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Is there any priority between the alpha blockers on voiding functions after transrectal ultrasound guided prostate biopsy?

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ABSTRACT

Objective: Transrectal ultrasound–guided prostate biopsy is the gold standard in the diagnosis of prostate cancer. Major and minor complications may develop at varying rates after prostate biopsies, one of which is voiding impairment. This study aimed to evaluate whether all alpha1-blockers were effective in preventing voiding impairment after a transrectal ultrasound–guided prostate biopsy and if so, was one superior to the others.

Material and methods: This study included 240 patients who underwent a transrectal ultrasound–guided 12-core prostate biopsy and were prospectively randomized. Of the patients, 40 received 10 mg alfuzosin, 40 received 4 mg doxazosin, 40 received 8 mg silodosin, 40 received 0.4 mg tamsulosin, and 40 received 5 mg terazosin beginning on the day before the biopsy and for the following 30 days. The international prostate symptom score (IPSS), maximal flow rate, and post-void residual urine were recorded in all the patients before the procedure and on post-biopsy days 7 and 30. All he patients were followed up and questioned about voiding difficulty and acute urinary retention after the procedure.

Results: In all the alpha1-blocker groups, the IPSS and post-void residuals were statistically significantly lower, and the maximal flow rate was statistically significantly greater on post-biopsy days 7 and 30 compared with the baseline values ($p<0.05$). No patient in any of the alpha1-blocker groups developed acute urinary retention after the biopsy.

Conclusion: To prevent voiding impairment and deterioration in the quality of life after a prostate biopsy, preemptive therapy with alpha1-blockers may have a protective role, especially in patients with large prostate volumes.

Keywords: Alpha blockers; biopsy; prostate; voiding impairment

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Introduction

Prostate cancer is the most common non-skin malignancy among men in European countries and the United States.[1,2] Transrectal ultrasound–guided systematic prostate needle biopsy has been the gold standard in detecting prostate cancer since Hodge et al.[3-5] described it in 1989. In European countries and the United States, more than a million transrectal ultrasound–guided prostate biopsies are performed every year.[6] Although transrectal ultrasound–guided prostate biopsy is considered safe and is usually performed on an outpatient basis, this procedure often has well-known minor complications, such as hematuria, fever, rectal bleeding, genitourinary tract infection, hematospermia, vasovagal episodes, anal pain, and discomfort.[4-6] Furthermore, transrectal ultrasound–guided prostate biopsy is associated with new onset or worsening of voiding impairment and erectile dysfunction.[7] Several studies have shown that transrectal ultrasound–guided prostate biopsy has an impact on voiding, and the rate of voiding difficulty and acute urinary retention after prostate biopsy has been reported as 1.2% to 51.5%.[4-8]

To the best of our knowledge, there has been relatively little research about the beneficial effect of tamsulosin on voiding after a transrectal ultrasound–guided prostate biopsy.[8,9] This study aimed to investigate whether alpha$_1$-blockers recommended by the European

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Association of Urology and the American Urological Association guidelines for treatment on lower urinary tract symptoms suggestive of benign prostatic obstruction have a preventive effect on voiding impairment after transrectal ultrasound–guided prostate biopsy on patients with prostate volume of ≥40 mL. We also evaluated whether any of these alpha-blockers have different preventive effects on voiding impairment after a transrectal ultrasound–guided prostate biopsy.

Material and methods

This prospective study confirmed by the institutional ethics committee, consisting of the members from the Turkish Ministry of Health and the University of Mersin School of Medicine (approval #2018409). All patients who participated in the study were informed about the study and received written consent A total of 952 patients who underwent transrectal ultrasound–guided prostate biopsy owing to abnormal digital rectal examination and/or serum prostate specific antigen (PSA) findings, including elevated PSA level and abnormal PSA derivatives were assessed in the study. Exclusion criteria of the study were systemic disorders (diabetes mellitus and neurologic diseases), bleeding diathesis, recent anticoagulation, genitourinary tract infections, and patients with prostate volumes of <40 mL. Patients with a history of prior medical or surgical treatment of benign prostatic hyperplasia, urethral instrumentation or urethral surgery, acute urinary retention, and transrectal ultrasound–guided prostate biopsy were excluded.

