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ORIGINAL ARTICLE

The effect of alpha blocker treatment prior to prostate biopsy on voiding functions, pain scores and health-related quality-of-life outcomes: A prospective randomized trial

Effet du traitement par alpha-bloquant avant la biopsie de la prostate sur les fonctions vesicale, les scores de douleur et les résultats de qualité de vie liés à la santé: un essai prospectif randomisé

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KEYWORDS
Alpha blocker;
Health related quality of life;
Pain;
Prostate biopsy;
Voiding dysfunction

Summary
Purpose. — To evaluate the effect of alpha-blocker treatment prior to transrectal ultrasound-guided prostate biopsy (TRUS-Bx) on voiding functions, pain scores and health-related quality-of-life outcomes.
Materials and methods. — From January 2018 to April 2019, a total of 112 patients underwent TRUS-Bx due to elevated prostate-specific antigen (PSA) or abnormal digital rectal examination findings. Patients were divided into 2 groups depending on whether they received pharmacological treatment before biopsy. Group 1 consisted of patients with no alpha-blocker treatment prior to biopsy and Group 2 consisted of patients who received Tamsulosin for one week before biopsy continuing for one week after biopsy. Voiding function was evaluated three times using

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the validated International Prostate Symptom Score (IPSS) and uroflowmetry (maximal flow rate (Qmax) and residual volume (PVR)). The Turkish version of the Medical Outcomes Study Short Form 36-item Questionnaire (SF-36) was used to assess health-related quality of life. Pain scores were rated according to the Visual Analogue Scale (VAS) just after the biopsy procedure. **Results** Mean IPSS and Qmax on the post-biopsy 7 day were significantly in favor of Group 2 ($P < 0.001$, $P = 0.004$). Although post-biopsy day 7 PVR was similar between the groups, $\triangle 1$ PVR was significantly in favor of Group 2 ($P = 0.004$). Mean VAS score was 2.7 ± 2.3 for the Tamsulosin group and 4.2 ± 2.2 for the control group ($P = 0.001$). There was no significant difference between two groups according to baseline and postoperative 1st month SF-36 scores.
Conclusion. — Alpha-blocker therapy prior to TRUS-Bx is effective in preventing voiding dysfunction and biopsy-related pain in patients undergoing TRUS-Bx.
Level of evidence. — 2.

MOTS CLÉS
Alpha-bloquant ;
Qualité de vie liée à la santé ;
Douleur ;
Biopsie de la prostate ;
Dysfonctionnement de la vesicale

Résumé
Objectif. — Évaluer l'effet du traitement par alpha-bloquant avant la biopsie de la prostate guidée par échographie transrectale (TRUS-Bx) sur les fonctions de miction, les scores de douleur et les résultats de qualité de vie liés à la santé.
Matériels et méthodes. — De janvier 2018 à avril 2019, un total de 112 patients ont été traités avec TRUS-Bx en raison d'une élévation de l'antigène spécifique de la prostate (PSA) ou toucher rectal anormal. Les patients ont été divisés en 2 groupes selon qu'ils aient reçu ou non un traitement pharmacologique avant la biopsie. Le groupe 1 comprenait des patients sans traitement alpha-bloquant avant la biopsie et le groupe 2, des patients ayant reçu de la tamsulosine une semaine avant la biopsie se poursuivant une semaine après la biopsie. La fonction mictionnelle a été évaluée à trois reprises à l'aide du score IPSS (International Prostate Symptom Score) validé et de la débitmétrie urinaire (débit maximal (Qmax) et résidu post-mictionnel (RPM)). La version validée du questionnaire abrégé de 36 questions de l'étude sur les résultats médicaux (SF-36) a été utilisée pour évaluer la qualité de vie liée à la santé. Les scores de douleur ont été évalués selon l'échelle visuelle analogique (EVA) juste après la procédure de biopsie.
Résultats. — Les IPSS et Qmax moyens 7 jours après la biopsie étaient significativement en faveur du Groupe 2 ($p < 0{,}001$, $p = 0{,}004$). Bien que la RPM au jour 7 après la biopsie soit similaire entre les groupes, la RPM $\triangle 1$ était significativement en faveur du groupe 2 ($p = 0{,}004$). Le score VAS moyen était de $2{,}7 \pm 2{,}3$ pour le groupe Tamsulosine et de $4{,}2 \pm 2{,}2$ pour le groupe témoin ($p = 0{,}001$). Il n'y avait pas de différence significative entre deux groupes en fonction des scores au SF-36 du 1er mois postopératoire et du 1er mois postopératoire.
Conclusion. — Le traitement par alpha-bloquant avant TRUS-Bx est efficace pour prévenir le dysfonctionnement mictionnel et la douleur liée à la biopsie chez les patients traités par TRUS-Bx.
Niveau de preuve.— 2.

