Saturation and standard biopsy of the prostate: comparative analysis of efficiency and safety at various prostate-specific antigen levels (Clinical research)

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ABSTRACT

Relevance: Prostate cancer (PCa) remains a leading cause of morbidity and mortality among men. Traditional diagnostic methods face limitations in detecting clinically significant cancer. Saturation biopsy, which involves collecting tissue from more points, has improved diagnostic accuracy, especially in patients with elevated prostate-specific antigen (PSA) levels. This study compares saturation and standard biopsies regarding PSA levels, cancer detection rates, and complication frequency.

Prostate biopsy is the primary diagnostic method for PCa. Saturation biopsy, involving more than 21 cores, is recommended for patients with previously negative biopsy results but persistent suspicion of PCa. We analyzed our experience to evaluate the applicability of saturation biopsy as a primary diagnostic method for patients suspected of having PCa.

The study aimed to assess the efficiency of saturation biopsy compared to the traditional biopsy technique in patients at various prostate-specific antigen levels.

Materials and Methods: This study included 1807 patients divided into two groups. Group 1 (n=93) underwent saturation biopsy with tissue sampling from 21-28 cores for PSA levels between 4 and 10 ng/mL. Group 2 (n=1714) underwent a standard biopsy with 12 cores for PSA levels between 3.9 and 19.7 ng/mL. Outcomes were evaluated using the Clavien-Dindo classification.

Results: PCa detection rates were 50.5% in Group 1 and 46.4% in Group 2. Among patients with PSA levels below 10 ng/mL, saturation biopsy demonstrated superior detection rates (50.5% vs. 42.4%). The complication rates in both groups approximated 5%, with no significant differences observed.

Conclusion: Saturation biopsy is an effective diagnostic method for patients with PSA levels between 4 and 10 ng/mL. It improves cancer detection without increasing the risk of complications. This method is recommended as a primary diagnostic tool for selected patient categories.

Keywords: *Prostate cancer (PCa), saturation biopsy, PSA levels, diagnosis, complications.*

Сатурационная и стандартная биопсия предстательной железы: сравнительный анализ эффективности и безопасности при различных уровнях простат-специфического антигена (клиническое исследование)

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АННОТАЦИЯ

Актуальность: Рак предстательной железы (РПЖ) остается ведущей причиной заболеваемости и смертности среди мужчин. Традиционные методы диагностики сталкиваются с ограничениями в выявлении клинически значимого рака. Внедрение сатурационной биопсии, предполагающей забор тканей из большего числа точек, улучшило диагностическую точность, особенно у пациентов с повышенными уровнями простат-специфического антигена (ПСА). Проводится сравнительный анализ сатурационной и стандартной биопсий в зависимости от уровня ПСА, выявляемости рака и частоты осложнений.

Биопсия предстательной железы является основным методом диагностики РПЖ. Сатурационная биопсия предстательной железы более чем из 21 точки рекомендуется пациентам, у которых ранее были отрицательные результаты биопсии, но сохраняется подозрение на РПЖ. Мы проанализировали наш опыт для оценки применимости сатурационной биопсии предстательной железы в качестве первичной диагностики пациентов с подозрением на РПЖ.

Цель исследования – оценить эффективность сатурационной биопсии предстательной железы в сравнении с традиционной формой биопсии у пациентов с различными уровнями простат-специфического антигена.

Материалы и методы: Исследование включало 1807 пациентов, разделенных на две группы. В первой группе (n=93) проводилась сатурационная биопсия с забором ткани из 21–28 точки при снижении ПСА от 4 до 10 нг/мл. Во второй группе (n=1714) выполнялась стандартная биопсия из 12 точек при повышении ПСА от 3,9 до 19,7 нг/мл. Для измерения результатов использовалась шкала Clavien-Dindo.

Результаты: Выявляемость РПЖ 50,5% в первой группе и 46,4% во второй группе. Среди пациентов с уровнями ПСА до 10 нг/мл сатурационная биопсия показала преимущество (50,5% против 42,4%). В этих группах часто наблюдается рост около 5% без существенных доказательств.

Заключение: Сатурационная биопсия предстательной железы является эффективным методом диагностики у пациентов с уровнями ПСА от 4 до 10 нг/мл, что позволяет повысить выявляемость инновационного метода без увеличения риска развития. Этот метод рекомендуется для использования при первичной диагностике у пациентов определенных категорий.

