

ORIGINAL ARTICLE

INTRAMUSCULAR DICLOFENAC Vs PERIPROSTATIC LIDOCAINE INJECTION FOR CONTROLLING PAIN UNDERGOING TRANSRECTAL ULTRASOUND GUIDED PROSTATIC BIOPSY

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Background: Transrectal ultrasound (TRUS) technique for getting prostatic tissue for histopathology is now the standard procedure for malignant lesions of the prostate and imperative diagnostic investigation of patients with clinical specks of prostatic neoplasia. During TRUS guided biopsy, pain control has been important issue therefore, highly potent analgesia before this procedure should be considered on high priority according to current census. Therefore, we compared intramuscular diclofenac injection with sensory blockade of injection lidocaine to abolish pain undergoing prostatic biopsy with TRUS technique. **Methods:** Total 200 patients were selected for this study having raised PSA values and suspicious nodule on Digital Rectal Examination. These patients were segregated into two groups by randomization. Group “A” received intramuscular diclofenac and group “B” were infiltrated with lidocaine injection for sensory blockade. **Results:** Patients in group A was having mean age of 64.5±5.8 years while for group B patients was 65.6±4.9 years ($p=0.16$). Both groups have statistically insignificant difference in their mean PSA values ($p=0.24$) and mean prostatic volume ($p=0.22$). The mean pain scores on visual analogue scale in groups A was 3.5±0.8 and in group B it was 2.4±0.8 ($p<0.001$). 60% group A patients reported with mild or no pain compared to 90% in group B. ($p<0.001$). **Conclusion:** Local blockade with lidocaine injection has better pain control as compared to patients experienced pain with intramuscular diclofenac used for prostatic biopsy through TRUS technique.

Keywords: Transrectal Ultrasound; Biopsy; Periprostatic block; Diclofenac; Lidocaine; Prostate

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INTRODUCTION

“Transrectal ultrasound (TRUS) guided” technique for getting the prostatic tissue is now a sophisticated method in the hands of expertise. The efficacy, indications, complications and technique of the biopsy has been extensively assessed. Until the mid-1990s the investigations regarding the patient’s tolerance did not begin. Local infiltration with injection lidocaine is better than local application of lidocaine and prilocain cream.¹ According to current consensus therefore effective analgesia is mandatory before the biopsy procedure.² TRUS has become requisite in diagnostic investigation of patients with rising of the prostatic specific antigen (PSA)³ and clinical speck of prostatic neoplasia due to alteration in the gland due to abnormality on the “digital rectal examination”.

About 11–90% of patients have pain during the exam, according to some series making the perception of this diagnostic procedure traumatic.⁴ Generally, it is accepted that patients with suspicious finding on rectal examination, raised PSA value more than 4 ng/L, PSA velocity more than 0.4–0.75 ng/ml/yr⁵ should undergo TRUS Guided biopsy. As early as 1996 the use of periprostatic nerve block (PPNB) using local anaesthetic (lidocaine) had been introduced for reducing pain during prostatic biopsy. The benefit of PPNB has been assessed and decisively proved by many studies.

The sextant sampling is inadequate an accord has been reached in recent years; suggested is sampling with 8 cores or more.⁶ In a report by Crudwell *et al*, prostate biopsy has been reported to be associated with an unacceptable pain and anxiety.⁷ TRUS has completely change the approach towards getting prostatic tissue⁹, as less morbidity is associated with this approach. According to studies, due to sextant biopsy technique 22–30% of malignant lesions will be missed and detection rate can be improved by getting more number of biopsies⁹, Hodge et al introduced that sextant technique is the standard procedure for malignant prostatic nodules⁸ in 1989. Patients having constantly raised values of PSA and no malignancy on initial biopsies, should have further biopsies up to 60 (saturation biopsies) to reach the diagnosis of suspected malignancy (stereotactic template mapping).¹⁰ The use of sedo-analgesia rarely reported in United Kingdom, in 2013 a “Urological Society of Australia and New Zealand” reported that I/V sedation or general anaesthesia is utilized by 57% of urologists for suspected malignant lesion of prostate, “periprostatic infiltration of local anaesthetic” by 28%, and without any anaesthesia or analgesia by 4% .