Introduction

Transrectal ultrasound-guided biopsy of the prostate (TRUS-Bx) is considered as a standard of care for diagnosis of prostate cancer. Many doubts about the biopsy process related with morbidity and harmful effects of biopsy are known. In some patients, bothersome post biopsy symptoms can lead to increased anxiety, distinct from distress related to diagnosis of prostate cancer [1]. Problems related to TRUS-Bx may cause further limitation and acts against its wide use as a main diagnostic tool due to major levels of anxiety or depression. The major side effects are local pain, hematuria, hematospermia, dysuria and fever [2,3].

In addition to these undesirable side effects, the effect of TRUS-Bx on the effect of voiding dysfunction is a matter of curiosity. Mild or moderate lower urinary tract symptoms (LUTS) inpatients may exacerbate after biopsy or 0.2—2.6% of patients will develop acute urinary retention (AUR) [4—6]. The pathophysiology that causes biopsy-related voiding dysfunction is a matter of fact [7]. Traumatic instrumentation of the prostate may be responsible for voiding impairment by increasing the bladder outlet resistance [8]. Alpha-blocker treatment beginning before the biopsy procedure

can relieve bladder resistance by relaxing the bladder neck outlet and preventing voiding impairment in this group of patients [9]. In this prospective randomized trial, we evaluated the effect of alpha-blocker treatment prior to prostate biopsy on voiding functions, pain scores and health-related quality-of-life outcomes.

Materials and methods

After ethical approval of the local ethics committee and written informed consent from all patients, between January 2018 and April 2019, patients who underwent TRUS-Bx due to elevated PSA (greater than 3 ng/mL) or/and positive rectal examination findings were prospectively evaluated. After the power analysis, eligible patients for the study were randomized into two groups. Randomization was made by flipping a coin. Group 1 consisted of patients with no alpha blocker treatment prior to biopsy and Group 2 consisted of patients who received tamsulosin 0.4 mg once a day for one week before biopsy continuing for one week after biopsy. Primary endpoint was the difference between 7th day IPSS and baseline IPSS (△1IPSS), secondary endpoints were Qmax, pain scores and health related quality of life outcomes. Exclusion criteria were as follows; patients who had prior prostate biopsy, receiving medical therapy for benign prostatic hyperplasia (BPH), with a history of surgical treatment for prostate, severe diabetes mellitus, severe coagulation disorders, rectal disease such as anal fissure, anal fistula or hemorrhoid, patients with concomitant malignancies and neurological diseases.

Voiding function was evaluated three times using the validated IPSS and uroflowmetry (maximal Qmax and PVR): before Tamsulosin treatment, at the end of the postoperative 1st week and postoperative 1st month. △1 was defined as the difference between 7th day and baseline voiding results and △2 was defined as the difference between 1st month and baseline voiding results.

The Turkish version of the Medical Outcomes Study Short Form 36-item Questionnaire (SF-36) was used to assess health-related quality of life [10]. All patients completed the SF-36 form two times: before Tamsulosin treatment and postoperative 1st month.

Biopsy was performed in patients with negative urine culture. All patients used oral ciprofloxacin 500 mg for antibiotic prophylaxis one day before biopsy and three days thereafter. All patients underwent periprostatic nerve blockade with 10 mL of 2% prilocaine prior to biopsy. Standardized 12 core biopsy was performed with an 18 G needle.

Patients' pain scores were rated according to the Visual Analogue Scale (VAS) just after the biopsy procedure.

Histopathological results and biopsy related complications were recorded. Two groups were compared according to the patient characteristics, voiding functions, pain scores and health related quality of life outcomes.