Ключевые слова: *рак предстательной железы (РПЖ), сатурационная биопсия, уровень простат-специфического антигена (ПСА), диагностика, осложнения.*

Қанықтылық және стандартты оң жақ бетінің биопсиясы: әртүрлі простата-спецификалық антиген деңгейлеріндегі тиімділік пен қауіпсіздіктің салыстырмалы талдауы: клиникалық сынақ

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АҢДАТПА

Өзектілігі: Қуық асты безінің қатерлі ісігі ерлер арасындағы аурушаңдық пен өлімнің негізгі себебі болып қала береді. Дәстүрлі диагностикалық әдістер клиникалық маңызды ісіктерді анықтауда шектеулерге тап болады. Көптеген жерлерден тіндерді алуды қамтитын қанықтыру биопсиясы, әсіресе простата-спецификалық антиген (PSA) деңгейі жоғары емделушілерде диагностикалық дәлдікті жақсартты. Бұл зерттеу PSA деңгейлері, қатерлі ісіктерді анықтау жылдамдығы және асқыну жиілігі тұрғысынан қанықтыру мен стандартты биопсиялардың салыстырмалы талдауын қамтамасыз етеді. Қуық асты безінің биопсиясы - простата обырын диагностикалаудың негізгі әдісі. Бұрын теріс биопсия нәтижелері бар, бірақ қуық асты безінің қатерлі ісігіне тұрақты күдігі бар емделушілерге 21-ден астам өзекті қамтитын қанықтыру биопсиясы ұсынылады. Қуық асты безінің қатерлі ісігіне күдікті науқастар үшін қанықтыру биопсиясының негізгі диагностикалық әдісі ретінде қолдану мүмкіндігін бағалау үшін тәжірибемізді талдадық.

Зерттеу мақсаты: әртүрлі простата-спецификалық антиген деңгейлері бар науқастарда дәстүрлі биопсия әдісімен салыстырғанда қанықтыру биопсиясының тиімділігін бағалау болып табылады.

Материалдар мен әдістер: Бұл зерттеу екі топқа бөлінген 1807 пациентті қамтиды. 1-топқа (n=93) 4 және 10 нг/мл арасындағы PSA деңгейлері үшін 21-28 өзектен тін үлгісін алу арқылы қанықтыру биопсиясы жасалды. 2-топ (n=1714) 3,9 және 19,7 нг/мл арасындағы PSA деңгейлері үшін 12 өзегі бар стандартты биопсиядан өтті. Нәтижелер Клавиен-Диндо классификациясы арқылы бағаланды.

Нәтижелер: Қуық асты безінің обырын анықтау көрсеткіші 1-топта 50,5% және 2-топта 46,4% құрады. PSA деңгейі 10 нг/мл-ден төмен емделушілер арасында қанықтыру биопсиясы анықтаудың жоғары көрсеткіштерін көрсетті (50,5% қарсы 42,4%). Екі топта да асқыну деңгейі шамамен 5% құрады, айтарлықтай айырмашылықтар байқалмады.

Қорытынды: Қанықтыру биопсиясы PSA деңгейі 4 және 10 нг/мл аралығындағы науқастар үшін тиімді диагностикалық әдіс болып табылады, асқыну қаупін арттырмай, қатерлі ісіктерді анықтауды жақсартады. Бұл әдіс пациенттердің таңдалған санаттары үшін негізгі диагностикалық құрал ретінде ұсынылады.

Түйінді сөздер: *Простата обыры, қанықтыру биопсиясы, простата-спецификалық антиген (PSA) деңгейі, диагностикасы, асқынулары..*

Introduction: Prostate cancer (PCa) is a leading cancer and one of the main causes of death in men. According to the World Health Organization (WHO), more than 1.4 million new cases of PCa were registered in 2020, making it the second most common malignant disease in men after lung cancer. The importance of timely and accurate diagnosis of PCa is emphasized by its high prevalence and significant impact on patients' quality of life [1].

The main method for diagnosing PCa is prostate biopsy, which is performed under the control of the prostate-specific antigen (PSA) level. However, the standard 12-core biopsy does not always provide sufficient accuracy, especially in patients with moderately elevated PSA levels and negative results from previous biopsies. Insufficient accuracy of the standard method can lead to missing clinically significant cancer, which delays timely treatment [2].

In recent years, the saturation biopsy method has been actively studied, in which tissue is collected from a larger number of points (more than 20), including peripheral and transitional zones of the prostate gland. It is assumed that an increase in the number of biopsy points allows for an increase in cancer detection, especially in patients with a PSA level of 4 to 10 ng/mL, for whom standard biopsy is less effective [3, 4].

