The Safety and Feasibility of Transperineal Prostate Biopsy Under Local Anaesthesia

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ABSTRACT

Introduction and objective

Prostate cancer is the most commonly diagnosed malignancy in men, and transperineal biopsy is increasingly preferred for its lower infection risk. This study assessed the safety and tolerability of combining pudendal nerve block with periprostatic anaesthesia for transperineal ultrasound-guided prostate biopsy.

Materials and methods

A total of 64 patients underwent periprostatic anaesthesia along with bilateral pudendal nerve block. Visual analogue scale (VAS) pain score was used to evaluate discomfort and pain at three key stages of the procedure: the infiltration of the anaesthetic, the insertion of the ultrasound transducer and the biopsy needle punctures.

Results

The median pain score for prostate biopsy under local anaesthesia was reported as 3 on visual analogue scale (VAS), demonstrating that the procedure is generally well-tolerated by patients. Among the different stages of the procedure, anaesthetic infiltration was identified as the most painful. Only a small number of the patients experienced mild complications, including LUTS, hematuria, acute urinary retention, or fever.

Conclusion

The prostate biopsy under local anaesthesia has proven to be a safe, effective, and well-tolerated method for most patients. Local anaesthesia offers an adequate level of comfort and safety, comparable to other techniques, but with reduced risks and costs. The study confirmed that most patients experience minimal discomfort and present minor complications, making this method a preferred option for prostate biopsies in clinical practice.

Keywords: Local anaesthesia; Prostate cancer; Pudendal nerve block; Safety; Transperineal biopsy.

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Introduction

The most diagnosed cancer in men is prostate cancer (PCa), with an estimated 1.4 million diagnoses and 375.000 deaths worldwide in 2020 [1] [2]. In Europe, it is the third cancer-related cause of death in men and the most frequently diagnosed cancer in men [3]. Transrectal ultrasound-guided prostate biopsy (TRUSPB) has become the standard technique for the early detection of prostate cancer [4]. The two primary approaches to performing a prostate biopsy are the transrectal and transperineal pathways [5].

The transrectal (TR) ultrasound-guided biopsy technique was initially introduced by Cooner et al. and subsequently refined by Hodge et al [6] [7]. The transperineal (TP) prostate biopsy emerged as an alternative technique and, after years of development, has gained increasing adoption due to its lower risk of infectious complications and improved detection rate for anterior prostate cancers [8] [9] .

At present, the most dependable and widely utilized imaging method for diagnosing prostate cancer is multiparametric pelvic magnetic resonance imaging (mpMRI) combined with the Prostate Imaging-Reporting and Data System (PIRADS) Score version 2.0. [10] [11]. Modern prostate biopsy techniques are based on the computerised 3D merging of the ultrasound and MRI images to provide better vision during the procedure (Fusion Biopsy) [12][13]. However, the method is expensive due to high equipment costs. Cognitive fusion of ultrasound and MRI images has recently emerged as a cheaper and easier alternative to computerised fusion biopsy [14] [15].
Managing pain during the transperineal biopsy procedure involves two main considerations. Sedation or general anaesthesia provides effective pain control but adds to both aesthetic risk and patient costs[8]. On the other hand, local anaesthesia raises questions about its ability to sufficiently control pain, allowing patients to tolerate the procedure and remain still to facilitate biopsy accuracy. However, single-center studies have demonstrated that certain local anaesthesia techniques for transperineal biopsy can effectively manage pain, showing promising results in clinical settings [16] [17] [18].

A comprehensive prospective study was conducted within the Urology Department of the Craiova Clinical Emergency Hospital with the objective of thoroughly evaluating the safety profile of the pudendal nerve block combined with periprostatic anaesthesia during ultrasound-guided transperineal prostate biopsy. This investigation aimed to provide detailed insights into the procedural outcomes, patient tolerability, and potential benefits of this anaesthetic technique in improving the overall experience for patients undergoing prostate biopsy.

