Original Article

# Comparison of the Analgesic Effects of Intrarectal 2% and 5% Lidocaine Gel in Adult Nigerian Men Undergoing Transrectal Prostate Biopsy

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ABSTRACT

**Background:** Prostate biopsy is a painful procedure. There is no generally accepted consensus among urologists on choice of analgesia. **Aim:** This study aims to compare the use of 2% lidocaine gel and 5% lidocaine gel on pain control in patients undergoing transrectal prostate biopsy. **Methods:** This was a prospective randomized study comparing the use of 2% and 5% lidocaine gel for anesthesia during prostate biopsy. Sixty-eight patients were enrolled into the study. Using a simple random sampling technique, the patients were divided into two groups. Group A (34) patients had 2% lidocaine gel, while Group B (34) patients had 5% lidocaine gel instilled before transrectal prostate biopsy. Pain assessment was made at finger insertion, during core-needle prostate puncture, and postoperatively at 5, 10, 30, and 60 minutes for each patient using the visual analog scale. **Results:** The two groups of patients had similar intra-operative pain control during finger insertion and at needle puncture. The mean VAS of the 2% group was 1.32 (SD ± 1.15), while those in the 5% group, it was 1.26 (SD ± 1.05), $P = 0.826$. The assessment for pain control at 5, 10, 30, and 60 minutes of the two groups using the mixed design repeated measures analysis of variance (ANOVA) showed that 5% group maintained a significantly better postoperative pain control at the different times $F = (1,66)$, $P < 0.001$. **Conclusion:** A total of 5% lidocaine gel provides better overall postoperative analgesia compared to 2% lidocaine gel for pain control during and after digitally guided prostrate biopsy in the long term.

**KEYWORDS:** *Lidocaine gel, prostate biopsy, prostate cancer, transrectal, visual analog scale*

## INTRODUCTION

Prostate cancer (PCa) represents a major global public health problem resulting in significant morbidity and mortality. In Nigeria, prostate cancer accounts for about 29.8% of new cases of cancer among men, making it the most common cancer in Nigerian men and the most common cause of cancer-related deaths in men.[1]

Suspicion of prostate cancer is based on abnormal digital rectal examination (DRE) findings and/or due to elevated serum PSA levels. A prostate biopsy is performed to further investigate these abnormalities and to ascertain the histological diagnosis as well as for prognostication.

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A prostate biopsy can be performed using ultrasound-guided or digitally guided transrectal approach. Transrectal ultrasound-guided prostate biopsy (TRUS) is the standard of care, but in resource-poor settings like ours where few ultrasound machines are available for large volumes of hospital patients, digital-guided biopsies are still common

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urological practice in third world countries like Nigeria.

The complications related to prostate biopsy are infrequent but range from minor to life-threatening conditions.[2] Pain is one complication of prostate biopsy that can occur during and immediately after the procedure and has a significant impact on the acceptance or refusal of the procedure. The pain associated with prostate biopsy may arise during the insertion of the finger and during multiple punctures with the biopsy needle.

Attempts to mitigate pain have evaluated several methods.[3] These methods have varying efficacy. There is currently no consensus among urologists on the best choice of anesthesia to use. There is a need for more research in this field to obtain cheap, reliable, and efficient analgesia for the procedure, especially in the setting of limited resources, long patient waiting time and limited manpower. This study aims to compare the efficacy of 2% lidocaine gel and 5% lidocaine gel for pain control in patients undergoing digitally guided transrectal prostate biopsy.

## Methods

This prospective, randomized, hospital based cross-sectional study of adult Nigerian men with suspected prostate cancer counseled for prostate biopsy was undertaken after approval from the University of Nigeria Teaching Hospital, Enugu (UNTH) Health Research Ethics Committee (vide approval number UNTH/CSA/329/VOL. 5, dated April 3, 2020) and was carried out by the principles of the Declaration of Helsinki, 2013. Written informed consent was obtained from the patient for participation in the study. The study was conducted between August 2020 and August 2021. The sample size was estimated using the formula for comparative study between two independent groups.[4] A sample size of 34 patients for each group was calculated at a value of 5% to detect PCa and precision of 80% on either side and an effect size of 1.64 using the previous study by Kim *et al*.,[5] as well as making up for 10% attritions. Therefore, a total sample size of 68 subjects was used for this study. Convenience sampling was used to select the patients.

