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**ARTICLE**

# Early clinical experience and learning curve of transperineal prostate biopsy with a novel angle-adjustable needle guide

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***Background:*** *The European Association of Urology (EAU) recommends transperineal biopsy (TPBx) due to its lower infection risk and higher diagnostic rate for anterior zone tumors. This study aims to assess the learning curve of TPBx using the Perino-Flex® angle-adjustable needle guide under local anesthesia.*
***Methods:*** *A retrospective observational analysis was conducted from November 2023 to March 2024, involving 100 patients who underwent TPBx with coaxial technique under local anesthesia. Data collected included patient demographics, procedure and room times, pain levels, anxiety scores, and complications. The study focused on comparing procedure times, pain scores, and complication rates to evaluate the learning curve over time.*

***Results:*** *The mean room time significantly decreased from 29.55 min in the first group to 19.95 min in the fifth ($p < 0.001$). Procedure time was reduced from 15.25 min in the first group to 7.50 min in the fifth ($p < 0.001$). Visual Analog Scale (VAS) scores during core sampling demonstrated a significant decrease after the first 20 patients (2.70 vs. 0.90 in the first and second quartile, respectively, $p < 0.001$), indicating a rapid gain in operator proficiency. When splitting the first 20 patients into two subgroups, pain scores significantly dropped after the initial 10 cases. Cancer detection rates remained stable across all groups. Notably, no infectious complications were observed throughout the study.*
***Conclusion:*** *This study highlights the learning curve for TPBx with an adjustable needle guide under local anesthesia. It shows that as experience grows, pain decreases and procedure times shorten, improving both patient comfort and efficiency. These findings offer valuable guidance for new practitioners to learn more quickly and achieve better diagnostic results.*

**Key Words:** learning curve, biopsy, angle-adjustable, prostate cancer, transperineal prostate biopsy

## Introduction

Prostate cancer (PCa) is the world's second most frequent cancer and the fifth leading cause of cancer death among men.[1] While prostate-specific antigen (PSA), digital rectal examination, PSA density (PSAD), and multiparametric prostate magnetic resonance imaging (mpMRI) are important for detecting prostate cancer, prostate biopsy remains the gold standard for diagnosis.[2]

The latest European Association of Urology (EAU) guideline recommends that prostate biopsy should preferably be done through the transperineal route due to lower risk of infectious complications and higher diagnostic rates of anterior zone tumors.[3] Traditional transperineal prostate biopsies (TPBx) are performed with a brachytherapy grid that requires multiple skin punctures, which cause pain and render

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them challenging to perform under local anesthesia.[4,5] Introduction of the coaxial needle biopsy technique makes TPBx easier to perform under local anesthesia.[6] The most challenging part of this technique is keeping the coaxial needle in the same plane as the ultrasound throughout the procedure. To overcome this difficulty, various needle guides have been developed.[7,8] Recently, a new generation of TPBx needle guides has been introduced into the market that enable angle and height adjustment following the insertion of the coaxial needle into the perineum (Perino-Flex®, Geotek Medical, Turkey, and TP Pivot Pro™ Civco Medical Solutions, USA).

As a popular and guideline-recommended technique, TPBx became the standard of care in our institution. Nevertheless, the learning curve of this procedure has not been reported yet. In this study, we aimed to evaluate the learning curve of TPBx with the first angle-adjustable needle guide system, Perino-Flex®. The primary endpoint of this study is to investigate whether the impact of this technique on cancer detection varies with increasing operator experience. The secondary endpoint is to assess the change in procedure duration in relation to procedural experience.

By discussing the learning curve and providing the convenience of this novel technique, we can guide beginners to understand the steps and key points of the TPBx procedure performed with an angle-adjustable needle guide and help them progress from the initial learning stage to proficiency. As soon as we know, this is the first study on the technical features and the learning curve analysis of this novel TP biopsy guide system.

