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PERIPROSTATIC NERVE BLOCK ALONG WITH ORAL TRAMADOL VERSUS OTHER FORMS OF ANALGESIC TECHNIQUE IN REDUCING PAIN IN PATIENTS UNDERGOING TRUS GUIDED PROSTATIC BIOPSY: A PROSPECTIVE COMPARATIVE STUDY

Urology

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ABSTRACT

Objectives: Prostate biopsy accompanied by transrectal ultrasonography has been accepted as the gold standard for the diagnosis of prostate cancer. This study aims for assessment of pain in relation to TRUS-guided biopsy of prostate and Comparative assessment of pain in patient receiving oral tramadol along with periprostatic nerve block versus other form of anaesthetic modalities for reducing pain in TRUS guided prostatic biopsy.

Method: A total of 60 men with abnormal PSA level and/or abnormal DRE who were undergoing prostatic biopsy for the first time were included in the study. Patients were randomized into 3 groups as patients receiving periprostatic nerve block and intraprostatic nerve block using 1% lignocaine (group 1), patients receiving periprostatic nerve block using 1% lignocaine, along with 100mg of oral tramadol (group 2) and patients receiving periprostatic nerve block alone using 1% Lignocaine (group 3). Prostate biopsies were taken in all patients following which they were assessed for pain and grading of pain was considered according to 10 point visual analog scale at the time of probe insertion, at the time of anesthesia, at the time of taking biopsy and after 30 min of completion of procedure.

Result: Group 1 recorded the minimum mean pain score during prostate biopsy which was significantly lower than group 3. Group 2 recorded significantly lower pain score at time of probe insertion and at anesthetic needle insertion than group 1. The group-2 also recorded significantly lower pain score at time of probe insertion, anesthesia and biopsy but not at 30 min post-biopsy than the control group. There is no significant difference in pain score at time of biopsy between group 1 and group 2. So, oral tramadol provides significant analgesia at all times except post procedure time. No major complications were reported with periprostatic block and intraprostatic nerve block.

Conclusion: At the end of the study it was observed that patient group which received periprostatic nerve block (1% lignocaine) with 100mg oral tramadol as a modality of anesthesia (i.e. Group 2), provides significant analgesia at all times expect post procedure time with added advantage of oral intake. We recommend the use of periprostatic block (1% lignocaine) with 100mg of oral tramadol in transrectal ultrasound guided prostate biopsies, because it is inexpensive, safe, easy to perform in outpatient clinics, and an effective anesthetic method.

KEYWORDS

Periprostatic nerve block, TRUS guided prostate biopsy,lignocaine,tramadol.

INTRODUCTION:

Prostate cancer is one of the most common form of urological cancer among men. Prostate biopsy accompanied by transrectal ultrasonography has been accepted as the gold standard for the diagnosis of prostate cancer. TRUS and biopsy of the prostate are the standard investigations for detecting prostate carcinoma. It is taken as an outpatient procedure in the United Kingdom. Almost 20% of patients report that pain is significant and that they would refuse repeat biopsy without analgesia[1]. Men scheduled for TRUS-guided biopsy experience considerable psychological stress. The reasons for this stress are manifold and include fear of diagnosis of cancer, the anal route of penetration, that the examined organ is part of the male sexual system, and the anticipated pain during the procedure. Although most of the morbidities are minor, they are traumatic and worrisome to the patient. Crundwell et al.[2] found moderate to severe pain scores during prostate biopsy in his patients. It is well known that anxiety is common in men before and during the procedure. Those people who are anxious experience higher pain scores, as in young people.[3] Similarly , patients having a past unpleasant experience have higher pain scores.