The inclusion criteria were all patients with abnormal DRE findings (e.g., hard prostate, loss of mobility of rectal mucosa over the prostate gland, and/or a nodular gland), elevated serum PSA above 4 ng/mL, or abnormal prostate findings on prostate ultrasound. Those with prostatitis, urinary tract infection, anal fissure, hemorrhoids, dementia, a history of allergy to lidocaine, bisacodyl suppositories, and patients with allergy to levofloxacin and metronidazole and those who required additional forms of analgesia to complete the procedure were excluded from the study.

Patients with lower urinary tract symptoms suspected to be due to prostate disease were evaluated with a medical history and physical examination, including a DRE. Laboratory investigations included an assessment for renal function, abdomino-pelvic ultrasound scan, and a serum PSA test. Patients who met the inclusion criteria were then counseled for prostate biopsy after obtaining a written informed consent. Patients were then randomized into two groups by a simple random technique. Group A received 2% lidocaine gel, while Group B received 5% lidocaine gel. Both patient and the pain assessor (anesthetist) were blinded to the type of anesthetic used.

After a minimal bowel preparation, a night before the procedure with bisacodyl (Ducolax) suppository, which was self-administered by the patient, on the morning of the procedure, each patient received prophylactic antibiotics (Intravenous ceftriaxone 1 g and 500 mg metronidazole) before the procedure. For patients in Group A, 10 mL of 2% lidocaine gel in a 10 mL syringe was instilled into the rectum using a short nozzle provided in the pack 5 minutes before the biopsy. The 2% lidocaine gel was presented as a 15 g tube of lignocaine hydrochloride (Barrett Hodgson Pakistan (PVT) Ltd. Batch number: B8467). For Group B patients, 10 mL of 5% lidocaine gel was used in the same manner as described above. The 5% lignocaine gel was of Uttaranchal Biotech Ltd. marketed by Neon Laboratories Ltd. Mumbai, India (Batch number: UN164045). After 5 minutes, an 18-gauge spring-loaded biopsy needle (Geotech semi-automatic spring loader with Batch number: GS1820 lot 0475211) was used to obtain 12 cores of tissues (6 cores from each lobe of the prostate – 3 cores from the most lateral part of each lobe and 3 from the parasagittal area of the same lobe) from the prostate for each patient using finger guide. At finger insertion into the rectum and during needle puncture of the rectal wall for the biopsy, the patients were asked to indicate the degree of pain on a scale which was then recorded by the anesthetist into a numeric value on the VAS. The scale ranged from 0 (no pain) to 10 (worse pain imaginable). Pain assessment was also repeated at 5, 10, 30, and 60 minutes after the procedure. No other analgesic was given. The strands of tissues obtained were preserved in 10% formalin in a universal bottle and sent for histology. Patient's vital signs were monitored throughout the procedure using the patient monitor. The primary outcome measure was the assessment of pain on VAS in patients undergoing transrectal prostate

biopsy. The secondary outcomes included assessment for complications with the use of lidocaine gel.

After the procedure, patients were observed for one hour in the recovery room before being allowed to go home upon achieving a Post-Anesthesia Care Unit (PACU) score of at least 8 out of 10. They were also advised to report to the emergency room or call the researcher in case of any complications related to the procedure. Oral antibiotics (Levofloxacin 500 mg daily and metronidazole 400 mg tds) was administered for 5 days post-procedure.

The data obtained from this study were analyzed using the Statistical Package for Social Sciences (SPSS) version 26 (Chicago, Illinois) and presented as texts, tables, and charts. Categorical variables were represented as frequencies and proportions, while continuous variables were represented as the means and standard deviations. The Chi-square test was used to analyze the relationship between categorical variables, while a mixed design repeated measure analysis of variance (ANOVA) was used to analyze the difference in intra-biopsy and post-biopsy pain assessment using VAS. All the analyses were two-tailed, and a *P* value of less than 0.05 was considered significant.

