

A single-office experience of day-case water vapor thermal therapy for benign prostatic hyperplasia

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Abstract. The present study aimed to clarify the feasibility, safety and efficacy of day-case water vapor thermal therapy (WVTT) using the Rezum system in an office-based setting. The present retrospective study included the data of 40 patients who underwent WVTT performed by a single surgeon at a single-unit urology clinic from March, 2023 to January, 2024, including 11 patients with complete urinary retention. The present study analyzed the operation time and hospitalization time on the day of the procedure. The International Prostate Symptom Score-Quality of Life (IPSS-QOL), post-void residual (PVR) volume, prostate volume (PV), medication use and adverse events (AEs) were monitored at baseline, and at 1, 2 and 3 months following treatment. All interventions were performed within a median period of 4.0 min (interquartile range (IQR), 2.0-11.0). The mean hospitalization time on the day of the procedure was 274.8±53.8 (standard deviation) min. Furthermore, the patients exhibited significant improvements in their QOL based on their IPSS-QOL scores. The PV and PVR volumes decreased significantly. Of the 40 patients, 39 (97.5%) voided spontaneously and were catheter-free at a median period of 12.0 days (IQR, 6.0-87.0) following the procedure. Benign prostatic hyperplasia medications were discontinued in 26 of the 40 (65%) patients. The median time to discontinuation was 58.0 days (IQR, 24.0-114.0). A history of urinary retention and more than six injections during a procedure were found to increase the risk of prolonged post-operative catheterization. Of the 40 patients, AEs were observed in 11 patients, including grade II gross hematuria in 2 patients (5%). On the whole, the present study demonstrated that day-case WVTT is feasible, effective and safe as an office-based, outpatient procedure.

Introduction

Lower urinary tract symptoms (LUTS) are very common among middle-aged males (1,2). In 40% of males >50 years of age, benign prostatic hyperplasia (BPH) is considered to be the cause of these symptoms (3). BPH is a benign hyperplasia of the periurethral region of the prostate that causes obstructive symptoms that significantly compromise the quality of life of patients. Over the years, numerous therapies have been developed to treat BPH. Although initial medications may be effective for mild to moderate symptoms, patients with moderate to severe symptoms may require surgical intervention. Transurethral resection of the prostate (TURP) has been the most commonly performed procedure and is considered the gold standard for the treatment of BPH (4). Although TURP has demonstrated efficacy in improving urinary symptoms, acute complications and long-term adverse events (AEs), such as erectile and ejaculatory dysfunction, incontinence, and other complications have been reported (5). Some studies have indicated the efficacy and safety of a wide variety of minimally invasive procedures for BPH, such as laser endoscopic enucleation, green light vaporization, prostatic artery embolization and UroLift (6-10). All these procedures aim at avoiding or reducing complications associated with TURP, while maintaining comparable outcomes. Water vapor thermal therapy (WVTT) using the Rezum system, which involves the administration of a transurethral injection of 103°C water steam into the prostate, is a type of minimally invasive treatment, which has demonstrated beneficial efficacy and safety profiles for the treatment of LUTS caused by BPH (11). A recent randomized clinical trial reported the safety and durable efficacy of WVTT performed in an office-based or ambulatory surgery center (12). The provision of day-case surgery would allow for greater patient flow and improve clinical care through increased efficiency (10).

Therefore, the present study was conducted in an aim to assess the feasibility, safety and efficacy of day-case WVTT as an office-based, outpatient procedure.

Patients and methods

Study design and setting. The present retrospective cohort study was conducted at Mizuhodai Urology in Fujimi, Japan (single-unit urology clinic). The Rezum system (Boston Scientific Corporation) was introduced at the clinic

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Key words: water vapor thermal therapy, Rezum, benign prostatic hyperplasia, office urology, day-case surgery

Table I. Inclusion and exclusion criteria used for the patients in the present study.