Originally a transperineal needle puncture was used after a local anaesthetic (LA), but even then it was a painful procedure. With the development of transrectal needle insertion in the late 1980s the LA was discontinued as rectal wall puncture causes no great discomfort and so transrectal biopsies were considered to be painless. During the last decade approach to prostatic biopsy has evolved from traditional sextant biopsy to several extended techniques involving the gathering of 8 to 12 biopsy core samples i.e. achieve better prostrate sampling, in each case and thus, increase our prostate cancer detection rate by 20 to 40 %. This increased number of cores translates to increased pain scores. Biopsy procedure without any form of analgesia or anesthesia for prostate cancer diagnosis causes pain or discomfort. Pain perception appears especially with the movement of probe during insertion into the anal canal. Various forms of anesthesia such as periprostatic lidocaine injection and transrectal gel have been used to increase patient adaptation.[4,5,6,7] Periprostatic block is inexpensive, safe, easy to perform and can be used in outpatient clinics as an effective anaesthetic method. Periprostatic block in combination with lidocaine gel, intraprostatic block, use of tramadol /codeine prior to the procedure has better result than periprostatic block alone in reducing pain

METHODS:

It is a Prospective randomized study done in Department of Urology, SCB Medical college, Cuttack between December 2016 to February 2019 among patients of suspected prostate carcinoma attending department of urology with required eligibility criteria were considered in this study**.** The institutional ethical review board at our hospital approved the study. Written consent was taken from all the patients before enrolling them for the study.

Inclusion Criteria:

- Men of age group 40-80 years
- PSA level more than 4ng/ml
- Patients undergoing biopsy for the first time
- Abnormal DRE (discrete nodule, focal induration , a diffusely hard prostate)

Exclusion Criteria:

- Patients with hypersensitivity to lignocaine.
- Known coagulopathy or hematological disorders.
- Bleeding hemorrhoids
- Acute anal fissures
- Patient with history of prior prostatic biopsy

A total of 60 men with abnormal PSA level and/or abnormal DRE who were undergoing prostatic biopsy for the first time were included in the study. Patients were divided into groups using envelopes (Block Randomization).

Group-1(20 Patients): Patients receiving periprostatic nerve block and intraprostatic nerve block using 1% lignocaine.

Group-2(19 Patients):Patients receiving periprostatic nerve block using 1% lignocaine, along with 100 mg of oral tramadol.

Group-3(21Patients):Patients receiving periprostatic nerve block alone using 1% lignocaine.

Barium enema was adviced on the morning of biopsy. Patients in all the groups are asked to take 500mg ciprofloxacin tablet 3 hours prior to biopsy and then another dose 12 hours after the procedure. Periprostatic Nerve Block (PPNB) with Mount Everest Technique was followed. In this technique the probe is adjusted to the sagital plane, with a 18-gauge, 16cm spinal needle is placed through the biopsy guide channel by a urologist under ultrasound guidance into the area where the prostatic innervation enters the gland. The probe is angled laterally until the notch between the prostate and the seminal vesicle is visualized and lignocaine (5 mL) was injected on each side. In the Intrapostatic Injection Technique, direct prostatic injection under untrasound guidance on both sides near the base. Three hours before the scheduled time of biopsy each patient of this group self-administered 100 mg of oral tramadol. TRUS guided prostatic biopsy performed and grading of pain according to 10 point visual analog scale noted for each patient at the time of probe insertion, at the time of anesthesia, at the time of taking biopsy and after 30 min of procedure. Patients were analyzed using unpaired Student's t-test

RESULTS:

The mean ages of the subjects in group-1 (64.7±10.5), group 2 (63.4±7.6) and in group-3 (59.5±12.1) was not significantly different between study groups (p=0.293).The mean patient PSA levels of the subjects in gorup-1 (14.7±13.1), group-2 (11.1±7.8) and in group-3 (11.6±11.2) was not significantly different between study groups (p = 0.262).The mean prostate volume of the subjects in gorup-1 (43.1±13.5), group-2 (46.4±18.9) and in group-3 (38.1±12.5) was not significantly different between study groups (p = 0.371).Table 1 shows mean of subjects in different groups.

