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ORIGINAL RESEARCH

Saddle Block for Transrectal Prostate Biopsy: A Comparison of the Analgesic Efficacy of 0.25% Bupivacaine and 0.375% Ropivacaine

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Abstract

Background: Prostate biopsy is a painful procedure, and the degree of pain is related to the number of core biopsies taken.
Objective: To compare the analgesic properties of hyperbaric bupivacaine 0.25% with 0.375% ropivacaine for saddle block in transrectal prostate biopsy.
Methods: This was a randomised double-blinded study. Eighty patients with indications for prostate biopsy presenting at the Day-Case Theatre in a Nigerian tertiary facility were randomised into two equal groups: B (Bupivacaine) and R (Ropivacaine). Group B received 1ml of 0.25% bupivacaine, while Group R received 1ml of 0.375% ropivacaine for saddle block, respectively. Pain assessment, home readiness, patients' satisfaction, and time to first analgesic request were assessed and compared between the two groups.
Results: The Bupivacaine group had an earlier onset of sensory block (11.90±4.10 minutes *vs* 23.70±8.65 minutes, p = 0.000), slower sensory block regression (48.73±9.32 minutes *vs* 24.88±4.21 minutes, p = 0.000), but delayed home readiness (47.23±15.93 minutes *vs* 29.88±8.58 minutes, p = 0.000), than patients in the Ropivacaine group. The pain scores during, immediately after and 30 minutes post-biopsy were lower in the Bupivacaine group: p = 0.010, p = 0.028 and p = 0.023 respectively. The time to first analgesic request was also longer in the Bupivacaine group (48.73±9.33 minutes) than for those in the Ropivacaine group (24.88±4.21 minutes) with statistical significance (p = 0.000).
Conclusion: Intraoperative analgesic properties were better in the Bupivacaine group than in the Ropivacaine group. However, home readiness was earlier in the Ropivacaine group.

Keywords: Analgesia, Bupivacaine, Pain assessment, Ropivacaine, Saddle block, Transrectal Prostate biopsy.

Introduction

Prostatic disease is one of the most common pathologies in men, with about 700,000 patients diagnosed with prostate cancer worldwide each

year. [1] Prostate biopsy is usually required to make a histologic diagnosis of prostate pathologies, including prostate cancer, benign prostatic hyperplasia, and chronic prostatitis.
Pain and discomfort remain a challenge during a prostate biopsy, with 65% to 90% of patients experiencing moderate to severe pain during the prostatic biopsy. [2] With this trend, anaesthesia for prostate biopsy is an important consideration, especially when taking more biopsy cores which will inflict more pain on the patients. Anaesthesia during a prostatic biopsy is currently considered mandatory, and performing the procedure without anaesthesia is considered malpractice. [3] Various methods of providing anaesthesia to alleviate pain and discomfort during the procedure include intrarectal lubricant agents (IRLA), periprostatic nerve blocks (PPNB), intraprostatic anaesthesia (I.P.A.), pelvic plexus blocks (PPB), caudal blocks (C.B.), pudendal nerve blocks (P.N.B.), use of non-steroidal anti-inflammatory drugs, tramadol, sedation with propofol, midazolam, nitrous oxide and recently, saddle block. [1] However, there is presently no consensus as to which of the methods is the best. [1] Caudal block has been used and has a high failure rate in adults (25% to 38%). [4] A prostatic biopsy is usually done as a day case procedure, and to ensure accelerated home readiness, local anaesthetics with fewer side effects must be used. [5]

Regional anaesthesia has been advocated as an ideal anaesthetic for ambulatory surgery, and this can be achieved with selective spinal anaesthesia. The concept of low dose selective spinal anaesthesia affords rapid recovery from anaesthesia, which is the focus of the present study. [6] The saddle block is low spinal anaesthesia that provides a segmental block for the perineum that selectively blocks the last four sacral spinal segments. [7]

A conventional dose of a long-acting local anaesthetic agent such as bupivacaine is not suitable for ambulatory anaesthesia because of the long duration and dense motor block that it provides. Using a low dose in the form of saddle block may allow surgical anaesthesia lasting just for the duration of the surgical procedure and, therefore, emergence and early ambulation. [8] Ropivacaine has consistently demonstrated an improved safety profile over bupivacaine as it has a lesser central nervous system and cardiac toxicity potentials than bupivacaine. [9] Therefore, this study aimed to compare the analgesic efficacy of 0.375% ropivacaine and 0.25% bupivacaine for transrectal prostatic biopsy under saddle block anaesthesia in an ambulatory setting.