Inclusion criteria	Criteria
1	Male subjects >50 years of age who had symptomatic BPH
2	IPSS-QOL score ≥ 4
3	Prostate volume >30 cm ³ to ≤ 90 cm ³
Exclusion criteria	Criteria
1	Active or history of UTI within the past 3 months
2	Any prior invasive prostate intervention
3	Suspicion of prostate cancer due to elevated PSA levels or PI-RADS ≥ 3 on an MRI

BPH, benign prostate hyperplasia; IPSS-QOL, International Prostate Symptom Score-Quality of Life; UTI, urinary tract infection; PSA, prostate-specific antigen; PI-RADS, Prostate Imaging Reporting and Data System; MRI, magnetic resonance imaging.

in March, 2023. All Rezum procedures during the study period were performed according to previously published techniques (11,13). Spinal anesthesia was applied for all the procedures.

Patient selection. The present study included the data of 40 patients who underwent the Rezum procedure from March, 2023 to January, 2024, including 11 patients who were catheterized due to complete urinary retention. The inclusion and exclusion criteria used are presented in Table I.

Data collection and definitions. The operation time and hospitalization time on the day of the procedure were analyzed. The patient characteristics, International Prostate Symptom Score-Quality of Life (IPSS-QOL) score, prostate volume (PV), post-void residual (PVR) volume measured by transabdominal ultrasound, catheterization, medication and AEs were monitored at baseline, and at 1, 2 and 3 months following treatment. AEs were defined according to the Clavien-Dindo classification (14).

Statistical analysis. Baseline and follow-up data were reviewed, with follow-up periods of 1, 2 and 3 months. All data are reported with appropriate descriptive statistics as follows: Normally distributed data are reported as the mean \pm standard deviation (SD) and non-normally distributed data are reported as the median and interquartile range (IQR). The changes observed in the patients from baseline were analyzed using repeated measures ANOVA followed by the Bonferroni post hoc test for each measure. The influence of a history of urinary retention and more than six injections on prolonged post-operative catheterization (>14 days) was assessed using multivariate logistic regression. A value of $P < 0.05$ was considered to indicate a statistically significant difference. Statistical analysis was performed using JASP (version 0.18.3, team JASP, <https://jasp-stats.org/>).

Results

Patient characteristics. A total of 40 patients were included in the present study. The median age of the patients was 71.5 years (IQR, 51.0-83.0). The mean PV was 56.9 ± 13.8 ml. Pre-operative catheterization, a history of urinary retention,

Table II. Patient characteristics.

Characteristic	Patients (n=40)
Age in years, median (IQR)	71.5 (51.0-83.0)
Performance status, median (IQR)	0 (0-2)
Preoperative medication for BPH, n (%)	
Alpha blocker	40 (100)
5-Alpha reductase inhibitor	30 (75.0)
Phosphodiesterase-5 inhibitor	5 (12.5)
Anticoagulants/platelet aggregation inhibitors, n (%)	5 (12.5)
Preoperative IPSS-QOL score, mean \pm SD	5.4 \pm 0.5
Pre-operative PVR in ml, mean \pm SD	291.0 \pm 419.9
Pre-operative prostate volume, mean \pm SD	56.9 \pm 13.8
Preoperative catheterization, n (%)	11 (27.5)
History of urinary retention, n (%)	15 (37.5)
Median lobe, n (%)	18 (45.0)

IQR, interquartile range; BPH, benign prostatic hyperplasia; IPSS-QOL, International Prostate Symptom Score-Quality of Life; SD, standard deviation; PVR, post-void residual volume.

and a median lobe were present in 27.5, 37.5 and 45.0% of patients, respectively (Table II).

Peri-operative data. All interventions were performed within a median period of 4.0 min (IQR, 2.0-11.0). The patients received a median of five injections (IQR, 4-7) and were hospitalized for a mean duration of 274.8 ± 53.8 min. A total of 5 patients made telephone inquiries during the first post-operative week (Table III).

Catheter management and medication use. The catheter was successfully removed following a median of 12.0 days (IQR, 6.0-87.0) in 39 (97.5%) patients. Catheter removal was successful in 29 (100%) patients without a pre-operative catheter following a median of 8 (IQR, 6.0-16.0) days. In 11 patients with a pre-operative catheter, catheters were successfully removed in 10 (90.9%) patients following a median of 32

Table III. Peri- and post-operative efficacy outcomes of the patients.

