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Is Periprostatic Nerve Block Innocent on Erectile Functions in Prostate Biopsy? Randomized, Controlled, Prospective Observational Study

Prostat Biyopsisinde Periprostatik Sinir Bloğu Erektil Fonksiyonlar Açısından Zararsız mıdır? Randomize, Kontrollü, Prospektif Gözlemsel Çalışma

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Abstract

Objective: Our aim was to determine the effects of periprostatic nerve block and intrarectal local anesthesia techniques applied during the prostate biopsy and accompanied by transrectal ultrasonography on the erectile function.
Materials and Methods: A total of 86 patients who underwent prostate biopsy between January 2020 and September 2021 were included in the study as two study groups. Forty patients (Group-1) received 10 mL intrarectal lidocaine gel 2%, and 46 patients (Group-2) underwent periprostatic nerve block with 10 ml lidocaine HCL 1%. We recorded demographic data (age, height, weight), PSA values before the biopsy procedure, prostate volumes, visual analogue scores (VAS), and post-procedure complications. Erectile function and changes over time was investigated with IIEF-5 questionnaire at the time of biopsy and 1, 3 and 6 months after the biopsy. Significance was set at $p<0.05$.
Results: The mean age was 61.08±6.05 years, and mean BMI, biopsy duration were 27.35±3.7 kg/cm2, 11.84±2.32 minutes respectively. PSA values, prostate volumes, and mean IPSS were 8.19±3.82 ng/ml, 56.8±23.8 cc, and 10.5±4.28, respectively, without any significant differences between the groups. No difference was found between two groups when mean IIEF-5 scores over time were compared with changes in erectile function ($p=0.907$). In-group comparisons of changes over time also yielded insignificant results in both groups (Group-1: $\chi2(4)=2.22$, $p=0.529$, Group-2: $\chi2(4)=6.61$, $p=0.086$).
Conclusion: Periprostatic nerve block does not affect erectile function negatively six months after the biopsy. Its initial negative effect on erectile function in the first month is temporary. Therefore, we concluded that periprostatic nerve block can be safely used during transrectal ultrasound-guided prostate biopsy in terms of erectile function.
Keywords: periprostatic nerve block, intrarectal local anesthesia, prostate, biopsy, erectile function

Özet

Amaç: Transrektal ultrasonografi eşliğinde yapılan prostat biyopsisi sırasında uygulanan periprostatik sinir bloğu ve intrarektal lokal anestezi tekniklerinin, erektil fonksiyonlar üzerine etkilerini değerlendirmektir.
Gereçler ve Yöntemler: Ocak 2020 ile Eylül 2021 tarihleri arasında prostat biyopsisi uygulanan toplam 86 hasta, iki çalışma grubu olarak çalışmaya dahil edildi. Kırk hastaya (Grup-1) 10 mL lidokain jel %2 intrarektal olarak uygulandı, 46 hastaya (Grup-2) 10 ml lidokain HCL %1 ile periprostatik sinir bloğu yapıldı. Demografik veriler (yaş, boy, kilo), biyopsi öncesi PSA değerleri, prostat hacimleri, görsel analog skorlar (VAS) ve biyopsi sonrası komplikasyonlar kaydedildi. Erektil fonksiyon ve erektil fonksiyonun zaman içerisindeki değişimi, biyopsi anında ve biyopsiden 1, 3 ve 6 ay sonra IIEF-5 anketi ile araştırıldı. Anlamlılık düzeyi $p<0.05$ olarak belirlendi.
Bulgular: Ortalama yaş 61.08±6.05 yıl, ortalama BMI, biyopsi süresi sırasıyla 27.35±3.7 kg/cm2, 11.84±2.32 dakikaydı. PSA değerleri, prostat hacimleri ve ortalama IPSS sırasıyla 8.19±3.82 ng/ml, 56.8±23.8 cc ve 10.5±4.28 idi ve gruplar arasında anlamlı farklılık bulunmadı. İki grup arasında zamanla ortalama IIEF-5 puanları karşılaştırıldığında erektil fonksiyondaki değişikliklerde fark bulunmadı ($p=0.907$). Zamanla erektil fonksiyondaki değişikliklerin grup içinde karşılaştırmalarında, her iki grupta da anlamsız sonuçlar elde edildi (Grup-1: $\chi2(4)=2.22$, $p=0.529$, Grup-2: $\chi2(4)=6.61$, $p=0.086$).
Sonuç: Periprostatik sinir bloğu, biyopsiden altı ay sonraki erektil fonksiyonu olumsuz etkilememektedir. İlk aydaki erektil fonksiyondaki olumsuz etkisi geçicidir. Dolayısıyla, transrektal ultrason eşliğinde prostat biyopsisi sırasında periprostatik sinir bloğun erektil fonksiyonlar açısından güvenle kullanılabileceğini düşünmekteyiz.
Anahtar kelimeler: periprostatik sinir bloğu, intrarectal local anestezi, prostat, biyopsi, erektil fonksiyon

