Comparison of pudendal and caudal nerve blocks for transrectal prostate biopsy in patients with anorectal disease

A prospective, randomized trial

Rahmi Aslan[1], Akif Erbin[2], Nedim Bedir[1], Kerem Taken[1], Recep Eryılmaz[1], Murat Demir[1], Kasim Ertas[3]

[1]Department of Urology, Van Yuzuncu Yil University, Faculty of Medicine,Van, Turkey; [2]Department of Urology, Health Science University, Basaksehir Cam Sakura City Hospital, Istanbul, Turkey; [3]Department of Urology, Lokman Hekim Hospital, Van, Turkey

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ABSTRACT

INTRODUCTION: Transrectal ultrasound (TRUS)-guided prostate biopsy is often associated with significant discomfort, particularly in patients with underlying anorectal conditions. Conventional local anesthesia techniques, including periprostatic nerve block — widely regarded as the gold standard — may be insufficient for adequate pain control in this patient population, thereby limiting the feasibility and tolerability of the procedure. This study aimed to assess the efficacy of pudendal nerve block (PuNB) and caudal nerve block (CaNB) in improving analgesia for patients with anorectal disease undergoing TRUS-guided prostate biopsy.

METHODS: This prospective, randomized controlled study included 91 patients presenting with elevated prostate-specific antigen (PSA) levels (≥4 ng/mL) and/or abnormal findings on digital rectal examination, along with coexisting anorectal pathology. Participants were randomly assigned to receive either a PuNB (n=46) or a CaNB (n=45) prior to undergoing TRUS-guided prostate biopsy. Pain intensity was evaluated using the visual analog scale (VAS) at three distinct time points: during local anesthetic administration (VAS-1), transrectal probe insertion and manipulation (VAS-2), and tissue sampling (VAS-3).

RESULTS: There were no significant differences between the groups in terms of VAS-1 and VAS-2 scores; however, the CaNB group demonstrated significantly lower VAS-3 scores compared to the PuNB group (1.80±0.89 vs. 2.17±0.70, p=0.048). No major complications were observed in either group throughout the study period.

CONCLUSIONS: Both PuNB and CaNB techniques provided effective analgesia during TRUS-guided prostate biopsy in patients with anorectal disease; however, CaNB was associated with significantly lower pain scores during the tissue sampling phase, suggesting it may offer superior pain control in this specific patient population. These findings support the consideration of CaNB as a preferable anesthetic approach in cases where conventional methods are insufficient due to anorectal comorbidities.

INTRODUCTION

Transrectal ultrasound-guided (TRUS) prostate biopsy is the definitive method for the histologic diagnosis of prostate cancer (PCa).[1] Although the procedure is diagnostically valuable, it frequently induces significant discomfort owing to the dense sensory innervation of the anal canal and perineal area. This discomfort may be especially evident in individuals with preexisting anorectal disorders, including hemorrhoids, anal fissures, or a history of anorectal surgery. In this patient population, the practicality of conducting TRUS-guided biopsy under local anesthetic is frequently constrained, necessitating general anesthesia in several instances to guarantee patient comfort and procedural efficacy.[2]

To alleviate procedure-related pain, many regional anesthetic procedures have been used, including periprostatic nerve block (PPNB), intrarectal lidocaine gel, pudendal nerve block (PuNB), and caudal nerve block (CaNB).[3,4] PuNB delivers localized analgesia by obstructing the pudendal nerve, which supplies sensation to the perineum and external anal sphincter. CaNB offers a broader anesthetic effect by anesthetizing the sacral nerve roots (S2–S4), potentially improving patient tolerance during probe insertion and biopsy sampling.[5,6]

Despite morphological and functional disparities, comparative data regarding the analgesic efficacy of PuNB vs. CaNB in patients with anorectal disease receiving TRUS biopsy are insufficient. This prospec-

tive, randomized controlled study aimed to compare the effectiveness of PuNB and CaNB in controlling pain during TRUS-guided prostate biopsy in patients with coexisting anorectal disease.

