

Caudal and Peri-Anal Nerve Block during Finger-Guided Transrectal Prostate Biopsy: A Randomized Single Blind Study

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Abstract

Background: Several studies have demonstrated the efficacy of caudal block in prostate biopsy but none has shown the efficacy of peri-anal nerve block. We aimed to compare the efficacy and tolerability of caudal and peri-anal nerve block in finger-guided prostate biopsy.

Methods and materials: Patients undergoing prostate biopsy were randomised by single blinding into 2 groups. Group 1 were biopsy done under caudal block (20 ml of 1% lignocaine with adrenaline) and Group 2 were those done under peri-anal nerve block (20 ml of 1% lignocaine with adrenaline). Visual analogue pain measurement was used to assess the pains of the patient at different stages of the procedure. Cooperativeness was assessed by a trained observer and graded accordingly.

Results: The groups were comparable in clinical details as demonstrated in age, BMI, duration of procedure and patients cooperativeness, $P > 0.05$. Middle aged men had worse post procedure pain in group 2, $p = 0.032$. Pain perception during biopsy was not significantly different in the two groups ($P > 0.05$). We did not observe any statistically significant difference when level of cooperativeness was cross tabulated with the anaesthetic techniques ($P = 0.976$). Cancer detection rate was 58.7% and 55.6% for caudal and perianal block respectively. Intercurrences suggestive of increased morbidity associated with the techniques were not observed.

Conclusions: The use of 20 ml of 1% Lignocaine with adrenaline for perianal block was capable of reducing the discomfort and pain associated with prostate biopsy and was quite compatible with the caudal protocol.

Keywords: Comparison; Caudal and Peri-anal block; Efficacy and tolerability; Finger-guided biopsy

Introduction

Prostate biopsy is the gold standard for establishing the diagnosis of prostate cancer. The biopsy can be done through trans-rectal ultrasound guided (TRUS) or digitally-guided method [1,2].

Prostate biopsy is mostly an office procedure that was previously performed without any form of anaesthesia because it was once believed to be mildly uncomfortable [3]. However, several studies have recorded significant amount of pain during the procedure [4]. Even the experience of little or no pains was recorded in centres with Trans-rectal Ultrasound (TRUS) guided biopsy facility. It is doubtful that significant pains would not attend finger-guided prostate needle biopsy (FGPNB). Nonetheless, there is paucity of data from centres practising only FGPNB.

Furthermore, due to neglect of the health sectors, most centres in the developing countries have no access to TRUS biopsy facilities. These centres depend mostly on FGPNB to make diagnosis. Pain has become an issue with most patients declining the offer of biopsy. When patient agrees to biopsy, Physicians struggle with patient to have the procedure completed or adequate sample taken.

In addition, common access to prostate is through the anal canal and rectum which are surrounded by sphincter muscles that have sensory innervations making the approach quite painful and thus rendering the procedure intolerable. The pain is mostly from the manipulation in the anal canal and rectum especially during FGPNB and the needle puncture in any method [5-9].

Currently, there is no universally accepted method of anaesthesia for prostate biopsy as evidenced by the numerous methods that have

been tried and reported in the literatures [10,11]. Several studies have reported the efficacy of caudal anaesthesia in finger-guided biopsy but literatures on the efficacy of peri-anal nerve block are scanty. It is important to compare the efficacy and tolerability of peri-anal anaesthesia with caudal nerve block. This will enable the Physicians determine the better options for the finger-guided needle biopsy (FGPNB) or even in TRUS. The objective of this study was to compare the efficacy and tolerability of caudal block versus peri-anal nerve block in men undergoing prostate biopsy. To the best of our knowledge, this is the first randomized study in this country.

Patients and Methods

This is a prospective; Single blind randomized study of men who underwent prostate biopsy at the urology clinic of Ekiti State University Teaching Hospital, Ado-Ekiti, Nigeria.

Patients were randomized into 2 groups: Group 1- biopsy done under caudal block and Group 2-biopsy under peri-anal nerve block. The study was conducted from January, 2016 to August, 2017.

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Inclusion criteria

1. Patients aged 40 years & above, with serum PSA>10 ng/ml which is our practice with low risk patients.
2. Patients with suspicious digital rectal examination (DRE) with any level of PSA.