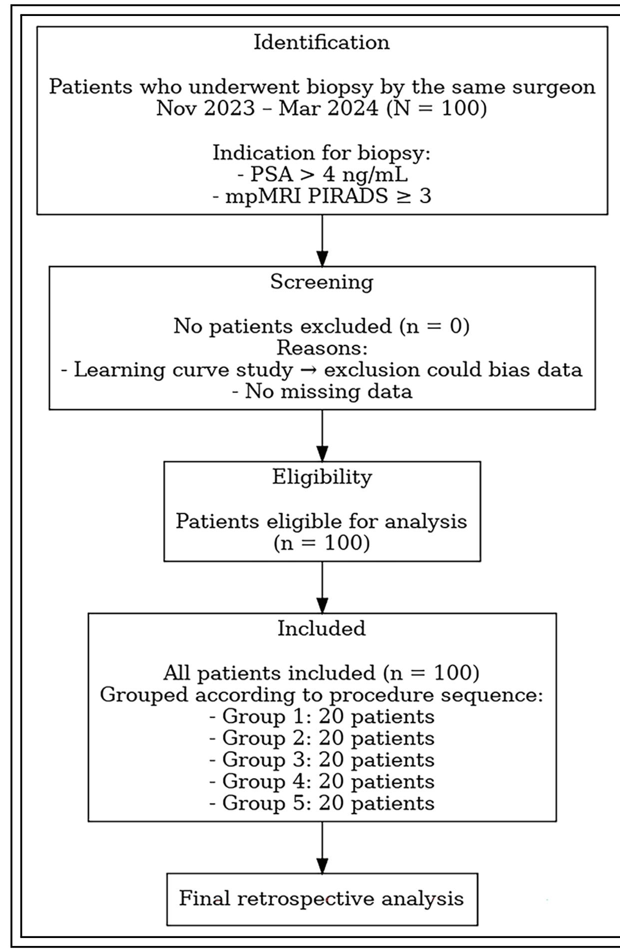


**FIGURE 1.** Flow diagram of this study

## Material and Method

### *Study population and design*

After the acquisition of consent from our Institutional Review Board and Ethics Committee (Dr. Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital Ethical Board, approval number: 2024-11/176), we conducted a retrospective analysis of the data of patients who underwent TPBx with coaxial technique under local anesthesia between November 2023 and March 2024 (Figure 1). Written informed consent was obtained. Data on age, PSA value, prostate volume, Visual Analog Scale (VAS) scores during biopsy, State-Trait Anxiety Inventory (STAI) scores, Beck Anxiety Inventory (BAI) scores, biopsy procedure times, histopathology results, and post-biopsy complications were recorded. The primary endpoint of this study is to investigate whether the impact of this technique on cancer detection varies with increasing operator experience. The secondary endpoint is to assess the change in procedure duration in relation to procedural experience. Biopsy decisions were taken based on the PSA levels (>4 ng/mL), the PSA density, and indications of abnormal digital rectal examination (DRE). Patients with acute urinary tract infections or coagulation problems were excluded. Patients with lesions where additional tissue sampling is considered based on mpMRI (≥PIRADS 3) were also excluded from the study for MR fusion biopsy by an experienced physician.

All biopsies were performed by a single, experienced urologist who first observed 5 transperineal biopsies and then conducted 5 biopsies under supervision. These 10 patients were excluded from the study.

### *Biopsy procedure*

After counseling and obtaining written informed consent, we performed urinalysis, urine culture, and coagulation profile. Without antibiotic prophylaxis and rectal cleansing, patients were positioned in the lithotomy posture. To improve perineal visibility, the scrotum was lifted with adhesive tape, and the perineal skin was sterilized with iodine solution. Subsequently, a biplanar transrectal ultrasonography (TRUS) probe (4CR biplane doppler ultrasound, Sonostar Technologies Co., Shenzhen, China), with linear and convex imaging planes, was used for imaging. The TPBx needle guide Perino-Flex® is attached to the ultrasound probe before inserting the probe into the rectum.