METHODS

Compliance with ethical standards

The Van YYU Clinical Research Ethics Committee approved the study on April 11, 2024, with approval number 01-04072018. The study protocol was thoroughly explained to all participants, and written informed consent was obtained from each individual prior to enrollment. Additionally, all procedures conducted in this study involving human participants adhered to the ethical standards set forth by the institutional and national research committees, as well as the 1964 Declaration of Helsinki and its subsequent amendments.

Study design

This prospective, randomized study included 115 male patients exhibiting elevated prostate-specific antigen (PSA) levels (≥4 ng/mL) and/or abnormal digital rectal examination (DRE) findings, all of whom presented with concomitant anorectal pathology. All cases were assessed by a general surgeon, confirming the presence of anorectal pathology: hemorrhoids (40%), anal stenosis (11%), anal fissure (21%), ulcerative colitis (9%), and prior surgery for perianal abscess or fistula (19%). All participants experienced significant pain during the DRE, and in 35% of cases, the examination could not be completed due to excessive discomfort. Significantly, 65% of patients were referred to our institution from external centers where TRUS biopsy could not be conducted under local anesthesia due to severe pain experienced during TRUS probe insertion.

Exclusion criteria encompassed the absence of anorectal pathology, previous prostate biopsy, chronic prostatitis, presence of a urinary catheter, diagnosed neurologic disorders (e.g., multiple sclerosis), uncontrolled hypertension, history of cerebrovascular accident, active urinary tract infection, and known bleeding diathesis or coagulopathy. Furthermore, patients exhibiting spinal deformities or contraindications to regional anesthesia were excluded from the study.

A total of 94 patients were randomized in a 1:1 ratio into two groups: the CaNB group (n=47) and the PuNB group (n=47). Computer-generated block randomization served as the allocation method, employing Stata Statistical Analysis Software (StataCorp, College Station, TX, U.S.) to ensure balanced group assignment and minimize selection bias. One patient in the CaNB group was excluded from the study due to tachycardia during the biopsy procedure, while two patients in the PuNB group were excluded for feeling unwell. A total of 46 patients from the CaNB group and 45 patients from the PuNB group were included in the final analysis. Figure 1 presents the flow diagram of the study, adhering to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

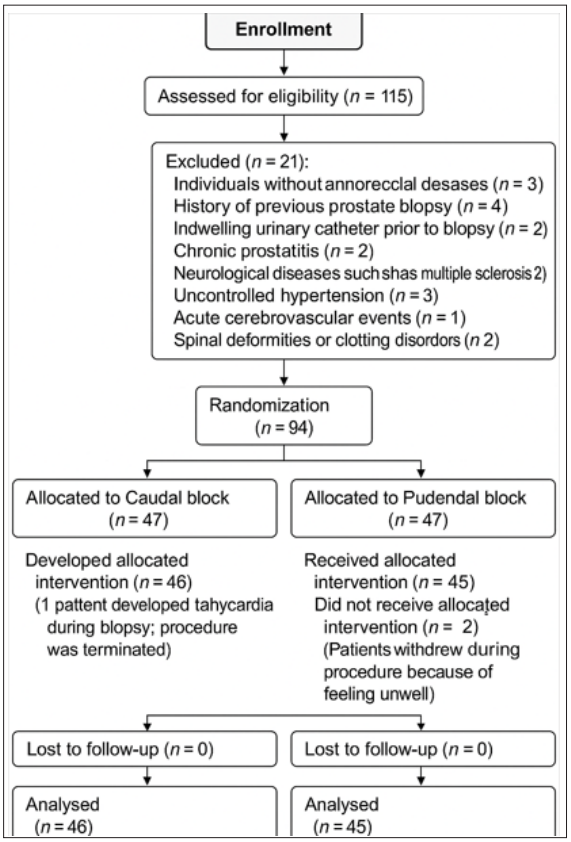

Figure 1. CONSORT flow diagram of the participants in the study.

Demographic characteristics and findings during and post-procedure for all groups were prospectively documented and analyzed comparably. Prostate volumes (PVs) were assessed using transrectal ultrasonography and computed with the prolate ellipsoid formula: width × length × height × 0.52.

Preprocedural evaluation

Antibiotic prophylaxis involved the administration of oral ciprofloxacin (500 mg) starting one day before the procedure and continuing at the same dosage for three days following the biopsy. On the morning of

the procedure, all patients received rectal cleansing via a rectal enema.