Statistical analysis

The sample size was calculated according to the power analysis (with 80% power and 5% type I error rate) of the previous studies' results; the minimum number of samples for each group was found to be 29 patients for △1Qmax and 37 patients for △1IPSS. Therefore, we have randomized a total of 112 patients into two groups as no treatment (Group 1) and Tamsulosin (Group 2) groups. The power of this study was found to be 0.996 ($P < 0.001$) using the variance analysis. These two groups were compared with Chi-square test, Fisher's exact test and independent sample t test. Statistical analyses were performed with the Statistical Package of Social Sciences (SPSS, Chicago, IL) version 21. Categorical variables were presented as numbers. Continuous variables were presented as means and standard deviations of mean. Statistical significance was set at a p value of 0.05.

Results

A total of 112 patients who met the inclusion criteria were included in this study. One of the patients in Group 1 was excluded from the study because of missing data. There were 56 patients in Group 1 and 55 patients in Group 2 (Fig. 1). The two groups were similar according to patient characteristics such as age, PSA and prostate volume. No statistical significance was found between the groups in terms of baseline voiding functions (IPSS, Qmax and PVR) (Table 1). Mean VAS score was 2.7 ± 2.3 for the Tamsulosin group and 4.2 ± 2.2 for control group ($P = 0.001$).

Post-biopsy day 7 IPSS was 15.5 ± 5.2 for Group 1 and 11.7 ± 4.2 for Group 2 ($P < 0.001$) and △1 IPSS was significantly in favor of Group 2 ($P < 0.001$). Mean Qmax on the post-biopsy day 7 was 12.1 ± 5.5 ml/sec and 15.1 ± 4.3 ml/sec for Group 1 and 2 respectively ($p = 0.004$) and △1 Qmax was also significantly in favor of Group 2 ($P < 0.001$). Although post-biopsy day 7 PVR was similar between the groups, △1 PVR was significantly in favor of Group 2 ($P = 0.004$). Voiding functions in the post-biopsy 1st month were also similar between the groups like the baseline values. The most common side effect after biopsy was hematuria in both groups. Other side effects were urinary tract infection, dysuria, hematuria, hematospermia and rectal bleeding. AUR occurred in one patient in the control group after the procedure. The rates of benign and malignant pathology were not different between the groups (Table 2). Health related Quality of Life results are given in Table 3. There was no significant difference between the two groups according to baseline and postoperative 1st month SF-36 scores.

Discussion

Benign prostatic hyperplasia (BPH) is a major public health issue because of its high prevalence, progressive nature, voiding symptoms such as dysuria but also storage symptoms such as urinary frequency, urgency, nocturia and associated economic costs [11]. While the disease is treated in patients presenting with symptoms, biopsy is needed for the diagnosis of cancer in suspected cases. In addition to the familiar side effects such as pain, hematuria, hematospermia, infection, and sepsis, TRUS-Bx can cause voiding dysfunction in some patients after the procedure. Zisman et al. first investigated the voiding functions after TRUS-Bx [12]. Several

