

Pain scores of patients undergoing finger-guided prostate biopsy using lignocaine and oral paracetamol at the University Teaching Hospital in Lusaka, Zambia – a cross-sectional study

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Purpose: To evaluate the pain scores of patients undergoing a finger-guided prostate biopsy using lignocaine intra-rectal gel and oral paracetamol at the University Teaching Hospital (UTH) in Lusaka, Zambia.

Materials and methods: This is a cross-sectional study comprised of 78 participants. Oral paracetamol (1 000 mg) was taken 30–60 minutes before the biopsy and 10 ml intra-rectal lignocaine gel was given three minutes before the biopsy. The Faces Pain Scale – Revised (FPS-R) tool was utilised to assess participants' pain scores after the finger-guided prostate biopsy.

Results: The participants were aged between 52 and 86 years. Of these, 51.3% did not consume alcohol while 85.9% were non-smokers. Participants with diabetes and neurological disorders accounted for 9% each. Additionally, 85.9% had lower urinary tract symptoms (LUTS) with a mean duration of five months, and 85.9% had abnormal digital rectal exam (DRE) findings. Of the participants, 16.7% had undergone a previous prostate biopsy. Only one participant (1.3%) had a normal prostate-specific antigen (PSA) level while the mean PSA level in the study was 53.93 ng/mL. The mean prostate volume was 66.97 cc. On average six prostate punctures were performed per participant with a mean procedure duration of 8.95 minutes. The majority of participants (93.6%) had a pain score ≥ 4 while the average pain score was 5.87.

Conclusion: The average pain score associated with the combined use of intra-rectal lignocaine and oral paracetamol before the prostate biopsy was 5.87, which is above the pain score of ≤ 3 ; defined as the cut-off pain score of a minimally painful procedure.¹ Therefore, this combination does not provide adequate pain control during a prostate biopsy.

Keywords: finger-guided prostate biopsy, lignocaine intra-rectal local anaesthesia, pain score, Faces Pain Scale – Revised, paracetamol

Introduction

A prostate biopsy is the standard method for prostate cancer diagnosis. A transperineal or transrectal biopsy may be performed, the latter is the case in our setting. Either is a painful procedure, hence, a periprostatic nerve block is the standard method for pain control for a transrectal prostate biopsy.²

Although transrectal (and more recently transperineal) image-guided prostate biopsies are commonly practised in developed countries, in our resource-limited setting most prostate biopsies are still finger-guided. This makes it impossible to administer a periprostatic nerve block, a procedure that ensures patients experience minimal pain with reported pain scores of ≤ 3 on the Visual Numeric Scale (VNS). A score of ≤ 3 is the definition of adequate pain control during a surgical procedure according to the International Association for the Study of Pain (IASP).¹

Consequently, in our setting finger-guided prostate biopsies are performed with 2% lignocaine intra-rectal gel, often combined with oral analgesia taken before the procedure to try to minimise pain. A systematic review by Lee et al.³ in Australia showed that intra-rectal topical anaesthesia alone does not achieve adequate pain control during a prostate biopsy as it is associated with high pain scores. However, the pain scores associated with the use of lignocaine intra-rectal topical anaesthetic gel combined with oral analgesia have not been investigated and remain unknown even though finger-guided prostate biopsies are still widely performed in resource-limited countries like Zambia.

Another Zambian study by Nyangu stated that patients who were already taking oral analgesia before a prostate biopsy for other unrelated indications may have reported experiencing less pain compared to those who didn't take any form of analgesia.^{4,5} Hence the rationale for combining these two agents albeit the absence of well-conducted scientific research.