After exclusion, 240 consecutive patients were prospectively randomized to alfuzosin (n=40), doxazosin (n=40), silodosin (n=40), tamsulosin (n=40), terazosin (n=40), and control (n=40) groups. Patients in the treatment groups received 10 mg alfuzosin, 4 mg doxazosin, 8 mg silodosin, 0.4 mg tamsulosin, or 5 mg terazosin on a daily basis, 1 day before the prostate biopsy and for the following 30 days. The control group underwent transrectal ultrasound–guided prostate biopsy without any alpha$_1$-blocker treatment.

Main Points:

- Prostate cancer is the most common non-skin malignancy among men, and transrectal ultrasound–guided systematic prostate needle biopsy has been the gold standard in its detection.
- Transrectal ultrasound–guided prostate biopsy has well-known minor complications, such as hematuria, fever, rectal bleeding, genitourinary tract infection, hematospermia, vasovagal episodes, and anal pain and discomfort. Transrectal ultrasound–guided prostate biopsy is also associated with worsening of voiding impairment and erectile dysfunction.
- This study aimed to investigate whether alpha$_1$-blockers had a preventive effect on voiding impairment after a transrectal ultrasound–guided prostate biopsy on patients with prostate volumes ≥40 mL.
- To prevent voiding impairment and deterioration in life quality because of the prostate biopsy, preemptive therapy with any alpha$_1$-blocker is required, especially in patients with large prostate volumes.

All the participants received prophylactic oral ciprofloxacin 500 mg 60 minutes before the biopsy and continued (twice daily) taking this for another 3 days. Bowel preparation with a self-administered Fleet's enema was performed 2 hours before the process. Initially, morphologic assessment and volume calculation of prostates were performed. The volume of the prostate and transitional zone was calculated by ellipsoid formula (volume [mL]=0.524×height×length×width [cm]). All the patients then received 2% lidocaine injection (5 mL) into the corner between the prostatic base and the seminal vesicles for each side through a 22 G×20 cm Chiba needle (Angiotech, Gainesville, FL, USA). Following the periprostatic nerve blockade, a standard of 12 cores prostatic tissue was taken using a disposable 18 G x 20 cm biopsy needle (Angiotech Tru-Core I, Gainesville, FL, USA) driven by the multiple usage of an automatic spring-loaded biopsy gun (MD TECH, Gainesville, FL, USA). Transrectal ultrasound–guided prostate biopsy was performed as described previously.[10] All the procedures were performed on the patients in the left decubital position, using a transrectal ultrasound system (Siemens Sonoline Adara, Erlangen, Germany with 7.5-MHz biplanar probe) by the same urologist (M.B.). After biopsy, all the patients were informed about the possible post-procedural complications. The patients were instructed to return to the urology clinic or the emergency department at our institution if they suspected any complications, including being unable to void, fever, flushing, chills, weakness, heavy bleeding, or clots. Simple urine analysis and urine culture were performed when the patients had dysuria, increased frequency of urination, and/or lower abdominal or flank pain. Blood culture was performed in patients with fever. Symptomatic and febrile urinary tract infections were defined according to the definition of the Centers for Disease Control and Prevention. Symptomatic urinary tract infection was defined as "the presence of dysuria, increased frequency of urination, and/or lower abdominal or flank pain, and positive urine culture." Febrile urinary tract infection was defined as "the presence of fever of 38°C and above accompanied by at least 1 symptom of the lower urinary tract with or without a positive urine culture in the absence of a positive blood culture." Maximum flow rate was measured using uroflowmetry (MMS Medical Measurement Solar®, the Netherlands), and post-void residual urine was calculated using ellipsoid formula by transabdominal ultrasound system (Siemens Sonoline Adara, Erlangen, Germany, with 3.5-MHz convex probe) after the uroflowmetric study. Voiding difficulty was described as the new onset or worsening of subjective complaints. It was evaluated using a

self-administered verbal rating scale (grading 0–5; 0 no voiding difficulty; 1–2 mild; 3 moderate; and 4–5, severe).[7,8]

On the post-biopsy days 7 and 30, the patients were followed up and questioned for the presence of voiding impairment, including voiding difficulty and acute urinary retention and other biopsy-related complications. Before the biopsy, and 7 and 30 days after the procedure, the maximum flow rate and post-void residual were measured in all the patients. They also completed the validated international prostate symptom score (IPSS) questionnaire and quality of life (QoL) scale (8th question of IPSS).