Pain assessment

Pain intensity was assessed using an 11-point visual analog scale (VAS), from 0 (no pain) to 10 (unbearable pain), at three different stages of the procedure.[7] The assessments were performed by a urologist who was blinded to the type of anesthesia used, and the scores were recorded immediately after each corresponding stage: after local anesthetic injection (VAS-1), after transrectal probe insertion and manipulation (VAS-2), and immediately after biopsy sampling (VAS-3) (Figure 2).

Before the procedure, all patients received comprehensive instructions on assessing and reporting their pain and discomfort levels using the VAS.

Caudal nerve block technique

A 22-gauge intravenous line was inserted in the anesthesia unit, and isotonic fluid infusion commenced at a rate of 3 ml/kg/h. Baseline hemodynamic parameters were documented via automated blood pressure monitoring, electrocardiography, and peripheral oxygen saturation assessment. No premedication was provided. Patients were placed in the left lateral decubitus posture. Aseptic skin preparation was conducted using povidone-iodine. The sacral hiatus was located through palpation. Subsequently, 1 cc of 2% lidocaine was administered at the needle insertion site. A 22-gauge caudal needle was introduced through the dermis at a 45° angle. After penetrating the sacrococcygeal ligament, the injection solution — comprising 0.5 mg/kg bupivacaine combined with 0.5 µg/kg isotonic fentanyl — was diluted to a total volume of 10 ml. A preliminary test dose of 3 ml was provided; in the absence of indicators suggestive of spinal anesthesia, the remaining 7 ml was injected over a duration of 15–20 seconds.

Pudendal nerve block technique

After positioning the patient in the lithotomy position, the perineal area was aseptically prepared with an iodine-based antiseptic solution. Before administering the PuNB, the anatomical position of the ischial spine was determined through digital rectal manipulation (DRM). A bilateral pudendal nerve block was performed using a transperineal approach with a 22-gauge, 20 cm spinal needle. Following DRM guidance, 10 mL of 1% lidocaine was administered, with 5 mL injected on each side, into the percutaneous tissue located just posterior to the attachment of the sacrospinous ligament to the ischial spine. The procedure began roughly five minutes following the administration of the local anesthetic.

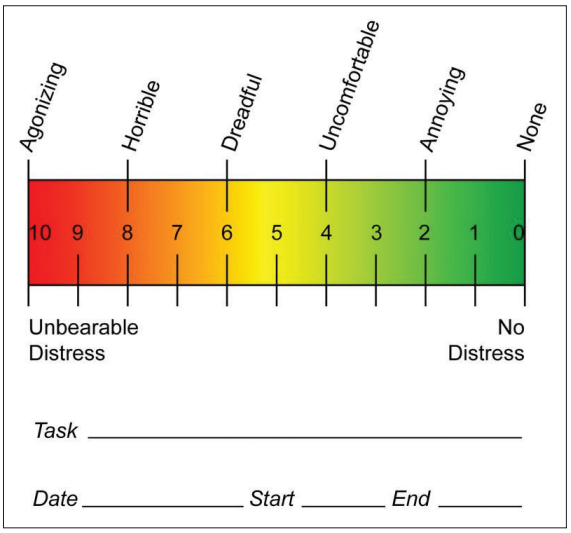

Figure 2. Visual analog scale.

Table 1. Comparison of patient demographic characteristics and baseline data

Variables	PuNB group (n=45)	CaNB group (n=46)	p
Age, year, mean ± SD	62.3±6.5	60.8±8.5	>0.05†
BMI, kg/m², mean ± SD	26.8±5.32	26.05±2.7	>0.05†
Comorbidities			>0.05‡
DM, n (%)	10 (22.2)	11 (23.9)	
CVD, n (%)	5 (11.1)	6 (13)	
PSA, ng/mL, mean ± SD	14.71±9.50	17.29±11.34	>0.05†
PV, mean ± SD	75.7±44.8	73.3±33.9	>0.05†
PCa, n (%)	17 (37.7)	16 (34.7)	>0.05‡

†Mann-Whitney U test. ‡Pearson's Chi-squared test. BMI: body mass index; CaNB: caudal nerve block; CVD: cardiovascular disease; DM: diabetes mellitus; PCa: prostate cancer; PSA: prostate-specific antigen; PuNB: pudendal nerve block; PV: prostate volume; SD: standard deviation.