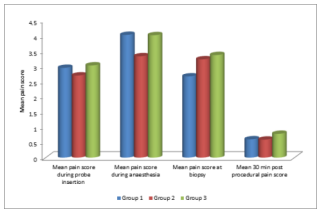
Group 1 recorded the minimum mean pain score during prostate biopsy which was significantly lower than group 3. Group 2 recorded significantly lower pain score at time of probe insertion and at anesthetic needle insertion than group 1. The group-2 also recorded significantly lower pain score at time of probe insertion, anesthesia and biopsy but not at 30 min post-biopsy than the control group. There is no significant difference in pain score at time of biopsy between 1 and 2. So, tramadol provides significant analgesia at all times expect post procedure time. Mean pain score of respective groups are shown in table 2 depicted in figure 1.

(Table 1)

	Group 1	Group 2	Group 3	p-value
Mean ages of subjects	64.7±10.5	63.4±7.6	59.5±12.1	0.293
Serum PSA (ng/mL)	14.7±13.1	11.1±7.8	11.6±11.2	0.262
Prostate vol. (cc)	43.1±13.5	46.4±18.9	38.1±12.5	0.371

(Table 2)

MEAN PAIN SCORE DURING	Group 1 VS Group 3	Group 1 VS Group 3	Group 3	Group 1 VS Group 2
Mean pain score during probe insertion	2.94±0.77 (P=0.621)	2.69±0.77 (P <0.000)	3.02±0.85	P<0.000
Mean pain score during anesthesia	4.02±1.12 (P=1.000)	3.32±0.62 (P=0.002)	4.01±1.46	P<0.000
Mean pain score at biopsy	2.66±0.69 (P<0.000)	3.22±0.51 (P=0.002)	3.36±0.94	P=0.117
Mean 30 min post procedural pain score	0.60±0.78 (P=0.256)	0.59±0.63 (P=0.320)	0.78±0.74	P=0.775



(Figure 1)

DISCUSSION:

In our study, the mean pain scores in group 1 during probe insertion, during anesthesia, during biopsy, and 30 min after biopsy were 2.94 ± 0.77, 4.02 ± 1.12, 2.66 ± 0.69, 0.60 ± 0.78, respectively. The mean pain scores in group 2 during probe insertion, during anesthesia, during biopsy, and 30 min after biopsy were 2.69 ± 0.77, 3.32 ± 0.62, 3.22 ± 0.51, 0.59 ± 0.63, respectively . The mean pain scores in group 3 during probe insertion, during anesthesia, during biopsy, and 30 min after biopsy were 3.02 ± 0.85, 4.01 ± 1.46, 3.36 ± 0.94, 0.78 ± 0.74, respectively. Group 1 recorded the minimum mean pain score of 2.66 during prostate biopsy which was significantly lower than group 3 ($P<$ 0.001). Group 2 recorded significantly lower pain score at time of probe insertion and at anesthetic needle insertion than group 1. The tramadol group also recorded significantly lower pain score at time of probe insertion, anesthesia and biopsy but not at 30 min post biopsy than the control group. There is no significant difference in pain score at time biopsy between 1 and 2. So tramadol provides significant analgesia at all times expect post procedure time with added advantage of oral intake. Post procedure pain is less than 1 so not significant at all. So tramadol provides significant analgesia at all times expect post procedure time with added advantage of oral intake.

In their study Soloway et al. (2000) stated that anesthesia and analgesia were necessary during biopsy, and they reported that pain was lower in all patients who underwent biopsy with a periprostatic nerve blockage[8].

But over the years it has been established by various authors that PNB is very effective for TRUS-guided prostate biopsy pain. Since its introduction by Nash *et al*., this technique has gone further to the extent of a gold standard technique of prostate biopsy[9]. Various authors in their study found it very effective than placebo, control, and other analgesic methods.

In a study Obek et al. (2004) categorized patient into four groups including a control group, a periprostatic blockage group, a periprostatic blockage with intrarectal gel group, and a tramadol (opioid analgesic)[10]. They showed that the group in which analgesia and anesthesia were provided undertook the procedure far better than the control group, which received no treatment for pain. They also reported that when periprostatic blockage was administered along with intrarectal gel, the combination provided the best analgesia.