The coaxial needle entry point was selected at the perineal level, approximately 15–20 mm above the anus and 10–15 mm off the midline on both sides, based on the prostate's size and height.[9] The skin was injected with 2 mL of 1% Lidocaine using a 22 G needle. A 15 G, 10 cm long coaxial introducer needle has been inserted through the Perino-Flex® (Figure 2), and the tip of the needle has been placed a few millimeters away from the perineum skin. It is important to mention that the 15 G coaxial introducer needle was not yet placed into the perineum. It was used to stabilize and block the bending of 22 G Chiba needle during the administration of the anesthetic injection. Afterwards, a 22 G, 25 cm long Chiba-type needle was inserted through the introducer needle into the perineum, and the path from the perineal skin to the prostatic apex was injected with 5 mL of 1% Lidocaine. Furthermore, a 5 mL 1% Lidocaine was administered around the neurovascular bundles. Similar procedures were performed on the opposite side. After this, the 15 G coaxial introducer needle is placed into the perineum. The tip of the introducer needle is inserted two centimeters deep from the perineal skin, where it ultimately serves as a re-entry route. Tissue samples were taken with an 18 G, 20 cm automated biopsy gun (EstaCore Pro, Geotek Medical, Ankara, Turkey) under biplanar ultrasonography guidance. Twelve systematic cores were extracted from the prostate. The biopsy method involved a fan-shaped approach, sampling from both sides of the posterior medial, posterior lateral, and anterior sectors of the peripheral zone.

### *Statistical analysis*

Statistical analyses were performed with SPSS version 29 (IBM Corp., Armonk, NY, USA). Descriptive statistics, including mean, median, frequency, and standard deviation, were assessed after testing for normal distribution with the Kolmogorov-Smirnov test. The Mann-Whitney U test compared continuous variables between two groups, while one-way ANOVA or Kruskal-Wallis tests were used for more than two groups. Fisher's Exact or Chi-Square tests evaluated categorical variables, with significance set at $p < 0.05$.

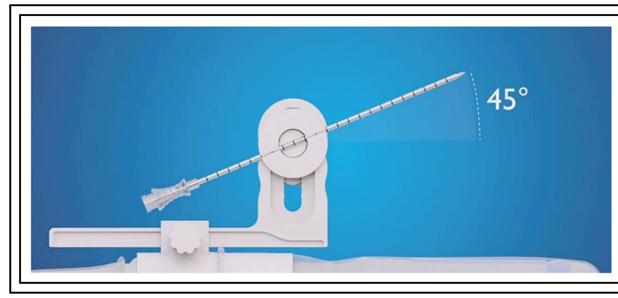


**FIGURE 2.** Perino-flex®, geotek medical, turkey, and TP pivot pro™ civco medical solutions, USA

## Result

### *Patient demographics*

A total of 100 patients were included in the study, divided into five groups based on the order of the procedure learning curve. The mean age, PSA level, and prostate volume of the patients were consistent across the groups, with no significant difference observed ($p = 0.873$, $p = 0.758$, and $p = 0.980$, respectively). The pathological outcomes remained comparable across all groups. The proportion of patients diagnosed with any form of cancer ranged from 45% to 55% across the groups, indicating consistency in detection rates throughout the learning curve. The rate of post-biopsy complications, including hematuria, hematospermia, urinary retention, and infections, did not differ significantly among the groups ($p = 0.992$). Notably, there were no infectious complications observed across the study group.