It is very obvious that for management of prostate cancer we need to have tissue diagnosis. TRUS guided prostate biopsy under local infiltration of injection lidoaine gives us a proper sample for

histopathology. Our aim was to minimize the discomfort during this procedure using periprostatic infiltration of injection lidocaine as compared to intramuscular injection of diclofenac.

MATERIAL AND METHOD

A total of 200 patients suspected of having cancerous lesions were included in the study through a randomized controlled trial (RCT) study design, comparing PPNB using lidocaine and diclofenac intramuscular injection in the Department of Institute of Kidney Disease Hayatabad Peshawar since February 2014 to April 2016. The calculation of an adequate sample size is crucial in any clinical study and optimum number of participants required to reach an acceptable and valid results. We select sample size according to acceptable level of significance, power of study, expected effect size, underlying event rate and standard deviation in the population. Every patient with raised PSA level had equal chance to be considered for the study and choice of one patient did not affect the chance of another's selection According to hospital register, the inflow of patients who are suspected for prostate cancer is approximately 03 patients per week. The project was designed to be executed for two years and considering minimum of two patients per week who meet the inclusion criteria for study, the proposed sample size at the start of the study was 200 (100 in each group) and the required sample size was met during the study period.

This study included patient with raised value of "prostate-specific antigen" more than 4.0 ng/ml and findings on "digital rectal examination", i.e., focal indurations, nodular prostate and harder prostate. Patients of prostatitis, hypogastric pain, "inflammatory bowel diseases", rectal anomalies, urinary infections, and hypersensitivity to lidocaine. Patients segregated randomly in two groups by lottery method: 100 patients in intramuscular diclofenac group (Group A), 100 patients in periprostatic nerve block group using lidocaine (Group B). One hour before the procedure in Diclofenac group intramuscular injection containing 75milligram of diclofenac was injected into gluteal region. In the nerve block group, 5 mL of 1% lidocaine was infiltrated lateral to the junction between the base of the prostate and the seminal vesicle with 22-gauge needle 3 minutes prior to biopsy. All patients were given instructions before procedure to describe the pain according to the VAS. Pain during and after biopsy was checked using a visual analogue scale (VAS) which comprises of 10 points (0 means no pain and 10 means excruciating pain). Pain was graded on a scale from 0–10 with 0 (no pain), 1–3(mild), 4–6 (moderate), and 7–10 (severe pain). Each patient in each Group had

standard 12 random core biopsies taken, three from the left lobe and three from the right lobe of prostate, 3 from apex and 3 from base. The mean pain score of the whole study sample was 3 ± 0.9 . SPSS version 20 was used to store and analyse data. Prior to the procedure an informed consent was obtained by the patients. Prophylactic antibiotics administration was initiated, ciprofloxacin 500mg twice daily for 3-day to prevent infection 1 day prior to biopsy.

RESULTS

The study was conducted on 200 patients with high PSA levels and scheduled for TRUS guided prostate biopsy. The average age of the whole study sample was 65.1 ± 5.4 years. The mean prostate specific antigen level of the whole study sample was 6.15 ± 1.22 ng/ml and mean prostate volume was 57.1 ± 4.3 cm³. Comparing the baseline characteristics of the study sample between group A and group B, we found no significant difference in age of patients group ($p=0.16$), Prostate Specific Antigen ($p=0.24$) and mean prostatic mass ($p=0.22$). Table-1

From introduction of the probe per rectum to the end of the procedure mean time was 18 min for the whole study sample. The difference between mean pain score on VAS between both groups was statistically significant with patients in group A reported more pain compared to group B. ($p<0.001$). Table-2

No pain or mild pain was reported on probe insertion by 75% of the patients in the whole study sample of 200 while moderate pain experienced by 25%. No patient complained of severe pain. Mild or no pain experienced by 60% in group A compared to 90% in group B. ($p<0.001$) (Figure-1). All patients in two groups were comparable in age, PSA values, prostatic volume, findings of the "digital rectal examination". Patients were reviewed by the urologist three weeks after biopsy and data were recorded.