Methods

Study design
The study was a prospective, randomised, double-blinded study for patients undergoing prostatic biopsy at the day-case theatre of the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife. Patients in the American Society of Anesthesiologists (A.S.A.) physical status I, II or III aged 45 to 75 years were included.
The sample size was determined using the formula for comparison of means between two groups [10]. The standard deviation for the duration of sensory blockade with ropivacaine was 44 minutes from a previous study by Gautier *et al*. [13]. With a margin error of 5%, power of 80% and 10% attrition, the total sample size was 80.

Patients who met the inclusion criteria were evaluated at the pre-anaesthetic clinic a week before the day of surgery. All the patients were trained on the use of the Visual Analogue Scale (VAS) for pain assessment. The patients were randomised into two groups (R and B) consisting of 40 patients in each group using a computer-generated set of random numbers. Each patient picked a numbered envelope sequentially in

blocks of ten and handed it over to one of the investigators. This investigator opened the opaque envelope to identify the patient's group and prepare the drug according to the group inside each envelope. This scheduled drug was handed over to the principal investigator (B.J.O.), who instituted the block. The investigator was blinded and did not know the groups until the end of the study, when this was disclosed by the statistician who prepared the randomisation sequence. Another investigator (O.S.O.), unaware of the grouping, assessed analgesic efficacy and side effect profile.

In the theatre, baseline vital signs including the pulse rate, blood pressure, respiratory rate, peripheral oxygen saturation, E.C.G. monitoring and temperature measurement were recorded. Intravenous access was instituted with a size 18G cannula, and all patients were preloaded with 10 ml/kg of normal saline. Patients were then placed in the sitting position with the back flexed and with both feet on a stool. Under aseptic technique, the L_4 / L_5 intervertebral space was identified and infiltrated with 1ml of 2% lignocaine. A 25 G Whitacre spinal needle was passed through an introducer with the side hole directed caudally. Correct placement of the needle was ascertained by a free flow of the cerebrospinal fluid after withdrawal of the stylet. Group R received 1ml of 0.375% ropivacaine, while Group B received 1ml of 0.25% hyperbaric bupivacaine. The spinal needle, together with the introducer, was removed and the site of injection dressed appropriately.

The patient was kept in the sitting position for five to seven minutes to enable the local anaesthetic to gravitate down and block the saddle area before positioning the patient supine. The level of sensory blockade was tested using loss of sensation to temperature with a cold cotton wool swab. A block-level of S2 to S5 was considered adequate for surgery. Motor block was assessed using the modified Bromage score. The onset of motor block was taken as the time elapsing from intrathecal injection to time of inability to raise the lower limb on command (Bromage score of 4). After that, the patient was positioned in the left lateral decubitus position for biopsy. The time taken from intrathecal injection of local anaesthetics (ropivacaine or bupivacaine) to absence of response to cold cotton wool at S5 dermatome was taken as the time of onset of sensory block. The blood pressure was checked every three minutes for the first fifteen minutes and every five minutes until the end of the procedure.

Pain was assessed with the aid of visual analogue scale (VAS) before the commencement of the biopsy (P1), during biopsy puncture of the prostate (P2), immediately after biopsy (P3), 30 minutes after the procedure (P4) and every 30 minutes till discharge. The VAS was explained to the patient using an imaginary horizontal line from 0 to 10 cm in length. Other parameters assessed in each patient included: duration of sensory block (which was taken as time from onset of the block to regression to S5 dermatome), the duration of motor block (from the time of administration of local anaesthetic to the regression of motor block to modified Bromage score of 0), willingness to have a repeat biopsy if indicated, duration of entire procedure and number of biopsy specimens taken.