Material and methods

The study protocol received formal approval from the institutional ethics committee, ensuring adherence to ethical standards and regulatory guidelines. Patient recruitment for the study was conducted over an eight-month period, spanning from February 2024 to October 2024. Enrolment criteria were based on established clinical indications for prostate biopsy, which included men with either abnormal findings on digital rectal examination (DRE) and/or elevated prostate-specific antigen (PSA) levels or mpMRI findings suggestive of malignancy and willing to be enrolled. These criteria were designed to recruit a representative cohort of patients requiring diagnostic evaluation for suspected prostate malignancy.

The exclusion criteria for this study were carefully defined to ensure the safety of participants and the integrity of the results. Patients were excluded if they exhibited altered mental status or were unable to comprehend the study protocol, as this could compromise informed consent and compliance. Additional exclusion criteria included a history of daily narcotic or analgesic use, which might influence pain perception and confound outcomes, and documented allergies to study medications, such as lidocaine, to prevent adverse reactions. Patients with active anorectal conditions, bleeding

disorders, or those on anticoagulant therapy were also excluded due to the increased risk of procedural complications. Furthermore, individuals with active urinary tract infections or uncontrolled diabetes were omitted from the study, as these conditions could introduce additional risks or interfere with the interpretation of biopsy outcomes.

A total of 81 patients were evaluated for eligibility. Of these, 17 were excluded because they met the exclusion criteria, 8 declined to provide written informed consent, 9 could not be included in the final evaluation because of cooperation deficiency, resulting in 64 patients, who underwent transrectal ultrasound (TRUS)-guided transperineal prostate biopsy with local anaesthesia.

Category	Data
Patients (n=)	64
Age (y)	70.3 ± 8.0
PSA (ng/mL)	12.1 ± 6.5
Abnormal DRE (%)	51.56 %

Table 1. Patient characteristics

No sedation was given, and no other type of anaesthesia was added.

Prostate biopsy was performed using TRUS Toshiba/Canon Aplio 500 ultrasound system and the high-performance ultrawideband endorectal biplane transducer PVL-715RST with enhanced Precision+ technology and 170° (convex) and 56 mm (linear) wide field of view with a 7 MHz probe attached. The perineal area was disinfected with Povidone-iodine solution.

Periprostatic local anaesthesia was administered with 20 mL 1% lidocaine solution under TRUS guidance. The procedure was started with bilateral pudendal block. The approach was transperineal and the landmark was identified by palpating the ischial tuberosity on each side.

After creating a skin mark 1.5-2.0 cm posterior and medial of the landmark, a 22-gauge spinal needle was inserted with the guidance of the index finger placed in the rectum. The needle was directed perpendicularly to the skin in both horizontal and sagittal planes. Once the needle reached a position just beneath the ischial spine, 5 mL of 1% lidocaine was injected following an aspiration test. The needle was then withdrawn about 1 cm, and another 5 mL of aesthetic was administered. This procedure was repeated on the opposite side. Successful blockade of the pudendal nerves was assessed by the absence of pinprick sensation in the perineum 5-10 minutes after injection. If sensation was still present, an additional 5 mL of lidocaine was injected on one side. After skin infiltration with anaesthetic, 22-gauge spinal needle was inserted transperineally on each side about 2.0 cm above the rectum line. The anaesthetic was injected under ultrasound guidance into the region of the prostatic vascular pedicle at the prostate base just lateral to the junction between the seminal vesicle and prostate, and along the needle path on each side. The needle was checked for blood upon aspiration to prevent direct intravascular injection. The injection's separation of tissue layers was verified using TRUS guidance. A 10-minute wait allowed the anaesthesia to take full effect.

Under TRUS guidance, 12 to 18 biopsy cores were collected using disposable Bard MaxCore 18G biopsy guns and a transducer-mounted adjustable needle bracket. The biopsies were performed using a systematic and cognitive fusion approach for

patients who had undergone prostate mpMRI prior to the procedure.

Following the biopsy procedure, patients were examined to check for any signs of rectal or urethral trauma, haemorrhage, LUTS or any other postoperative complications.

