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COMPARATIVE EVALUATION OF COMBINED INTRARECTAL LIDOCAINE GEL AND PERIPROSTATIC NERVE BLOCK VERSUS CAUDAL BLOCK IN TRANSRECTAL ULTRASOUND GUIDED PROSTATE BIOPSY

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ABSTRACT **Introduction:** The periprostatic nerve block (PNB), which appears to be the gold standard for pain relief during transrectal ultrasound guided prostate (TrusP) biopsy, has been shown to be ineffective in providing adequate anesthesia during transrectal ultrasound (Trus) probe insertion into the anorectum, necessitating the use of another technique to achieve 'balanced' anesthesia. The goal of this study was to see if caudal block (CB) vs combined intrarectal lidocaine gel and periprostatic nerve block (cGPNB) would offer appropriate anesthesia at all phases of TrusP.

Methods: Patients with TrusP indications were randomly assigned to either cGPNB (Group A) or CB (Group B) and data was collected prospectively (Group B). Following anesthesia, Trus probe insertion, biopsy needle penetration of the prostate, and 1 hour after biopsy, a comparison of the numerical rating pain score (NRS) between two groups was performed.

Results: In both groups, there were 50 patients. NRS score after anesthesia (P = 0.56), prostate biopsy needle penetration (P = 0.65), and 1 hour after the procedure (P = 0.145), there was no significant difference seen between the two arms of the research. During probe insertion, there was no statistically significant difference in the number of patients experiencing no/mild pain between the two arms (P = 0.65). In both arms, none of the participants experienced severe discomfort. For subsequent biopsies, all patients in Group A versus 46 (92%) in Group B will choose the same anaesthetic (P = 0.124). Conclusions: cGPNB delivers balanced anesthesia with high patient tolerability at all stages of TrusP.

KEYWORDS :

INTRODUCTION

The most common approach for acquiring specimens for histological diagnosis of prostate cancer is transrectal ultrasound guided prostate (TrusP) biopsy. following evidences that the sextant approach fails to sufficiently sample the prostate, many urologists have embraced the extended biopsy protocol.[1,2] The requirement for sufficient anesthesia is highlighted by the proportionate increase in pain with the number of biopsy cores. [3] Pain was measured during Trus probe insertion, prostate needle puncture, and shortly after TrusP in previous studies. [4] Caudal block (CB), a type of regional anaesthetic, looks to be a balanced anesthesia for TrusP, with the main drawback being transitory paraparesis in some patients, which could slow down the procedure. Furthermore, previous studies have not established the level of discomfort experienced by the patient during anesthetic administration. [5]

The periprostatic block looks to be the gold standard for TrusP and is arguably the most widely utilized anaesthetic. [6] Studies have demonstrated that it is effective during prostate needle puncture and shortly after a biopsy, but not during the insertion of the Trus probe into the anorectum. Intrarectal lidocaine gel (ILG), on the other hand, has been shown to provide pain relief solely during Trus probe implantation into the anorectum. [7] While CB has long been known for its good anal sphincter relaxation and pain control, [5] data comparing it to combined ILG and periprostatic nerve block is lacking (cGPNB). To our knowledge, no study has compared the pain alleviation provided by cGPNB with CB at all stages of the process. When compared to CB, we evaluated whether cGPNB will offer a balanced anesthetic throughout anesthesia application, Trus probe insertion into the anorectum, prostate needle puncture, and 1 hour after biopsy.

METHODS

This is a prospective ethical committee approved study done at Shyam shah medical college Rewa, over a period of 1 years (September 2020 to September 2021). We randomly assigned patients who met any of the inclusion criteria of abnormal digital rectal examination, PSA >4 ng/ml, and abnormal transrectal ultrasound (Trus) scan findings to one of two cohorts based on the anesthetic to be administered before TrusP. cGPNB was attributed to group A, while CB was attributed in Group B. The study excluded patients with visual/hearing impairment, back pain/paraplegia/paraparesis from any source, and painful anorectal diseases.

All patients were given a one-day bowel preparation that included a liquid diet, Dulcolax (bisacodyl), and ciprofloxacin. Before the operation, all anticoagulants were stopped.

In Group A, 20 mL of 2% lidocaine gel was injected into the anorectum, and the examiner's dominant hand's index finger was used to massage the gel into the prostate and anal region. The Trus probe with a needle guide was placed into the anorectum around 10 minutes later. The needle guide was then inserted with a 22-gauge, 20 cm long, Echo tip, Skinny needle with Chiba tip (cook medical brand). Under ultrasound guidance, 5 ml of 2% lidocaine was injected into each of the basal (at the confluence of the seminal vesicle and the base of the prostate) and apical regions of the prostate (Figure 1).

The prostate was evaluated using the Trus method (which takes about 5 minutes). After the anaesthetic had settled, a biopsy of the prostate was performed under ultrasound guidance.

In group B, a 23G hypodermic needle was used to inject 20 ml of 2% lidocaine into the sacral canal in the prone position. An initial 2 ml of this 20 ml of 2 percent lidocaine was used to anaesthetize the epidermis and subcutaneous tissue above the sacral hiatus.

