Asian Journal of Research and Reports in Urology

Volume 6, Issue 1, Page 90-94, 2023; Article no.AJRRU.104820

Efficacy of Voltaren Suppository in Adjunct with Peri- Prostatic Nerve Block with Lignocaine as Analgesia for Transrectal Ultrasound- Guided Biopsy of Prostate

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Authors' contributions

This work was carried out in collaboration among all authors. Author HYK was the main author. Author NAN continuously supervised and made the necessary corrections for the manuscript. Author MAK had been helping in providing datas. All authors read and approved the final manuscript.

Article Information

Open Peer Review History:
This journal follows the Advanced Open Peer Review policy. Identity of the Reviewers, Editor(s) and additional Reviewers, peer review comments, different versions of the manuscript, comments of the editors, etc are available here: https://www.sdiarticle5.com/review-history/104820

Original Research Article

Received: 14/06/2023
Accepted: 20/08/2023
Published: 28/08/2023

ABSTRACT

Objectives: To evaluate the efficacy of suppository voltaren as an adjunct analgesia during transrectal ultrasound (TRUS) biopsy using numerical pain score.
Methods: A total of 48 patients who were subjected to TRUS biopsy of prostate were enrolled in this study. The patients were randomly divided into 2 groups equally. In group 1, the patients received the standard peri- prostatic nerve block (PPNB) consisting of 10ml of 1% lignocaine. In group 2, the patients received peri- prostatic nerve block consisting of 10ml 1% lignocaine and in addition of voltaren suppository 100mg which was administered 1 hour before the procedure. During procedure, the patients were assessed on their pain score using numerical pain score 0-10 during insertion of transrectal probe, administration of peri- prostatic nerve block, during biopsy and 1- hour post- biopsy.

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Results: There was significant lower pain score in with regard to group 2 patients during probe insertion, PPNB administration and during biopsy. Pain score 1 hour post- procedure was not significant as the pain score in both groups were generally low.
Conclusions: We believe that by adding voltaren suppository 100mg 1 hour before the procedure would be an advantage for patients as this study had shown significant lower pain score throughout the procedure with no increase in morbidity.

Keywords: TRUS; PPNB; voltaren suppository.

ABBREVIATIONS

TRUS : transrectal ultrasound
PPNB : peri- prostatic nerve block

1. INTRODUCTION

Transrectal ultrasound- guided (TRUS) biopsy of prostate gland is a widely used method in the diagnosis of prostate carcinoma. Approximately 65%- 90% of men experienced mild to severe pain during this procedure and about 20% of men reported that they were not willing to undergo the biopsy again without analgesia [1]. *Crundwell et al* found that 24% of their patients experienced pain score greater than 5 on an analogue scale of 0 to 10 [2,3].

Pain is defined as unpleasant sensory and emotional experience associated with actual potential or actual tissue damage [4]. Pain is generally experienced during placement and movement of the trans- rectal ultrasound probe into anal canal, during needle puncture for local anesthesia (PPNB block) and during puncturing of needle biopsy [5].

In anorectum, the apex of the prostate gland is below the dentate line. Areas below dentate line is sensitive to pain as they are innervated by inferior rectal nerve originating from pudendal nerve [2]. Superior to the dentate line, the anorectum is innervated by splanchnic nerve, derived from S3-S4 spinal segments through the pelvic and prostatic plexus. Therefore, the pain below the dentate line is inadequately controlled by the periprostatic nerve block alone. Additional pudendal nerve block or a simpler topical anesthetic application is needed [5].

Suppository voltaren with recommended dose of 100mg provides additional pain relief when used in combination with the peri- prostatic nerve block since these reduces the pain caused by probe insertion and needle punctures, which is not controlled by the periprostatic nerve block alone [5,6].

Thus, we performed a randomized control comparison study between TRUS biopsy with peri- prostatic nerve block using 10ml of 1% lignocaine (group 1) and TRUS biopsy with peri-prostatic nerve block using 10ml 1% lignocaine with additional of suppository voltaren 100mg 1hour before TRUS biopsy (group 2).