Peri- and post-operative efficacy outcomes	Patients (n=40)
Duration of operation in min, median (IQR)	4.0 (2.0-11.0)
Number of injections, median (IQR)	5.0 (4.0-7.0)
Intraoperative complications, n (%)	
None	39 (97.5)
Catheter for irrigation	1 (2.5)
Duration of hospitalization in minutes, mean \pm SD	274.8 \pm 53.8
Number of phone inquiry within 1 week after operation, no. of patients	5
Total number of successful catheter removal, n (%)	39 (97.5)
Total days until successful catheter removal, median (IQR)	12.0 (6.0-87.0)
Successful catheter removal in 29 patients without a pre-operative catheter, n (%)	29 (100)
Total days until successful catheter removal, median (IQR)	8.0 (6.0-16.0)
Successful catheter removal in 11 patients with a pre-operative catheter, n (%)	10 (90.9)
Total days until successful catheter removal, median (IQR)	32.0 (28.0-87.0)
Total rate of discontinuation of BPH medication, n (%)	26 (65.0)
Total days until discontinuation of BPH medication, median (IQR)	58.0 (24.0-114.0)

IQR, interquartile range; BPH, benign prostatic hyperplasia; SD, standard deviation.

Table IV. Potential risk factors for prolonged postoperative catheterization (>14 days).

Parameters/potential risk factors	OR (CI), P-value
History of urinary retention	32.450 (3.247-324.276), 0.003
No. of injections \geq 6	15.578 (1.677-144.689), 0.016

OR, odds ratio; CI, confidence interval.

(IQR, 28.0-87.0) days (Table III). BPH medications were discontinued by 26 of 40 (65.0%) patients. The median time to discontinuation was 58.0 days (IQR, 24.0-114.0) (Table III). A history of urinary retention and more than six injections during the procedure increased the risk of prolonged postoperative catheterization (>14 days) (Table IV).

Functional outcomes. The patients exhibited significant improvements in their QOL based on their IPSS-QOL scores. The PV and PVR volumes decreased significantly. When comparing baseline to follow-up, the mean post-operative IPSS-QOL scores at 1, 2 and 3 months following treatment decreased significantly by 66.6, 81.7 and 88.0%, respectively. PV significantly decreased by 25.3, 34.0 and 37.2% at 1, 2 and 3 months following treatment, respectively. The PVR volume also decreased significantly from baseline to 1, 2 and 3 months following treatment by 24.0, 23.2 and 40.8%, respectively (Figs. 1-3). All the related results are presented in Table V.

Safety outcomes. Over the course of the follow-up period, AEs were observed in 11 patients, including Clavien-Dindo grade II gross hematuria in 2 (5%) patients and grade II urinary tract infection (UTI) in 1 (2.5%) patient. In total, 4 patients

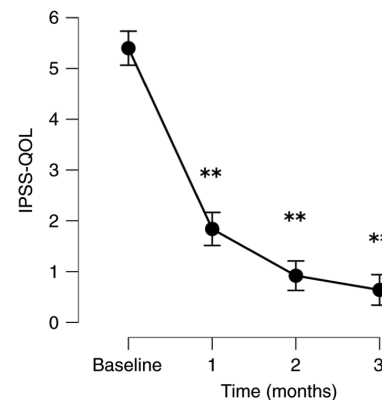


Figure 1. IPSS-QOL score at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 25 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. **P<0.001, vs. baseline. IPSS-QOL, International Prostate Symptom Score-Quality of Life.

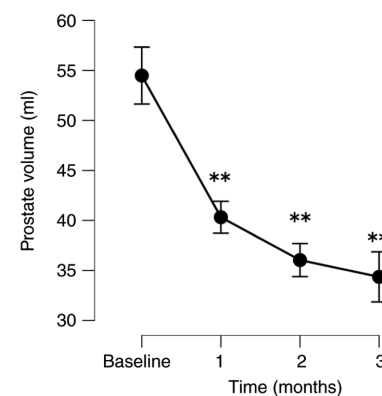


Figure 2. Prostate volume at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 25 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. **P<0.001, vs. baseline.

Table V. Changes in the outcomes of patients from baseline to 3 months.