The anal sphincter's laxity was used to determine when anesthesia takes effect. After Trus evaluation of the prostate, a Trus probe with needle guide was introduced into the anorectum about 5 minutes later, and a biopsy of the prostate was performed under ultrasound guidance after Trus examination of the prostate.

All biopsies were performed with a 7.5 Hz Trus probe (Mindray device, DP2200 model) and its associated needle guide. During lidocaine gel instillation, PNB, and TrusP, all patients were positioned left lateral. For all of the biopsies, a biopsy gun with an 18G size, a 25 cm length, and a 22 mm penetration depth was employed. All of the patients' biopsies were performed by the same team of investigators, which included a urologist, anesthetists, and a unit nurse. After periprostatic infiltration, the pain was measured using the numerical pain rating scale (NRS), 1 h after lidocaine or CB administration, following Trus probe insertion, after each of the 10 core needle biopsies (average NRS was then calculated), and after each of the ten core needle biopsies (average NRS was then calculated). The unit nurse, who was blinded to the type of anaesthetic, performed all of the pain assessments using NRS.

The unit nurse recorded the patients' subjective impressions of the anaesthetic, the incidence of limb weakness in Group B, and other problems in both arms.

IBM SPSS Statistics for Windows Version 21.0 was used to analyze the data. The results were divided into four categories: (1) No pain (NRS =

0), (2) Mild pain (NRS = 0.1–3), (3) Moderate pain (NRS = 3.1–7), and (4) Severe pain (NRS = >7). The Mann–Whitney U test was used to compare the age and BMI of the patients in the two groups. The NRS groups in the two arms of the trial were compared using a t-test, prostate volume, and patients' subjective perceptions of anesthesia were analyzed using Pearson Chi-square/continuity correction as appropriate.

RESULTS

A total of 100 individuals were enrolled in the study, with 50 in each arm. Table 1 illustrates the demographics of the two arms. The age (P = 0.36), BMI (0.314), total PSA (0.313), and prostate volume (0.18) of the patients were all identical in both groups.

Table 1: Demographic Data

Patient demographics	cGPNB (*n*=50)	CB(*n*=50)	P value
Mean age (years)	67.2±9.2	63.7±7.8	0.36
BMI range (kg/m2)	15.4-33.6	16.8-35.5	-
Mean BMI (kg/m2)	24.9±4.1	24.7±4.4	0.314
Total PSA range (ng/ml)	3.9-167.5	4.9-92.4	-
Median total PSA (ng/ml)	9.8±12.8	8.6±10.8	0.313
Prostate volume range (ml)	26.0-202.0	19.9-238.0	-
Median prostate volume (ml)	62.0±58.4	58.7±47.3	0.18
BMI: Body mass index, PSA: Prostate specific antigen, cGPNB: Combined gel and periprostatic neve block, CB: Caudal block			

After anesthesia, 13(26%) against 17 (34%) of the patients in Groups A and B had no pain, 32 (64%) versus 27 (54%) had mild pain, and 5 (10%) versus 6 (12%) had moderate pain, while none of the patients in Groups A and B had severe pain (P = 0.567).

In Groups A and B, 19 (38%) compared to 38 (76%) reported no pain during probe insertion, 27 (54%) compared to 10 (20%) reported mild discomfort, and 4 (8%) compared to 2 (4%) reported significant pain. During probe insertion, none of the patients in either group had acute discomfort.

During prostate biopsy needle puncture, the analysis of NRS groups revealed that 16 (32%) versus 28(56%) had no pain, 25 (50%) versus 18 (36%) had mild pain, 6 (12%) versus 3 (6%) had moderate pain, and 3 (6 %) versus 1 (2%) had severe pain in Groups A and B, respectively (P = 0.65). The majority of patients experienced little or mild pain 1 hour after the biopsy, with no statistically significant change in the distribution of NRS categories between the two study arms (P = 0.147) (table 2).

Table 2: Comparison Of Numerical Rating Pain Score Between The Combined Gel And Periprostatic Nerve Block And Caudal Block Groups

Indices		cGPNB (*n*=50)	CB (*n*=50)	P value
Application of anesthesia	No pain Mild pain Moderate pain Severe pain	13 (26%) 32(64%) 5(10%) 0	17(34%) 27(54%) 6(12%) 0	0.567
Probe insertion	No pain Mild pain Moderate pain Severe pain	19(38%) 27(54%) 4(8%) 0	38(76%) 10(20%) 2(4%) 0	0.01
Biopsy needle puncture	No pain Mild pain Moderate pain Severe pain	16(32%) 25(50%) 6(12%) 3(6%)	28(56%) 18(36%) 3(6%) 1(2%)	0.065
One hour after biopsy	No pain Mild pain Moderate pain Severe pain	38(76%) 8(16%) 4(8%) 0	42(84%) 8(16%) 0 0	0.145

NRS: Numerical pain rating scale, cGPNB: Combined gel and periprostatic neve block, CB: Caudal block

The procedure was rated as very bearable by 31 (62%) versus 38 (76%) patients in Groups A and B, respectively, and fairly tolerable by 18 (36%) and 10 (20%) patients in Groups A and B, respectively. Only a few patients in both groups deemed it intolerable. None of them thought the operation was particularly unpleasant. (Table 3) There was no statistically significant difference in these distributions between the two groups (P = 0.234).