### *Pain and anxiety scores*

Pain scores assessed by VAS during various stages of the procedure showed a noticeable improvement with experience. The VAS scores during biopsy gun firing significantly decreased from $2.70 \pm 1.95$ in the first group to $0.70 \pm 0.73$ in the fifth group ($p < 0.001$). VAS during probe insertion and local anesthesia injection were also decreased, but they showed no statistically significant difference. Additionally, the VAS scores for the entire procedure showed a trend towards lower pain in later groups, though not statistically significant ($p = 0.337$). Furthermore, when

TABLE 1. **Comparison of pain scores and procedure durations between the first and second groups of ten patients**

| | First ten | Second ten | $p$-value† |
|---|---|---|---|
| **Visual analog scale (VAS) score**, mean ± SD (min-max) | | | |
| During probe insertion | 3.30 ± 2.62 (1–10) | 3.20 ± 0.91 (2–5) | 0.353 |
| During local anesthesia injection, | 3.80 ± 2.34 (1–7) | 2.40 ± 1.57 (1–6) | 0.190 |
| During biopsy gun firing | 3.90 ± 1.91 (2–6) | 1.50 ± 1.57 (1–6) | **0.007** |
| Entire procedure | 3.70 ± 1.33 (2–6) | 2.20 ± 0.78 (1–3) | **0.015** |
| **Room time (minutes)**, mean ± SD (min-max) | 33.20 ± 5.26 (28–45) | 25.90 ± 3.54 (21–32) | **0.002** |
| **Procedure time (minutes)**, mean ± SD (min-max) | 17.90 ± 3.24 (14–24) | 12.60 ± 4.16 (8–20) | **0.015** |

**Note.** †Mann-Whitney U Test. Bold $p$-values indicate the statistical significance, which means they are less than 0.05.

we divided the first group into two 10-patient groups, we found that the first 10 patients showed higher VAS scores during biopsy gun firing compared to the second 10 patients (3.10 ± 2.10 vs. 2.30 ± 1.80), indicating that operator proficiency improved rapidly within the first 20 cases (Table 1 Comparison of pain scores and procedure durations between the first and second groups of ten patients). Anxiety scores, measured by STAI-Trait and STAI-State, as well as BECK anxiety scores, showed no significant variation across the groups ($p = 0.589$, $p = 0.876$, and $p = 0.563$, respectively).

### *Procedure and room times*

A significant reduction in both room time and procedure time was observed as the operator gained more experience (Figure 3). The mean room time decreased from 29.55 min in the first group to 19.95 min in the fifth group ($p < 0.001$). Similarly, the procedure time showed a significant decrease, from 15.25 min in the first group to 7.50 min in the fifth group ($p < 0.001$) (Table 2). Similar to VAS scores, the mean room and procedure times for the first 10 patients were significantly longer compared to the second 10 patients as well (32.00 ± 5.00 min vs. 27.10 ± 4.50 min, $p = 0.002$; 17.90 ± 3.24 min vs. 12.60 ± 4.16 min, $p = 0.015$, respectively).

## Discussion

Learning curve studies are important for using new techniques effectively, especially in medicine. These studies show how healthcare professionals improve their skills over time. They focus on the early challenges, how quickly skills are learned, and when performance becomes steady. This information helps create training programs, set realistic goals, and keep patients safe during the first stages of using new techniques.[10] Selecting the right variables is crucial; these include biopsy process metrics and patient outcomes.[4,11] While cancer detection rate is vital, it's influenced by patients' characteristics and the urologist's skill, which evolve over time. Focusing solely on outcomes may overlook the impact of surgical expertise.[12] To address this, we included procedure and room times in our analysis and uniquely assessed pain and anxiety scores as well.

The learning curve associated with TPBx, particularly when using a novel needle guide, is an important consideration for clinicians and researchers. This is the first study to evaluate the learning curve of TPBx under local anesthesia with an angle- and height-adjustable needle guide regarding patients' pain and anxiety scores, cancer detection rates, and procedure time. This study showed that pain scores and procedure times during TPBx under local anesthesia declined as the team gained experience.