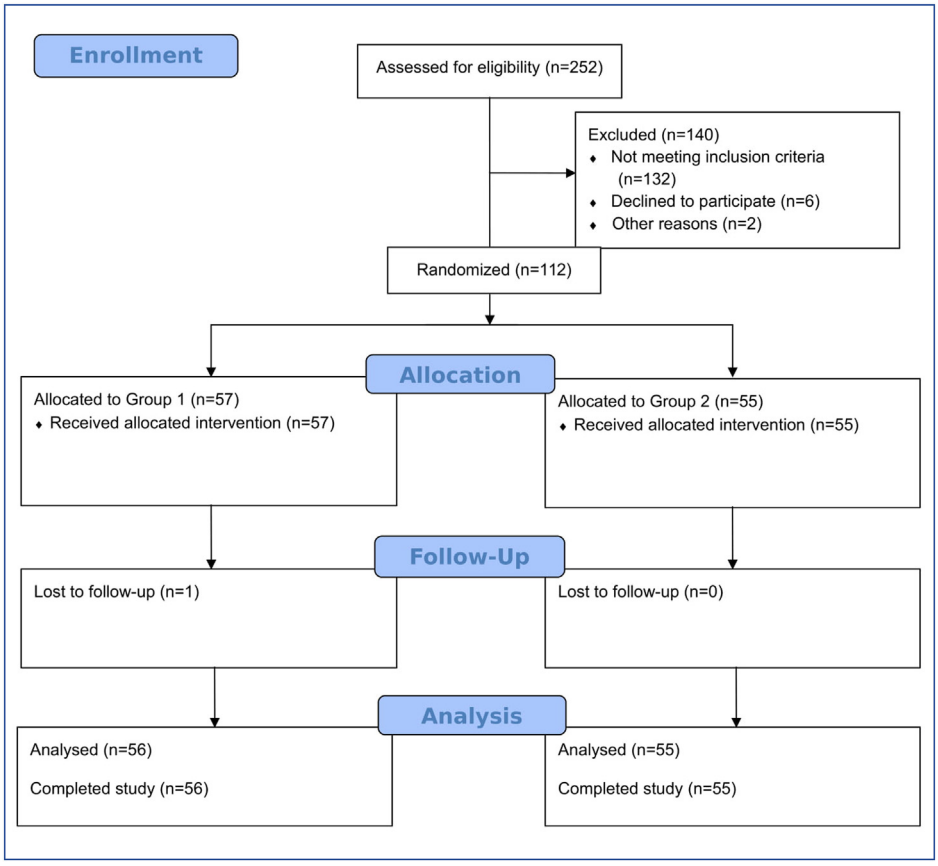

Figure 1. CONSORT diagram of the study.

other studies supported the alterations in voiding functions after TRUS-Bx [12—14]. After the negative effect of biopsy on voiding functions was shown, pharmacological treatment before biopsy was introduced in order to reduce these negative effects. 5-alpha-reductase inhibitors which act by reducing the prostate microvessel density and decreasing the rate of hemorrhagic symptoms after prostate biopsy, and alpha-blockers which reduce the sympathetic tone of blood vessels resulting in decreased vascular resistance and minimized local hemorrhagic adverse effects are common drugs that are used for this purpose [9,15]. In this study, we investigated the effect of alpha-blocker treatment on voiding dysfunction after biopsy, as well as its effect on pain occurring during biopsy. We also examined health-related quality-of-life outcomes in the 2 groups. The exact mechanism of biopsy-related voiding impairment has not been clearly defined [6]. In two studies exploring causative factors for biopsy-related voiding impairment, an increased transitional zone volume was reported as a risk factor for urinary retention [12,13]. The rate of difficult voiding after TRUS-guided biopsy was found to be between 0.8-40% in different studies [12—14]. In another comparative study, Chung et al. presented their results after TRUS-Bx and reported that the PVR was increased and Qmax was decreased on post-biopsy day 7 in the control, compared with their baselines [7]. In the tamsulosin group this was entirely the opposite. They found that post-biopsy AUR developed in none of the patients (0%) in tamsulosin group, but AUR occurred in two patients (4.5%) in the control, after 8-core TRUS-Bx [7]. These results were supported by Bozlu et al. in which IPSS was significantly decreased on postbiopsy days 7 and 30 compared with the baseline value, and Qmax was significantly elevated on postbiopsy day 30 in the tamsulosin group [6]. AUR after the biopsy procedure developed in 1 patient in the tamsulosin group and 3 patients in the control group [6]. Borboroğlu et al. reported high incidence of AUR (10%) after biopsy with an average of 22.5 cores. This high rate can be attributed to the sampled core number and biopsy technique [8]. In the current study, there was a significant difference in IPSS scores on post-biopsy 7 day between patients without any medication and the tamsulosin group (IPSS was 15.5 ± 5.2 for Group 1 and 11.7 ± 4.2 for Group 2 ($P < 0.001$) and $\Delta 1$ IPSS was significantly in favor of Group 2 ($P < 0.001$)). $\Delta 1$ Qmax was significantly in favor of Group 2 ($P < 0.001$) and $\Delta 1$ PVR on the 7th day was significantly in favor of Group 2 ($P = 0.004$). While AUR occurred in one patient in the control group after the procedure, none of our patients in the tamsulosin group experienced AUR.

TRUS-Bx is associated with significant pain and discomfort in a proportion of men [16]. Predictors of pain include young age, anxiety level, anorectal compliance, prostate volume and number of biopsy cores; while pain seems not to be affected by using 16- versus18-gauge needles. One study showed that more than 50% of patients reported moderate to intolerable pain even with intrarectal lidocaine application before the procedure [17]. Hence, effective analgesia before TRUS-Bx is considered mandatory according to current consensus [18]. All patients in our study group

Table 1 Patients' characteristics, pain scores and voiding functions of Group 1 and 2.