Despite the growing interest in saturation biopsy, questions remain about its comparative diagnostic value and safety

in clinical practice. The present study aims to compare saturation and standard prostate biopsies by such criteria as the detection rate of clinically significant cancer, the incidence of complications assessed by the Clavien-Dindo scale, and the effect of PSA levels on the diagnostic efficiency of the methods.

This study provides new data that may help optimize approaches to PCa diagnosis, improving patient treatment outcomes and prognosis.

The study aimed to assess the efficiency of saturation biopsy compared to the traditional biopsy technique in patients at various prostate-specific antigen levels.

Materials and Methods: The study was conducted at "Belon Medical" center (Astana, Kazakhstan) from March 2013 to December 2015. The aim was to compare the diagnostic value and safety of saturation and standard prostate biopsies. The work was organized as a retrospective study, including patients with clinical suspicion of PCa.

The study included 1807 men aged 42 to 76 years with PSA levels of 4 to 20 ng/mL. All patients had abnormalities in digital rectal examination or transrectal ultrasound, indicating a high risk of malignancy. Individuals with previous radical prostatectomy, chemotherapy or radiotherapy, and severe comorbidities that could affect the interpretation of the results were excluded.

The patients were divided into two groups. Group 1 included 93 patients who underwent saturation prostate biopsy, which involved taking tissue from 21-28 points under periprostatic infiltration anesthesia. Group 2 of 1,714 patients underwent a standard 12-point biopsy under topical anesthesia [5]. All procedures were performed under transrectal ultrasound control using an automatic biopsy gun and 18G needles.

The average age of patients in Group 1 was 59 years, while in Group 2, it was 68 years. The incidence of complications was assessed within 30 days after the procedure, and their severity was classified according to the Clavien-Dindo scale. Mild complications, such as urinary tract infections and bleeding, were classified as levels I and II, while severe complications, including sepsis and thrombosis, were classified as levels III and IV. [6].

SPSS version 22.0 software was used for statistical analysis. Frequency data were compared using the χ^2 test, and the t-test was used to analyze mean values. The level of statistical significance was set at $p < 0.05$ [7].

The study was conducted in compliance with ethical standards and with the consent of all participants.

Results: The study detected PCa in 50.5% of patients in the saturation biopsy group, which was more effective than 46.4% in the standard biopsy group. Among patients with a PSA level of up to 10 ng/mL, the cancer detection rate was significantly higher in the saturation biopsy group.

Table 1 – Prostate cancer detection rates by study groups

Group	PSA level (ng/mL)	Cancer detection (%)	Average age (years)	Complication rate (%)
Saturation biopsy	7.8	50.5	59	5.0
Standard biopsy	12.6	46.4	68	5.2

Table 2 – Cancer detection rates by PSA level

PSA level (ng/mL)	Saturation biopsy (%)	Standard biopsy (%)
Up to 10	50.5	42.4
10-20	49.7	46.4
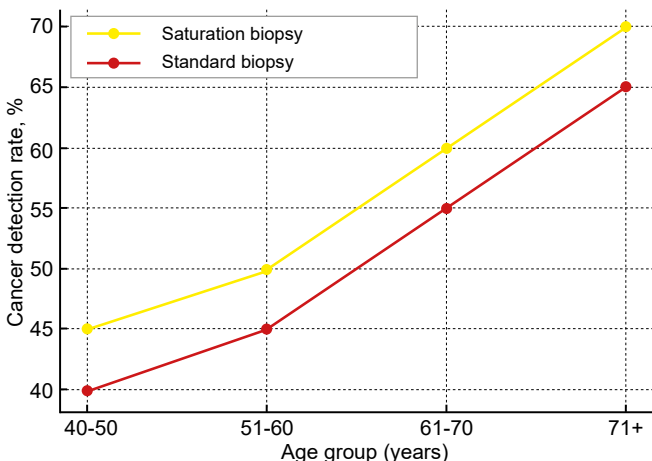
Percentage of prostate cancer detection by age group (saturation vs standard biopsy)
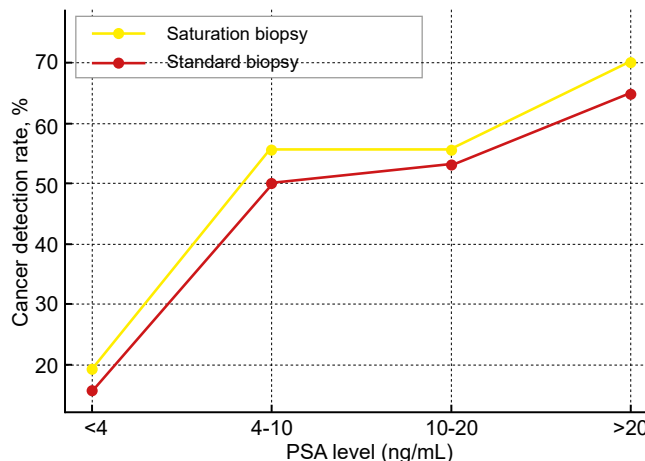