2. MATERIALS AND METHODS

A total of 48 patients who were subjected to TRUS biopsy of the prostate were enrolled. Indications of TRUS biopsy were any PSA more than 4ng/ml, abnormal digital rectal examination and those with life expectancy of more than 10 years.

Eligible patients were randomly assigned into 2 groups using online randomization application ' GraphPad Quick Cals'. 24 envelopes with standard treatment and 24 envelopes with adjunct suppository diclofenac 100mg are numbered 1- 48 following randomization. These envelopes were then sealed and kept in the clinic.

Group 1 consisted of patients who had10ml of 1% lignocaine for peri- prostatic nerve block while group 2 consisted of patients who had 10ml of 1% lignocaine for peri- prostatic nerve block with additional of suppository voltaren 100mg. An hour before procedure, patients in group 2 were instructed to insert the suppository.

The patients were placed in left lateral decubitus position. TRUS biopsy was performed in clinic setting, using an 8-MHz transrectal probe. The size of the prostate will be measured (including the height x width x length x 0.52 of the prostate), followed by administration of PPNB with lignocaine 1% of 10ml and finally, systematic 12 cores of biopsy with 6 cores from each the right and the left prostate were performed.

All patients were assessed on their pain score using numerical pain score of 0-10 during insertion of probe, during administration of local anesthesia, during biopsy and 1 hour after the biopsy.

All patients were counselled regarding complications of procedure such as per rectal bleeding, hematuria, haematospermia, urinary tract infection and urosepsis. They were seen in the clinic in 6 weeks post- procedure to assess for the complications.

3. STATISTICS

The sample size calculation with 2 groups in this study was based on standard deviation of pain score of 2.29 type 1 error of 0.05 and a probability power of 0.8. With an additional 20% dropout rate, the sample size is 24 samples per group.

We performed data analysis using the IBM SPSS Statistics for Windows Version 24.0. Independent t- test was used for normally distributed numerical data between two independent groups in age group while the Mann- Whitney test was used in not normally distributed data which is the serum PSA, prostate volume, pain score during probe insertion, pain score during PPNB block, pain score during biopsy and pain score 1 hour post- procedure.

4. RESULTS

A total of 48 patients were enrolled for this study. 24 patients received only standard PPNB while another 24 patients received standard PPNB and suppository voltaren 100mg 1 hour before the procedure.

There was no significant difference in mean age in group 1 and group 2 (mean age 66.92 vs 66.25, p=0.029). The mean of prostate volume in group 1 and group 2 were 61.85 and 68.27 respectively. The mean of serum PSA in group 1 was 119.5 while in group 2, it was 389.5.

There was significant difference in pain score during probe insertion during TRUS biopsy. The mean of “group 1” was 4.5 while the mean pain score of “group 2” was 2.29 with p value of 0.003. In group 1 where only PPNB with lignocaine was given while in group 2 where PPNB with lignocaine and an additional suppository voltaren of 100mg was given 1 hour prior to the procedure, there was significant lower pain score between the 2 groups (mean of pain score group 1: 4.17, group 2: 2.79, p= 0.027). There was also statistic difference in pain score during biopsy between group 1 and group 2 (Mean group 1: 4.96, Mean group 2: 2.83, p= 0.005).

However, there was no statistical difference in pain score after 1 hour post- procedure with mean score of 1.25 in group 1, mean score in group 2: 0.83 with p= 0.201.

There were no patients with significant bleeding that requires hospitalization or intervention. (7 patients with haematospermia and 4 with hematuria). None of the patients had fever or developed urosepsis post- procedure.

5. DISCUSSION

TRUS biopsy of prostate is still the standard procedure in Malaysia for diagnosing prostate carcinoma as it is a simple procedure and is done in the clinic. Generally, TRUS biopsy can be an uncomfortable procedure with mild to severe pain score whereby, most patients were unable to tolerate the pain especially during insertion of probe, administration of PPNB and during biopsy [1]. 20% of patients would not opt this procedure for the second time due to the pain [2].