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Introduction

Transrectal ultrasonography-guided (TRUSG) prostate biopsy is frequently performed in outpatient settings due to its ease, lack of need for hospitalization, and low rate of severe complications. However, recent studies and clinical experience have shown that patients experience discomfort and pain during the procedure, contrary to earlier beliefs that the procedure was painless without local anesthesia [1]. Periprostatic nerve block (PPNB) was first described by Soloway and Obek in 2000 [2], and since then has become a widely agreed method for pain relief during TRUSG prostate biopsy.

PPNB has currently been recommended as the standard anesthesia technique for TRUSG prostate biopsy by American Urological Association (AUA) and the European Association of Urology (EAU) [3,4]. However, other techniques including intrarectal local anesthesia (IRLA) with lidocaine gel, intravenous sedation and general anesthesia may also be employed, depending on patient preference, medical history, and the clinical decision of the physician.

Although TRUSG prostate biopsy is generally considered safe, it may lead to complications such as bleeding, infection, urinary retention, pain and lower urinary tract symptoms. Moreover, it has been claimed that it may impair erectile function [5-8]. Various studies have demonstrated that the effect on erectile function is short-lived and transient. In fact, our previous study indicated impairment of erectile function up to six months after biopsy [9]. Another study with a follow up period of three months suggested that the effect on erectile function might be related to inflammation caused by the biopsy procedure itself [10]. However, it is not clear whether the impairment of erectile function is due to the anesthesia technique used during the biopsy or the inflammation caused by the biopsy procedure.

Herein, we aimed to compare the IRLA and PPNB, two anesthetic methods administered for prostate biopsy, on erectile function following the procedure.

Materials and Methods

This study was performed in Ankara City Hospital Urology Clinic after obtaining approval of Ankara City Hospital No. 1 Ethics Committee on 03.10.2019, with the reference number E1/026/2019, and Turkish Medicines and Medical Devices Agency on 16.01.2020, with the reference number 66175679-514.05.01-E.12529.

The study included 114 patients who underwent TRUSG prostate biopsy due to suspected prostate cancer (PCa) in the Urology Clinic of Ankara City Hospital between January 2020 and September 2021. Twenty-eight patients were excluded due to urethral catheterization for urinary retention after biopsy, undergoing genitourinary procedures within six months of biopsy or inability to contact with during the follow up period or unwillingness to continue participating in the study.

This clinical trial was planned as a randomized, controlled, prospective, observational study. The patients were randomized into two groups with the sealed envelope method: Group 1 (n=40) received 10 mL intrarectal lidocaine gel 2%, and Group 2 (n=46) was injected with 5 mL lidocaine HCl 2% (10 ml in total) to each side along the vascular nerve bundles, posterolateral to the prostate. The duration of PPNB was recorded, and prostate biopsy was performed 10 minutes after the block.

We also noted PSA levels, International Prostate Symptom Score (IPSS) scores, body mass index (BMI), concomitant systemic disorders related to erectile dysfunction (ED), and medications that could potentially affect erectile function. Transrectal ultrasonography and prostate biopsy were performed by the same Urology specialist using a Hitachi® EUB-400 ultrasonography device, a 7.5 MHz biplane transrectal probe (Hitachi, Tokyo, Japan), and an 18G 25 cm biopsy needle (Geotek®, Geotek Medical, Ankara, Turkey). All patients received antibiotic prophylaxis (ciprofloxacin 1x500 mg) starting the day before the biopsy and continuing for five days after the biopsy. The ellipsoid formula was employed to calculate the prostate volumes, 12 core prostate biopsies were obtained from the patients, and they were observed for early complications for two hours after the biopsy.

Pain and discomfort levels were determined with visual analogue scale (VAS) at six different time points: during local anesthesia procedure (VAS 1), during insertion and movement of the USG probe in the rectum (VAS 2), during biopsy needle penetration into the prostate and biopsy (VAS 3), 30 minutes after biopsy (VAS 4), 2 hours after biopsy (VAS 5), and the first day following the biopsy (VAS 6).