There is a scarcity of studies on pain regarding finger-guided prostate biopsies. The use of paracetamol has largely been investigated in combination with other oral agents for a trans-rectal ultrasound-guided biopsy, but not in combination with topical intra-rectal anaesthesia. Pendleton et al.⁶ in Florida compared the oral combination of tramadol 75 mg, Acetaminophen 650 mg and a periprostatic nerve block with 1% lignocaine versus an oral placebo and periprostatic nerve block. The researchers concluded that the oral combination of tramadol, Acetaminophen, and a periprostatic nerve block was associated with lower pain scores ($p = 0.0008$). In Finland, Visapää et al.⁷ compared oral paracetamol 500 mg, codeine 30 mg and a periprostatic nerve block versus a periprostatic nerve block alone. They reported that the combination of paracetamol and codeine with the periprostatic nerve block was associated with lower pain scores compared to the periprostatic nerve block alone ($p = 0.01$).

Using a validated tool (the FPS-R), the objective of this study was to evaluate the pain scores of patients who take oral paracetamol and are given 2% lignocaine intra-rectal gel before undergoing a finger-guided prostate biopsy at the UTH in Lusaka, Zambia.

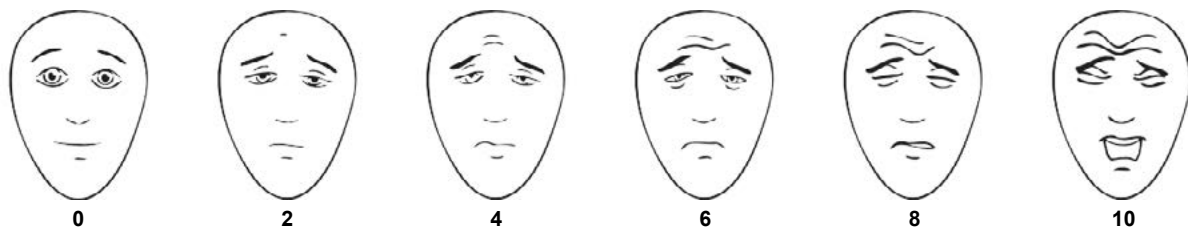


Figure 1: Faces Pain Scale – Revised

Materials and methods

This study was a cross-sectional observational study conducted on patients who take paracetamol and are given intra-rectal lignocaine gel before a prostate biopsy at the UTH in Lusaka, Zambia. Study approval was obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC), approval number: REF.2161-2021. Informed consent was obtained from each participant.

The study recruited 78 participants who had an indication for a prostate biopsy. Oral paracetamol (1 000 mg) was taken 30–60 minutes before the biopsy, and 10 ml of 2% intra-rectal lignocaine gel was administered three minutes before the biopsy. Participants then proceeded to have a finger-guided transrectal prostate biopsy using an 18G Tru-Cut biopsy needle. Immediately after the procedure, the participant had their pain score determined by the research team using the FPS-R (Figure 1).¹

Results

The participants in this study were aged between 52 and 86 years. The mean, median and mode for age were 71.3, 71, and 75 years respectively, with an age range of 34 years. Of the participants, 38 (48.7%) were alcohol consumers and the remaining 40 (51.3%) did not consume alcohol; 11 (14.1%) were smokers and the majority

were non-smokers ($n = 67$, 85.9%). LUTS were reported by 67 (85.9%) participants whilst 11 (14.1%) did not have LUTS. The average duration of LUTS was 8.5 months while the shortest and longest durations were one and 72 months respectively.

Figure 2 shows the distribution of pre-existing comorbidities that may be directly relevant to pain perception. Seven (9%) participants had diabetes, seven (9%) had some form of neurological disorder, 21 (26.9%) had other comorbidities, and the majority (43 participants, 55.1%) had no pre-existing medical conditions. A total of 13 participants (16.7%) had undergone a previous prostate biopsy while 65 (83.3%) were undergoing a prostate biopsy for the first time. DRE was normal in 11 (14.1%) participants and abnormal in 67 (85.9%). The average prostate volume was 66.97 cc, with the smallest prostate being 25 cc and the largest being 251 cc. Prostate volumes were measured by transabdominal ultrasound scan.

