



## The effect of local anesthesia types on erectile function in TRUS biopsy: A prospective study

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### ABSTRACT

**Aim:** To evaluate the effect of local anesthesia types on erectile function during transrectal ultrasound guided biopsy (TRUS-Bx).

**Methods:** Between February 2014 and February 2015, 50 men who underwent TRUS-Bx at our institution were included in this prospective study. The 50 patients were randomized and divided into two groups according to the type of anesthesia used. All patients were asked to indicate the level of pain experienced on a visual analogue scale (VAS) 10 min after the TRUS biopsy. All patients had to fill in the IIEF standardized questionnaire. Groups were evaluated in terms of pre-biopsy IIEF score (IIEF-1), post-biopsy 1st month IIEF score (IIEF-2) and post-biopsy 2nd month IIEF score (IIEF -3). Patient characteristics, mean VAS score and IIEF score were compared between the two groups.

**Results:** The mean age, IIEF-1, tPSA level, prostate volume and VAS score were 60.86±0.95 years, 18.68, 6.81±0.54 ng/ml, 51.10±3.82 cc and 3.5±0.26 in all patients, respectively. The difference in VAS scores between the groups was statistically significant. In Group 1 the IIEF-1, IIEF-2, and IIEF-3 were different from each other statistically. There was no statistically significant difference between IIEF-1 and IIEF-3 scores in group 2. So it was observed that the initial IIEF scores were reached at the end of the second month in group 2 administered 12.5 g 2% lidocaine HCl gel.

**Conclusion:** Our study indicates that although local periprostatic anesthesia by injecting 6 ml of 2% lidocaine provides more effective anesthesia for pain relief, intrarectal 12.5g 2% lidocaine HCl gel maintains less impact on erectile dysfunction for TRUS-Bx.

**Keywords:** Prostate biopsy; erectile dysfunction; local anesthesia.

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## Introduction

Prostate cancer is the most common malignancy in males and is the second most common cause of death due to malignancy [1]. Screening, detection and diagnosis of prostate cancer are currently based on serum prostate-specific antigen (PSA) level, digital rectal examination (DRE) and transrectal ultrasound guided biopsies (TRUS-Bx). Transrectal prostate needle biopsy (TPNB) has been the standard urological procedure to detect prostate cancer since it was introduced by Hodge et al. [2]. Although it is well tolerated by many patients, the procedure can cause significant pain and discomfort [3]. Both clinical and laboratory experience have shown that TRUS-Bx is associated with considerable pain and anxiety and may interfere with sexual function and potency [4,5].

In the international literature, studies have investigated the effect of TRUS-Bx on erectile dysfunction (ED). Most have demonstrated that these post-biopsy effects occur over a short period of time and are transient [5-9]. Several theories and hypotheses regarding this effect have been proposed but an exact mechanism is still unknown. Local anesthesia prior to biopsy is a crucial part of TRUS-Bx for pain control. Although there is no consensus about anesthesia to be applied, essentially the pain to be felt by patient must to be reduced [10]. Several methods for local anesthesia during TRUS-Bx are available, including periprostatic nerve blockade, topical rectal administration or intraprostatic injection of local anesthetics [11]. In this study, we aimed to evaluate the effect of local anesthesia types on erectile function during TRUS-Bx.

## Methods

Between February 2014 and February 2015, 50 men who underwent transrectal ultrasound

prostate biopsy (TRUS-Bx) at our institution were included in this prospective study. The institutional review board approved the protocol and all participants provided their informed consent for TRUS-Bx prior to the procedure. The 50 patients that were included in the study were randomized and divided into two groups according to the type of anesthesia used; flipping a coin was used for randomization. Group 1 patients (n=26) underwent local periprostatic anesthesia by injecting 6 ml of 2% lidocaine through a 18 gauge needle in each side of the prostate gland guided by TRUS and whereas Group 2 patients (n=24) were administered two packages of 12.5 g 2% lidocaine HCl gel (Cathejell) intrarectally 10 min prior to biopsy without any additional anesthesia.

Indications for biopsy were elevated serum PSA levels (>4ng/mL) and/or suspicious digital rectal examination findings. Exclusion criteria included previous prostate biopsies, lidocaine allergy, hemorrhagic diathesis, recto-anal pathology, diabetes mellitus, neurologic diseases, known erectile dysfunction or impotence and inability to rate visual analog scale (VAS). Moreover, patients who were diagnosed with high grade prostatic intraepithelial neoplasia (HGPIN) and/or atypical small acinar proliferation (ASAP) and/or prostate cancer on pathologic evaluation of the TRUS-Bx were not included either. If the initial EF domain score was below 11 on the International Index of Erectile Function (IIEF), patients were excluded.