According to the EAU guideline, TPBx is the preferred diagnostic technique for PCa.[3] Studies have shown that TPBx has a superior cancer detection rate for clinically significant PCa and a lower incidence of infectious complications than the transrectal approach.[13] Despite these advantages, the primary challenge with TPBx is the pain associated with the procedure. For this reason, it is generally performed under spinal or general anesthesia, rather than as a simple local outpatient procedure. Traditionally, TPBx procedures use a mechanical stepper unit with a brachytherapy grid or similar needle guide, which requires multiple needle passes through the perineum, making local anesthesia impractical.[14] To overcome this limitation, the freehand TPBx technique was developed, using an access cannula that allows multiple needle passes through a single entry

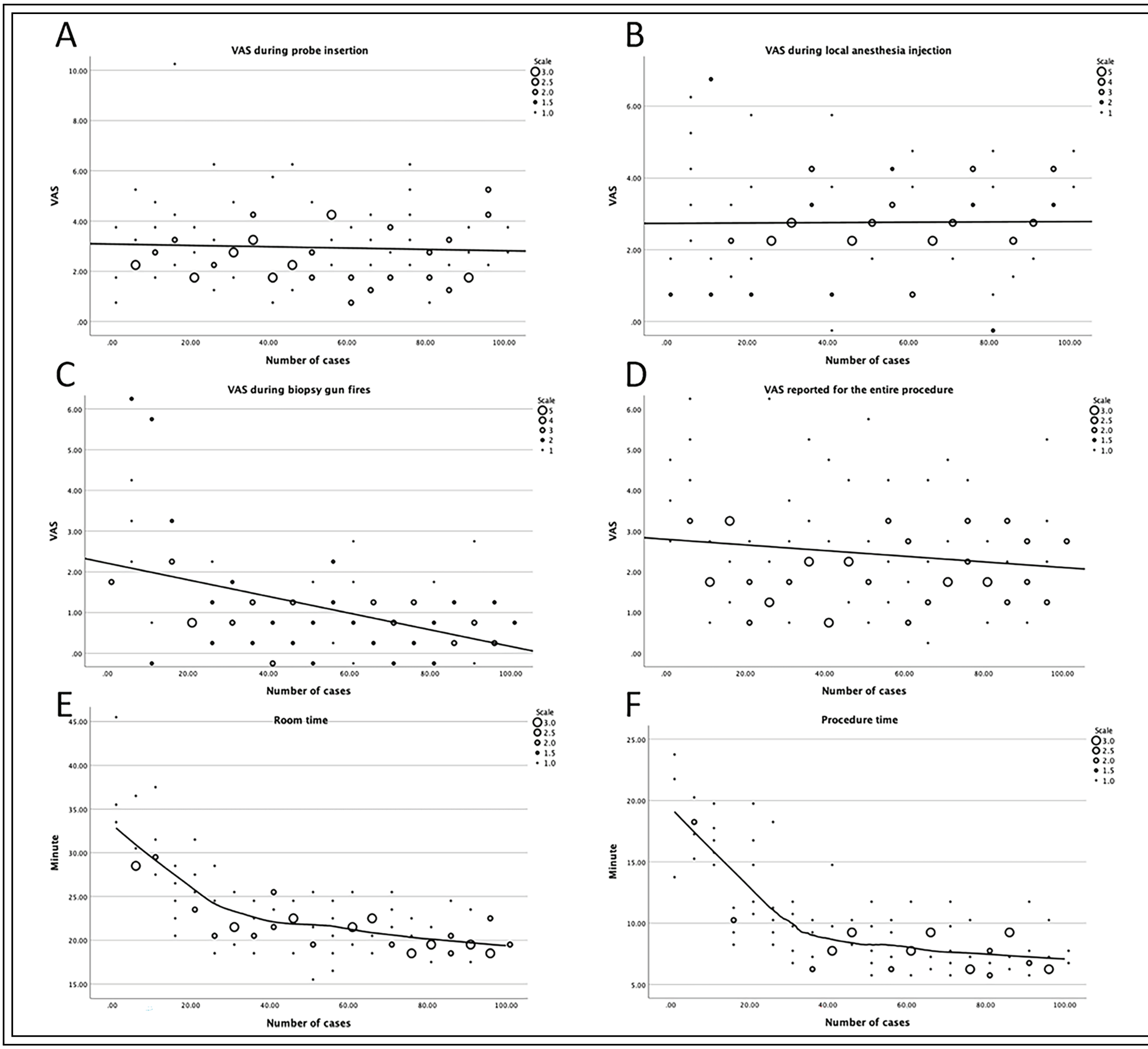


**FIGURE 3.** Visual analog scale (VAS) scores and room times change with experience. (**A**) VAS during probe insertion; (**B**) VAS during local anesthesia injection; (**C**) VAS during biopsy gun fires; (**D**) VAS reported for the entire procedure; (**E**) room time; (**F**) procedure time

point.[15] However, this technique demands technical skill to keep the biopsy needle aligned with the ultrasound transducer.[16,17] Several needle guides have been created to assist with this alignment, but as they lack height and angle adjustments, the physician must adjust both the ultrasound transducer and needle together inside the rectum to target different prostate areas. This can increase patients' pain and discomfort, and also reduce sonographic image quality due to the prostate's movement.[18] The new TP needle guide, Perino-Flex®, offers angle and height adjustment functions, allowing precise needle alignment without moving the transducer in the rectum. The perimo-flex and other similar new generation angle adjustable TPBx needle guides combine the strengths of single and double freehand TP biopsy techniques, providing a more stable probe and consistent sonographic image.

Several studies have documented the learning curve for TPBx, particularly when transitioning from the more commonly used transrectal approach. According to Ramacciotti et al.,[19] the transperineal

TABLE 2. **Demographic characteristics of patients, along with pain scores, anxiety scores, and procedure durations**

