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Original Article

Transrectal ultrasound guided prostate biopsy in university of Benin teaching hospital: effect of prostate volume on pain amongst Nigerian patients

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Abstract: Prostate volume has been reported to have an effect on the severity of pain during prostate biopsy. This study assessed the effect of prostate volume on pain during TRUS guided prostate biopsy when apical peri-prostatic block is compared with intra-rectal xylocaine gel. This was a prospective randomized study which involved 90 patients. Group (A) had 2% intra-rectal plain xylocaine gel instillation, while Group (B) had peri-prostatic block with 1% plain xylocaine infiltration. Both groups were further stratified into prostate volume of < 50 mls and ≥50 mls. An 11 point visual analogue scale was used to assess pain during probe insertion, biopsy and 1 hour after biopsy. The mean pain score analyzed for each group. The mean pain score for Group (A) patients with prostate volume < 50 mls was 3.22.2, 7.31.7 and 2.11.4 during probe insertion, biopsy, and one hour after biopsy respectively. For Group (A) patients with prostate volume ≥50 mls, the mean pain score recorded was 2.81.8, 5.71.6, and 2.31.8 during probe insertion, biopsy and one hour after biopsy respectively (P{during biopsy} = 0.003). For Group B patients, the mean pain score during probe insertion, biopsy and one hour after biopsy for patients with prostate volume < 50 mls was 3.11.8, 2.81.7, 1.00.6 respectively. While for patients with prostate volumes ≥50 mls, the mean pain scores were 2.91.8, 3.21.8 and 1.30.9 respectively. This study revealed that prostate volume did not affect the severity of pain during prostate biopsy when apical peri-prostatic block was used as the anesthetic agent. Significantly reduced pain during trans-rectal ultrasound guided biopsy of the prostate for all prostate volumes. Intra-rectal xylocaine though inferior to peri-prostatic block was more effective for patients with prostate volume ≥50 mls.

Keywords: Anesthesia, pain, pain score, peri-prostatic nerve block, prostate biopsy, prostate cancer

Introduction

Prostate cancer is one of the most frequently diagnosed cancers in men, with about 700,000 new cases worldwide each year [1]. Trans-rectal ultrasound (TRUS) guided prostate biopsy is the accepted gold standard for diagnosing prostate cancer [2-4]. It is the most commonly performed invasive urologic procedure [5]. In the United States it is estimated that 1 million prostate biopsies are carried out annually by Urologist [6, 7]. Prostate biopsy is generally considered a minor procedure, however, studies have reported that about 65-90% of patients complain of discomfort or pain [8, 9]. About 20% of patients refuse prostate biopsy due to pain [10, 11]. The causes of pain during TRUS-Guided biopsy include placement of the probe into the anal canal, movement of the probe within the rectum and needle penetration of the prostatic capsule [12, 13].

Investigators differ in their opinion with regards to the effect of prostate volume on pain associated with TRUS-Guided biopsy of the prostate. A retrospective study of 568 patients that had TRUS-Guided biopsy of the prostate in a Chinese tertiary center revealed that basal peri-prostatic nerve block was inefficient for large prostate volume with regards to its analgesic effect, it was however found to be superior to intra rectal xylocaine for the procedure [14]. This implies that patients with large prostate volume tend to have more pain during the procedure and thus, will require superior anesthesia. This was also the finding of a prospective randomized study among Koreans. In that study, the relationship between pain and pros-

tate volume during trans-rectal ultrasound guided prostate biopsy was assessed among 71 patients. The study revealed that prostate volume is directly related to the patient's degree of pain during TRUS guided prostate biopsy. They concluded that patients with larger prostate volumes tend to feel more pain during and after TRUS guided prostate biopsy [15].

However the outcome of studies by some authors indicates that larger prostate volume is not associated with increased pain during the procedure [16, 17].

This study aims to assess the effects of prostate volume on pain during TRUS guided prostate biopsy when apical peri-prostatic block is used. This will aid appropriate decision with regards to choice of anaesthesia when carrying out prostate biopsy amongst Nigerian males and also asses the efficacy of apical peri-prostatic block for various prostate volumes in this category of patients.