All patients in Group A, compared to 46 (92%) in Group B, were willing to have a second biopsy under the same anaesthetic (P = 0.124). However, in Groups A and B, 11 (22%) and 14 (28%), respectively, would prefer a better anaesthetic (P = 0.43) (Table 3).

Table 3: Patient's Subjective Assessment Of The Effectiveness Of Anesthesia

Indices		cGPNB (n=50)	CB (n=50)	P value
Tolerability	Very tolerable Fairly tolerable Intolerable Very intolerable	31(62%) 18(36%) 1(2%) 0	38(76%) 10(20%) 2(4%) 0	0.234
Willingness to undergo subsequent biopsy with same anesthesia?	Yes No	50(100%) 0	46(92%) 4(8%)	0.124
Preference for a better anesthesia?	Yes No	11(22%) 39(78%)	14(28%) 36(72%)	0.43

cGPNB: Combined gel and periprostatic neve block, CB: Caudal block

DISCUSSION

Our study evaluated for pain during anaesthetic administration, which has been exceedingly rare in previous studies. Despite the differences in the route and procedure of anesthesia administration, the distribution of the NRS groups across the two arms of our study showed that pain during anesthesia may not be significantly different when needle injection is required to deliver the anaesthetic agent in a non-sedated patient, regardless of the route.

Previous studies have shown that pain experienced during probe insertion into the anorectum without anaesthetic is greater than pain experienced during prostate biopsy needle puncture. [8] This level of discomfort may discourage patients, particularly those with a tight anal sphincter, from proceeding with the treatment (s). The most often used anesthesia, periprostatic nerve block (PNB), has been demonstrated to be ineffective in providing adequate anesthesia during Trus probe implantation. As a result, an agent must be added to the PNB to make it a 'balanced' anesthesia that provides enough pain relief throughout the treatment. As an adjunct to PNB, a variety of medications have been studied, including local muscle relaxants, prilocaine lidocaine cream, and sedation. [4] Lidocaine gel is a better adjunct since it is inexpensive, readily available, easy to use, and safe. Because a prior study found that prostate biopsy without anesthesia is associated with significant pain, we did not include a placebo group in our trial. [9]

When compared to PNB, Stirling et al. [7] found that ILG reduces pain during probe insertion but not during biopsy needle puncture. This finding is supported by our research, which found that lidocaine gel is associated with significant pain alleviation during probe insertion, with the majority of patients in Group A having light discomfort, only 3 (5.4%) having moderate pain, and none having severe pain. CB has long been known for its ability to relax the anal sphincter. [5] There is, however, a scarcity of data comparing cGPNB and CB.

Our findings revealed that considerably more patients in the CB arm, 41 (77.4%), reported no pain at all compared to 22 (39.3%) in the cGPNB arm (P = 0.01). There was no significant difference (P = 0.65) between the two arms of the trial when individuals with no discomfort/mild pain were compared (53 (94.6) versus 52 (98.1)).

Our findings revealed that both cGPNB and CB offered adequate pain relief during prostate biopsy needle penetration and 1 hour after biopsy, with no significant difference in the NRS group between the two trial arms. This, however, contradicts the findings of Horinaga et al. [10], who found that periprostatic nerve block was superior than CB. However, the low dose of lidocaine (10 ml of 1%) utilized in their investigation may have contributed to the differences.

Patients in the cGPNB were more eager to endure additional biopsies under the same anaesthetic than those in the CB, according to their

subjective assessments. Similarly, although the differences were not statistically significant, the number of patients who would prefer a 'better' form of anaesthetic for subsequent biopsies other than the one given to them was lower in the cGPNB group. The momentary difficulty to walk immediately after the treatment experienced by 37.7% of patients in the caudal arm of the trial, necessitating short supervision, could be one reason for this subjective preference for cGPNB. Because no prolonged observation is necessary, this could result in a greater turnover rate for cGPNB. The procedure-related complication rate was evaluated between the two trial arms, and there was no statistically significant difference between them.

The effectiveness of cGPNB in pain control during Trus probe insertion into the anorectum, Chiba needle puncture of the prostate capsule for anaesthetic administration, TruCut biopsy needle penetration of the prostate, and 1 hour after biopsy is demonstrated in this study. It also demonstrated that cGPNB was superior in terms of patients' subjective assessments of preference, with no significant infective complication rate despite the theoretical danger of infection inoculation during Chiba needle puncture of the prostate capsule for anaesthetic delivery.

In conclusion we found that cGPNB is a 'balanced anesthesia' for TrusP since it provided effective pain control at all stages of the procedure and was preferred by more patients for subsequent biopsies. When compared to CB, it has no statistically different infective or other biopsy/anesthesia related consequences.

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