| Characteristic | First group | Second group | Third group | Fourth group | Fifth group | *p*-value |
|---|---|---|---|---|---|---|
| Age, mean ± SD | 63.95 ± 7.57 | 63.85 ± 6.84 | 66 ± 7.98 | 64.50 ± 6.65 | 63.75 ± 8.53 | 0.873[a] |
| PSA (ng/mL), median | 8.15 (8.30) | 7.15 (2.89) | 7.17 (5.57) | 5.78 (7.19) | 8.44 (7.52) | 0.758[b] |
| Prostate volume (cc), median | 55 (46.50) | 60 (26.75) | 52 (30.50) | 53 (29.25) | 59.50 (32) | 0.980[b] |
| Pathologies, n (%) | | | | | | 0.999[c] |
| Benign | 11 (55) | 10 (50) | 9 (45) | 10 (50) | 10 (50) | |
| All cancers | 9 (45) | 10 (50) | 11 (55) | 10 (50) | 10 (50) | |
| Insignificant | 3 (33.3) | 3 (30) | 3 (27.3) | 3 (30) | 3 (30) | |
| Significant | 6 (66.7) | 7 (70) | 8 (72.7) | 7 (70) | 7 (70) | |
| Complications, n (%) | | | | | | 0.992[d] |
| None | 18 (90) | 18 (90) | 18 (90) | 19 (95) | 19 (95) | |
| Hematuria | 1 (5) | 1 (5) | – | – | – | |
| Hematospermia | 1 (5) | 2 (10) | 2 (10) | 1 (5) | 1 (5) | |
| Urinary retention | 1 (5) | – | – | – | – | |
| Infections | – | – | – | – | – | |
| VAS scores, mean ± SD (min-max) | | | | | | |
| During probe insertion | 3.25 ± 1.92 (1–10) | 3.15 ± 1.34 (1–6) | 2.75 ± 1.37 (1–6) | 2.85 ± 1.35 (1–6) | 2.75 ± 1.25 (1–5) | 0.813[b] |
| During anesthechic injection | 3.10 ± 2.07 (1–7) | 2.85 ± 1.18 (1–6) | 2.60 ± 1.19 (0–5) | 2.70 ± 1.12 (1–5) | 2.55 ± 1.35 (0–5) | 0.988[b] |
| During biopsy gun firing | 2.70 ± 1.95 (0–6) | 0.90 ± 0.64 (0–2) | 0.95 ± 0.88 (0–3) | 0.65 ± 0.59 (0–2) | 0.70 ± 0.73 (0–3) | **<0.001**[b] |
| Entire procedure | 2.95 ± 1.31 (1–6) | 2.50 ± 1.50 (1–6) | 2.25 ± 1.33 (1–6) | 2.35 ± 1.18 (0–5) | 2.20 ± 1.05 (1–5) | 0.337[b] |
| Room time (minutes), mean ± SD (min-max) | 29.55 ± 5.75 (21–45) | 23.15 ± 3.54 (18–31) | 21.65 ± 2.72 (16–26) | 20.95 ± 1.93 (19–25) | 19.95 ± 1.95 (18–24) | **<0.001**[b] |
| Procedure time (minutes), mean ± SD (min-max) | 15.25 ± 4.54 (8–24) | 10.50 ± 4.02 (6–20) | 8.75 ± 2.15 (6–15) | 7.95 ± 1.92 (6–12) | 7.50 ± 1.63 (6–12) | **<0.001**[b] |
| STAI-Trait, mean ± SD | 26.15 ± 10.84 | 29.50 ± 12.35 | 26.35 ± 13.46 | 29.15 ± 11.67 | 30.15 ± 15.64 | 0.589[b] |
| STAI-State, mean ± SD | 52.35 ± 8.11 | 51.40 ± 7.48 | 51.00 ± 11.84 | 53.85 ± 8.93 | 52.50 ± 10.91 | 0.876[b] |
| BAI score, mean ± SD | 14 ±6.07 | 11.05 ± 6.01 | 12.35 ± 11.62 | 12.05 ± 6.78 | 13.60 ± 10.01 | 0.563[b] |