But it is far from settlement as others found procedure still very painful. Wu *et al*. proposed that PNB is not effective for prostatic biopsy pain[11]. Bozlu *et al*. proposed in 2004 that PNB and tramadol have no analgesic effect during prostate biopsy[12].

So need for better analgesic was felt and in 2005 when Mutaguchi*et al*. proposed a new intraprostatic analgesia technique to anaesthetize the prostate that requires blocking all sensory nerves from the posterior and anterior sides[13]. They found that in 71 patient out of 170 patients have mean pain score of 1.9 as compared to 2.6 in PNB. This was found to be clinically significant. We also found similar result but with the combination of PNB and INB. We also find that tramadol is effective at probe insertion and at anesthetic application where intraprostatic block is not effective.

Conde*et al*. in 2006 found that bilateral PNB is better analgesic than oral morphine[14].

Cam *et al*. also reported that combining intraprostatic local anesthetic and PNB is an effective form of analgesia[15]. They used this technique in 100 patient and found it to be very effective with mean pain score of 0.75 as compared to 2.17 of PNB alone.In our study, we also found similar result.

In 2007, Lee *et al*. published results of their study in which they divided 152 patients in three groups[16]. One group received PNB alone, other received INB alone and third received both. They found that group with both PNB and INB has best pain control at time of anesthesia and biopsy. It was found to be statistically significant. In our study, a significant pain difference was found only at time of biopsy.

Obek*et al*. found that tramadol has role in prostate biopsy but could not comment much. In our study, tramadol has proved its role at time of probe insertion and at nerve block time[17].

In 2008, Olmez*et al*. published a study comparing intramuscular

lornoxicam and tramadol and found tramadol as significantly better analgesic. In our study, oral tramadol was found better at certain times of procedure[18].

Hirsh *et al*. also found tramadol to be effective as analgesia at time of biopsy[19].

The result of our study i.e. better pain suppression is very much similar to the above mentioned studies conducted by various authors in the past, as the inclusion criteria that we adopted in our study was not significantly different from those followed by other authors in terms of patient's age, presenting symptoms suggestive of LUTS, PSA value, duration of procedure and methods of assessing pain scores.

In our study, no major complications were reported with periprostatic block and intraprostatic nerve block. The most common was pain due to puncture with the needle used for injecting local anesthesia (~50 % of patients).

Other minor complications included

- The need for repeated injections during the biopsy procedure
- Degradation of the image resolution due to anesthetic injection.
- Minimal rectal bleeding after biopsy.
- Haematuria, fever

Systemic toxicity, infection and urinary incontinence were not seen in any of the group

CONCLUSION

This study was conducted over a period of two years and included 60 patients who were for the first time, undergoing TRUS guided prostate biopsy. Patients were randomly divided into 3 groups, each group receiving different kind of anesthesia prior to biopsy. There was no significant difference between the patients on the basis of age, prostate volume and PSA score. “Mount Everest technique” was utilized for the biopsy procedure. Following biopsy, pain experienced by the patients during the procedure was evaluated using “10 point Visual Analog Scale”. Mean number of patients experiencing pain during the procedure was calculated for each group using “Student t-test and ANOVA”.

At the end of the study it was observed that patient group which received periprostatic nerve block (1% lignocaine) with 100mg oral tramadol as a modality of anesthesia (i.e. Group 2), provides significant analgesia at all times expect post procedure time with added advantage of oral intake.

The findings of our study are supported by similar results obtained by several other investigators in the past, in terms of less pain and, and fewer complications associated with it.

We recommend the use of periprostatic block (1% lignocaine) with 100mg of oral tramadol in transrectal ultrasound guided prostate biopsies, because it is inexpensive, safe, easy to perform in outpatient clinics, and an effective anesthetic method. Therefore, depriving the patient of adequate analgesia during the procedure would be considered below standards of care today.

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