After the procedure, patients were asked to rate their pain using the visual analogue scale (VAS) from 0 to 10, where 0 represented "No pain" and 10 indicated "Worst pain."
Pain scores were assessed at three time points: local anaesthetic infiltration, ultrasound probe insertion and biopsy gun firing.

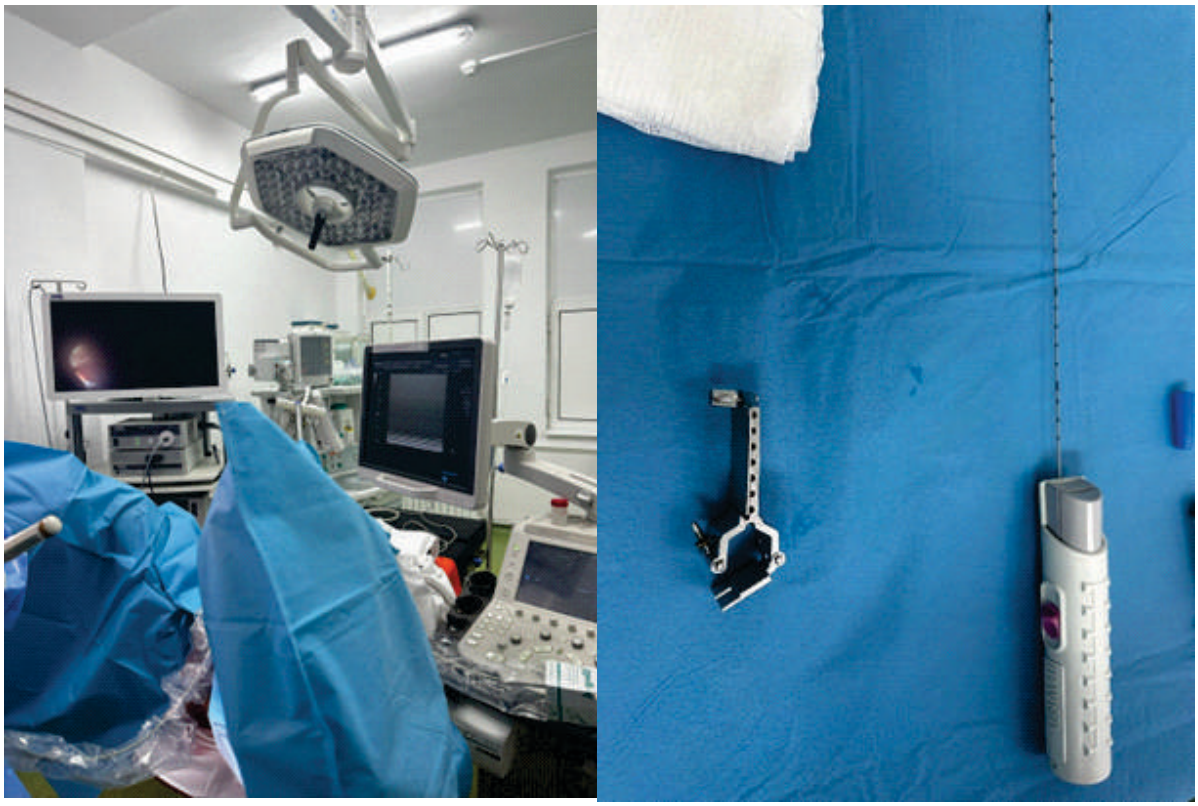


Figure 1. Patient positioning, ultrasound system placement, disposable 18G Bard MaxCore biopsy gun

Results

A total of 64 patients underwent transperineal prostate biopsy using local anaesthesia (Table 1). The mean age of the patients was 70.3 with a mean PSA level of 12.1±6.5 ng/ml and approx. 51,56% of them had abnormal digital rectal examination (DRE).

The visual analogue score (VAS) analysis for pain during prostate biopsy under local anaesthesia reveals distinct levels of discomfort across the different stages of the procedure.