The patients' satisfaction with the level of pain control was measured using a 4-point Likert scale. Rescue analgesia was to be provided in the event of a failed or inadequate block with intravenous tramadol 0.5mg/kg. Relatives who were patient's escorts were asked to note the time of first analgesic requirement post-biopsy, which was used to calculate the mean duration of analgesic effect. The time of first micturition post-biopsy was also noted, and failure to pass urine one hour after the procedure was regarded as retention and such patients were catheterised. Home readiness was defined as when patients

could fulfil the following conditions: vital signs within 20% of the pre-anaesthetic value, the full return of sensations to S5, no motor block, ambulation without support, absence of nausea and vomiting, and absence of excessive bleeding. These variables were measured every 10 minutes till patients were discharged. All the patients were observed and for side effects for at least one hour in the Recovery Room before discharge.

Ethical approval informed consent.

Ethical clearance for the study was obtained from the Ethics and Research Committee of the Institution (protocol number ERC/2016/03/15) on 03 April 2017. Data collection was done from 04 April 2017 to 31 October 2017.

Exclusion criteria

Patients who declined participation and those who had chronic back pain, bleeding disorder, neurological deficit, known allergy to local anaesthetic drugs and those with contraindications to subarachnoid block were excluded from the study.

Data analysis

The data were analysed using the Statistical Package for Scientific Solutions (SPSS) software version 17.0 (SPSS Chicago, IL). The baseline characteristics of both arms of the study were compared using the Chi-Square test for categorical variables and Student's t-test for continuous variables such as pain score and vital signs. The results were presented using charts and tables. A p-value <0.05 was considered statistically significant.

Results

A total of eighty-five patients met the eligibility criteria, but 80 patients who consented were randomised into two groups: 40 patients in Group B and 40 patients in Group R.

Table I shows the demographic characteristics of the patients. There was no statistically significant difference in the mean age (p = 0.778), weight (p = 0.325) or BMI (p = 0.123) between the two groups. Table II shows the height of the sensory block achieved just before the commencement of the biopsy. The highest level of sensory block attained was the 10^{th} thoracic dermatome. Fifty per cent of patients in Group B had a higher level of sensory block (T10 and T11) than those in Group R. The heights of sensory blocks attained are as shown in Table II.

Table III shows the meantime to the onset of sensory block in Group B was 11.90±4.10 minutes while it was 23.70±8.65 minutes for Group R (p = 0.001). There was no motor block in either group. The mean time to sensory block regression to S_5 in Group B was 48.73±9.32 minutes compared to 24.88±4.21 minutes in Group R. There was a statistically significant difference between the two groups in terms of duration of sensory block regression to S_5 (p = 0.001). The mean time to the first analgesic requirement in Group B was 229.27±95.41 minutes compared to 120.45±105.88 minutes in Group R (p = 0.000).

The time to home readiness ranged from 30 minutes to 60 minutes in Group B with a mean and standard deviation of 47.23±15.93 minutes, while it ranged from 20 minutes to 45 minutes with a mean of 29.88±8.58 minutes in Group R (p = 0.002). All the patients in both groups had a baseline pain score (P_1) of zero. The range of pain scores at different time intervals (P_1+P_2 +P_3 +P4) in Group B was 0 to 2cm, while in Group R, the range was 0 to 4cm.Therefore, the intraoperative pain score (P2), immediately after biopsy (P3) and 30 minutes after biopsy (P4), were higher in Group R than in Group B with statistical significance (p = 0.010, 0.028, and 0.023, respectively) as shown in Table IV. The side effects observed in Group R included one case each of shivering and post-dural puncture headache while Group B recorded no side effects.