Data	Group 1 ($n=56$)	Group 2 ($n=55$)	P
Age (yr), mean ± SD (min–max)	63.6 ± 6.4 (50–76)	63.6 ± 6.4 (46–75)	0.979
PSA (ng/ml) mean ± SD (min–max)	8.2 ± 6.7 (3.1–35)	10.1 ± 6.7 (3.4–47)	0.224
Prostate volume (cm^3), mean ± SD (min–max)	50.3 ± 17.5 (20–100)	56.8 ± 22.6 (20–130)	0.126
VAS, mean ± SD (min–max)	4.2 ± 2.2 (0–8)	2.7 ± 2.3 (0–10)	0.001
Voiding functions			
IPSS, mean ± SD (min–max)			
Baseline IPSS	12.8 ± 5.2 (3–25)	13.1 ± 4.9 (3–25)	0.758
7th day IPSS	15.5 ± 5.2 (3–26)	11.7 ± 4.2 (4–22)	< 0.001
Δ1 IPSS	2.7 ± 2.3 (−2 ± 8)	−1.4 ± 2.8 (−8 ± 6)	< 0.001
1st month IPSS	15.6 ± 5.7 (5–26)	13.6 ± 6.5 (3–35)	0.087
Δ2 IPSS	3.1 ± 3.5 (−8 ± 10)	0.4 ± 4.4 (−9 ± 13)	0.002
Qmax (mL/s), mean ± SD (min–max)			
Baseline Qmax	13.8 ± 5.2 (6.3–34)	14.3 ± 4.4 (5.6–23)	0.598
7th day Qmax	12.1 ± 5.5 (3–30)	15.1 ± 4.3 (7–25)	0.004
Δ1 Qmax	−1.7 ± 2.8 (−11 ± 2.9)	0.8 ± 1.5 (−2 ± 6.8)	< 0.001
1st month Qmax	13.2 ± 4 (6–27)	14.3 ± 4.8 (7–32)	0.267
Δ2 Qmax	−0.4 ± 3.3 (−8.8 ± 8.7)	−0.1 ± 3.5 (−9.6 ± 9)	0.592
PVR (ml), mean ± SD (min-max)			
Baseline PVR	25 ± 28.1 (0–110)	36.3 ± 30.3 (0-110)	0.064
7th day PVR	40.4 ± 63 (0–400)	21.3 ± 22.9 (0–80)	0.053
Δ1 PVR	15.5 ± 65.2 (−55 ± 350)	−15.1 ± 29.4 (−80 ± 60)	0.004
1st month PVR	19.8 ± 23.8 (0–100)	20.8 ± 23 (0–100)	0.826
Δ2 PVR	−4.2 ± 34.9 (−110 ± 60)	−15.5 ± 30 (−80 ± 50)	0.099

Δ1: the difference between 7th day and baseline results; Δ2: the difference between 1st month and baseline results; PSA: Prostate specific Antigen; IPSS: International Prostate Symptom Score; PVR: Post-voiding Residue; Qmax: Maximal flow rate; VAS: Visual Analogue Scale. *T*-test and Chi^2 test analysis were used between Group 1 and 2.

Table 2 Side effects and pathological results after TRUS-Bx.

Data	Group 1 ($n=56$)	Group 2 ($n=55$)	P
Pathological result			
Benign	43 (76.8)	40 (72.7)	0.680
Malignant	13 (23.2)	15 (27.3)	
Side effect			
Negative	26 (46.4)	27 (49.1)	0.751
Positive	30 (53.6)	28 (50.9)	
Urinar tract infection, n (%)	3 (5.6)	2 (3.6)	0.492
Disuria, n (%)	10	7	0.393
Hematuria, n (%)	17	16	0.769
Hematospermia, n (%)	2	6	0.148
Rectal bleeding, n (%)	4	4	0.975
AUR, n (%)	1	0	–

AUR: Acute urinary retention. Chi^2 test analysis and Fisher's exact test were used between Group 1 and 2.

underwent periprostatic nerve blockade with 10 mL of 2% prilocaine prior to biopsy. Standardized 12 core biopsy was performed with 18 G needle. Another important issue in the current study was to find the effect of alpha-blocker therapy on pain during the procedure. To obtain these results, we used VAS scoring just after the biopsy procedure. There was statistical significance between the 2 groups according to VAS scores. Alpha-blocker treatment seems to be effective in reducing pain during the procedure in patients undergoing biopsy. Alpha-blockers causes relaxation on the prostate and bladder neck, and therefore they can affect potential side effects due to prostate biopsy. There are a limited number of studies examining the effect of alpha blockers on pain during and after prostate biopsy. Consistent with our study, although not statistically significant, Zamuner et al. found that alpha-blocker therapy before the biopsy prevented pain after TRUS-BX. However, they evaluated the pain 24 hours after TRUS-Bx [9].