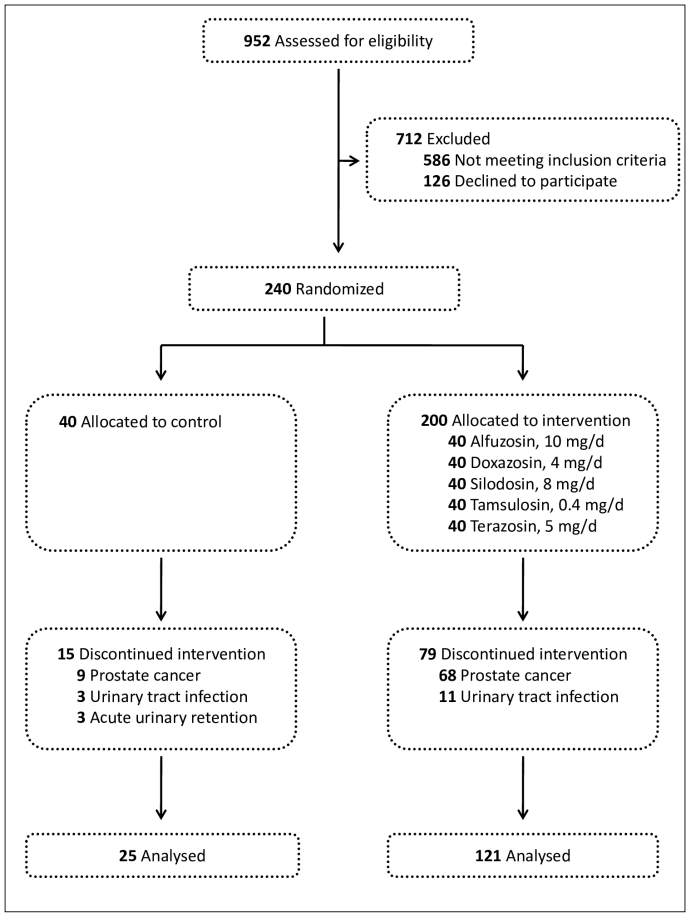

Figure 1. The CONSORT flow diagram

Pathological results were discussed with the patients on post-biopsy day 7, and the patients with confirmed prostate cancer (77 [32.1%] patients) were removed from the study. Patients who had symptomatic or febrile urinary tract infection (14 [5.8%] patients) within 30 days post biopsy were also excluded. Maximum flow rate, post-void residue, IPSS, and QoL scale were crosschecked with the patients who did not experience acute urinary retention after biopsy (Figure 1).

Statistical analysis

The sample size was calculated as 72 patients with 95% confidence interval (CI) and 124 patients with 99% CI. The Statistical Package for Social Sciences for Windows version 17.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. The normality distribution of the numeric parameters were tested (Shapiro-Will test). Descriptive statistics were expressed as mean±standard deviation unless otherwise stated. Statistical analyses were performed using Pearson's chi-squared test to compare the proportions. General linear model repeated measures test was performed to present differences among the repeated measures that were done for IPSS, QoL, maximum flowrate, and post-void residual urine and the interaction effect between repeated measures and study groups. At the same time, post-hoc test using Bonferroni correction was done to compare study groups in this analysis. A p value <0.05 was considered statistically significant.

Results

Statistical analysis of baseline patient characteristics showed no significant difference among the groups in age, serum PSA level, prostate volume, transitional zone volume, IPSS, QoL scale, maximum flow rate, and post-void residual urine (Table 1).

None of the patients in the alpha$_1$-blocker groups developed acute urinary retention after the biopsy, but it occurred in 3/28 (10.7%) patients of the control group on post-biopsy day 2 to day 4 (2.66±1.15, median 2; Figure 2). All of those 3 patients were reported to have hematuria, but none had clot retention and infectious complications. A urethral catheter was inserted, and alpha$_1$-blockage was underway for the management of acute

Table 1. Baseline characteristics of all the patients

	Control (n=25)	Alfuzosin (n=24)	Doxazosin (n=25)	Silodosin (n=23)	Tamsulosin (n=26)	Terazosin (n=23)	p
Age (years)	61.96±5.43	59.79±6.84	62.32±6.98	61.56±8.57	60.84±6.85	62.65±5.36	0.704
PSA (ng/mL)	11.20±15.36	12.35±13.46	13.06±17.15	13.91±15.33	12.16±11.10	11,64±12.67	0.989
Prostate volume (mL)	54.35±14.49	59.04±15.99	58.36 ±17.32	57.39±22.01	61.15±25.50	58.08±17.72	0.873
Transitional zone volume (mL)	27.71±7.84	31.16±9.31	30.92±11.80	29.52±12.26	31.23±16.63	28.69±9.89	0.838

PSA: prostate specific antigen

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urinary retention. The catheter was removed 5 days after it had been inserted. No recurrent acute urinary retention occurred in these patients during the following 30 days.