**Note.** [a]One-Way ANOVA Test; [b]Kruskal-Wallis Test; [c]Chi-Square Test; [d]Fisher's Exact Test. VAS, Visual Analog Scale; STAI, State-Trait Anxiety Inventory; BAI, Beck Anxiety Inventory. Bold *p*-values indicate the statistical significance, which means they are less than 0.05.

approach has been associated with a steep learning curve, primarily due to the unfamiliar anatomical orientation and the need for precise needle placement under ultrasound guidance.

In a recent study by Gereta et al.,[4] the median room time for the first quarter of patients was 48 min, while for the last quarter of patients, this rate was 47 min ($p = 0.075$). In our study, the average room time for the first group of patients was 29.55 min, with a maximum time of 45 min. By the fifth quintile, the average dropped to 19.95 min, and the maximum room time was 24 min ($p < 0.001$). Moreover, Gereta et al. reported that the median procedure time for the first quarter was 17 min, whereas the median procedure time decreased to 13 min in the last quarter ($p = 0.018$). In our study, the average procedure time for the first group was 15.25 min, with the longest procedure lasting 24 min. By the last group, the average procedure time was 7.50 min, and the longest procedure lasted 12 min ($p < 0.001$). Similar to a comparative study, we observed that procedure times decreased as the number of cases increased. The difference in procedure times between these two studies can be attributed to two main reasons. First, the biopsy techniques used differ: Gereta's study employed cognitive TPBx, while our study utilized standard TPBx. Second, the shorter procedure times observed in our study group may be due to the angle and height adjustment functions of the novel needle guide.

Additionally, Gereta et al.[4] declared that detection rates for overall Pca and clinically significant Pca remained stable throughout the dour the study quarters, at 61% and 50%, respectively. The incidence of complications such as hematuria and hematospermia, predominantly mild (Clavien-Dindo ≤ Grade I), did not vary significantly across quarters. Our detection rates for overall and clinically significant prostate cancer were 50% and 35%. Both cancer detection rates and the complications in our study showed no difference between the groups as well.

