# 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.

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## 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

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

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 ± SD | 5.4±0.5 |
| Pre-operative PVR in ml, mean ± SD | 291.0±419.9 |
| Pre-operative prostate volume, mean ± SD | 56.9±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.

*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 ± SD | 274.8±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 ≥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

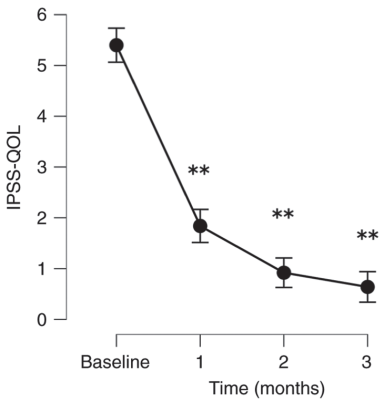


Figure 1. IPSS-QOL score at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 25 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. **P<0.001, vs. baseline. IPSS-QOL, International Prostate Symptom Score-Quality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

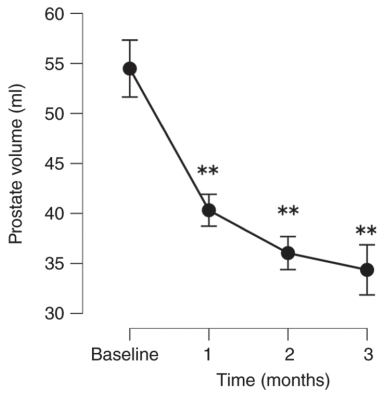


Figure 2. Prostate volume at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 25 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. **P<0.001, vs. baseline.

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.

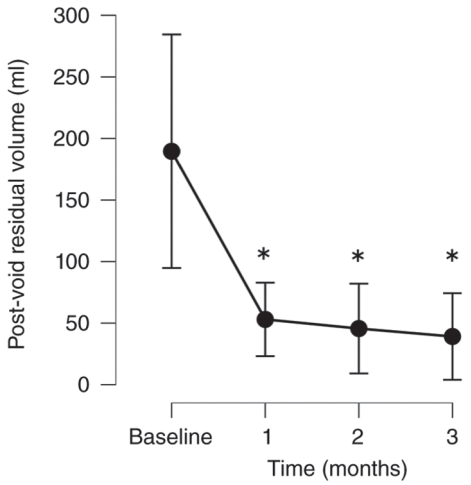


Figure 3. Post-void residual volume at baseline, and at 1, 2 and 3 months following water vapor thermal therapy. A total of 24 patients were analyzed up to the 3-month follow-up time. Values are the mean and error bars represent 95% CI. *P<0.005, vs. baseline.

(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 ≥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 WVTT as an office-based outpatient procedure in a real-world cohort.

Table VI. Safety outcomes.

| | Patients (n=40) | |
|---|---|---|
| Safety outcomes | 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 WVTT 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 WVTT (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.

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