Table I: Demographic characteristics of the patients in the two groups

	Groups, n (%)			
Variables	**Bupivacaine (B) (n = 40)**	**Ropivacaine (R) (n = 40)**	**Total (n = 80)**	**p value**
Age in years				
45-54	1 (2.5)	2 (5.0)	3 (3.8)	
55-64	11 (27.5)	12 (30.0)	23 (28.8)	0.642
65-74	23 (57.5)	21 (52.5)	44 (55.0)	
≥75	5 (12.5)	5 (12.5)	10 (12.5)	
Mean ± S.D.	66.8±6.0	66.4±6.6	66.6±6.3	0.778*
Range	51-75	46-75	46-75	
Weight (Kg)				
Mean ± S.D.	68.08±9.8	70.80±14.40	NA	0.325
Range	48-92	46-101	46-101	
BMI (kg/m²)				
Underweight (<18.5)	0 (0.0)	1 (2.5)	1 (1.3)	
Normal weight (18.5-24.9)	22 (55.0)	18 (45.0)	40 (50.0)	0.123
Overweight (25.0-29.9)	15 (37.5)	11 (27.5)	26 (32.5)	0.423*
Obese (≥30.0)	3 (7.5)	10 (25.0)	13 (16.3)	
Mean ± SD	25.18±3.66	25.99±5.12	25.58±4.44	
Range	19.2-37.3	18.0-36.7	18.0-37.3	
Duration of procedure(minutes)	22.48±7.38	23.13±10.49	-2.786	0.520

SD- Standard Deviation

Table II: Height of sensory block at the onset of biopsy

Sensory block	*Group B*	*Group R*
	n=40(%)	**n=40(%)**
T10	**0 (0.0)**	**6 (15.0)**
T11	**0 (0.0)**	**14 (35.0)**
T12	**11 (27.5)**	**18 (45.0)**
L1	**14 (35.0)**	**2 (5.0)**
L2	**15 (37.5)**	**0 (0.0)**
L3	**0 (0.0)**	**0 (0.0)**

Figure 1 shows the patients' satisfaction with analgesia. There was no report of dissatisfaction, but a higher percentage of the patients in Group B were very satisfied (29; 36%) than those in Group R (18; 22.5%).

Discussion

This study demonstrated that 0.25% of bupivacaine has better analgesic properties compared to 0.375% ropivacaine in patients requiring prostate biopsy under saddle block as a day-case procedure. The onset of sensory block was faster with bupivacaine than ropivacaine. This can be explained by the higher

lipid solubility of bupivacaine compared to ropivacaine. The onset time of conduction block is directly correlated with the lipid solubility of local anaesthetic. [12] Bhat and colleagues [13] compared equipotent doses of isobaric bupivacaine and ropivacaine for a subarachnoid block in left lateral position at L3/L4 in patients requiring lower limb surgeries using 0.75% isobaric ropivacaine with 0.5% isobaric bupivacaine.

Table III: Block parameters and home readiness in the two groups

Parameters	*Group B (n = 40)*	*Group R (n = 40)*	*t*	*p value*
	Mean ± S.D.	Mean ± S.D.		
Time of onset of sensory block (min)	11.90±4.10	23.70±8.65	-7.796	0.001
Time to sensory block regression to S5 (min)	48.73±9.32	24.88±4.21	14.75	0.001
Time to first analgesic request(min)	229.27±95.41	120.45±105.88	4.83	0.000
Home readiness(min)	47.23±15.93	29.88±8.58	6.07	0.002

Table IV: Mean pain scores in the two groups at different periods

Parameters	**Group B (n = 40) Mean ± SD (Range)**	**Group R (n = 40) Mean ± SD (Range)**	**t**	**p value**
P1	0.00±0.00 (0-0)	0.00±0.00 (0-0)	N.A.	NA
P2	0.53±1.4 (0-1)	0.75±0.27 (0-4)	-2.657	0.010
P3	0.10±0.30 (0-1)	0.48±1.01 (0-4)	-2.244	0.028
P4	0.15±0.43 (0-2)	0.53±0.93 (0-3)	-2.311	0.023

SD – Standard Deviation. P1= Pain score before biopsy, P2 = Pain score during biopsy, P3 = Pain score immediately after biopsy, P4 = Pain score before home discharge.