The 5-item International Index of Erectile Function (IIEF-5) questionnaire was employed on the day of the prostate biopsy to determine the baseline erectile functions of the patients. The IIEF-5 consists of five questions that evaluate erectile function, each scored between 1 and 5. The total IIEF-5 score ranges from 5 to 25 points, with interpretations as follows: 5-7 points indicate “severe” erectile dysfunction (ED), 8-11 points indicate “moderate” ED, 12-16 points indicate “mild-moderate” ED, 17-21 points indicate “mild” ED, and 22-25 points indicate “no ED”.

During the follow-up period, IIEF-5 scores were documented during the outpatient clinic visits at months 1, 3, and 6, after the prostate biopsy. If the patients did not present at the outpatient clinic within the specified timeframes, we made effort to contact them using their provided contact information.

Histopathological reports of the prostate biopsy were recorded carefully. We also documented any complications within 15 days of the biopsy (early complications) and the ones that appeared during the 6-month follow-up period (late complications).

Statistical Analysis

We performed the statistical analysis with Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS Inc., Chicago, IL, USA). The confidence interval was determined as 95% for all analyses.

Kolmogorov-Smirnov test was used to determine normality of distribution of quantitative data. It was observed that the quantitative data, with the exception of age, did not conform to a normal distribution. Consequently, we compared two study groups with Student’s t-test for age, and with Mann-Whitney U test for other quantitative data.

We used Friedman test to determine the significance of changes in IIEF-5 scores before and after prostate biopsy since the data did not follow a normal distribution. Chi-square test was employed to analyze qualitative variables. $P<0.05$ was considered as statistically significant in all analyses.

Table 1. Baseline clinical characteristics of groups

Variables	Group 1 (n=40)	Group 2 (n=46)	P value
Age (years)	59.85±6.68 (60.5)	62.15±5.29 (62)	0.078
BMI (kg/cm2)	27.7±4.3 (26.4)	27.02±3.1 (26.3)	0.775
Biopsy time (minutes)	11.75±1.82 (12)	11.91±2.7 (12)	0.947
PSA (ng/ml)	7.79±3.27 (6.55)	8.56±4.26 (7.55)	0.544
Prostate volume (ml)	57.4±21.9 (55.5)	56.4±25.6 (48)	0.530
IPSS	10.4±3.85 (10.5)	10.6±4.67 (9.5)	0.771

BMI: body mass index; PSA: prostate specific antigen; Data presented as mean ± standard deviation with median values in parenthesis

Table 2. Comparison of VAS results between groups

VAS Scores	Group 1 (n=40)	Group 2 (n=46)	P value
VAS-1	1.05±0.99 (1)	2.9±1.37 (3)	**0.000***
VAS-2	2.6±1.06 (2)	3±1.56 (3)	**0.223**
VAS-3	4.5±1.45 (4)	1.54±1.19 (1)	**0.000***
VAS-4	2.47±1.2 (2.5)	1.24±0.92 (1)	**0.000***
VAS-5	1.78±0.97 (2)	1.17±0.88 (1)	**0.002***
VAS-6	1.2±0.79 (1)	0.85±0.87 (1)	**0.030***

VAS: visual analogue scale; * Statistical Significant for Mann Whitney U Test; Data presented as mean ± standard deviation with median values in parenthesis

Table 3. IIEF-5 averages and comparisons of groups over time

Time of IIEF-5	Group-1 (n=40)	Group-2 (n=46)	P value*
Biopsy day	21±3.97 (22)	20.8±4.32 (22)	0.909
1st Month	20.1±4.65 (21)	20.2±5.06 (22)	0.838
3rd Month	20.05±5.36 (22.5)	21.04±4.75 (23)	0.511
6th Month	20.57±4.86 (22)	20.93±5.14 (23)	0.637
P value**	0.529	0.086	

IIEF-5: 5-item international sexual function index; Data presented as mean ± standard deviation with median values in parenthesis; * Comparison of averages between groups at the time with Mann Whitney U Test; **Comparison of changes within group over time with Friedman Test

Results

The mean age of 86 patients who participated in and completed the follow-up period was 61.08±6.05 years. The mean BMI was 27.35±3.7 kg/cm². The mean biopsy time was 11.84±2.32 minutes. The mean PSA, prostate volume, and IPSS of the patients were 8.2±3.82 ng/ml, 56.8±23.8 cc, and 10.5±4.28, respectively.