Postprocedural monitoring and followup

Patients were monitored in a clinical environment for at least three hours post-biopsy. Patients without immediate post-procedural complications were subsequently discharged. Three weeks post-procedure, all participants underwent re-evaluation to assess

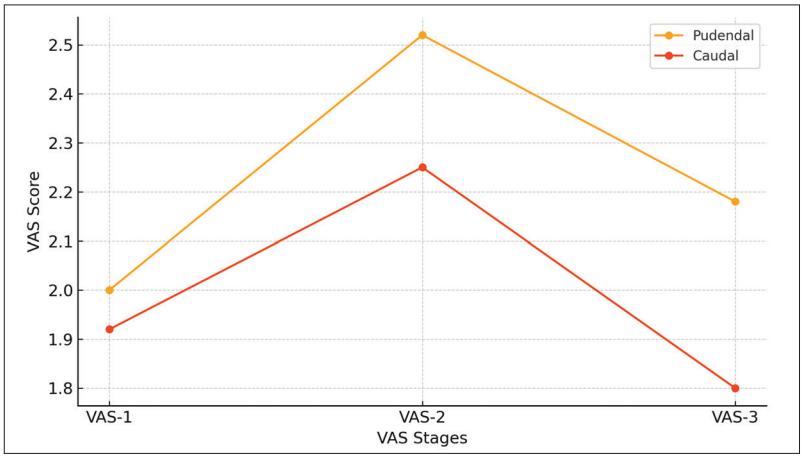

Figure 3. Comparison of visual analog scale (VAS) scores between pudendal nerve block and caudal nerve block.

Table 2. Comparison of VAS scores between the groups

Variables	PuNB group (n=45)	CaNB group (n=46)	p
VAS-1 (local anesthetic application), mean ± SD	2.01±0.9	1.93±0.89	0.19*
VAS-2 (probe insertion manipulation), mean ± SD	2.51±0.89	2.25±1.29	0.11*
VAS 3 (sampling), mean ± SD	2.17±0.70	1.8±0.89	**0.048***

*Independent sample t-test. Bolded value indicates statistical significance. CaNB: caudal nerve block; PuNB: pudendal nerve block; SD: standard deviation; VAS: visual analogue scale.

Table 3. Comparison of complications between the groups

Variables	PuNB group (n=45)	CaNB group (n=46)	p
Rectal bleeding, n (%)	1 (2.2%)	0 (0.0%)	
Hematuria, n (%)	2 (4.4%)	2 (4.4%)	
Urinary retention, n (%)	0 (0.0%)	0 (0.0%)	
Acute prostatitis, n (%)	1 (2.2%)	0 (0.0%)	
Urosepsis, n (%)	0 (0.0%)	0 (0.0%)	
Allergic reaction, n (%)	0 (0.0%)	0 (0.0%)	
Total, n (%)	4 (8.8%)	2 (4.4%)	0,242‡

‡Pearson's Chi-squared test. CaNB: caudal nerve block; PuNB: pudendal nerve block.

potential complications and histopathologic outcomes. Complications, including rectal bleeding, hematuria, and hematospermia that resolved spontaneously during the clinical course, were classified as mild complications. In contrast, massive rectal bleeding, hematuria, acute urinary retention, acute prostatitis, urosepsis, and allergic reactions were categorized as severe complications.

Statistical analysis

The statistical analysis of the data was conducted using IBM SPSS Statistics for Windows 25.0 (IBM Corp., Armonk, NY, U.S.) software. Continuous variables were presented as mean ± standard deviation (SD) for normally distributed data and as median with interquartile range (IQR) for non-normally distributed data, as assessed by the Shapiro-Wilk test. Categorical variables were represented as frequencies and percentages.