Table 3 Comparison of Health related Quality of Life results between the groups.

Data	Group 1 ($n=56$)	Group 2 ($n=55$)	P
SF-36 (Baseline)			
Physical functioning, mean ± SD (min—max)	74.2 ± 20.8 (10—100)	73.8 ± 25.8 (0—100)	0.933
Physical role limitations, mean ± SD (min—max)	79.3 ± 30.3 (0—100)	72.2 ± 37.3 (0—100)	0.319
Emotional role limitation, mean ± SD (min—max)	71.2 ± 36.2 (0—100)	75.2 ± 38.3 (0—100)	0.612
Vitality, mean ± SD (min—max)	58.5 ± 23.8 (0—100)	66.5 ± 24.6 (0—100)	0.114
Emotional well-being, mean ± SD (min—max)	66.9 ± 18.9 (28—100)	69.7 ± 20.1 (20—100)	0.496
Social functioning, mean ± SD (min—max)	78.9 ± 23.3 (0—100)	73.5 ± 22.3 (25—100)	0.252
Pain, mean ± SD (min—max)	78.8 ± 24.2 (0—100)	75.5 ± 25.2 (0—100)	0.512
General health, mean ± SD (min—max)	61.8 ± 17.3 (32—100)	62.3 ± 21.9 (10—100)	0.9
SF-36 (postoperative 1st month)			
Physical functioning, mean ± SD (min—max)	77.5 ± 17.8 (30—100)	75.7 ± 23.1 (5—100)	0.683
Physical role limitations, mean ± SD (min—max)	76.6 ± 28.9 (0—100)	77.1 ± 25.3 (0—100)	0.927
Emotional role limitation, mean ± SD (min—max)	68.7 ± 36.7 (0—100)	74.7 ± 37.1 (0—100)	0.431
Vitality, mean ± SD (min—max)	64 ± 22.5 (10—100)	70.6 ± 23.4 (0—100)	0.168
Emotional well-being, mean ± SD (min—max)	74.7 ± 19.9 (31—100)	73.5 ± 19.4 (36—100)	0.776
Social functioning, mean ± SD (min—max)	79.3 ± 23 (0—100)	79.5 ± 17.6 (35—100)	0.961
Pain, mean ± SD (min—max)	70.3 ± 17.8 (30—100)	74.1 ± 18.7 (30—100)	0.317
General health, mean ± SD (min—max)	61.9 ± 19.2 (25—100)	68 ± 19.3 (26—100)	0.129

T-test analysis was used between Group 1 and 2.

The most common side effect of the procedure was hematuria in both groups. The second most common side effect was dysuria and no major complication was observed. There was no difference between the two groups according to complications.

Interestingly, there was no significant difference between the two groups according to baseline and postoperative 1st month SF-36 scores. This can be a result of the similarity in complications between the groups and evaluating the quality of life at the end of the 1st month.

The current study has some limitations. Our analyses stratified by biopsy result were based on small numbers because of the strict inclusion criteria and, for that reason, should be considered exploratory. Because of the small number of patients in the current study, randomization by flipping a coin can be considered as a limitation of the study. Block randomization would be better method for studies with a small number of patients, like our study. Also the lack of a placebo use and open label arm is a limitation of this study. A meta-analysis by Eredics et al. showed a placebo effect on IPSS and Qmax, but this improvement was statistically lower than the improvement in alpha blocker use [19]. In the current study, the effect of Tamsulosin use on voiding functions and pain after TRUS-Bx was evaluated and Tamsulosin use was found to be effective to reduce post-biopsy symptoms and pain.

Conclusions

In conclusion, preoperative Tamsulosin treatment resulted in statistically significant improvements in IPSS, Qmax and pain scores. Although, a protocol change cannot be made with the results of the current study, we think that preoperative Tamsulosin may be beneficial especially in patients with high pre-biopsy symptom scores. Larger placebo controlled randomized studies are needed to support our findings.

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None.

Disclosure of interest

The authors declare that they have no competing interest.

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