In the control group, 10 (35.7%) patients and 8 (6.6%) patients in the alpha$_1$-blocker groups were reported to have voiding difficulty on post-biopsy day 7 (p<0.001; Figure 2). Subgroup analysis of alfuzosin, doxazosin, silodosin, tamsulosin, and terazosin groups in terms of voiding difficulty were 4.2%, 8.0%, 4.3%, 7.7%, and 8.7%, respectively, and revealed no significant difference across the groups (p=0.749). In the control group, 5 (17.9%) patients had mild, 3 (10.7%) had moderate, and 2 (7.1%) had severe voiding difficulty. None of the patients were reported to have severe voiding difficulty in the alpha$_1$-blocker groups. On post-biopsy day 30, only 2 patients in the control group were reported to have subjective voiding difficulty.

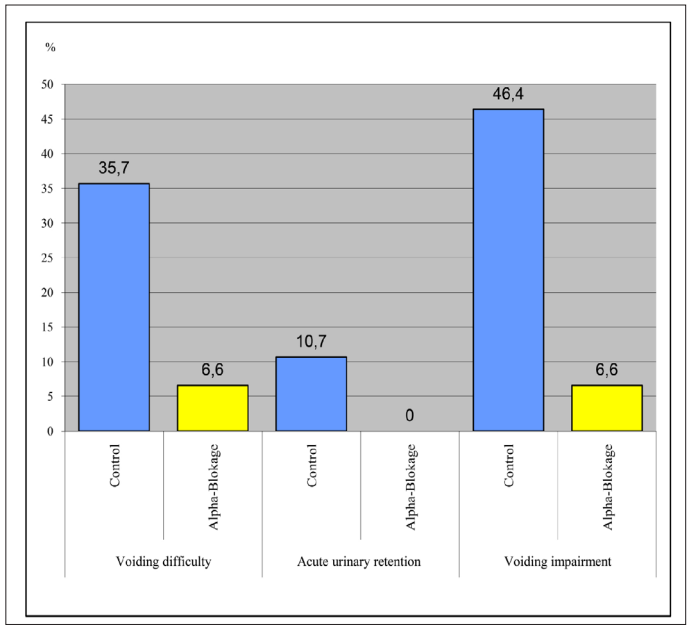

Figure 2. Comparison of voiding impairment after prostate biopsy between control and alpha$_1$-blocker groups

The IPSS, QoL scale, and post-void residual urine were significantly higher, and the maximum flow rate was significantly lower in the control group on post-biopsy day 7 compared with the baseline values (p<0.05) (Table 2). On post-biopsy day 30, no significant difference was found across these parameters compared with the baseline values (p >0.05). In all alpha$_1$-blocker groups, the IPSS, QoL scale, and post-void residual urine were significantly lower, and the maximum flow rate was significantly higher on post-biopsy days 7 and 30 compared with the baseline values (p<0.05) (Table 2). Among the alpha$_1$-blocker subgroups, these effects were found to be similar (p>0.05). Detailed statistical analysis is shown in Table 3.

Discussion

The unfavorable impact of prostate biopsy on voiding were first described by Zisman et al.[7] and since then, a lot of studies have shown that voiding impairment after a prostate biopsy is not uncommon.[5,8,11-15] A very wide range of its reported rate (1.2%–51.5%) stems from the differences in patient characteristics, usage of various questionnaire methods, and biopsy techniques.[4-8]

Table 2. Pre and post-biopsy IPSS, QOLscale, maximum flow rate, and post-void residual values in patients who voided by urethra