Two study groups were similar for mean age, BMI, biopsy time, number of cores, PSA value, prostate volumes, and IPSS **(Table 1).** Two groups were also similar for prevalence of comorbidities such as hypertension and diabetes mellitus, which are associated with ED (pHT=0.26, pDM=0.27).

The mean VAS-1 score were significantly smaller in Group 1, however VAS-2 scores were not significantly different when two groups were compared (p=0.223). VAS 3, VAS-4, VAS-5 and VAS-6 scores were significantly higher in the IRLA group **(Table 2).**

Baseline IIEF-5 scores, on the day of prostate biopsy, were not significantly different in two study groups (p=0.909) indicating no difference between two groups for erectile functions. Two groups were compared for any change in erectile function after the biopsy procedure. The mean IIEF-5 scores 1 month after the biopsy were smaller than the mean score on the day of biopsy and 6 months after biopsy in both groups **(Table 3),** however, the differences were not statistically significant in either group (Group-1: $\chi^2(4)=2.22$, p=0.529, Group-2: $\chi^2(4)=6.61$, p=0.086).

The mean IIEF-5 scores changed over time in both groups, however it was determined that the changes in IIEF-5 scores did not cause significant differences between two groups **(Figure 1).**

A total of four patients experienced complications which were classified as grade 2 or lower according to the Clavien-Dindo complication classification system. Two groups were similar early and late complication rates (p=0.595 for both).

After histopathological results, the rate of the patients with

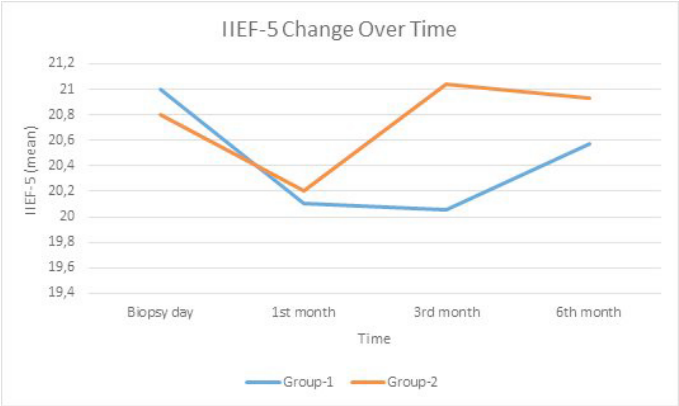


Figure 1. Graphic of IIEF-5 Changes Over Time

Gleason 3+3 prostate adenocarcinoma to the patients with benign prostatic hyperplasia was determined as 29.03% and 27.8% in groups 1 and 2, respectively (p>0.05).

Discussion

Prostate biopsy is the primary method to obtain a histopathological diagnosis in case of suspected PCa. Although mostly considered safe, it is together with potential complications. ED is a rare complication of prostate biopsy besides more frequent ones including bleeding, infection and difficult urination [3,4]. ED has been defined as failure to have an adequate penile tumescence for a satisfactory sexual performance and/or inability to maintain it throughout the sexual intercourse [11]. It may have neurogenic, psychogenic, vasculogenic, anatomical, hormonal, or drug-related causes [12]. According to Zisman et al. [5] ED resulting from prostate biopsy may arise due to direct damage to neurovascular structures or may be due to secondary trauma, for example neural compression resulting from hematoma or edema. We hypothesized that possible nerve injury and inflammation due to periprostatic nerve block could disturb erectile function. Therefore, we planned this study to investigate whether the anesthesia method had any effect on erectile function in the patients who had TRUSG prostate biopsy.