All patients who had sterile urine culture before the procedure received an enema on the morning of the procedure. Oral levofloxacin (500 mg daily, for 5 days, started the night before the biopsy) was given. All procedures were performed by an urologist from our

clinic. After the patients were positioned in left lateral decubitus, either intrarectal 12.5 g 2% lidocaine HCl gel (Cathejell) was applied digitally on the anterior anal wall and prostate surface or periprostatic anesthesia was performed with 6 ml of 2% lidocaine which was bilaterally injected with a 18 Gauge spinal needle (Chiba Biopsy Needle, Geotek, Turkey) into the region of the prostatic vascular pedicle on each side. After administration of the local anesthetics, the biopsy was performed using a 7 MHz transrectal probe (Siemens) to determine the prostatic volume and record the appearance of the prostate in both the transverse and longitudinal plane. Afterwards, 12 core systematic TRUS-Bx was performed via 25 cm 18 Gauge automatic biopsy gun (Disposable Biopsy Device, Geotek, Turkey). All patients were asked to indicate the level of pain experienced on a visual analogue scale (VAS) 10 min after the TRUS biopsy. Pain intensity measured by VAS with 0 point/cm represents no pain, 10 points/cm for maximum intolerable pain, and is reported as mean and standard deviation. All complications such as vasovagal hypotension, hematuria, rectal bleeding, urethrorrhagia, hematospermia, lower urinary tract symptoms (LUTS), fever, and other possible complications during and after the procedure were recorded. Patients were invited for follow-up 2 months after the procedure. Data were obtained by four scheduled personal interviews and recorded in a questionnaire that reflected the sexual profile of patients. All patients had to fill in the IIEF standardized questionnaire and the EF domain score was estimated [12,13]. The first evaluation concerning sexual function took place immediately before patients were informed of the need for biopsy, before the actual

procedure took place, one month after the biopsy, patients were evaluated again after pathology results were discussed, whereas the last evaluation took place in the second month after the biopsy.

### **Statistical analysis**

Patient characteristics, mean VAS score and IIEF score were compared between the two groups. Group 1 patients underwent local periprostatic anesthesia by injecting 6 ml of 2% lidocaine through an 18 gauge needle in each side of the prostate gland guided by TRUS and whereas Group 2 patients were administered two packages of 12.5 g 2% lidocaine HCl gel intrarectally 10 min prior to biopsy without any additional anesthesia. Mann Whitney U and Wilcoxon test were used for statistical analyses. A  $p$  value  $< 0.05$  was considered statistically significant. Descriptive statistics were given as mean  $\pm$  standard error. The statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS.21.0) software program.

### **Results**

The mean age, initial IIEF score before biopsy (IIEF-1), tPSA level, prostate volume and VAS score were  $60.86 \pm 0.95$  years, 18.68,  $6.81 \pm 0.54$  ng/ml,  $51.10 \pm 3.82$  cc and  $3.5 \pm 0.26$  in all patients, respectively. The characteristics of the patients in group 1 and 2 are summarized in Table 1. The difference in VAS scores between the groups was statistically significant ( $p < 0.05$ ). The VAS score in group 1 administered periprostatic lidocaine infiltration was lower.

In addition, groups were evaluated in terms of pre-biopsy IIEF score (IIEF-1), post-biopsy 1st month IIEF score (IIEF-2) and post-biopsy 2nd month IIEF score (IIEF -3). The mean IIEF scores and statistical results are seen in

Table 2 and 3. In Group 1 the IIEF-1, IIEF-2, and IIEF-3 were different from each other statistically (Table 3). There was no statistically significant difference between IIEF-1 and IIEF-3 scores in group 2 ( $p=0,136$   $z=-1,492$ ). So it was observed that the initial IIEF scores were reached at the end of the second month in group 2 administered 12.5 g 2% lidocaine HCl gel.

**Table 1.** Characteristics of patients in the group 1 and 2.

| Parameters         | Group 1<br>(n=26) | Group 2<br>(n=24) | P<br>Value |
|--------------------|-------------------|-------------------|------------|
| Age                | 60.5±1.52         | 61.25±1.15        | 0.69       |
| IIEF-1             | 19.04±0.92        | 18.29±0.97        | 0.572      |
| tPSA               | 6.67±0.83         | 6.96±0.69         | 0.62       |
| Prostate<br>Volume | 43±3.32           | 59.88±6.75        | 0.064      |
| VAS Score          | 2.92±0.3          | 4.12±0.41         | 0.040      |

Mann Whitney U Test,  $P < 0.05$  statistically significant. IIEF: International Index of Erectile Function. PSA: prostate-specific antigen. VAS: Visual analog scale.

**Table 2.** Mean IIEF scores of pre-biopsy, post-biopsy 1st and 2nd months.

| Parameters | Group 1 (n=26) | Group 2 (n=24) |
|------------|----------------|----------------|
| IIEF-1     | 19.04±0.92     | 18.29±0.97     |
| IIEF-2     | 14.38±0.87     | 14.96±1.07     |
| IIEF-3     | 18.08±0.89     | 17.83±0.94     |

IIEF: International Index of Erectile Function.