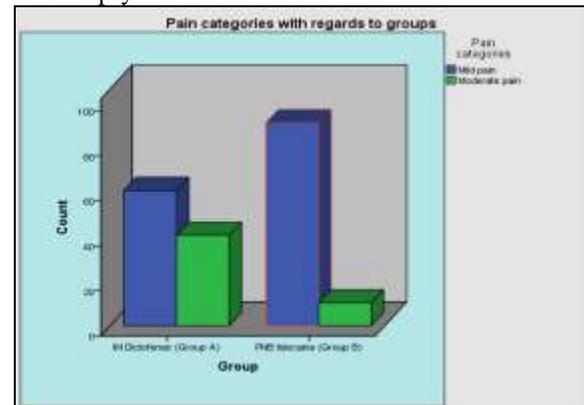


Figure 1: Comparison of pain categories across groups

Table-1: Baseline Characteristics

	Group	n	Mean	Std. Deviation	p-value
Age of the patient	IM Diclofenac (Group A)	100	64.5	5.8	0.16
	PPNB lidocaine (Group B)	100	65.6	5	
PSA Level	IM Diclofenac (Group A)	100	6.1	1.1	0.24
	PPNB lidocaine (Group B)	100	6.6	1.3	
Prostate volume	IM Diclofenac (Group A)	100	56.7	4.6	0.22
	PPNB lidocaine (Group B)	100	57.5	4.1	

Table-2: Mean Pain score between both groups

	Group	n	Mean	Std. Deviation	p-value
Pain score on VAS	IM Diclofenac (Group A)	100	3.5	0.7	< 0.001
	PPNB lidocaine (Group B)	100	2.5	0.8	

DISCUSSION

By PSA use and TRUS-guided biopsy Prostate cancer diagnosis has been revolutionized. In 1963 TRUS of the prostate was first introduced by Takahashi and Ouchi. Hodge *et al*, performed the first systematic sextant biopsy of the prostate. For reduction of pain and decreasing the discomfort related with prostate biopsy various types of local anaesthesia have been recommended recently. Gross haematuria, hemospermia, dysuria, and fever of prostate are commonly occurring complications of TRUS biopsy. For more than a decade this has been performed routinely without any anaesthesia, it is not without notable discomfort. Pain and discomfort still remain the most common side effects although improvements over the years, but still this does not mean that general anaesthesia is the option to be used routinely for TRUS guided prostate biopsy.¹² Literature has suggested various methods of pain relief during prostate biopsy which includes entonox, lidocaine gel and PPNB.¹³ In 1996 the Nash reported introduced PPNB¹⁴ as a landmark in alleviating pain during TRUS-guided prostate biopsy. There are reports about potential complications like haemorrhage and intravascular injection of local anaesthetic at several sites. Though optimum sites of PPNB remains controversial, a study suggests that apical injections were more effective. Due to two different sources of pain during the procedure; prostate capsule punctures and probe-related anorectal discomfort, single method is not sufficient for pain control, for comprehensive coverage the sequential combination would be first intuition. Notably, having lidocaine application rectally prior to PPNB infiltration, significantly reduces pain introduced by Obek *et al*, different types of local anaesthetics, analgesics, non-steroidal anti-inflammatory drugs and muscle-relaxants have been co-administered to augment the PPNB.⁴ IRLA+Local blockade were more effective in reducing biopsy pain concluded recently reported by Liu *et al*. The efficacy of these local infiltrated medicines discretely shown complications.¹⁵ In a review of “TRUS guided

biopsy” analgesia reported by Autorino *et al*.¹⁶ This systematic review was made possible by the Unsuggested PPNB±application of lidocaine gel intrarectally remains as the gold standard for Transrectal-UltraSound-guided prostatic biopsy.

In one study on 150 patients mean pain score after periprostatic infiltration was (2.4)¹⁷, almost similar result was obtained in our study (2.5) mean pain score for local infiltration. In another study conducted on 157 patients for TRUS-guided biopsy, found mean pain score 1.53 (0.7)¹⁸ for periprostatic lidocaine infiltration, but in our study, mean pain score was (2.5). Also, one other study on 98 patients infiltrating local anaesthesia, found mean pain score (3.0)¹⁹, but our study showed mean pain score of (2.5). Therefore, from different studies it was concluded that local infiltration of anaesthesia is superior technique to other methods of pain control during TRUS-guided prostate biopsy.

CONCLUSIONS

Periprostatic lidocaine injection is simple, well tolerated and acceptable technique for TRUS guided prostate biopsy and we recommend it for TRUS-guided prostate biopsy.

AUTHORS' CONTRIBUTION

SIA: basic idea, methodology, study design. H: literature review and references. ZK: data entry and analysis. IM: consent and data collection. RJ: discussion and conclusion.

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