Materials and methods

Study design

This is a prospective randomized study carried out over one year. It involved consecutive patients presenting at the outpatient urology clinic of University of Benin Teaching Hospital Edo State. Patients were randomized into two groups. Group A: Intra-rectal xylocaine gel group (I-X) and Group B: Peri-prostatic block group (P-P). It was a double blind study; both the researchers and patients were blinded to the groups and measurement of outcome measures.

Inclusion and exclusion criteria

Inclusion criteria included patients with elevated prostate specific antigen (PSA) level and abnormal digital rectal examination. Exclusion criteria included patients with painful anorectal conditions, bleeding diathesis, strictures and allergy to local anesthetic.

Methods

Apical infiltration of 10 mls of 1% xylocaine (5 mls on each side) was carried out under Trans-rectal ultrasound guidance using a 7 inch, 22 gauge spinal needle for Group A. Group B patients had 10 mls of intra-rectal instillation of xylocaine gel before insertion of ultrasound probe.

Prostate volume was measured before commencement of needle biopsy. Patients were further stratified using prostate volume cut off of < 50 mls and ≥ 50 mls in both groups.

Pain during insertion of probe and capsular penetration was assessed immediately after biopsy using an 11 point visual analogue scale (0 = no pain; 10 = most severe pain). Pain after an hour was also recorded before discharge. Patients were followed up in out-patient clinic for 1 month to assess for complications.

Data collection and statistical analysis

Data was collected using a researcher administered proforma and analysed using statistical package for social sciences (SPSS) version 21.0. Results were expressed as mean and using figures and tables. Test of association was done using student t-test. Level of significance was set at $P < 0.05$.

Ethical approval was obtained from the institution ethics committee. Written informed consent was also obtained from patients who participated in this study.

Results

Patient demographics

The mean age of the entire study population was 68.6 ± 9.2 years. Patients in Xylocaine group were slightly younger (66.5 ± 8.7 years) than those in P-P block group (70.8 ± 9.3 years). Most of the patients in both groups {95.6% (I-X group) and 97.8% (P-P group)} were above 50 years of age. The mean (sd) PSA value for intra-rectal xylocaine group (I-X) was 54.0 ± 39.7 ng/ml while for P-P block group was 50.0 ± 53.6 ng/ml. This difference was not statistically significant ($P = 0.916$) (**Table 1**).

Patient clinical characteristics

Lower Urinary Tract Symptoms (LUTS) were the most common clinical feature among both intra rectal xylocaine (I-X) (97.8%) and peri prostatic (P-P) block (100.0%) study groups. The median (range) duration of symptoms was 36.0 (1-410) months in the intra rectal xylocaine (I-X) group and 24.0 (3-468) months in the peri prostatic

Table 1. Age of study population

Variable	Frequency (%)		Test statistic	*p*-value
	Xylocaine (n = 45)	P-P block (n = 45)		
Age group				
40-49	2 (4.4)	1 (2.2)	Fishers' exact = 5.337	0.251
50-59	5 (11.1)	1 (2.2)		
60-69	20 (44.4)	18 (40.0)		
70-79	15 (33.3)	17 (37.8)		
≥ 80	3 (6.7)	8 (17.8)		
Mean (sd) age	66.5 ± 8.7 (years)	70.8 ± 9.3 (years)	t = -2.270	0.026

Table 2. Clinical characteristics of study population

Variable	Frequency (%)		Test statistic	*p*-value
	Xylocaine (n = 45)	P-P block (n = 45)		
Presenting symptoms				
LUTS	44 (97.8)	45 (100.0)	Fishers exact = 1.011	1.000
LUTS + ED	1 (2.2)	0 (0.0)		
Median (range) duration of symptoms	36.0 (1, 410) months	24.0 (3, 468) months		0.735*
Catheter in-situ				
Yes	20 (44.4)	11 (24.4)	χ^2 = 3.986	0.046
No	25 (55.6)	34 (75.6)		
Median (range) duration of catheter in-situ	2 (1, 24) months	4.5 (1, 12) months		0.076*
Indication for biopsy				
Abnormal DRE	5 (11.1)	8 (17.8)	χ^2 = 1.329	0.520
Elevated PSA	10 (22.2)	12 (26.6)		
Both	30 (66.7)	25 (55.6)		
Mean ± sd QOL	4.27 ± 1.08	4.46 ± 1.10	t = -0.655	0.515

*Mann-Whitney U test.