Figure 2 – Prostate cancer detection graph for saturation and standard biopsy by prostate-specific antigen (PSA) level (saturation vs standard biopsy)

Figure 1 shows the PCa detection rate depending on patients' age group for saturation and standard biopsies. The graph shows that the PCa detection rate increased with age, and saturation biopsy revealed higher rates in all age categories.

Figure 2 shows the percentage of cancer detection depending on the PSA level for saturation and standard biopsy, clearly demonstrating the differences in PCa detection rates between two biopsy methods at different PSA levels.
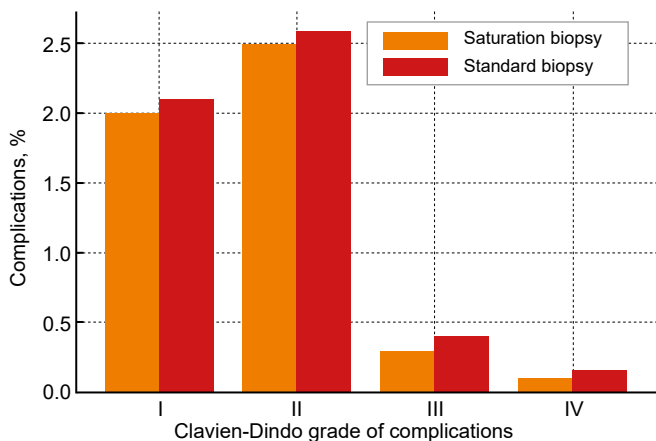
Figure 3 – Clavien-Dindo complications in prostate cancer
(saturation vs standard biopsy)

Figure 3 shows the distribution of complications according to the Clavien-Dindo scale for both groups for saturation and standard prostate gland biopsies.
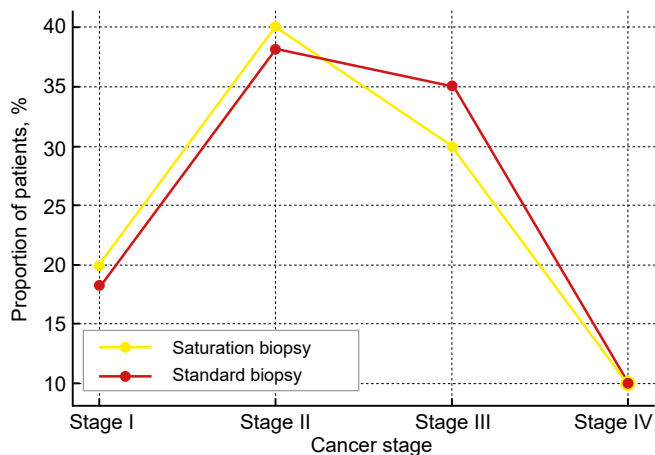

Figure 4 – Distribution of prostate cancer cases
by cancer stage

Figure 4 shows the distribution of patients by cancer stage detected by saturation and standard biopsies.
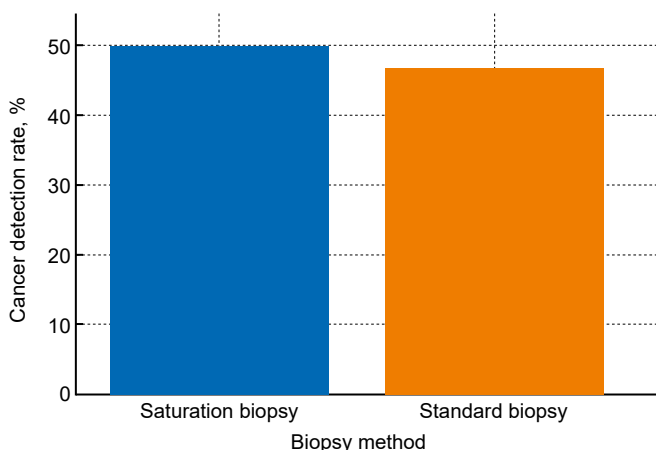

Figure 5 – Prostate cancer detection rate by biopsy method

Figure 5 shows a graph comparing the percentage of PCa detection using two biopsy methods: saturation (deep blue column) and standard (orange column) (visualization of a comparative analysis of the effectiveness of saturation and standard biopsy in diagnosing PCa, based on data on tumor detection, PSA level, average age of patients and complication rate).