They found that ropivacaine had a faster onset of the sensory block than isobaric bupivacaine, which is different from what was found in the present study. This may be due to various factors such as volume of distribution, baricity, caudal spread of heavy bupivacaine, L4/L5 level of saddle block and position used in the present study.

Sensory block regression in the present study was slower with bupivacaine than ropivacaine. The protein binding of local anaesthetic agents correlates with the duration of action and subsequent block regression. [14] Bupivacaine has a higher protein binding capacity than ropivacaine (95% *vs* 85%), which may explain its longer duration of action. Malinovsky *et al.* [15] and Dar *et al.* [16] also found a longer duration of the sensory block with hyperbaric spinal bupivacaine compared to ropivacaine. Delay in sensory block regression, while being an advantage in terms of duration of analgesia, may be a limitation where early discharge is preferred, such as in the ambulatory setting. Patients in the Ropivacaine group were discharged earlier than those in the Bupivacaine group in the present study.

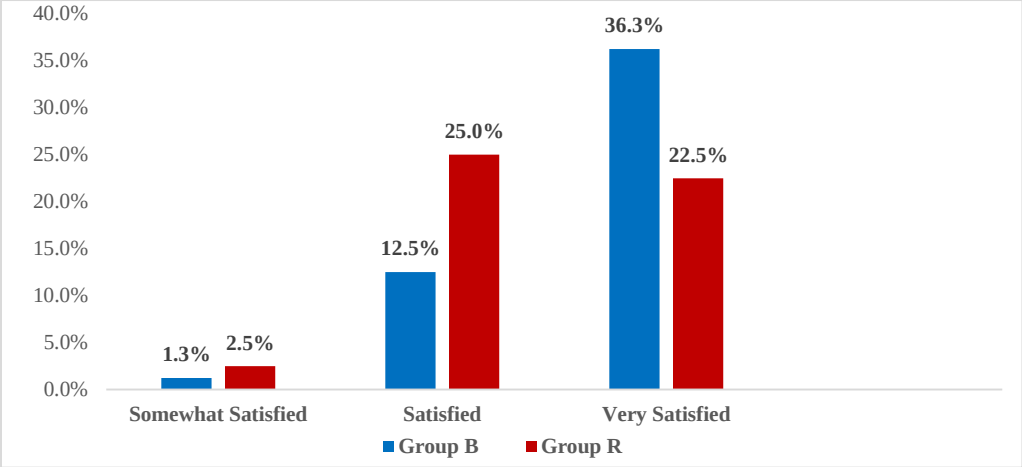

Figure 1: Patients satisfaction with the level of pain control/anaesthesia in the two groups

The pain scores were significantly lower in Group B during the biopsy, immediately post-biopsy, and 30 minutes after biopsy than in Group R. However, no patient required supplemental analgesia because of inadequate block in any of the groups, probably due to the short duration of the procedure. The short duration is a desirable feature in selecting cases suitable for ambulatory surgery. The higher pain scores in the Ropivacaine group at the stated times could mean that even at the equipotent dose ratio, ropivacaine is not as potent as bupivacaine. This is similar to the findings in the studies by Gautier [11] and Malinovsky. [15] These workers found that even at equipotent doses, bupivacaine provided better intraoperative and postoperative analgesia than ropivacaine. Ropivacaine is about two thirds as potent as bupivacaine. [16] This was considered in this study as the dose ratio of bupivacaine to ropivacaine used was 2:3.

Time to the first analgesic request was longer in patients in the Bupivacaine group compared to the Ropivacaine group. Bupivacaine has a longer duration of action as earlier alluded to Konda and others [17] compared 2ml (10mg) of 0.5% hyperbaric bupivacaine and 2mls of 0.75% (15mg) isobaric ropivacaine for spinal anaesthesia in patients scheduled for elective caesarean delivery. They found the time to the first analgesic requirement to be comparable in the two groups. The reason for this may be because higher doses were compared in their study. The use of a smaller dose of intrathecal bupivacaine has several advantages, such as reduced motor blockade duration, reduced incidence of side effects and reduction in discharge time. In the present study, there was no motor blockade in any of the patients. Obi and Nnodi [5] showed in their research that using a low dose of local anaesthetic will not result in a motor blockade. This is of importance in ambulatory settings. The development of motor block following subarachnoid block will delay discharge following ambulatory surgery.