(P-P) block study group. This difference was not statistically significant. Catheter was in-situ in 44.4% of patients in the intra rectal xylocaine (I-X) group and 24.4% in the peri prostatic (P-P) block study group. This difference was statistically significant (P = 0.046). Thirty (66.7%) patients in intra rectal xylocaine (I-X) group and 25 (55.6%) in peri prostatic (P-P) block group were referred for biopsy based on both elevated PSA results and abnormal digital rectal examination findings (P = 0.515). Mean Quality of Life scores (QOL) of patients were higher among patients in the peri prostatic block (P-P) group (4.46 ± 1.10) compared to intra rectal xylocaine (I-X) group (4.27 ± 1.08). This was however not statistically significant (P = 0.515) (**Table 2**).

Prostate volume of study population

The number of people with prostate volumes below and above 50 mls was similar between the two groups (P = 0.582). The mean (sd) prostate volume for intra-rectal xylocaine group (I-X) were 74.4 ± 48.3 mls while for peri-prostatic group (P-P) was 75.4 ± 40.4 mls. The difference was not statistically significant (P = 0.916) (**Table 3**).

Pain score and prostate volume with intra-rectal xylocaine gel group (Group A)

There was no statistically significant difference in the mean pain score during probe insertion between patients with < 50 mls and ≥ 50 mls prostate volume in Group A (P = 0.552).

There was a statistically significant difference in the mean pain score during biopsy between patients with < 50 mls and ≥ 50 mls prostate volume in Group A. The patients with less than 50 mls prostate volume had more pain (P = 0.003).

There was no statistically significant difference in the mean pain score post biopsy between

Table 3. Prostate volumes of study population

Prostate volume	Frequency (%)		Test statistic	*p*-value
	Group A (n = 45)	Group B (n = 45)		
< 50 mls	15 (33.3)	14 (31.1)	Fishers' exact = 1.300	0.582
≥ 50 mls	30 (66.7)	31 (68.9)		
Mean ± sd Prostate volume (mls)	74.4 ± 48.3	75.4 ± 40.4	t = -0.106	0.916

Table 4. Pain score and prostate volume within intra-rectal xylocaine gel group (group A)

Variable	Prostate volume		Test statistic	*p* value
	< 50 mls Mean ± sd	≥ 50 mls Mean ± sd		
Pain score during probe insertion	3.2 ± 2.2	2.8 ± 1.8	0.60	0.552
Pain score during biopsy	7.3 ± 1.7	5.7 ± 1.6	3.182	0.003
Pain score post biopsy	2.1 ± 1.4	2.3 ± 1.8	-0.369	0.714

Table 5. Pain score and prostate volume within peri-prostatic block group (group B)

Variable	Prostate volume		Test statistic	*p*-value
	< 50 mls Mean ± sd	≥ 50 mls Mean ± sd		
Pain score during probe insertion	3.1 ± 1.8	2.9 ± 1.8	0.348	0.729
Pain score during biopsy	2.8 ± 1.7	3.2 ± 1.8	-0.764	0.449
Pain score post biopsy	1.0 ± 0.6	1.3 ± 0.9	-0.942	0.351

Table 6. Prostate volume and mean visual analogue pain score during biopsy between xylocaine gel group (group a) and peri-prostatic block group (group B)

Variable Prostate volume	Pain during biopsy		Test statistic	*p* value
	Group A	Group B		
< 50 mls Mean ± sd	7.3 ± 1.7	2.8 ± 1.7	-7.123	P < 0.0001
≥ 50 mls Mean ± sd	5.7 ± 1.6	3.2 ± 1.8	-5.686	P < 0.0001

patients with < 50 mls and ≥ 50 mls prostate volume in Group A (P = 0.714) (**Table 4**).