Exclusion criteria

Excluded from the study were patients with chronic pain of any etiology, men with neurological deficits resulting in decreased perineal or rectal sensation, and those with known allergy to lignocaine. In addition, patients with American Society of Anaesthesiologists (ASA) physical status>3, previous prostate biopsies, inflammatory bowel disease, anorectal fissure/fistula, active urinary tract infection, and those with bleeding disorder. Patients who were on non-steroidal anti-inflammatory drugs (NSAIDs) less than 8 days prior to biopsy were excluded because of tendency to develop uncontrolled rectal bleeding due to inhibition of platelet function through irreversible inhibition of cyclooxygenase (COX) activity.

Data Collection and Procedure

Antibiotic prophylaxis of intravenous 500 ml of 0.2 g ciprofloxacin was administered one hour before the procedure. No patient reacted to this drug.

Biopsy procedure

The choice of the anaesthesia by the patient was a single-blind procedure. The blinding was done by an independent observer using the code (L) for procedure done under perianal infiltration and (C) for caudal anaesthesia. The coding was sequentially numbered and enclosed in a sealed envelope deposited at the urology clinic. As soon as the patient met the inclusion criteria, he was allowed to pick one of the opaque envelopes and was allocated accordingly.

Patients under local infiltration of lignocaine

Patient was placed on a left lateral position while routine cleansing and draping done. Twenty millilitres [20 ml] of 1% xylocaine with adrenaline was withdrawn and infiltrated around the peri-anal region to block the pudendal nerve that supply the external sphincter muscle at the 3,6,9 and 12 o'clock using 23G gauge needle with 10 ml syringe. This led to the paralysis of the anal sphincter and allowed easy access to the prostate gland.

About 3 minutes to 5 minutes were allowed for the anaesthetic effect to take place and a size 14 gauge tru-cut (Disposable guillotine needle for coaxial soft tissue biopsy with semi-automatic action 14 G × 20 cm. VigeoS-1. Via Dell'Alpino, made in Italy) needle was guided into the site of the nodule or any chosen site [using the plastic tubing both as a carrier and guide for the tru-cut needle which was aided into the site by the lubricated left index and middle fingers] and the gun was shot to take the biopsy. The procedure was repeated at different sites until reasonable amount of tissue was taken. At least not less than six bites were taken and the tissue placed inside a formalin-contained specimen bottle for histological analysis.

Patients under caudal infiltration

The sacral region was aseptically cleaned with cetrimide and methylated spirit. The sacral hiatus was identified by palpating both sacral cornua and the dimple between the cornua. The skin over the sacral hiatus was infiltrated with 3-5 ml of 1% lidocaine using a small-

gauge needle. Lidocaine in a dose of 15-20s of 1% with adrenaline was deposited in the caudal space using a size 23 gauge needle. The needle was adjusted by slightly flattening it and advanced 1 to 2 cm into the caudal space following penetration of sacrococcygeal membrane. A feeling of a 'click' ('give') indicated penetration of the sacrococcygeal membrane. The syringe was aspirated before caudal injection to prevent inadvertent injection of lidocaine into blood vessels or subarachnoid space. The biopsy was taken as described under local infiltration of lignocaine.

Outcome measure

The following parameters were assessed; DCPB-during caudal or peri-anal nerve block, DIPFR-during introduction and presence of the finger in the rectum, DBP-during biopsy procedure, PP-30 minutes post procedure.

1. Pain score was assessed as DCPB; DIPFR; DBP; PP by using the visual analog scale (VAS) (done by the patient), where 0 represents no pain at all and 10 represents the worst pain ever felt. Visual analog scale is a method adopted to make some values numeric, which are unable to measure numerically (Figure 1). Two end definitions of the parameter to be evaluated are written on two ends of a 100 mm ruler and patient was asked to specify the point where his pain status was matched by making a dot on a ruler. The length of the distance from the site where no pain was present to the site where patient marked indicates pain of the patient.

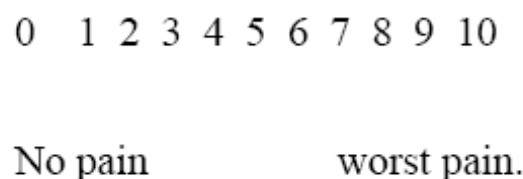


Figure 1: Visual analog scale.