		Control (I) (n=25)	Alfuzosin (II) (n=24)	Doxazosin (III) (n=25)	Silodosin (IV) (n=23)	Tamsulosin (V) (n=26)	Terazosin (VI) (n=23)
IPSS	Baseline	12.60±4.84	13.20±3.72	12.68±4.12	13.31±3.69	12.15±3.96	12.82±3.58
	Day 7	15.32±4.08	9.41±2.41	9.32±2.24	8.73±3.41	8.23±2.80	9.13±2.36
	Day 30	12.64±4.48	8.79±2.02	8.56±2.51	7.86±2.94	7.73±1.99	8.30±1.94
QoLscale	Baseline	2.21±0.91	2.58±1.05	2.32±1.06	2.43±0.84	2.42±1.06	2.13±0.91
	Day 7	3.00±1.38	1.29±0.69	1.24±0.77	1.21±0.42	1.19±0.63	1.21±0.79
	Day 30	2.36±1.35	1.12±0.67	1.04±0.73	1.08±0.51	1.03±0.59	1.00±0.67
Maximum flowrate (mL/s)	Baseline	12.57±2.55	12.87±3.09	12.40±2.54	12.17±2.28	13.07±2.26	12.73±2.43
	Day 7	10.68±1.74	14.25±3.19	14.04±3.42	14.43±2.82	14.96±2.42	14.26±2.41
	Day 30	12.12±2.14	15.45±2.97	15.16±3.35	15.60±3.58	16.15±1.75	15.34±2.10
Post-void residual urine (mL)	Baseline	54.67±16.99	52.33±18.07	49.24±17.55	48.95±16.14	55.53±14.94	52.95±17.48
	Day 7	66.24±19.91	32.41±11.85	29.88±12.85	34.17±14.19	35.30±13.26	34.39±12.17
	Day 30	55.32±16.85	30.66±11.96	26.28±12.26	31.00±13.38	31.50±16.29	32.26±11.87

IPSS: international prostate symptom score; QoL: Quality of life

Table 3. The results of general linear model repeated measures (Time: baseline, day 7, day 30)

	Tests of within-subjects effects		Tests of between-subjects effects		Post-hoc tests (Bonferroni)	
	Effect	p	Source	p	Multiple comparisons	p
IPSS	Time	<0.05	Group	<0.05	I-II, I-III, I-IV, I-V, I-VI	<0.05
					II-III, II-IV, II-V, II-VI	>0.05
	Time*group	<0.05			III-IV, III-V, III-VI	>0.05
					IV-V, IV-VI	>0.05
QoL scale	Time	<0.05	Group	<0.05	I-II, I-III, I-IV, I-V, I-VI	<0.05
					II-III, II-IV, II-V, II-VI	>0.05
	Time*group	<0.05			III-IV, III-V, III-VI	>0.05
					IV-V, IV-VI	>0.05
Maximum flow rate (mL/s)	Time	<0.05	Group	<0.05	I-II, I-IV, I-V, I-VI	<0.05
					I-III, II-III, II-IV, II-V, II-VI	>0.05
	Time*group	<0.05			III-IV, III-V, III-VI	>0.05
					IV-V, IV-VI	>0.05
Post-void residual urine (mL)	Time	<0.05	Group	<0.05	I-II, I-III, I-IV, I-V, I-VI	<0.05
					II-III, II-IV, II-V, II-VI	>0.05
	Time*group	<0.05			III-IV, III-V, III-VI	>0.05
					IV-V, IV-VI	>0.05

IPSS: international prostate symptom score; QoL: quality of life

However, the majority of the studies has reported an increase in IPSS and a decrease in the maximum flow rate and the quality of life after a biopsy.

The exact pathophysiological mechanism of the biopsy-related voiding corruption has not been clearly described. However, instrumental trauma to the prostate, prostatic edema/swelling, and increased alpha-receptor sensitivity were proposed as the explanation of increased bladder outlet resistance after prostate biopsy.[8,13] In addition, many risk factors have been described in this process, such as prostate volume, transitional zone volume, ratio of transitional zone to total prostate volume, and baseline IPSS.[4,7,16] One of the most important factors in voiding impairment after a transrectal ultrasound–guided prostate biopsy is the prostate volume. When the prostate is relatively large, more vigorous trauma to the prostate may occur because of the maneuvers to reach the prostatic base.[7,13] Zisman et al.[7] have reported that the transitional zone volume is independent, and the prostate volume is a marginal factor in subjective voiding impairment on post-biopsy day 7 (p=0.03 and p=0.06, respectively). Zaytoun et al.[16] have indicated that greater prostate volume is associated with increased risk for acute urinary retention after a transrectal ultrasound–guided prostate biopsy. Similarly, Chiang et al.[17] have shown that a prostate volume of 45 mL is the cut-off value to indicate which patients would be more prone to having acute urinary retention post biopsy. In addition to all these findings, Aktas et al.[13] have reported that prostate biopsy has negative effects on the patient's QoL, especially in patients who have a prostate volume greater than 38.8 mL. We also included patients with prostate volumes of ≥40 mL in our study according to the literature.