**Table 3.** Statistical results for IIEF scores.

|   | Group 1         |                 |                 | Group 2             |                 |                 |
|---|-----------------|-----------------|-----------------|---------------------|-----------------|-----------------|
|   | IIEF2-<br>IIEF1 | IIEF3-<br>IIEF1 | IIEF3-<br>IIEF2 | IIEF2<br>-<br>IIEF1 | IIEF3-<br>IIEF1 | IIEF3-<br>IIEF2 |
| Z | -4.302          | -2.618          | 3.952           | -3.474              | -1.492          | -3.218          |
| P | .000            | .009            | .000            | .001                | .136            | .001            |

Wilcoxon Test,  $P < 0.05$  statistically significant. IIEF: International Index of Erectile Function.

## Discussion

There are several known and well-studied complications of prostate biopsy. These include hematuria and hemospermia in 20-50% [14-16]. Patients are routinely counseled that hematuria and hemospermia are known side effects and that this has no implication on sexual activity. Patients are instructed that they may engage in sexual activity after the biopsy without harm to themselves or their partner.

Erectile dysfunction after prostate biopsy has been underestimated and the exact etiology is unknown. Several studies have attempted to determine the exact incidence and etiology of this potential erectile dysfunction after prostate biopsy. In 2006, Chrisofos et al. directly examined the extent of ED after TRUS-Bx and found a non-significant difference regarding rates of ED at baseline versus 1 month and 3 months [6]. Contrary to this publication, later studies have found significant differences in the rates of ED after prostate biopsy [7,8,17].

In 2006 a small study with only 46 men did not show increased erectile dysfunction after TRUS-Bx, but the authors did claim that evaluating potency prior to biopsy was of extreme importance [6].

As quality of life measures have increased in the literature, a study in October 2010 showed that erectile dysfunction was more common early after prostate biopsy but often improved over time [9]. This study showed that periprostatic nerve block did not seem to change the overall effect on erections after biopsy. Another study showed that mean pain scores were lower in patients receiving levobupivacaine nerve block, but there was no change in erectile function of these patients [18].

Our study shows that a majority of men who

undergo prostate biopsy had a significant decrease in IIEF score and we found that the decrease in score continued until 2 months after the biopsy.

There are many known and most likely still unknown risk factors for erectile dysfunction in men in the general population. We did not control for any of these other risk factors, including other medical co-morbidities such as coronary artery disease and diabetes mellitus or environmental factors such as smoking. We recognize the implications of decreased erectile function after prostate biopsies; therefore we are continuing to evaluate potential causes at our institution [19].

Although we note limitations to this study, it is important to recognize the many strengths of this study including its prospective design. Unlike other studies it does not have the potential recall biases of retrospective reviews of this nature. Although the IIEF-5 does not ask about a patient's desire or attempt at erection, it is a well-known and validated universally accepted questionnaire to evaluate quality of erectile function in men. We have the advantage of completing this questionnaire pre-biopsy and at multiple time points post-biopsy for each patient, which allowed for direct comparison of each patient to himself as the control for changes in scores [19].

TRUS-Bx is a common procedure, performed on an outpatient basis to diagnose prostate cancer. However, it has considerable impact on patient well-being that starts before and lasts for weeks after the procedure [5]. Pain and great discomfort are common complaints of patients despite the wide use of automatic spring-loaded biopsy guns [20]. Lately, it seems that an increasing number of urologists administer some form of anesthesia in order to

minimize the unwanted side effects of prostate biopsy. One option for local anesthesia is periprostatic infiltration with lidocaine. Prostate biopsy-related pain originates from the autonomic fibers innervating the prostate that pass through the prostatic pedicle adjacent to the seminal vesicles. Hence, application of an anesthetic into this area may potentially reduce the resulting pain [21,22]. Our study supported the theory that lidocaine infiltration is more effective anesthesia for pain relief than lidocaine HCl gel only. But it is also not known that if type of anesthesia has implication on sexual activities.

In the present study, we wished to evaluate whether lidocaine infiltration had any effect on the sexual function of patients. We compared a group of patients who had local anesthesia with periprostatic lidocaine infiltration to another group who were given 12.5 g 2% lidocaine HCl gel only intrarectally. It is possible that erectile dysfunction may be caused by direct anatomical damage i.e. neurovascular bundle damage, or secondary trauma e.g. nerve compression due to hematoma or edema during infiltration with the local anesthetic [5]. In our study although we did not evaluate our patients regarding their general psychogenic profile, degree of anxiety, extroversion or introversion, it was observed that the initial IIEF scores were reached at the end of the second month in group 2 administered 12.5g 2% lidocaine HCl gel.

### **Conclusion**

Our study indicates that although local periprostatic anesthesia by injecting 6 ml of 2% lidocaine provides more effective anesthesia for pain relief, intrarectal 12.5 g 2% lidocaine HCl gel maintains less impact on erectile dysfunction for TRUS-Bx. Further studies are required to confirm our findings.

**Ethics Committee Approval:** *The study was approved by the Ethics Committee of Ankara Education and Research Hospital (2014.07.09/ No: 0555 – 4618).*

**Informed Consent:** *Written informed consent was obtained from the patients who participated in this study.*

**Conflict of Interest:** *No conflict of interest was declared by the authors.*

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