The data indicate that saturation biopsy demonstrates a slightly higher percentage of detection of malignant neoplasms compared with the standard technique. This supports the hypothesis of greater diagnostic sensitivity and accuracy of the extended biopsy method, especially in patients with elevated PSA levels and negative results of primary standard studies.

Detection of prostate cancer
In Group 1, RPC was detected in 47 patients (50.5%), and in Group 2 – in 796 patients (46.4%).

Among patients with PSA levels up to 10 ng/mL, the cancer detection rate was significantly higher in the saturation biopsy group.

In patients with PSA levels up to 10 ng/mL in Group 2, cancer was detected in 42.4% of patients, and in patients with PSA levels from 10 to 20 ng/mL – 49.7%.

Comparison with complications
There were no significant differences in complication rates between the two groups. Complications after biopsy included bleeding, infection, and urinary retention.

Additional observations
Patient age was an important factor in assessing the risk of developing PCa. In Group 1, the average age was 59 years, while in Group 2, it was 68 years, which indicates the need for saturation biopsy in younger patients with suspected PCa.

Discussion: The study results demonstrated that saturation prostate biopsy is a more accurate diagnostic method in patients with PSA levels from 4 to 10 ng/mL. The detection rate of clinically significant cancer was 50.5%, which exceeds the indicators of standard 12-core biopsy, where the cancer detection rate reached 42.4% with similar PSA levels [8]. This emphasizes the advantage of the method in groups of patients with moderately elevated PSA levels, where standard biopsy is often not informative enough.

Analysis of complications showed that saturation biopsy does not increase the risk of side effects. The incidence of complications such as urinary tract infections, mild bleeding, and urinary retention was comparable between the two groups, confirming the method's safety. According to the Clavien-Dindo scale, most complications were classified as levels I and II, not requiring major interventions, which makes saturation biopsy a safe method for implementation in clinical practice [9].

An interesting observation was lower differences in diagnostic efficiency between saturation and standard biopsy in patients with PSA levels above 10 ng/mL. This indicates that at high PSA levels, the risk of cancer remains significant, regardless of the biopsy method used. Such patients require increased attention and additional diagnostic approaches to assess the extent of the tumor process.

Thus, the study results confirm that saturation biopsy can be recommended as a primary diagnostic procedure for patients with 4 to 10 ng/mL PSA levels. The introduction of this method into routine practice allows for the timely diagnosis of clinically significant cancer, which is especially important for making decisions on early initiation of radical treatment. However, saturation biopsy should be considered cautiously in patients with PSA levels above 10 ng/mL since its advantages in this group are less pronounced [10].

The findings highlight the need for an individual approach when choosing a prostate biopsy method. Saturation biopsy may be an important addition to existing diagnostic standards, providing higher accuracy in detecting cancer in patients with moderately elevated PSA levels while remaining a safe diagnostic method.

Conclusion: The study demonstrated a significant advantage of saturation prostate biopsy in diagnosing clinically significant cancer in patients with moderately elevated PSA levels. The cancer detection rate in this group

reached 50.5%, significantly higher than the standard biopsy rates. These results emphasize the importance of introducing saturation biopsy into routine clinical practice, especially for patients with PSA levels from 4 to 10 ng/mL, for whom standard diagnostic methods have limited informativeness.

A key feature of saturation biopsy is its safety. The frequency of complications, such as infections and bleeding, remained at the standard biopsy level, confirming the method's applicability in everyday clinical practice. This opens up prospects for its widespread use, especially in centers engaged in early diagnosis of oncological diseases [11].

However, the study found minimal differences in diagnostic performance between saturation and standard biopsy in patients with PSA levels above 10 ng/mL. Standard diagnostic methods can be used in such cases without significantly reducing detection quality. This highlights the need for further research to optimize diagnostic strategies in patients with high PSA levels, including molecular and genetic markers and additional imaging techniques.

The obtained results contribute to the development of modern approaches to diagnosing PCa and form the basis for further research in personalized medicine. The use of saturation biopsy improves the detection of clinically significant tumors, reducing the risk of missing aggressive forms of cancer. This is especially important for the timely initiation of radical treatment, which can ultimately lead to improved prognosis and improved quality of life for patients.

This study opens up prospects for further study of the role of saturation biopsy in a comprehensive approach to PCa diagnostics, including its combination with the latest imaging techniques and biomarkers. These data highlight the importance of continuously improving diagnostic strategies in urology to increase the accuracy and efficiency of cancer detection.

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