The average VAS overall score was 3.
During the anaesthetic infiltration phase average VAS was 4.5±3.1. 14% of patients (9) reported no pain (VAS 0), while 25% (16) experienced mild pain (VAS 1-3). Moderate pain (VAS 4-6) was reported by 28% (21) of patients, and severe pain (VAS 7-10) was experienced by 33% (18). This stage appears to cause significant discomfort for a large proportion of patients, particularly with the highest incidence of severe pain among all stages.

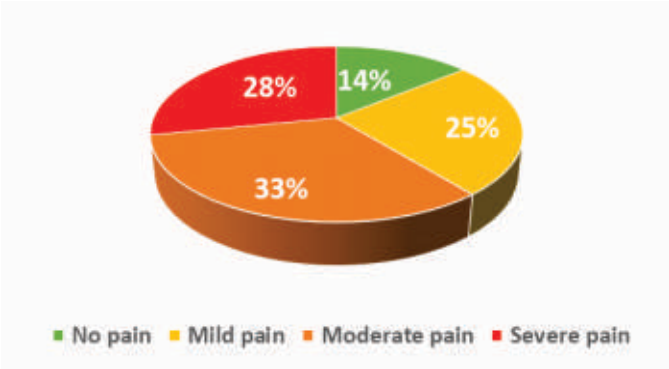


Figure 2. VAS score during anaesthetic infiltration

In the ultrasound probe insertion phase average VAS was 1.8±32.3. 45% of patients (29) reported no pain, while 38% (24) experienced mild pain (VAS 1-3). Moderate pain (VAS 4-6) was reported by 14% (9) of patients, and only 3% (2) experienced severe pain. This phase was the least painful for most patients, with half of them reporting no pain at all.

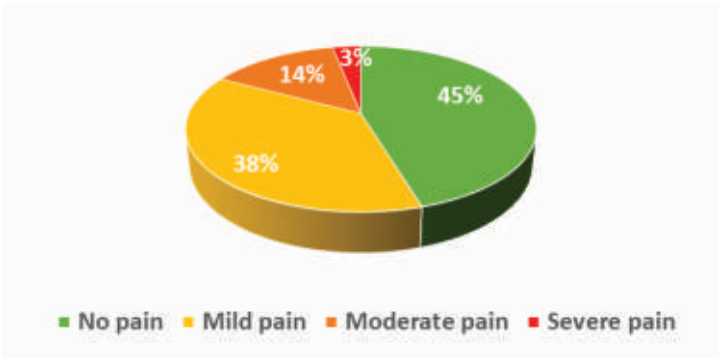


Figure 3. VAS score during ultrasound probe insertion

During the biopsy puncture phase average VAS was 2.7±2.9. 36% of patients (23) reported no pain, while 30% (19) experienced mild pain (VAS 1-3). Moderate pain (VAS 4-6) was reported by 25% (16), and severe pain (VAS 7-10) was experienced by 9% (6). Although this stage was more uncomfortable than probe insertion, it caused less severe pain compared to the anaesthetic infiltration phase.

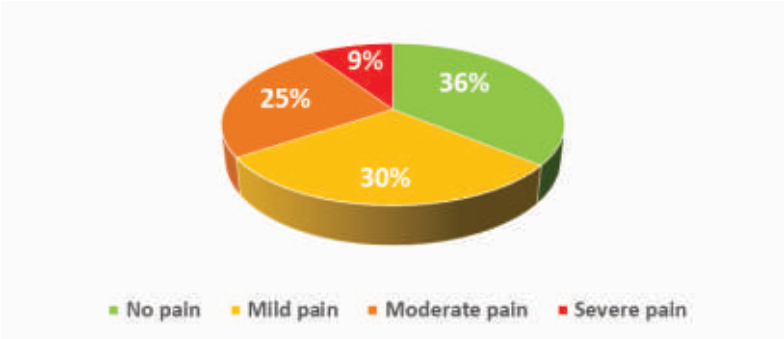


Figure 4. VAS score during biopsy punctures

Procedure	No pain (VAS 0)	Mild pain (VAS 1-3)	Moderate pain (VAS 4-6)	Severe pain (VAS 7-10)
Anaesthetic infiltration	9	16	21	18
Ultrasound probe insertion	29	24	9	2
Biopsy punctures	23	19	16	6