As the assumptions for parametric tests were not satisfied, differences in demographic and baseline variables between groups were analyzed using the Mann-Whitney U test. In comparing VAS scores, the independent sample t-test was used for normally distributed data, and the Mann-Whitney U test was used for non-normally distributed data. Categorical variables were compared using the Pearson's Chi-squared test. A p-value of ≤0.05 was considered indicative of statistical significance.

RESULTS

No statistically significant differences were seen between the groups for age, body mass index (BMI), comorbidities, PSA levels, PV, and PCa rates (Table 1).

The VAS-1 and VAS-2 ratings were similar among the groups. The VAS-3 scores in the CaNB group were significantly lower (2.17±0.70 vs 1.80±0.89, p=0.048) (Figure 3, Table 2).

No statistically significant difference was observed between the groups regarding severe complications (Table 3). No complications related to anesthesia administration were observed in any patient.

DISCUSSION

Pain during TRUS-guided prostate biopsy can be experienced in three distinct phases; however, the most intense pain is typically reported during the insertion and manipulation of the rectal probe. This initial acute pain often exacerbates patient anxiety, thereby increasing discomfort throughout the subsequent tissue sampling process As a result, overall patient comfort is diminished, which may adversely affect the procedural success.

Currently, the PPNB is the most commonly employed analgesic technique prior to biopsy.[8,9] Multiple studies have demonstrated that PPNB significantly reduces pain perception during biopsy in many

patients.[10,11] Nonetheless, the efficacy of this local anesthesia method alone remains inconclusive, as not all investigations have confirmed its effectiveness.[12] Recent high-level evidence suggests that PPNB may be insufficient in alleviating pain associated particularly with probe insertion and manipulation; hence, alternative anesthesia techniques have been explored and proposed.[13-15]

Anorectal disorders are highly prevalent, affecting approximately one-quarter of the adult population. For instance, in the U.S., hemorrhoid prevalence ranges from 4.4–39%, and anal fissures from 1.0–1.5%, while fecal incontinence affects 7–18% and evacuation disorders 12–19% of adults.[16] In individuals with these conditions, TRUS-guided biopsy procedures are, as expected, significantly more painful compared to healthy individuals.

In a study conducted by Kravick et al, all patients with anorectal disorders reported experiencing severe pain during DRE.[17] They reported that DRE could not be performed in approximately one-third of patients with anorectal disorders due to severe pain. Moreover, 55% of the patients in their study were unable to undergo prostate biopsy using standard local anesthesia techniques for the same reason.

Similarly, in our previous study, we found that DRE was markedly painful in many patients with anorectal disorders, and that routine anesthesia methods were insufficient for obtaining prostate biopsies in the majority of cases.[18] In this patient population, intense pain is experienced both during the insertion of the ultrasound probe and throughout the biopsy procedure. A considerable proportion of these patients are unable to tolerate biopsy procedures under conventional PPNB or other standard anesthesia techniques. Consequently, general anesthesia can often be needed for such cases.

Given the increased resource utilization and potential risks associated with general anesthesia, regional blockade techniques may offer a more favorable and practical alternative. Caudal block necessitates an anesthesiologist's presence; however, it is less resource-intensive and safer than general anesthesia, as it eliminates the need for airway manipulation and the use of an operating room. In facilities with consistent anesthesiology support, caudal block remains a viable alternative to general anesthesia for patients with anorectal pathology.

Numerous studies have demonstrated the efficacy and safety of both caudal and pudendal nerve blocks in the surgical management of anorectal diseases.[19,20] Moreover, a growing body of recent literature has reported the successful application of these regional anesthesia techniques in transrectal prostate biopsy procedures;[4-6,18] however, to date, no studies have directly compared the effectiveness of CaNB vs. PuNB specifically in patients with underlying anorectal disorders undergoing prostate biopsy.

In the present study, nearly all patients in both groups successfully completed the prostate biopsy procedure. Our results demonstrated that the CaNB technique was significantly superior in terms of patient comfort, as evidenced by lower visual VAS scores during TRUS probe insertion and manipulation; however, no statistically significant difference was observed between the groups regarding pain intensity during the anesthetic injection and the biopsy itself. This finding may be attributed to the broader and more diffuse anesthetic coverage achieved by CaNB, in contrast to the more anatomically confined and localized effect of the PuNB.