Furthermore, we evaluate the VAS scores during TPBx. We believe that for invasive procedures performed under local anesthesia, pain is the key point for applicability. Interestingly, VAS scores for steps, including probe insertion, local anesthesia injection, and the overall procedure, did not show statistically significant differences. However, during core sampling, VAS scores significantly decreased after the first 20 patients. In fact, when we divided the first 20 patients into two subgroups, the scores showed a dramatic reduction after the first 10 patients. We attributed this to the effective application of local anesthesia being achieved after the initial 10 cases. Although there was no difference in the overall procedure pain score between the groups, the decreasing operation times were correlated with reduced pain. Notably, after the first 40 patients, both room time and procedure time significantly decreased. We believe that the reduced times associated with increased experience had a positive impact on pain.

Experience and case volume help overcome the learning curve. Operators with higher case volumes achieve proficiency faster, reducing procedure time. Our study reflects this trend, showing that clinicians performing more procedures with the needle guide improved in both efficiency and patient comfort, indicating a volume-dependent learning curve. Our study is reinforced by the expertise and dedication of our specialized team. Operating as a clinic with a strong focus on uro-oncology, we bring a profound understanding of perineal anatomy, which enhances both the accuracy and confidence of our procedures. Moreover, our nursing staff possesses significant experience in prostate biopsy protocols, a factor that we believe plays a critical role in minimizing both operation times and patient room stay durations. This synergy of specialized medical knowledge and proficient procedural support contributes to streamlined processes and elevated patient care outcomes.

This study had certain limitations. Firstly, the urologist conducting the transperineal prostate biopsies had prior experience with transrectal biopsies. This existing expertise may have contributed to a shorter learning curve for transperineal biopsy procedures. Also, this is a single surgeon and a single-center study with a dedicated prostate biopsy team, so our findings may not be fully representative for other medical institutions. Second, our cases were systematic TPbx, and thus our outcomes may not be totally applicable to other techniques, such as cognitive or software MRI/US fusion biopsies. Third, the absence of data from radical prostatectomy specimens restricts the ability to provide accurate detection rates. Without histopathological confirmation from prostatectomy samples, the true positive rates and potential underdetection or overdetection associated with the biopsy procedures may not be fully assessed. This limits the comprehensiveness of the learning curve analysis in reflecting actual diagnostic performance. Despite these limitations, our study will serve as a valuable guide for all clinics looking to start TPBx procedures.

## Conclusions

In conclusion, this study provides valuable data on the learning curve associated with transperineal prostate biopsy (TPBx) using a novel angle and height-adjustable needle guide system under local anesthesia. These findings demonstrate that with increased experience, there is a significant reduction in both procedural pain and operation times, which can enhance patient comfort and procedural efficiency. Additionally, this guide has been shown to reduce procedural time and pain compared to other approaches. By highlighting the key factors influencing the learning curve, this study aims to guide new practitioners in achieving proficiency more rapidly, ultimately contributing to improved diagnostic practices and patient care.

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## Author Contributions

Erdem Öztürk: Writing—review and editing, Writing—original draft, Methodology, Data curation, Conceptualization. Tuncel Uzel: Writing—review and editing, Writing—original draft, Formal analysis, Data curation. Mustafa Işikdoğan: Writing—original draft, Writing—review and editing, Data curation. İsa Daği: Writing—review & editing, Writing—original draft, Data curation. Nurullah Hamİdİ: Writing—original draft, Data curation. Halil Başar: Writing—review and editing, Supervising. All authors reviewed the results and approved the final version of the manuscript.

## Availability of Data and Materials

The data sets generated or analyzed during the current study are not publicly available due to personal data protection law but are available from the corresponding author on reasonable request.

## Ethics Approval

This research adhered to the principles outlined in the Declaration of Helsinki and obtained ethical approval from the Dr. Abdurrahman Yurtaslan Ankara Oncology Hospital Training and Research Ethics Committee under decision number 2024-11/176.

## Informed Consent

Written informed consent was obtained.

## Conflicts of Interest

The authors declare no conflicts of interest to report regarding the present study.

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