Same pathophysiology and clinical features between the lower urinary tract symptoms suggestive of benign prostatic obstruction and the voiding impairment after a transrectal ultrasound–guided prostate biopsy have encouraged some authors to use alpha$_1$-blocker treatment to prevent this impairment.[8,9,18] However, the effect of only tamsulosin on voiding impairment post biopsy has been investigated until now. We planned this study considering that if lower urinary tract symptoms suggestive of benign prostatic obstruction and voiding impairment after a transrectal ultrasound–guided prostate biopsy have similar pathophysiology, and tamsulosin improves both conditions, other alpha-blockers should have a similar effect.

Bozlu et al.[8] have reported in 2003 that alpha$_1$-blocker treatment with tamsulosin before a biopsy and for a brief period afterward resulted in a decrease in voiding deterioration after a transrectal ultrasound–guided prostate biopsy. The study included 66 consecutive patients who experienced transrectal ultrasound–guid-

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ed 12-core prostate biopsy and were prospectively randomized into 2 groups. Of the patients, 33 were treated with tamsulosin (0.4 mg daily) beginning the day before the biopsy and for the following 30 days, and the remaining 33 patients did not receive tamsulosin (control group). Compared with baseline, tamsulosin was related with a significant decrease in IPSS and an increase in the maximum flow rate, although poor voiding parameters were observed on day 7 in the control group. The voiding impairment rate was 12.1% and 51.5% in the tamsulosin group and the control group, respectively ($p<0.001$).

Similar results were reported in another study,[9] which had a similar study design as that of Bozlu et al.[8] This study included 88 sequential patients who underwent transrectal ultrasound–guided 8-core prostate biopsy and were prospectively randomized. In this study, 44 of the patients were treated with tamsulosin (0.2 mg daily) starting from the day before the biopsy and for the following 7 days. The remaining 44 patients had prostate biopsy without tamsulosin treatment and served as the control group. In contrast to the control group, in the tamsulosin group, maximum flow rate was significantly increased, and post-void residual urine did not increase on post-biopsy days 1 and 7. After the biopsy, acute urinary retention developed in 4.5% of the control group, but no acute urinary retention was observed in the tamsulosin group. However, the IPSS did not change after biopsy in both the groups significantly. In a current prospective randomized study, Sefik et al.[18] have evaluated the effect of alpha-blocker treatment prior to transrectal ultrasound–guided prostate biopsy on voiding functions and pain scores. The authors reported similar results as ours and the other articles that discussed above-mean IPSS and maximum flow rate on post-biopsy day 7 were significantly in favor of the tamsulosin group than the control group. They also suggested that the use of alpha-blockers reduced post-biopsy pain as well as improved voiding dysfunction. This is an interesting finding and should be evaluated in future studies on this subject.

It is known that all the alpha$_1$-blockers used in the treatment of lower urinary tract symptoms suggestive of benign prostatic obstruction are superior to the placebo and have similar effects. However, there is no study showing the efficiency of alpha$_1$-blockers other than tamsulosin for the prevention of voiding impairment post biopsy. Our study showed that alpha$_1$-blockers, which are recommended by the European Association of Urology and the American Urological Association guidelines for the treatment of lower urinary tract symptoms suggestive of benign prostatic obstruction, are effective in preventing voiding impairment post biopsy, and the efficiency of one is not superior to the others. However, the absence of a placebo arm is the limitation of our study.

Transrectal ultrasound–guided prostate biopsy has a measurable temporary impact on voiding, especially in patients with larger prostate volumes. Therefore, to prevent voiding impairment and deterioration of QoL because of prostate biopsy, we recommend preemptive therapy with any alpha$_1$-blockers in patients with a large prostate volume (>40 mL) that may pose a risk of voiding dysfunction after a prostate biopsy.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Mersin University (Approval No: 2018/409).

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

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – M.B., EA.; Design – O.E., B.S., M.T.; Supervision – O.E., E.A.; Data Collection and/or Processing – B.S., O.E., M.T.; Analysis and/or Interpretation – E.A., O.E., M.T.; Literature Search – M.B., O.E., B.S.; Writing Manuscript – B.S., O.E., M.T.; Critical Review – B.S., M.B.

Conflict of Interest: The authors have no conflicts of interest to declare.

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