The PuNB is considered a more practical option in routine urologic practice, as it is technically less invasive and can be administered without the need for an anesthesiologist; however, its efficacy may be limited in certain cases due to anatomical variability, which can lead to suboptimal analgesic outcomes. In contrast, the CaNB offers broader and more effective analgesia by targeting multiple sacral nerve roots. Nevertheless, this technique is technically more demanding and is typically performed by an anesthesiologist, which may limit its accessibility and widespread use in standard urologic settings.

Comparative data on CaNB and PuNB remain scarce in the existing literature. Wang et al highlighted the clinical efficacy of CaNB in providing adequate analgesia during TRUS-guided prostate biopsies,[21] whereas we emphasized the technical simplicity and feasibility of PuNB, particularly in outpatient urologic practice.[4,14]

Kravick et al reported that the administration of perianal analgesia prior to TRUS-guided prostate biopsy enabled successful completion of the procedure in patients with anorectal disorders.[17] Similarly, our previous study also demonstrated that CaNB facilitated effective and complication-free biopsy in a comparable patient population;[18] however, both studies were observational in nature and lacked a randomized, comparative design.

In the present study, two regional anesthesia techniques — caudal and pudendal nerve blocks — were prospectively compared in a randomized manner specifically in patients with anorectal disease undergoing TRUS-guided prostate biopsy. Both techniques were found to significantly reduce pain during the procedure. CaNB was associated with superior analgesia compared

to PuNB, particularly during TRUS probe insertion and manipulation; however, no significant difference was observed between the two techniques in terms of pain experienced during local anesthetic administration or prostate tissue sampling.

To the best of our knowledge, this is the first prospective, randomized study to directly compare CaNB and PuNB in this specific patient population. The findings suggest that while both techniques are effective in reducing procedural pain, CaNB provides significantly better overall pain control, particularly during the most discomfort-inducing phases of the biopsy. From an anatomical perspective, CaNB provides broader sensory coverage by anesthetizing the sacral nerve roots S2–S4, which innervate the prostate, perineum, and surrounding structures. This extensive distribution may account for its superior analgesic efficacy. In contrast, PuNB, while more targeted, may offer limited coverage in certain patients or be technically challenging to administer accurately due to anatomical variations.

Limitations

This study has several limitations that should be acknowledged.

First, although the prospective, randomized design enhances the strength of the findings, the sample size was relatively modest, which may limit the generalizability of the results to broader patient populations.

Second, the study was conducted at a single center, potentially introducing center-specific biases related to practitioner experience or institutional protocols.

Third, the subjective nature of pain assessment using the VAS, although widely accepted, may be influenced by individual pain thresholds, anxiety levels, and prior experiences, which were not controlled for in the analysis. Additionally, although both nerve blocks were performed by experienced clinicians, slight variations in technique or anatomical differences among patients may have affected the consistency and effectiveness of the blocks. Importantly, the procedures were not performed under image-guided nerve localization, which could have improved precision, particularly for pudendal nerve block.

Fourth, long-term outcomes, such as delayed complications, patient satisfaction, and willingness to undergo repeat biopsy, were not evaluated, which limits the ability to assess the broader clinical impact of each anesthesia technique. Future multicenter studies with larger sample sizes and long-term followup are warranted to confirm and expand upon these findings.

And finally, another limitation is the inherent subjectivity of the VAS, as descriptors like 'dreadful,' 'horrible,' or 'agonizing' may be interpreted differently by individual patients, even with standardized instructions provided.

Despite these limitations, given the scarcity of data in this unique patient population, our study still provides clinically relevant evidence supporting the role of regional nerve blocks in TRUS-guided prostate biopsy

CONCLUSIONS

Although CaNB demonstrated superior outcomes based on VAS-3 scores, its implementation in routine clinical practice is limited by technical complexity and the frequent need for administration by an anesthesiologist. In contrast, PuNB can be more readily performed by urologists without anesthesiology support, rendering it a more accessible and practical option in standard urology practice.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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CORRESPONDENCE: Dr. Akif Erbin, Department of Urology, Health Science University, Basaksehir Cam Sakura City Hospital, Istanbul, Turkey; akiferbin@hotmail.com