Parameter	Baseline	1 month	2 months	3 months
IPSS-QOL				
No. of patients analyzed	40	33	32	25
Absolute, mean (SD)	5.4 (0.5)	1.8 (0.9)	1.0 (1.1)	0.6 (1.0)
Change, mean (SD)		-3.6 (1.1)	-4.4 (1.1)	-4.8 (1.1)
% Change, mean		-66.6 (17.3)	-81.7 (19.3)	-88.0 (18.0)
P-value		<0.001	<0.001	<0.001
PV				
No. of patients analyzed	40	34	32	25
Absolute, mean (SD)	56.9 (13.8)	43.1 (15.4)	37.0 (13.8)	34.4 (13.0)
Change, mean (SD)		-14.0 (7.8)	-18.6 (8.6)	-20.1 (10.1)
% Change, mean		-25.3 (14.5)	-34.0 (15.7)	-37.2 (17.6)
P-value		<0.001	<0.001	<0.001
PVR				
No. of patients analyzed	40	34	32	24
Absolute, mean (SD)	291.0 (419.9)	50.2 (58.2)	48.2 (46.9)	39.1 (43.3)
Change, mean (SD)		-214.4 (355.6)	-234.6 (382.3)	-150.4 (265.5)
% Change, mean		-24.0 (78.8)	-23.2 (80.5)	-40.8 (39.1)
P-value		0.004	0.002	0.001

IPSS-QOL, International Prostate Symptom Score-Quality of Life; SD, standard deviation; PV, prostate volume; PVR, post-void residual volume.

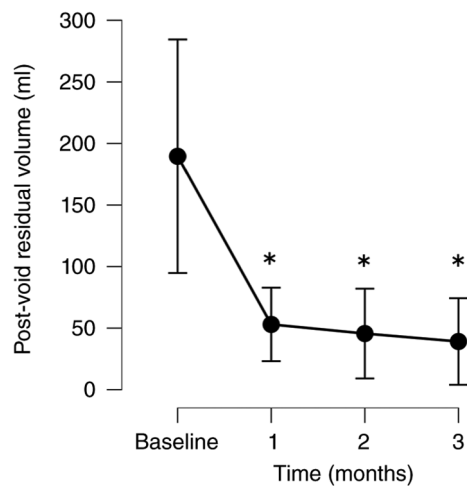


Figure 3. Post-void residual volume at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 24 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. *P<0.005, vs. baseline.

(10%) had an episode of UTI, and 2 patients (5%) had urinary frequency and dysuria. In addition, 1 patient (2.5%) had an episode of urinary tract pain. No grade \geq III Clavien-Dindo events occurred in any of the patients (Table VI).

Discussion

The aim of the present study was to evaluate the feasibility, efficacy and safety profile of day-case WVT as an office-based outpatient procedure in a real-world cohort.

Table VI. Safety outcomes.

Safety outcomes	Patients (n=40)	
	Clavien-Dindo classification (14)	
Adverse events, n (%)	Grade I	Grade II
Gross hematuria	0	2 (5.0)
Urinary frequency	2 (5.0)	0
Urinary tract infection	3 (7.5)	1 (2.5)
Urinary tract pain	1 (2.5)	0
Dysuria	2 (5.0)	0

All interventions were performed within a median period of 4.0 min without intraoperative complications. No case required unscheduled post-operative visits or hospitalization. These results suggest that day-case, office-based WVT is feasible, similar to other minimally invasive therapies for BPH (10,15,16). In the present study, spinal anesthesia was applied on all procedures, and all patients could leave the office in ~4 h on the day of the procedure. Although a recent meta-analysis revealed that intravenous anesthesia was mainly applied during WVT (17), the results of the present study suggest that spinal anesthesia may also be considered as an option.

In previous studies, the time to post-operative catheter removal was between 0 and 7 days (11,12,18-20). In the series

of patients in the present study, the catheterization time was 8 days in patients without pre-operative catheter-dependent urinary retention (Table III). Furthermore, the present study demonstrated that the catheter-free rate in the subgroup of patients with a pre-operative catheter was 90.9% following a median of 32 days. These results are in accordance with those of a previous study (20). These data also suggest that the time to the first trial of post-operative catheter removal should be prolonged in pre-operatively catheterized patients. Furthermore, the data presented herein indicate that a history of urinary retention significantly increases the risk of prolonged post-operative catheterization. The first trial of post-operative catheter removal should also be prolonged in patients with a history of catheterization. According to the logistic regression analysis performed herein, more than six injections during the procedure significantly increased the risk of prolonged post-operative catheterization. As reported in a previous study, the use of more injections may result in a greater degree of inflammation and tissue edema, which may result in a longer catheterization period (21).

