12 cores of prostate biopsy method under the guidance of rectal ultrasound in prostate cancer diagnosis [Thesis]*. Ho Chi Minh University of Medicine and Pharmacy; 2020.
8. Efesoy O, Bozlu M, Cayan S, Akbay E. Complications of transrectal ultrasound-guided 12-core prostate biopsy: a single center experience with 2049 patients. *Turk J Urol*. 2013;**39**(1):6–11. [PubMed ID: 26328070]. [PubMed Central ID: PMC4548577]. <https://doi.org/10.5152/tud.2013.002>.
9. Vu Le C, Vu Van T, Nguyen Tien D, Nguyen Van A, Nguyen Viet C, Do Vu P, et al. Preoperative assessment and postoperative evaluation of prostate cancer after radical prostatectomy. *Indian J Urol*. 2008;**24**(Suppl 2):S129.
10. Nguyen TH, Tran VN, Tran HT, Le QT, Quach VTP, Le TB, et al. Clinical and para-clinical characteristics and results of prostate biopsy of 12 samples under the guidance of transrectal ultrasound at can tho university of medicine and pharmacy hospital. *Can Tho Journal of Medicine and Pharmacy*. 2022;**55**:73–80. <https://doi.org/10.58490/ctump.2022i55.383>.
11. Epstein JI. An update of the Gleason grading system. *J Urol*. 2010;**183**(2):433–40. [PubMed ID: 20006878]. <https://doi.org/10.1016/j.juro.2009.10.046>.