## Result

Sixty-eight adult male patients with features suggestive of prostate cancer were recruited into the study. The mean age of the participants in Group A was 67.82 years (SD ± 6.54), while the mean age of the patients in Group B was 67.12 years (SD ± 8.43). There was no significant difference in mean age between the two groups, $P = 0.701$.

The mean PSA value was 66.88 ng/mL in the study participants, while the mean prostatic size was 90.38 g (SD ± 86.21). Patients in the 2% lidocaine group had a significantly higher mean PSA value (99.74 ng/mL, SD ± 149.23) than those in the 5% group (34.02 ng/mL, SD ± 30.92), $P = 0.014$. Patients in the 2% group had a mean prostate size of 86.74 g (SD ± 97.45), while those in the 5% group, they had a mean prostate size of 94.10 g (SD = 74.62), $P = 0.731$.

The combination of abnormal DRE findings and an elevated PSA value accounted for the most common indication for prostate biopsy in the 2% group and 5% group, representing 61.80% and 64.70%, respectively, while those that had prostate biopsy due to an elevated PSA value only for group A and group B constituted 35.30% and 35.30%, respectively.

Table 1 shows the mean VAS score for both finger insertion and core-needle punctures of the prostate for the 2% lidocaine and 5% lidocaine groups. The intra-biopsy and post-biopsy VAS assessment showed that the two groups of patients had similar intra-operative pain control during the finger insertion and core-needle tissue sampling. The mean VAS score in the 2% group was 1.32 (SD ± 1.15), while those in the 5% group had a mean VAS score of 1.26 (SD ± 1.05), $P = 0.826$.

Table 2 shows the mean VAS scores for the two groups at 5, 10, 30, and 60 minutes. The 2% group had a higher mean VAS of 3.65, 3.41, 3.06, and 1.59 at 5,10, 30, and 60 minutes, while 5% group maintained lower scores of 0.62, 0.97, 1.00, and 0.21 at 5, 10, 30, and 60 minutes, respectively.

A mixed design repeated measures ANOVA showed that those in the 5% group had significantly better postoperative pain control at 5, 10, 30, and 60 minutes after the biopsy F (1, 66) 59.78, $P < 0.001$. No side effect was reported with the use of lignocaine gel in the two groups.

**Table 1: Distribution of mean VAS at finger insertion and mean VAS score during biopsy**

| | Mean VAS | SD | *P* |
|---|---|---|---|
| 2% lidocaine | 1.32 | ±1.15 | 0.826 |
| 5% lidocaine | 1.26 | ±1.05 | 0.826 |

## Discussions

The use of lidocaine gel in prostate biopsy can improve pain control and reduce anxiety during prostate biopsy. Ehrenstrom *et al*.[6] first published the important anesthetic role of lidocaine gel. Unlike other forms of anesthesia for prostate biopsy, it offers the advantage of being cheap and readily available, it does not require the service of an anesthetist before its use, and it can be used in the office setting with little or no side effects.

The socio-demographic variables of the two groups in this study were essentially similar. This is consistent

**Table 2: The comparison between the mean VAS of the 2% and 5% lidocaine groups in the post-biopsy period**

| Post-op time (minutes) | 2% lidocaine mean VAS | SD | 5% lidocaine mean VAS | SD | F (1, 66) ANOVA | *P* |
|---|---|---|---|---|---|---|
| 5 minutes | 3.65 | 2.17 | 0.62 | 0.78 | 59.78 | *P*<0.001 |
| 10 minutes | 3.41 | 2.02 | 0.97 | 0.63 | 59.78 | *P*<0.001 |
| 30 minutes | 3.06 | 2.00 | 1.00 | 0.92 | 59.78 | *P*<0.001 |
| 60 minutes | 1.59 | 1.73 | 0.21 | 0.48 | 59.78 | *P*<0.001 |

with the mean age of diagnosis of prostate cancer in our environment from previous studies.[4] This also correlates with similar findings from other regions of the country.[7]

The combination of an abnormal DRE finding and elevated PSA accounted for the commonest indication for prostate biopsy (group A: 61.8% and group B: 67.30%). These features invariably connote an advanced disease in the patients. The previous studies conducted in Nigeria[7-9] have shown that late presentation is the most common form of presentation. This has been attributed to the lack of cancer screening programs in the country and due to low health insurance coverage to take care of the high cost of the screening, biopsy, and treatment.