The data of the present study indicate a significant improvement of QOL with a reduction in IPSS-QOL by 66.6% at 1 month following the procedure. This confirms data from prior studies (12,13,22-24). The PV and PVR volume decreased by ~40% at 3 months following treatment. These results are consistent with those of previous studies (12,13,22).

In terms of safety outcomes, AEs were observed in 11 patients, including grade II UTI and gross hematuria; however, no patients had a grade ≥III event. As these results are comparable to those of previous studies (11,12,20), it can be assumed that WVTT can be safely performed as an office-based, outpatient procedure.

The present study has certain limitations, which should be mentioned. The present study was a single-office, retrospective study with a select number of patients. Additionally, a fundamental limitation of the present study was that follow-up time points were not tightly controlled. Despite these limitations, significant improvements in QOL and urinary function were observed at all follow-up time points.

In conclusion, the present study demonstrates that day-case WVTT is feasible, effective and safe as an office-based, outpatient procedure. Further investigations are required however, to determine patient groups for whom WVTT may be indicated and to identify the advantages of WVTT for other minimally invasive treatments for BPH.

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Availability of data and materials

The datasets used and/or analyzed in the current study are available from the corresponding author on reasonable request.

Author's contributions

TO conceived and designed the study, obtained the patients' data, performed data analysis, and wrote and edited the manuscript. The author has read and approved the final manuscript. TO confirms the authenticity of all the raw data.

Ethics approval and consent to participate

Written informed consent was obtained from all study subjects for their participation in the present study. Ethical approval was obtained from the Ethics Committee of Mizuhodai Urology (Fujimi, Japan; reference no. 1001). Written informed consent was obtained from the patients for publication of the present study and any related images.

Patient consent for publication

Not applicable.

Competing interests

The author declares that he has no competing interests.

References

1. Vuichoud C and Loughlin KR: Benign prostatic hyperplasia: Epidemiology, economics and evaluation. *Can J Urol* 22 (Suppl 1): S1-S6, 2015.
2. Wei JT, Calhoun E and Jacobsen SJ: Urologic diseases in America project: Benign prostatic hyperplasia. *J Urol* 173: 1256-1261, 2005.
3. Zhang SJ, Qian HN, Zhao Y, Sun K, Wang HQ, Liang GQ, Li FH and Li Z: Relationship between age and prostate size. *Asian J Androl* 15: 116-120, 2013.
4. Foster HE, Dahm P, Kohler TS, Lerner LB, Parsons JK, Wilt TJ and McVary KT: Surgical Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline amendment 2019. *J Urol* 202: 592-598, 2019.
5. Friedl A, Schneeweiss J, Stangl K, Mühlstädt S, Zachoval R, Hruby S, Gründler T, Kivaranovic D, Fornara P, Lusuardi L and Brössner C: The adjustable transobturator male system in stress urinary incontinence after transurethral resection of the prostate. *Urology* 109: 184-189, 2017.
6. Brassetti A, DE Nunzio C, Delongchamps NB, Fiori C, Porpiglia F and Tubaro A: Green light vaporization of the prostate: Is it an adult technique? *Minerva Urol Nefrol* 69: 109-118, 2017.
7. Checcucci E, Vecchia A, De Cillis S, Piramide F, Volpi G, Amparore D, Pecoraro A, Piana A, Granato S, Verri P, *et al*: New ultra-minimally invasive surgical treatment for benign prostatic hyperplasia: A systematic review and analysis of comparative outcomes. *Eur Urol Open Sci* 33: 28-41, 2021.
8. Jones P, Rai BP, Nair R and Somani BK: Current status of prostate artery embolization for lower urinary tract symptoms: Review of world literature. *Urology* 86: 676-681, 2015.
9. Jones P, Rajkumar GN, Rai BP, Aboumarzouk OM, Cleaveland P, Srirangam SJ and Somani BK: Medium-term Outcomes of Urolift (Minimum 12 Months Follow-up): Evidence from a systematic review. *Urology* 97: 20-24, 2016.
10. Yilmaz M, Karaaslan M, Polat ME, Tonyali S, Aybal HÇ, Şirin ME, Toprak T, Tunç L, Gratzke C and Miernik A: Is day-case surgery feasible for laser endoscopic enucleation of the prostate? A systematic review. *World J Urol* 41: 2949-2958, 2023.
11. McVary KT, Gange SN, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Rousseau M, Beahrs JR, Kaminetsky J, *et al*: Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol* 195: 1529-1538, 2016.