One participant (1.3%) had a normal PSA level of 1.06 ng/mL. Prostate biopsies were conducted based on an abnormal DRE finding of a hard nodular prostate gland, while the rest had raised PSA values. The mean PSA level was 53.93 ng/mL while the median and mode were 37.34 ng/mL and 100 ng/mL respectively. Figure 3 illustrates the distribution of PSA values for this study.

Most participants had six prostate punctures ($n = 62$, 79.5%). The average duration of the biopsy procedure was 8.95 minutes with minimum and maximum durations of three and 20 minutes respectively.

Figure 4 shows the distribution of pain scores in this study. One participant (1.3%) reported experiencing no pain during the prostate biopsy procedure (pain score of 0). Four (5.1%) participants reported a pain score of 2, 17 participants (21.8%) reported a score of 4, but 21 participants (26.9%) and one participant (1.3%) reported pain

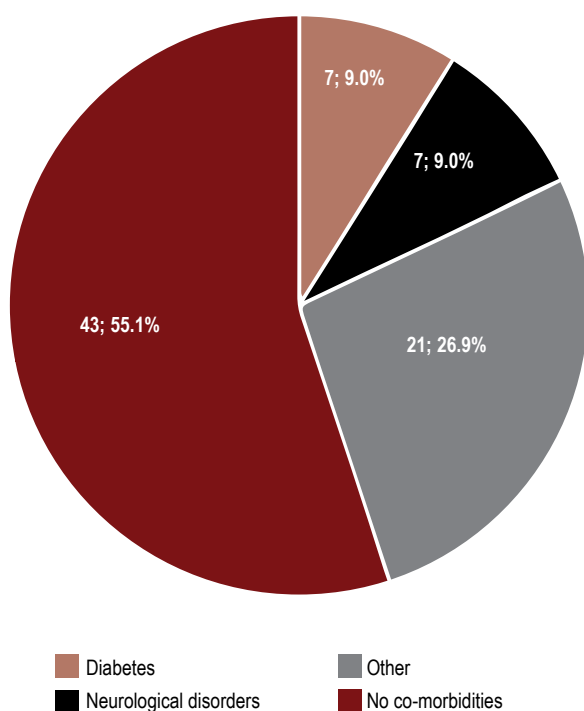


Figure 2: Distribution of comorbidities

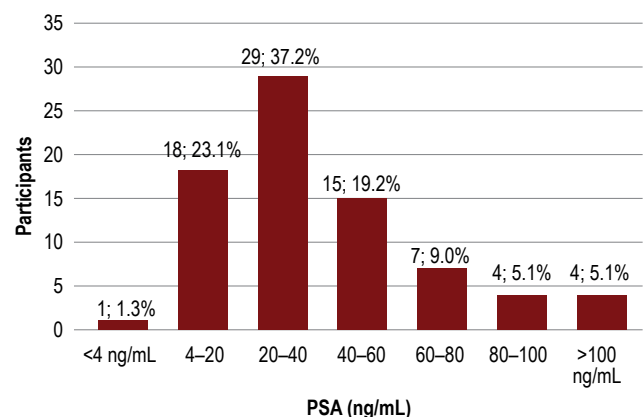


Figure 3: Distribution of PSA (ng/mL)

Table 1: Summary statistics of pain scores

n	Mean	Median	Mode	Minimum	Maximum	Range
78	5.87	6	6	0	10	10

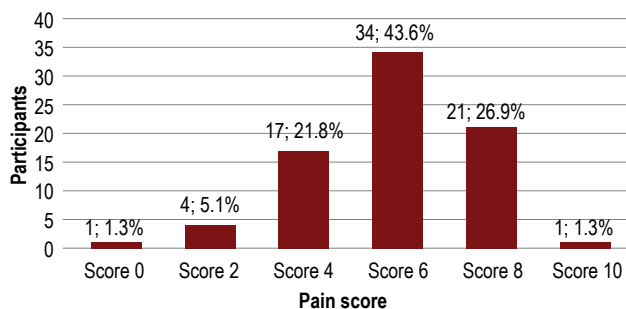


Figure 4: Distribution of pain scores

scores of 8 and 10 respectively. A pain score of 6 was the mode ($n = 34$, 43.6%). Table 1 summarises the statistics of the pain scores.