The risk of ED after prostate biopsy is usually low, but the procedure may lead to temporary or, in rare cases, permanent ED. In our study published in 2008 [9] that included 97 patients who underwent TRUSG prostate biopsy with periprostatic nerve block, the mean IIEF-5 score was 19.1 before the biopsy, it decreased to 17.1 after one month and to 16.8 after 6 months, supporting our hypothesis. That study also demonstrated decreased sexual function in the female partners of the patients within a 6-month period after biopsy. In another study, Kamali et al. [13] excluded patients who underwent radical prostatectomy for malignancy and those who had hormone therapy and radiotherapy after biopsy, and similarly reported a significant decrease in IIEF-5 scores 1, 3, and 6 months after biopsy compared to the pre-biopsy scores, however interestingly prostate biopsies were performed under general anesthesia in that study. Klein et al. [8] followed up the patients for three months and compared erectile functions in the ones who had and did not have PPNB. The authors indicated that the number of cores, age or local anesthesia did not have any long-term effects on erectile function. That study reported a significant difference in the mean baseline IIEF-5 scores between the groups that had and did not have PPNB. The authors observed lower baseline IIEF-5 scores in the patients who did not have PPNB, and IIEF-5 scores decreased more in this group. In another study, Sönmez et al., [14] aimed to minimize pain without affecting erectile function negatively during transrectal prostate biopsy, and they demonstrated that the group that had PPNB had lower mean VAS scores both during and after the procedure compared to the IRLA group. Additionally, when examining changes in erectile function over a one-month period, the authors observed decreased IIEF-5 scores in the IRLA group, however scores increased in the PPNB group although the difference was not statistically insignificant. In 2006, Stravodimos et al. [15] included 62 patients who had either IRLA or PPNB into their study. The study compared the IIEF scores between two groups at the time of information for the need of a prostate biopsy, during the prostate biopsy, and 10 and 20 days after the biopsy. In that study, although the number of patients with ED increased 10 days after the biopsy, it was reported that ED recovered within 20 days after biopsy. The authors also reported that the variations in the numbers of patients with ED paralleled each other between two anesthesia methods. A meta-analysis by Mehta et al. [16] evaluated erectile functions after prostate biopsy and the pre-biopsy IIEF-5 score was regarded as the baseline value. That meta-analysis reviewed three studies which compared baseline IIEF-5 scores with the scores two weeks later, 22 studies which compared baseline scores with the ones 4 weeks later, 18 studies which compared baseline scores with the ones three months later, and 10 studies which compared baseline scores with the ones six months later. The authors concluded that there was a significant impairment in erectile functions within 4 weeks after the biopsy, however comparison with the results of the 3rd and 6th months revealed that the impairment was temporary. In the current study, we compared sexually active patients at the time and after transrectal prostate biopsy based on the anesthesia method applied. In our study, the patients who were on the medications that could affect erectile function were excluded, and we observed a similar distribution of comorbidities that could affect erectile function in two study groups. We also compared the anesthesia methods for pain perception at six time points using VAS. We found significantly lower VAS scores during and after the biopsy in the group that underwent PPNB. On the biopsy day, IIEF-5 scores were similar between two study groups in our study. During the 1-month follow-up period, we noted similar declines in erectile function in both groups. We observed an increase in IIEF-5 scores compared to the 1st month scores in both groups 6 months after biopsy.

It cannot be denied that the suspicion of prostate cancer itself may have a significantly effect on sexual function. Stravodimos et al. [15] demonstrated that some patients who did not have ED developed it after they were informed about the need for biopsy. Helfant et al. [17] studied 85 patients and found that those with a positive prostate biopsy for cancer experienced a greater loss of sexual function compared to the ones without cancer. Although the higher mean age in the group with prostate cancer poses a

limitation to that study, it was argued that the impairment of sexual function observed in the cancer group following the biopsy, using the same method, was attributed to psychogenic factors. In our study, two study groups included similar numbers of patients with biopsy-proven prostate cancer (Gleason Score 6). Furthermore, a possible reason for the increase in IIEF-5 scores 3 and 6 months after biopsy compared to baseline scores in the PPNB group may be attributed to the benign result of the prostate biopsy. However, the lack of pre- and post-biopsy assessments to determine the overall psychogenic profile and the level of anxiety is a limiting factor in our study.

Small number of patients included in our study is also considered as a limitation. Furthermore, the efficacy of IRLA, which is applied based on the absorption capacity of the rectal mucosa and has shown to exert comparable pain-relieving effects to PPNB in some studies [18], continues to be a subject of debate. We believe that the novelty of our study design constitutes its primary strength.

Conclusion

Our data clearly demonstrated that PPNB (Periprostatic Nerve Block) offers a significant advantage over IRLA (Intrarectal Local Anesthesia) in alleviating pain during prostate biopsy procedures. Furthermore, our results indicate that any negative effect on erectile function resulting from the periprostatic nerve block is temporary, and erectile function returns to the pre-biopsy levels within 3 months. It is critical to note that initial ED is temporary. Consequently, we concluded that PPNB may be safely used in transrectal ultrasound-guided prostate biopsy procedures.

Ethics Committee Approval: This study was performed in Ankara City Hospital Urology Clinic after obtaining approval of Ankara City Hospital No. 1 Ethics Committee on 03.10.2019, with the reference number E1/026/2019, and Turkish Medicines and Medical Devices Agency on 16.01.2020, with the reference number 66175679-514.05.01-E.12529.
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