Table 1. Showed mean of age, PSA and prostate volume in group 1 (standard PPNB) and group 2 (standard PPNB and suppository voltaren)

	Group 1	Group 2
Mean Age	66.92	66.25
PSA	119.58	389.5
Prostate volume	61.85	68.79

Proximal to the dentate line, prostate is innervated by splanchnic nerve derived from S3-S4 through pelvic and prostatic plexus. Below the dentate line where the apex of the prostate is, the nerve innervation is through inferior rectal nerve from pudendal canal. Hence, the pain in this area is inadequately controlled by peri-prostatic nerve block. An additional pudendal nerve block or topical anesthetia application such as suppository voltaren is recommended [5].

Voltaren suppository is available in most hospitals in our country and is easily administered by patients. The suppositories were not visualized during the procedure because the suppositories had dissolved within 1 hour of administration [2,7].

Table 2. Representation of pain score and significance between group 1 and group 2

Pain score	Group 1	Group 2	Significance
Probe insertion	4.5	2.29	*P= 0.003*
During PPNB	4.17	2.79	*p= 0.27*
During biopsy	4.96	2.83	*p=0.005*
1 hour post procedure	1.25	0.83	*p=0.201*

Irer B et al recommended administration of voltaren suppository during TRUS biopsy as it is simple, non- invasive and effective method of pain control. Pain scores were evaluated during end of biopsy 2 hours and 1 day after biopsy. Pain scores at all times were lower in patients who received suppository voltaren than in placebo group [1].

Haq et al showed improved comfort in patients after voltaren suppository treatment during TRUS biopsy. A significant difference in mean pain score was noted in treatment group (2.8) as compared to control group (4.9) [2]. The study of Singh JC et al also showed that there was significant lower pain score in the group with lignocaine injection & voltaren suppository as compared to their control group - lignocaine injection and glycerin as placebo [8].

Ragavan N et al published an article in The Journal of Urology in August 2005 comparing pain score of 3 groups- group1: only lidocaine PPNB, group 2: only voltaren suppository and group 3:a combination of lidocaine PPNB and voltaren suppository. Pain during biopsy and pain post- procedure were significantly lower in lignocaine group and combination group [9].

In an article published in year 2013 by Haroon et al, 100 patients were recruited with 1 arm of patients with voltaren suppository and 10cc of 2% xylocaine gel were given pre-procedure while another arm consisted of patients with only xylocaine gel. The mean pain score at the time of probe insertion, immediately after taking biopsy cores and 2 hours after biopsy were statistically significantly higher in the arm of only xylocaine gel as compared to the combination analgesia of xylocaine and voltaren suppository [10].

Aus G et al published an article in Scandinavian Journal of Urology and Nephrology in the year of 2009. Different analgesias were in included in his study for TRUS biopsy of the prostate gland. Voltaren suppository100mg was proven to be an effective analgesias in comparison with placebo [11].

The patients were evaluated during the procedure and no drug- related adverse events were observed. The patients were given clinic appointment 6 weeks later to evaluate for any major TRUS biopsy- related complications. No major complications were seen in both groups.

We would recommend the use of voltaren suppository as an adjunct to PPNB during TRUS biopsy of the prostate as this helps in reducing pain score during the procedure.

6. CONCLUSION

TRUS biopsy can be an unpleasant experience during this procedure. We believe by adding voltaren suppository 100mg 1 hour before the procedure would be an advantage for patients as shown in this study which showed significant lower pain score throughout the procedure. As for pain 1 hour post- procedure, the mean of pain score in both groups were generally low with pain score of 1 and below in both groups. Complications in both groups were not significant and were not debilitating in both groups. None of the patients required any hospitalization.

CONSENT

Patient's written consent had been collected and preserved by author (s) as per international standard or universities standard.

ETHICAL APPROVAL

This study is registered with Malaysian National Medical Research Register, Research ID RSCH ID-21-00210-XGU and approval from Medical Research & Ethics Committee was obtained.

ACKNOWLEDGEMENTS

I would like to acknowledge and give thanks to my supervisor, Dr Noor Azam Nasuha for his upmost support and guidance for this research. I would like to thank Urology Unit of Hospital Raja Perempuan Zainab II, Kelantan for their encouragement in completing this research. I would also like to acknowledged my colleagues and friends who have helped and guided me through this research.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/104820