Table 2. Visual analogue scale pain scores (total of 64 patients)

Out of the 64 patients included, a relatively small proportion experienced mild postoperative complications (9 patients, 14%). The most common complication reported was lower urinary tract symptoms (LUTS), affecting 5 patients (7.81%). Hematuria was observed in 4 patients (6.25%), while acute urinary retention occurred in 2 patients (3.13%). Fever was the least frequent complication, reported in only 1 patient (1.56%). These complications are generally considered mild and manageable, reflecting the overall safety of the procedure under local anaesthesia.

Complication	n= (%)
LUTS	5 (7.81%)
Hematuria	4 (6.25%)
Acute urinary retention	2 (3.13%)
Fever	1 (1.56%)
Total	9 (14.06%)

Table 3. Postoperative complications

There were no patients that requested interruption of the procedure, indicating that the level of discomfort experienced was tolerable within the limits of local anaesthesia. Consequently, there was no need to escalate to loco-regional or general anaesthesia as an alternative. This outcome suggests that the chosen aesthetic protocol provided adequate pain management throughout the procedure, eliminating the necessity for conversion to more invasive forms of anaesthesia.

Discussion

In recent years, there has been a notable shift toward the transperineal (TP) approach for prostate biopsies. This transition has been driven by the desire to minimize complications associated with faecal contamination inherent to the transrectal route. However, many centres have adopted TP biopsy under general anaesthesia, often requiring operating room time. The necessity for sedation or general anaesthesia is largely attributed to patient

discomfort caused by the exaggerated positioning required for the placement of a stepper and grid, along with the repeated skin punctures for each biopsy. Advancements have recently been made in device technologies to allow for TP biopsy to be performed under local anaesthesia.

In our study, we thoroughly evaluated the feasibility, tolerability, and safety of performing transperineal prostate biopsy (TPB) under local anaesthesia (LA). Our findings demonstrated that this method is both practical and well-tolerated by patients.

Similarly, Jacewicz et al. conducted a mutlicenter retrospective study on 377 patients to evaluate prostate cancer (Pca) detection rates (CDR), pain, and adverse events using a novel, free-hand TPBx technique, based on elastic fusion of magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) under local anaesthesia with an overall csPCa of 52% [19].

In our study the most painful part of the local anesthesia TP prostate biopsy was the anesthesia infiltration as reported by the patients. Kun et al. had similar results in a prospective study but using the PrecisionPoint system between May 2016 to November 2017 in both the day surgery and outpatient environments [20].

Prostate biopsy techniques are rapidly evolving, particularly in the area of transperineal (TP) methods. Since the introduction of TP biopsy with the standard template approach, many centers have transitioned to performing only MRI-targeted biopsies.

In our study, we used a combined targeted and systematic approach for the best diagnostic results as shown in previous studies [15].

Study limitations

Our study has several limitations that include the small sample size and the single-centre design that may not reflect outcomes in other settings.
Additionally, the study's reliance on patient-outcomes, such as the Visual Analogue Score (VAS) to assess pain and effectiveness, introduces an element of subjectivity, as individual pain tolerance and perception can vary widely. The lack of a comparison group further complicates the contextualization of results against alternative biopsy techniques. Future multicentre studies with larger cohorts and objective measures would enhance the validity of the findings.

Conclusion

This study highlights that transperineal (TP) biopsy performed under local anaesthesia is a safe, effective, and well-tolerated procedure. The reported average pain score for the most discomforting part of the procedure was 4.5/10. The total operative time, including anaesthesia, was notably shorter with patients also experiencing reduced recovery times compared to other anaesthesia methods. This efficiency not only conserves resources but also enables a greater number of patients to undergo biopsies within the same timeframe. Further research is essential to validate the outcomes of this pilot study.

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