Discussion

The Pearson chi-square test was used to determine the factors that were associated with pain. There was a statistical association between the pain scores and the following variables: alcohol consumption, pre-existing comorbidities, abnormal DRE findings, and PSA level. All the other variables were not statistically associated with pain.

The statistical association between the pain score and alcohol consumption ($p = 0.042$) concurs with findings by Zale et al.⁸ who reviewed 66 studies relating to the association between pain and alcohol. They reported that people who consumed alcohol were 80% more likely to experience less pain than non-alcohol consumers ($p < 0.05$) and concluded that alcohol has a pain-dampening effect.

The pain scores are statistically associated with the presence of relevant pre-existing comorbidities; ones which may affect pain perception ($p = 0.005$). Patients with diabetes mellitus are known to be at risk of developing diabetic neuropathy, which can result in a lowered ability to feel pain. In a systematic review with a meta-analysis by Sierra-Silvestre et al.⁹ concerning altered pain processing in 2 422 patients with diabetes, it was reported that diabetic patients showed loss of nerve function and higher pain thresholds (lower pain scores) ($n = 2422$, $p < 0.001$).⁹ These findings coincide with the results of this study.

Neurological disorders are also known to influence pain perception.¹⁰ This is not surprising since such patients are likely to feel less pain (or greater pain in certain circumstances) as a result of an altered central nervous system (CNS) structure, function, or chemistry depending on the pathological process at hand.

There was a statistical association between the pain scores and abnormal DRE findings ($p = 0.004$). This concurs with Nakai et al. who reported an association between abnormal DRE findings and pain scores ($p < 0.001$).¹¹

Also, an association between the pain score and a raised PSA level was noted ($p = 0.014$). However, the findings by Han et al.

contradict this finding when they studied the factors influencing pain during a prostate biopsy and reported no statistical association between pain score and PSA level ($p = 0.822$).⁵

The majority of participants ($n = 73$, 93.6%) reported a pain score of 4 or higher (Figure 4). The average pain score was 5.87. According to the IASP, the optimal pain score for a procedure to be considered minimally painful is ≤ 3 .¹

A study by Tolani et al. concluded that pain scores associated with intra-rectal lignocaine gel were 6.8 ± 2.2 .¹³ In comparison, several studies have revealed that the use of 2% lignocaine gel alone (without concomitant use of paracetamol or any other analgesic agent) was associated with mean pain scores > 3 . Another study by Leung et al. concluded that the pain scores associated with the use of intra-rectal lignocaine gel versus placebo were not statistically significant ($p = 0.66$).¹²

By comparing the study by Tolani et al. (which reported an average pain score of 6.8 with the use of intra-rectal lignocaine gel alone) with this study (which has found an average pain score of 5.87 with the use of paracetamol and lignocaine intra-rectal gel), it is clear that the pain scores associated with the use of paracetamol and lignocaine gel are marginally superior to the use of lignocaine gel alone.¹³ However, it is critical to note that both these methods of pain control during a prostate biopsy are associated with considerable levels of pain when compared to the optimal IASP pain score of ≤ 3 .

Conclusion

The mean pain score associated with the use of both oral paracetamol and lignocaine intra-rectal gel before a finger-guided prostate biopsy is above the IASP acceptable pain score of ≤ 3 , as the average pain score in this study is 5.87.

Conflict of interest

The author declares no conflict of interest.

Funding source

No funding was received for the study.

Ethical approval

Study approval was obtained from the local ethics committee, the University of Zambia Biomedical Research Ethics Committee (UNZABREC), approval number: REF.2161-2021. Informed consent was obtained from each participant.

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