The occurrence of side effects was minimal in the present study. There was only one case of shivering, which occurred in the Ropivacaine group. This low incidence may be because of the small dose of local anaesthetic used. Shivering is known to increase oxygen consumption, ventilation and cardiac output, resulting in increased morbidity in patients with limited cardiopulmonary reserve, such as may be found in the elderly population. [18] While shivering following subarachnoid block is a relatively

common complication, the incidence appears to be lower with saddle block. [19, 20] There was a case of post-dural puncture headache, which was managed conservatively. The low incidence of shivering recorded in this study is because most of the patients were elderly, and small gauge pencil-point needles (25G) were used. The overall incidence of post-dural puncture headache (PDPH) in a study by Phani and colleagues [21] was lower in patients above the age of 50 years compared with patients younger than 50 years.

The time to home readiness was significantly longer in Group B than Group R. Various scoring systems have been described for determining home readiness in ambulatory surgery. The modified Aldrete scoring system assesses patients' activity, respiration, circulation, consciousness, oxygen, and saturation. [22] It was found that even though there was no significant difference in the time to ambulate in the two groups, there was a significant difference in the time to home readiness. The faster home discharge in Group R might be due to the shorter duration of sensory block and faster regression to S_5. This is similar to the finding in the study conducted by Parekh *et al.* [23] comparing 0.75% isobaric ropivacaine with 0.5% isobaric bupivacaine spinal anaesthesia in elective inguinal hernia. It was found that patients in the Ropivacaine group achieved faster home discharge compared to those in the Bupivacaine group. The shorter duration of action of ropivacaine is useful in ambulatory surgery, especially for the early mobilisation of patients following a regional anaesthetic where early home discharge is highly desirable. Other authors [24, 25] also found that ropivacaine has a shorter sensory and motor blocks duration.

The Equipotency of ropivacaine with bupivacaine has been a subject of discussion. In their study on day-case arthroscopy, Gautier et al. [11] found that 8mg of bupivacaine was equipotent to 12mg of ropivacaine, and this dose ratio was replicated in this study. Malinovsky and others [15] in patients having urologic endoscopic surgery used the same dose ratio used by Gautier *et al.* [11] and found that intrathecal ropivacaine provided similar motor and haemodynamic effects to bupivacaine but less potent anaesthesia than bupivacaine. These are similar to the findings in the present study.

The saddle block used in this study still gave the same level of satisfaction with either bupivacaine or ropivacaine. However, the number that was very satisfied was higher in the Bupivacaine group than the Ropivacaine group. In the study by Obi and Nnodi, [5] all their patients were satisfied with the saddle block. However, theirs was not a comparative study as only bupivacaine was used. In another study done by Obi *et al.* [19], patients in the saddle block group expressed better satisfaction than patients with a peri-prostatic nerve block for prostatic biopsy. It was asserted that the technique of anaesthesia might be one of the determinants of patient satisfaction.

Limitation of the study

Different urologists performed the biopsies with varying levels of experience. This may have given room for individual variation in the amount of pain felt by the patients and the duration of the procedure.

Conclusion

Saddle block with an equal volume of 0.25% Bupivacaine provided better intraoperative analgesic properties than 0.375% Ropivacaine in terms of sensory block, prolonged first analgesic requirement, pain scores and level of satisfaction. However, ropivacaine may be preferable in the ambulatory setting on account of its short duration of action.

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Authors' Contributions: B.J.O., FAF, and S.A.A. conceived and designed the study. B.J.O., O.S.O. and FAF did data analysis and interpretation. O.S.O., FAF and S.A.A. drafted the manuscript. All the authors reviewed the draft for sound intellectual content. All the authors approved the final version of the manuscript.

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