Various local and regional anesthetic procedures have been tried to reduce the pain experienced by patients during prostate biopsy. However, these procedures require multiple needle punctures and therefore more pain for the patient. The use of lidocaine gel has the advantage of avoiding needle punctures, thereby reducing the pain associated with local injection of the anesthetic agent. In this study, the mean VAS scores during biopsy in the 2% and 5% groups were 1.32 and 1.26, respectively, with a *P* value of 0.826. All the patients had mild pain (1–3). These values showed no statistically significant difference in pain perception in the 2% lidocaine and 5% lidocaine groups at finger insertion and during needle puncture of the prostate. The implication is that the two agents had almost the same pain control effect in these instances. However, we found that the use of 5% lidocaine gel led to better pain control than 2% gel in the postoperative period.

A mixed design using the ANOVA measuring tool repeatedly showed that those in the 5% group maintained significantly better postoperative pain control at 5, 10, 30, and 60 minutes of the biopsy ($P < 0.001$).

There is paucity of reports on the use of 5% lidocaine gel for prostate biopsy. Yishai *et al*.[10] in a clinical trial performed at the ASSAF-Harofeh Medical Center showed that anorectal application of 5% lidocaine cream reduces pain before the application of periprostatic nerve block for transrectal ultrasound-guided biopsy in a randomized, prospective controlled study. Issa *et al*.[11] at Emory University in their study showed that the use of 2% intrarectal lidocaine gel is a simple, safe, and efficacious method of providing satisfactory anesthesia in men undergoing transrectal prostate biopsy. The study recommends routine administration of 2% lidocaine gel in all patients for this procedure. They also reported little or no side effect profile from the use of local lidocaine gel like in our study.

Patients in the 2% group had a mean prostate volume of 86.74 g, while those in the 5% group had a mean prostate size of 94.10 g ($P = 0.731$). There was no significant difference in the mean prostate size (volume) for the two groups. The mean VAS score for the two groups was not statistically significant [Table 1]. The implication of this finding is that our patients had similar pain tolerance irrespective of prostate size during and after transrectal biopsy using topical lidocaine gel, any difference observed in the outcomes from the two groups will not be due to differences in prostate sizes. However, Yun *et al*.[12] in their study of the relationship between pain and prostate volume during transrectal prostate biopsy reported that patients with larger prostate volumes tend to feel more pain during and after TRUS-guided prostate biopsy. This is not consistent with our findings.

Although the incidence of adverse effects with lidocaine HCL 2% jelly is quite low, caution should be exercised particularly when employing large amounts, since the incidence of adverse effects is directly proportional to the total dose of local anesthetic agent administered. Some of these adverse effects include cardiovascular depressant effects which may lead to cardiac arrest. Other side effects include allergic reactions which may manifest as cutaneous lesions, urticaria, redness, edema, or anaphylactoid reactions.[13] None of the patients reported any side effects from the use of either the 2% or 5% lidocaine gel.

A major limitation of this study was the limited availability of literature on the use of 5% lidicaine gel. Secondly, the use of the VAS is limited by the respondents' motivational and cognitive characteristics. This may render the VAS subjective. Finally, this study would have been done preferably using a tran-srectal ultrasound guide.

In conclusion, the preoperative intrarectal instillation of 5% lidocaine gel provides better overall analgesia in the long term compared to 2% lidocaine gel when used for anesthesia in transrectal prostate biopsy. It is recommended that the 5% lidocaine gel should be used in place of 2% lidocaine gel where available.

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### Conflicts of interest

There are no conflicts of interest.

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