12. McVary KT, Gittelman MC, Goldberg KA, Patel K, Shore ND, Levin RM, Pliskin M, Beahrs JR, Prall D, Kaminetsky J, *et al*: Final 5-year outcomes of the multicenter randomized sham-controlled trial of a water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol* 206: 715-724, 2021.
13. Dixon CM, Cedano ER, Pacik D, Vit V, Varga G, Wagrell L, Larson TR and Mynderse LA: Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. *Res Rep Urol* 8: 207-216, 2016.
14. Dindo D, Demartines N and Clavien PA: Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240: 205-213, 2004.
15. Miller LE, Chughtai B, Dornbier RA and McVary KT: Surgical reintervention rate after prostatic urethral lift: Systematic review and meta-analysis involving over 2,000 patients. *J Urol* 204: 1019-1026, 2020.
16. Sciacqua LV, Vanzulli A, Di Meo R, Pellegrino G, Lavorato R, Vitale G and Carrafiello G: Minimally invasive treatment in benign prostatic hyperplasia (BPH). *Technol Cancer Res Treat* 22: 15330338231155000, 2023.
17. Yang J, Wu W, Amier Y, Li X, Wan W, Liu C, Zhang Y and Yu X: Efficacy and safety of Water Vapor Thermal Therapy in the treatment of benign prostate hyperplasia: A systematic review and single-arm Meta-analysis. *BMC Urol* 23: 72, 2023.
18. Bole R, Gopalakrishna A, Kuang R, Alamiri J, Yang DY, Helo S, Ziegelmann MJ and Köhler TS: Comparative postoperative outcomes of rezūm prostate ablation in patients with large versus small glands. *J Endourol* 34: 778-781, 2020.
19. Johnston MJ, Noureldin M, Abdelmotagly Y, Paramore L, Gehring T, Nedas TG, Rajkumar G, Emara A and Hindley RG: Rezūm water vapour therapy: Promising early outcomes from the first UK series. *BJU Int* 126: 557-558, 2020.
20. McVary KT, Holland B and Beahrs JR: Water vapor thermal therapy to alleviate catheter-dependent urinary retention secondary to benign prostatic hyperplasia. *Prostate Cancer Prostatic Dis* 23: 303-308, 2020.
21. Babar M, Loloi J, Azhar U, Tang K, Ines M, Singh S, Iqbal N and Ciatto M: Rezūm outcomes in relationship to number of injections: Is less more? *J Endourol* 37: 157-164, 2023.
22. Bausch K, Zahiti L, Schrutt M, Wetterauer C, Halbeisen FS, Ebbing J and Seifert HH: Water vapor thermal therapy of lower urinary tract symptoms due to benign prostatic obstruction: Efficacy and safety analysis of a real-world cohort of 211 patients. *World J Urol* 41: 1605-1612, 2023.
23. Elterman D, Bhojani N, Vannabouathong C, Chughtai B and Zorn KC: Rezūm therapy for ≥80-mL benign prostatic enlargement: A large, multicentre cohort study. *BJU Int* 130: 522-527, 2022.
24. Whiting D, Noureldin M, Abdelmotagly Y, Johnston MJ, Brittain J, Rajkumar G, Emara A and Hindley R: Real-world early outcomes and retreatment rates following water vapour ablative therapy for symptomatic benign prostatic hyperplasia. *Eur Urol Open Sci* 39: 72-78, 2022.



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