2. Complications were documented immediately after the procedure and 1 week follow-up in the clinic.

3. Duration of the procedure (min) from induction of anaesthesia to completion of biopsy.

4. Patient's cooperativeness during the procedure was assessed as "very cooperative," "mildly cooperative," or "uncooperative". The number of body movements or groans signifying discomfort was used arbitrarily to determine the categories. The same trained staff nurse of the unit observed the patient and graded as follows: no movement at all=very cooperative, 1-2 movements=mildly cooperative, ≥ 3 movements=uncooperative 11.

All patients were observed for 2 hours or more, during which they were assessed for immediate complications. Patients without complication were discharged home to see in the next clinic day for review for presence or absence of delayed complications.

Ethical issue

Written consent was obtained from the patients after adequate information was given on the procedure, benefits and possible complications. The Institutional Review Board of Ekiti State University Teaching Hospital approved this study (approval number: EKSUTH/A67/2017/05/006).

Patient characteristics	Group 1	Group	t	P-value
Patient's population	51	49		
Mean age in years(SD)	73.22 ± 9.88	71.29 ± 11.02	0.923	0.358
Mean weight (SD)	58.77 ± 15.89	62.22 ± 8.66	-1.342	0.183
Mean height (SD)	1.622 ± 0.08	1.805 ± 0.93	-1.403	0.164
Mean duration of procedure	6.71 ± 1.27	7.42 ± 2.35	-1.892	0.061
Mean BMI (SD)	22.53 ± 5.89	22.30 ± 5.77	-0.405	0.686
Patient's cooperativeness			0.0001	0.972
Cooperative	50 (98.0%)	47(95.9%)		
Not cooperative	1(2.0%)	2(4.1%)		
Post procedure pain by age group				
<65 years –mean	0.889	1.692		
65 years and above(mean)	0.571	0.806		
Group 1			0.921	0.362
Group 2			2.208	0.032
Cancer detection rate			58.70%	55.60%
*Group 1: biopsy under caudal block; Group 2: biopsy under peri-anal nerve block.				

*Group 1: biopsy under caudal block; Group 2: biopsy under peri-anal nerve block.

Table 1: Patient's clinical details.

Stage of procedure	Groups	Population	Mean	SD	t	P	95%CI	
							Lower	Upper
DCPB	1	51	8.14	3.69	1.828	0.071	-0.12	2.84
	2	49	6.18	3.75				
DIPFR	1	51	2.33	2.18	-0.159	0.874	-1.01	0.85
	2	49	2.41	2.52				
PP	1	51	0.62	0.94	-1.838	0.069	-0.86	0.03
	2	49	1.04	1.29				
DOP	1	51	6.71	1.27	-1.892	0.061	-1.46	0.04
	2	49	7.42	2.35				
DBP	1	51	2.88	2.22	-0.222	0.825	-0.97	0.77
	2	49	2.98	2.16				

*DCPB: During Caudal & Peri-anal Block; *DIPFR: During Introduction and Presence of The Finger in the Rectum; *DBP: During Biopsy Procedure; *PP: 30min-1hour post procedure; *DOP: Duration of Procedure. CI: Confidence Interval.

Table 2: Comparison of pain level at different stages of the procedure in the two groups.

Diagnosis	Caudal	Perianal	Total	%
BPH	5(32.6%)	17(31.5%)	32	32
PIN	2(4.4%)	3(5.6%)	5	5
CAP	27 (58.7%)	30 (55.6%)	57	57
Insufficient Sample	2	4	6	6
TOTAL	46	54	100	100
% Biopsied	46	54	100	100

*BPH: Benign Prostatic Hyperplasia; PIN: Prostatic Intraepithelia Neoplasia; CAP: Cancer of the Prostate

Table 3: Histological analysis of biopsy samples.

Statistical Analysis

Data were statistically analyzed using Statistical Package for the Social Sciences version 21 (SPSS Inc., Chicago, USA). Descriptive statistics were employed for continuous variables to determine mean ± standard deviation, and for categorical variables; Rates and percentages were used. Data were presented in tables and figure. Student's t-test was used to determine the differences in the means for continuous variables and chi-square test was employed for categorical data.