Pain score and prostate volume with peripros-tatic block group (Group B)

There was no statistically significant difference in the mean pain score during probe insertion between patients with < 50 mls and ≥ 50 mls prostate volume in Group B (P = 0.729).

There was no statistically significant difference in the mean pain score during biopsy between patients with < 50 mls and ≥ 50 mls prostate Group B (P = 0.449).

There was no statistically significant difference in the mean pain score post biopsy between patients with < 50 mls and ≥ 50 mls prostate volume in Group B (P = 0.351) (**Table 5**).

Prostate volume and mean pain score between (Group A) and (Group B)

There was a statistically significant difference in the mean pain score during biopsy for patients with prostate volume of < 50 mls when xylocaine group and peri-prostatic group were compared. Patients that had peri-prostatic block experienced less pain during the procedure (P < 0.0001).

There was a statistically significant difference in the mean pain score during biopsy for patients with prostate volume of ≥ 50 mls when xylocaine group and peri-prostatic group were compared. Patients that had peri-prostatic block experienced less pain during the procedure (P < 0.0001) (**Table 6**).

Discussion

The main findings of this study are that prostate volume does not have any effect on pain during biopsy when apical peri-prostatic block was used and that intra-rectal xylocaine gel had more pain reduction effect on patients with high prostate volumes. The mean pain score for patients that had intra-rectal xylocaine gel was however, higher than that for apical peri-prostatic block, thus making it an inferior anaes-

thetic agent when compared to apical peri-prostatic block.

Mean pain score during TRUS guided biopsy was found not to be statistically significant between prostate volumes of < 50 mls and > 50 mls in the apical peri-prostatic block group. This is in keeping with a prospective study [16] carried out to identify risk factors of pain during prostate biopsy. Findings of the study revealed that prostate volume has no effect on pain during TRUS guided prostate biopsy. In contrast to this were the findings of a prospective randomized study [15] that reported increasing pain with larger prostate volume. This implies that apical peri-prostatic block gives effective anaesthesia for prostate biopsy irrespective of the prostate volume.

Trans-rectal ultrasound guided prostate biopsy among patients in the intra-rectal Xylocaine gel group of this study revealed increased pain with lesser prostate volume (P = 0.003).

This was similar to what was found in a study [18] that randomized patients into four groups of: "no anaesthesia", "periprostatic block", "xylocaine gel" and sedo-analgesia group (midazolam and fentanyl). The study revealed a negative correlation between pain and prostate volume across all anaesthesia groups which is similar to the findings in the xylocaine group in our study.

The use of intra-rectal xylocaine gel may be considered for patients with big prostate(prostate volume > 50 mls) though peri-prostatic block gave a better pain reduction during prostate biopsy and should always be prioritized in this category of patients.

Outcome of this study also showed that apical peri-prostatic block statistically significantly reduced pain during biopsy irrespective of the prostate volume. Patients had less painful procedure with peri-prostatic block than with xylocaine gel irrespective of prostate volume. This is in keeping with the outcome of the studies [19-21] that prospectively compared apical prostatic block and intra-rectal lidocaine for TRUS-guided prostate biopsy. Therefore prostate biopsy for Nigerian patients will be well tolerated irrespective of the prostate volumes if apical peri-prostatic block is adopted as the mode of anesthesia.

The effect of age was also evaluated and shown not to have any impact on the outcome of this study as previous studies [19, 22], have shown that younger patients are more susceptible to pain due to low anorectal compliance as a result of higher sphincter tone. Conversely, in this study there was a statistically significant difference in age between periprostatic block group and intrarectal xylocaine instillation group, with periprostatic block group being younger P = 0.026, however, the periprostatic block group had less pain during biopsy (P = 0.003).

In conclusion, prostate volume had no effect on pain during prostate biopsy when apical peri-prostatic block is used. Apical peri-prostatic block achieved better pain control than xylocaine gel during prostate biopsy irrespective of prostate volume. Intra-rectal xylocaine gel may be considered for patients with large prostate when apical peri-prostatic block is not feasible.

Disclosure of conflict of interest

None.

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