Results

Table 1 shows that the patients' clinical details were quite comparable in age, BMI, duration of procedure and patients' cooperativeness, $P > 0.05$. But there was a significant difference in the post procedure pain between group 2 with regards to the elderly and the middle age men. Middle aged men had worse post procedure pain, $p = 0.032$.

Table 2 shows that there was no significant different in the pain perception during the procedure, $P > 0.05$.

Table 3 shows the cancer detection rate in the caudal and perineal block as 58.7% and 55.6% respectively.

Discussion

The generally acceptable means of diagnosing prostate cancer is histological examination of the prostate gland [12]. This is done through sampling of the prostatic tissue. The methods of prostatic tissue sampling have undergone several modifications from the techniques of the early 1900s of transperineal open biopsy to the current method of using Transrectal ultrasound guided biopsy [13].

More importantly, the advent of multiple prostatic tissue sampling with its associated discomfort has not been adequately addressed.

Majority of the patients were said to have experienced discomfort and this discomfort was proportional to number of cores taken [4].

While local infiltration of anesthetic agents into the prostate has been described as well as caudal nerve block, efficacy of peri-anal infiltration of anesthetic agent for prostate biopsy has not been fully described [14].

We sought to compare the efficacy and tolerability of caudal block with peri-anal nerve block in prostate biopsy. The mean age in both groups was similar with no significant difference ($P=0.36$). This is similar to the report of Wang et al. where there was no mean age difference between their populations [14]. But, the mean age in this study was higher than that of Wang et al. [14]. However, it was similar to the mean age reported by Badmus et al. [15] in the study of the burden of prostate cancer in Nigeria. The prevalent age group was not mentioned by Wang et al in their environment.

Regarding the pain measurement, there was no difference in the two methods of anaesthesia used. This study has revealed that peri-anal nerve block is as effective as caudal block with no significant difference in the rate of cooperativeness and also in the duration of the procedure in both cases ($P>0.05$).

The peri-anal nerve block acted by blocking the somatic nerve endings that are sensory to pains in the anal canal and also the innervations of the external anal sphincter composed of skeletal muscle that is under voluntary control, and supplied by pudendal nerves (S2-S4) [16]. This mechanism of action is also similar to that of caudal block where sacrococcygeal nerves which innervate the whole perineum involving the perianal region, rectum and prostate gland were also blocked [17-19].

This study findings were in agreement with those reported by some authors that caudal block could significantly reduce the level of pains during biopsy [18,19]. It is also consistent with the findings of Wang et al. that caudal block provides better anaesthesia than periprostatic nerve block plus intrarectal local anaesthesia for TRUS guided prostate biopsy without an increase of side effects [14]. Our study has established that peri-anal block could produce similar result to caudal block. Cancer detection rate was 58.7% and 55.6% in caudal and perianal block respectively (ratio 1:1). It therefore implies that peri-anal nerve block might be useful not only for FGPNB but also TRUS biopsy. Intercurrences suggestive of increased morbidity associated with the techniques evaluated, such as rectal bleeding, hematuria, or hematospermia, non-scheduled hospitalization, or infectious complications, were not observed.

Furthermore, this study was also consistent with report of Nystrom et al who used local perianal block for anal surgery and found it effective as sole method of anaesthesia for proctological operations [20]. Despite the efficacy of caudal block, perianal nerve block was much easier to administer and equally efficacious going by lack of significant difference in the mean duration of biopsy procedure ($P=0.64$). Moreover, the problem of complete closure of sacral hiatus [21] reported in some cases in caudal nerve block was not encountered in peri-anal nerve block.

Conclusion

It was concluded from the above that peri-anal nerve block was efficacious for finger guided prostatic biopsy and also well tolerated by men who underwent prostate biopsy. The ease of administration was superior in peri-anal than caudal block for prostate biopsy.

Recommendation

Therefore, we recommend that prostate biopsy should be done using perianal block for effectiveness and easy tolerability in FGPNB.

Limitations to This Study

This study was not designed to perform a sub-analysis as specific assessment of VAS scores based on age and prostate volume.

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